UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIOCAD JSC Plaintiff, – against – ROCHE HOLDING AG , F. HOFFMAN LA-ROCHE LTD., GENENTECH, INC. AND R-FARM JSC, Defendants.	**No. 1:16-cv-04226** **AMENDED COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiff BIOCAD JSC ("Plaintiff"), by and through its attorneys Feinstein & Partners PLLC, brings this action for damages and injunction under the antitrust laws of the United States and other federal and state causes of action against Defendants Roche Holding AG, F. Hoffman La-Roche Ltd., Genentech Inc. and R-Farm JSC (collectively, "Defendants") demanding a trial by jury. For the Amended 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 for injunction and 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 aimed at delaying and preventing altogether Plaintiff's entry on the U.S. market with cheaper lifesaving cancer drugs.

2. Plaintiff, a leading full-cycle pharmaceutical company in Eastern Europe, has spent the past 6 years and tens of millions of dollars on developing certain biosimilars, implementing a strategy to import these biosimilars into the U.S. and, otherwise, establishing operations in the U.S.

3. Defendants, on the other hand, have spent the past 6 years on developing and implementing an illegal and unlawful scheme to destroy Plaintiff's competing business and foreclose U.S. market to Plaintiff's biosimilars.

4. Since 2010, Plaintiff designed and developed biosimilars and built a special FDA-compliant facility to manufacture biosimilars and compete head to head in the U.S. with Roche's[1] three best-selling drugs that bring Roche over $20 Billion in annual sales. Almost 50% of such profits come from Roche's sales in the U.S., which remains the most lucrative market for Roche.

5. Specifically, Plaintiff opened a subsidiary in the U.S., hired and transferred business development personnel to the U.S., purchased necessary equipment and rented necessary facilities in the U.S., hired experts and consultants to assist with regulatory Food and Drug Administration ("FDA") approvals and contracted with distribution partners to complete U.S. entry and start importing biosimilars into U.S.

6. In preparation for entry to the U.S. market, by 2013, Plaintiff had completed a new manufacturing facility. Plaintiff spent substantial additional funds to make the manufacturing facility FDA-compliant, including advancing over US$ 6 Million only on acquisition of necessary equipment. Plaintiff hired over 25 people, including leading U.S. consultants and new full-time employees, with over 18,000 working hours spent just on quality improvements at the new manufacturing site.

7. This Plaintiff's manufacturing facility is the only one of its kind in Eastern Europe and one out of fifty (50) built worldwide, specializing in monoclonal antibodies Active Pharmaceutical Ingredients ("APIs").

[1] Defendants Roche Holding AG, F. Hoffmann-La Roche, Ltd. and Genentech, Inc. are referred to collectively as "Roche" throughout the Amended Complaint.

8. By 2016, Plaintiff had already tested other markets in 47 countries for distribution and sale of its biosimilars, had necessary facilities, equipment and manufacturing capabilities to import biosimilars into U.S., and lined up experts to help Plaintiff with regulatory approvals.

9. Knowing that Plaintiff's biosimilar 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 U.S. consumers and cancer patients, Defendants designed and implemented an illegal scheme to destroy Plaintiff's competing business, raise barriers to entry in the U.S. market and foreclose U.S. market to Plaintiff's cheaper biosimilars.

10. The scheme involved an astonishing array of illegal conduct that has deliberately targeted and severely burdened, not only Plaintiff, but also the U.S. domestic and import commerce, and consumers and cancer patients in the U.S.:

a) Predatory and discriminatory pricing scheme used to finance anticompetitive conduct at the expense of U.S. cancer patients,

b) Sponsoring operations and profits of an "independent" third-party distributor, Defendant R-Farm JSC ("R-Farm");

c) Illegal kickback schemes involving hospitals, doctors and other healthcare professionals employed by foreign government;

d) Limiting the distribution network in the U.S. in anticipation of biosimilar entry and with the intent to restrain trade;

e) Registration of a non-existent drug through R-Farm, a third-party distributor and related illegal tying arrangements;

f) Submitting fraudulent bids at government auctions and tenders.

11. Defendants' scheme and conspiracy involved both the U.S. and foreign conduct, where each Defendant played an integral role in the overall plan to restrict competition in the U.S., prevent Plaintiff from importing cheaper biosimilars into U.S. and maintain Roche's monopoly in the U.S.

12. It is precisely Roche's monopoly power and the ability to charge U.S. consumers over-inflated prices for oncology medication that allowed Roche to finance its predatory anticompetitive conduct.

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

14. More disturbing is the fact that Roche openly stated 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"[2].

15. If Defendants continue their anti-competitive conduct to exclude competition from the U.S. market, they will maintain their monopoly position in the U.S. beyond statutory permitted 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. consumers and cancer patients who will have to bear the unwarranted monopoly prices.

JURISDICTION AND VENUE

16. 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 for injunctions and to recover damages, including treble damages and the costs of suit, and reasonable attorneys' fees, against Defendants for the injuries sustained by Plaintiff.

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

[2] 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

18. 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 the matter in controversy is between citizens of a state and citizen of a foreign state or citizens of different states.

19. This Court has supplemental jurisdiction under 28 U.S.C. § 1367 over the following pendent and/or ancillary state law claims: (i) claims under New York General Business Laws §§ 340 *et seq.*; and (ii) claims pursuant to the New York common law.

20. This Court has personal jurisdiction over Defendants because Defendants' acts have caused significant injury to Plaintiff in this District. Moreover, Defendants established minimum contacts with this forum as a result of business activities regularly conducted within the State of New York and the Southern District of New York, which business activities derive substantial revenue from the sale of products within this District; Defendants expect their actions to have consequences within this District, and derive substantial revenue from interstate and international commerce. Moreover, the allegations of this Amended Complaint relate to products that are being sold, offered for sale, and distributed in this state, making "specific" personal jurisdiction appropriate in this case under *International Shoe* and related cases. In addition, 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.

21. 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, were found, derived substantial revenue or resided in the Southern District of New York.

PARTIES

22. Plaintiff BIOCAD JSC ("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 direct competitor of Defendants in manufacturing, distribution and/or sale of cancer treatment monoclonal antibodies. Plaintiff maintains a subsidiary and a facility in the U.S., and an FDA-compliant manufacturing facility in Russia for importation of biosimilars into the United State. Plaintiff anticipated FDA approval, and such FDA approval is probable.

23. Defendant Roche Holding AG ("Roche Holding") is a Swiss multinational health-care corporation that operates worldwide and is based in Basel, Switzerland, with headquarters at Grenzacherstrasse 124, Basel, 4070. Roche fully owns its direct and indirect subsidiaries, which include Defendants F. Hoffman-La Roche Ltd. and Genentech Inc., and comprise the so-called "Roche Group". Roche Group is controlled and managed worldwide by Roche Holding's Board of Directors and Executive Committee. Roche Group maintains one joint compliance department for all entities comprising the

Roche Group with joint conduct rules.

24. Defendant F. Hoffman-La Roche Ltd. ("FHL Roche") is a Swiss corporation based in Basel, Switzerland, with headquarters at Grenzacherstrasse 124, Basel, 4070 and pharmaceutical operations in the United States through its affiliate and agent, Genentech. FHL Roche, directly and through its affiliates, is engaged in the business of research, production, distribution and sale of oncological and other drugs, including *bevacizumab*, *trastuzumab* and *rituximab* worldwide, including in the United States and this District. Until 2009, FHL Roche operated in the United States through Hoffmann-La Roche Inc. with historic headquarters in New Jersey. Presently, Hoffmann-La Roche Inc.'s official website maintained by FHL Roche states that the U.S. pharmaceutical headquarters for FHL Roche is now Genentech.[3] FHL Roche conducts all business operations and carries out all the activities essential to FHL Roche's business in the U.S. through Genentech.

25. 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 with Corporation Service Company at 80 State Street Albany, New York 12207 designated as its registered agent. Genentech currently serves as the base and the headquarters for FHL Roche

[3] http://www.roche-nutley.com/ (last accessed September 14, 2016).

pharmaceutical operations in the United States.[4]

26. Defendant R-Farm JSC ("R-Farm") is a Russian-based pharmaceutical company and an official independent 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 Prospect 111B, Moscow 119421, Russian Federation. Since at least 2014, R-Farm conducts substantial pharmaceutical business in the United States and in New York through its subsidiary, R-Pharm US LLC, based in Princeton, New Jersey ("R-Pharm US"). R-Pharm US was established in 2014 as part of the R-Farm's strategy to expand into the United States.

27. All Defendants conspired and implemented as scheme designed to have substantial and adverse impact on the U.S. domestic and import commerce.

28. Defendants, directly and through affiliates they control, and through actions in this country and internationally, engaged in illegal and anticompetitive conduct designed to have a direct, substantial and reasonably foreseeable adverse impact within the United States. Such conduct did in fact have an effect of restraining competition in the U.S., raising barriers to entry and prices paid by consumers and cancer patients.

[4] http://www.gene.com/about-us (last accessed September 13, 2016).

FACTUAL ALLEGATIONS RELEVANT TO ALL CAUSES OF ACTIONS

I. MARKET OVERVIEW FOR MONOCLONAL ANTIBODIES USED TO TREAT CANCER

29. Cancer is a devastating disease affecting over 8 million Americans today. 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 such medications may be able to at least slow down the progression of cancer.

30. 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]

31. The United States dominates the oncology market and remains the most lucrative market for pharmaceutical companies. The United States alone spent $42.5 Billion on cancer drugs in 2014 and account for almost half of all sales of oncology drugs worldwide.[6]

32. The use of monoclonal antibodies in treating cancer has achieved considerable success in recent years. Monoclonal antibodies ("mAbs") are laboratory produced molecules that mimic naturally produced antibodies for oncology treatments and have a variety of applications, including cancer cell

[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

[6] *Id.*

marking, growth signal blocking, the delivery of chemotherapy toxins and the reduction of new blood vessel growth.

33. The dramatic increase in the size of the potential cancer market has prompted pharmaceutical companies to invest in the oncology sector with major focus on mAbs. Spending on targeted therapies, including mAbs, has been growing at a compound average growth rate of 14.6% over the past five years. The market for cancer mAbs was estimated at US$ 24 Billion in 2013, and is expected to grow to US$ 34 Billion by 2017.[7]

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

34. Roche Group, the largest oncology company in the world, currently has the largest portfolio of FDA-approved mAbs. Roche Group's three blockbuster drugs - *bevacizumab*, *trastuzumab* and *rituximab* – are manufactured and sold worldwide through Roche Holding's subsidiaries, Defendants FHL Roche and Genentech.

35. *Bevacizumab*, *trastuzumab* and *rituximab* are marketed and sold in the U.S. by Roche Holding through Genentech under the brand names Avastin®, Herceptin® and Rituxan®, respectively (collectively, "Drugs").

36. In 2013, out of US$ 24 Billion worth of profits from mAbs sold

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

worldwide, Roche pocketed US$ 21.2 Billion just from the sale of the Drugs according to Roche's financial statements - Avastin® (US$ 6.9 Billion), Herceptin® (US$ 6.7 Billion) and Rituxan® (US$ 7.6 Billion).[8] More importantly, almost 50% of Roche's worldwide profits came from the United States (US$ 9 Billion), which remains the most lucrative market for Roche.

37. Roche's profits from the Drugs remained steady bringing the pharma giant over US$ 20 Billion in sales each year in 2014[9] and 2015.[10] In fact, since their launch, the Drugs brought Roche over US$ 170 Billion.

38. Genentech originally developed the Drugs. Prior to Genentech being fully acquired by Roche Holding in 2009, FHL Roche operated under a license from Genentech to commercialize the Drugs outside the U.S. Prior to 2009, FHL Roche operated directly in the U.S. with headquarters located in Nutley, New Jersey.

39. After the acquisition, Roche Holding combined commercial business of Genentech and FHL Roche in the U.S. and moved the headquarters to San Francisco, California. Presently, Genentech acts and operates as an extension of Roche Holding and FHL Roche in the U.S. All of Roche Group's drugs are sold in the U.S. through Genentech, including Avastin®, Herceptin® and Rituxan®.

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

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

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

40. Roche's exclusivity rights to all three drugs in the U.S. are about to expire in 2018 and 2019.

III. ROCHE'S BLOCKBUSTER ONCOLOGY DRUGS

A. Avastin®

41. Roche's *bevacizumab,* developed, marketed and sold in the U.S. through 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.[11]

42. Avastin® 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 cancer from spreading.

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

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

C. Herceptin®

45. Roche's *trastuzumab,* developed, marketed and sold in the U.S. through Genentech under the brand name Herceptin®, is one of the most widely used breast cancer treatments currently on the market and continuously generates

[11] *Id.*

over US$ 6 Billion in annual sales[12].

46. 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.

47. 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.

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

49. Herceptin® has brought Roche US$ 58.2 Billion since its launch in 1998.

A. Rituxan®

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

51. 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.

52. Rituxan® attaches itself to these cells, marking them and making

[12] 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

them more visible to the immune system, which can then kill the infected cells.

53. 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[13]. This drug is considered the crowning jewel in a trio of cancer monoclonal antibodies developed by Roche, all of which are consistently big earners.

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

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

IV. PLAINTIFF IS THE LEADING PRODUCER OF BIOSIMILARS THAT DIRECTLY COMPETE WITH ROCHE'S STAR DRUGS

56. Plaintiff, a private pharmaceutical company with headquarters 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. Plaintiff intended and prepared to enter the U.S. market at the time when Roche's exclusivity rights expire.

57. Plaintiff is a full-cycle drug development and manufacturing company, doing everything from new molecule discovery and genetic engineering to large-scale commercial manufacturing and marketing support

58. Plaintiff started development of biosimilar mAbs in 2010,

[13] 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

including 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, comparative non-clinical and clinical studies and exportation of drugs, including into United States.

59. On April 4, 2014, Plaintiff received approval from the Russian Ministry of Health for its biosimilar of *rituximab* (BCD-020), currently marketed and sold under the brand name AcellBia®. The first sale of AcellBia® took place on October 13, 2014.

60. Plaintiff is now the world leader in sales of biosimilar *rituximab*. Plaintiff'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. On November 25, 2015, Plaintiff received approval from the Russian Ministry of Health for its biosimilar of *bevacizumab*, BCD-021. The first sale of BCD-021 took place on February 15, 2016.

62. On December 31, 2015, Plaintiff received approval from the Russian Ministry of Health for its biosimilar of *trastuzumab* (BCD-022), currently marketed and sold under the brand name HERtiCAD®. The first sale of HERtiCAD® took place on March 12, 2016.

63. By now, Plaintiff is the leading manufacturer of biosimilar mAbs,

direct competitor of Roche and the biggest threat to Roche's star oncology drugs – Avastin®, Herceptin® and Rituxan®.

V. PLAINTIFF'S MANUFACTURING CAPABILITIES AND EXPERIENCE IN IMPORT MARKETS

64. Presently, Plaintiff has two main production sites in St. Petersburg and Moscow regions, as well as an R&D and pilot manufacturing site. All facilities are GLP[14] and GMP[15] compliant.

65. Plaintiff's production facility in the Moscow region consists of two production facilities. A new manufacturing site was established in 2012 with the total area of over 30,000 square feet, over 20,000 of which being cleanrooms. The capacity output at this facility alone is three (3) million vials and four (4) million pre-filled syringes per year.

66. Since 2010 Plaintiff has been running an extensive work to market its most marginal products – biosimilars of *rituximab*, *trastuzumab* and *bevacizumab* – outside of Russia, including the United States. As a result,

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[14] **Good Laboratory Practice ("GLP") Compliance:** FDA requires producers of most FDA-regulated products to submit evidence of their products' safety in research and/or marketing applications pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) and Public Health Service Act. GLP Compliance includes careful inspections of facilities that perform nonclinical laboratory studies to determine compliance with Part 58 of Title 21 of the Code of Federal Regulations.

[15] **Good Manufacturing Practice ("GMP") Compliance:** GPM Compliance is the main regulatory standard for ensuring pharmaceutical quality of human pharmaceuticals. FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with GMP regulations, which contain requirements for the methods, facilities and controls used in manufacturing, processing, and packing of a drug product.

The approval process for new drug and generic drug marketing applications includes a review of the manufacturer's compliance with the GMP. FDA inspectors determine whether the firm has the necessary facilities, equipment, and skills to manufacture the new drug for which it has applied for approval.

Plaintiff has a number of license and distribution agreements with the partners in 47 countries.

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

VI. PLAINTIFF'S INTENT AND PREPAREDNESS TO ENTER THE U.S. MARKET

68. Starting from 2010 when Plaintiff commenced development of cancer treating mAbs, Plaintiff started preparations for entering the U.S. market, which remains the largest oncology market worldwide.

69. In 2010-2011, Plaintiff opened a subsidiary in the U.S., started transferring and hiring business development personnel in the U.S., and located premises to be used for U.S.-based operations.

70. On January 1, 2012, Plaintiff secured a lease at 27 Drydock Avenue, Boston, MA for over 4,000 square feet to be used as "biology laboratory, engineering laboratory, materials handling and storage, research and development, and/or product assembly, and office use associated with the foregoing uses".

71. Plaintiff also estimated and budgeted the cost of the U.S. market entry to be between US$ 60 Million and US$100 Million per molecule.

72. Plaintiff had the financial capability and resources to enter the U.S. market, including purchase necessary equipment, build and/or rent necessary facilities, improve manufacturing process, apply and receive FDA approvals and, otherwise, enter the U.S. market.

73. William Blair & Company, LLC, Plaintiff's outside consultant, prepared timeline of Biocad's development, including entrance on U.S. market and FDA approval:

> "After verification of product comparability at the commercial scale and the start of sales in Russia, for selected products, BIOCAD may decide to conduct additional comparability studies to allow registration in EU and/or US. This will include GLP-compliant non-clinical studies. We believe that in case of rituximab, an IND package could be available for submission to EMA by the end of 2014."

Excerpt from Biosimilar Development Strategy prepared by William Blair & Company, LLC, dated October 7, 2013.

74. In 2013 Plaintiff opened a new manufacturing site, aimed to support Plaintiff's strategy to enter the U.S. market. This new manufacturing facility is the only one of its kind in Eastern Europe and one out of 50 built worldwide, specializing in monoclonal antibodies Active Pharmaceutical Ingredients ("APIs").

75. In order to ensure FDA compliance of the new facility, Plaintiff hired a leading U.S. consulting company, BioProcess (USA), to meet the requirements of FDA and EU Regulatory Agency.

76. In fact, just to make this facility GMP and GLP compliant,

Plaintiff spent over US $6 Million on acquisition of necessary equipment and over $US 1 Million in incidental expenses like travel, consulting fees, etc. Plaintiff also hired over 25 people, including Plaintiff's full-time employees and external consultants with over 18,000 working hours spent just on quality improvements.

77. Quality Improvement Plan ("QIP") was developed in December of 2014 and included the following:

Quality Assurance Systems

- Risk Management system was revised and implemented.
- Change Control system was revised and implemented.
- Computerized system were developed and validated.
- Training system was revised and implemented. Computerized system were developed and validated.
- Non-conformances system was revised and implemented. Computerized system were developed and validated.
- Customer complaints system was revised and implemented.
- External Audit Program system was implemented.
- Batch Review and Release system was revised and implemented.
- Documentation Management system was revised and implemented. Computerized system were developed and validated.
- Quality Management Review system was revised and implemented.

Quality Control – Laboratories

- All procedures were revised and implemented in order to meet cGMP requirements.
- System for analytical method transfer was developed and implemented.
- All current and newly procured equipment were qualified according to cGMP.

Material Control

- Process for controlling labels and printed materials was revised and implemented.
- Material and product flows and storage space were revised.
- Warehouse and cold storage were revamped and re-qualified according to cGMP.
- Supplier qualification system was revised and implemented in order to meet cGMP requirements.
- All methods of transportation used for material transfer were validated.

Validation / Qualification

- Qualification and validation system was revised and implemented in accordance with cGMP.
- Equipment and premises were revamped and re-qualified in order to meet cGMP requirements (clean rooms, clean utilities, production equipment).
- All GMP critical computerized systems were validated. Disaster recovery plan and procedural of changes was established.

Hygiene / Pest Control / Access Control

- Pest control system was revised in order to meet cGMP requirements.
- Cleaning procedures was revised and implemented.
- Access control system was implemented in order to meet cGMP requirements. Archive was revamped in order to meet cGMP requirements.
- Material and personnel flows were revised in order to meet cGMP requirements.

78. The facility has undergone several audits, including by (a) Ray Collyer of SeerPharma Pte Ltd., March 17-21, 2014; (b) Tom Gerteisen, Ph.D. and Tatyana Touzova of Biologics Consulting Group, and Wolfgang Rudloff of GMP-Experts Consulting Group, November 10-20, 2014; and (c) Gilson Kobori of United Medical, October 1-8, 2015.

79. By 2016, Plaintiff entered into several consulting and service

agreements with Parexel in connection with preparation of documents for CHMP and EMA and organization of the Scientific Advice procedure at the EMA and Biological License Application (BLA) to the U.S. FDA for HERtiCAD®.

80. Plaintiff had invested 6 years and a substantial amount of funds and resources to establish operations in the U.S. and to prepare for U.S. market entry. Plaintiff anticipates FDA approval to sell biosimilars in the U.S. and plans to compete head to head against Roche by dramatically undercutting Roche's price for Avastin®, Herceptin® and Rituxan® in the U.S.

81. However, Defendants' conduct has delayed Plaintiff's planned entry on the U.S. market, caused Plaintiff to lay off personnel in the U.S. and is threatening Plaintiff with complete exclusion from the U.S. market as a competitor.

VII. BIOSIMILARS AND EFFECT OF THEIR ENTRY ON THE MARKET

82. Biosimilars are priced substantially below their brand-name drug equivalents. Congressional Budget Office estimates an eventual 40 percent price difference between brand drugs and biosimilars, resulting in about $140 million in savings for every $1 billion in sales of biological drugs.[16]

83. According to a study published by FTC, a market entry of

[16] Alex Brill, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*, p. 6 (July 2014)

biosimilars could save consumers $250 billion through 2024[17]. Other studies suggest that cost savings from biosimilars can range from $25 billion to $44 billion over 10 years.[18]

84. Typically, the first biosimilar drug enters the market at a significant discount. As more biosimilar or bioequivalent competitors enter the market, price competition accelerates, and the prices continue to fall steeply.

85. Thus, once exclusivity is lost and biosimilars entry occurs, an event known as the "patent cliff", the brand name manufacturer can expect a significant drop in profits.

86. Confronted with an imminent loss of profits at the patent cliff, Roche sought to stall or prevent altogether the entry of biosimilar competition.

VIII. ROCHE'S MONOPOLY POWER IN THE RELEVANT MARKETS[19]

A. U.S. Market for Bevacizumab

87. *Bevacizumab*, branded and marketed by Roche through Genentech in the U.S. under the name Avastin®, is a monoclonal antibody that intercepts the vascular endothelial growth factor, or VEGF, growth signal,

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[17] Steve Miller, *Presentation for FTC Biosimilars Workshop on Naming Proposals and Impact on Competition*, slide 7 (Feb. 4, 2014), *retrieved from* http://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/miller.pdf

[18] Martha M. Rumore and F. Randy Vogenberg, *Biosimilars: Still Not Quite Ready for Prime Time* (June 2016), *retrieved from* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4894513/

[19] U.S. market for *bevacizumab* and its equivalents, U.S. market to *trastuzumab* and its equivalents and U.S. market for *rituximab* and its equivalents are collectively referred to as "Relevant Markets" throughout the Amended Complaint.

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 cancer from spreading.

88. 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.

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

90. 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.[20]

91. Currently, Roche holds a monopoly in the relevant market because it is the exclusive seller of *bevacizumab* in the United States.

92. An increase in price of *bevacizumab* sold in the US would not cause consumers in the Unites States to procure *bevacizumab* from other countries. Only the presence in the U.S. market of other sellers of *bevacizumab* can render Roche unable to raise and maintain pricing without losing substantial sales. Competition from other sellers of *bevacizumab* in the U.S. is the only real source of price discipline for Roche.

[20] Genentech operates as an agent and extension of FHLR and Roche in the US, and is fully controlled by FHLR and Roche.

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

94. At all times relevant to this complaint, Defendants' exclusionary acts restricted entry of Plaintiff's biosimilars into U.S. market for *bevacizumab* and protected Roche's monopoly.

95. Defendants' scheme specifically targeted U.S. import and domestic commerce.

B. U.S. Market for Trastuzumab

96. *Trastuzumab*, branded and marketed by Roche through 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.

97. 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.

98. 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.

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

100. 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.[21]

101. Currently, Roche holds a monopoly in the relevant market because it is the exclusive sellers of *trastuzumab* in the United States.

102. An increase in price of *trastuzumab* sold in the U.S. would not cause consumers in the Unites States to procure *trastuzumab* from other countries. Only the presence in the U.S. market of other sellers of *trastuzumab* can render Roche unable to raise and maintain pricing without losing substantial sales. Competition from other sellers of *trastuzumab* in the U.S. is the only real source of price discipline for Roche.

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

[21] Genentech operates as an agent and extension of FHLR and Roche in the US, and is fully controlled by FHLR and Roche.

104. At all times relevant to this complaint, Defendants' exclusionary acts restricted entry of Plaintiff's biosimilars into U.S. market for *trastuzumab* and protected Roche's monopoly.

105. Defendants' scheme specifically targeted U.S. import and domestic commerce.

C. U.S. Market for Rituximab

106. *Rituximab*, branded and marketed by Roche through 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.

107. 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®.

108. 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.

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

110. 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.[22]

111. Currently, Roche holds a monopoly in the relevant market because it is the exclusive sellers of *rituximab* in the United States.

112. An increase in price of *rituximab* sold in the U.S. would not cause consumers in the Unites States to procure *be rituximab* from other countries. Only the presence in the U.S. market of other sellers of *rituximab* can render Roche unable to raise and maintain pricing without losing substantial sales. Competition from other sellers of *rituximab* in the U.S. is the only real source of price discipline for Roche.

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

[22] Genentech operates as an agent and extension of FHLR and Roche in the US, and is fully controlled by FHLR and Roche.

114. At all times relevant to this complaint, Defendants' exclusionary acts restricted entry of Plaintiff's biosimilars into U.S. market for *rituximab* and protected Roche's monopoly.

115. Defendants' scheme specifically targeted U.S. import and domestic commerce.

116. 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. By creating Gazyva® Roche is expected to engage in "patent hopping"[23] to artificially extend the patented lifecycle of Rituxan® since the two drugs share practically identical characteristics.

IX. DEFENDANTS CONSPIRED AND DESIGNED A SCHEME DIRECTED AT THE U.S. IMPORT AND DOMESTIC MARKETS AND INTENDED TO RESTRICT COMPETITION, EXCLUDE PLAINITFF AND MAINTAIN ROCHE'S MONOPOLY BEYOND STATUTORY PERMITTED PERIOD

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

[23] "Patent hopping" is a strategy undertaken by brand-name pharmaceutical companies in order to avoid the "patent cliff" and involves introducing a new drug just before the original drug's expiration date with very little modifications from the original drug. The new drug receives a fresh patent protection for 20 years. The company then shifts its patients from the old version of a drug to the new. This is usually done to preserve monopoly profits.

118. Plaintiff's biosimilars compete directly 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 Roche's monopoly in the U.S. market, Roche and other Defendants willfully and purposefully hatched a scheme to restrict U.S. market, delay or preclude altogether Plaintiff's imports into U.S. and maintain Roche's monopoly in the U.S. beyond the exclusivity period.

119. The scheme involved an astonishing array of illegal conduct that has deliberately targeted and severely burdened, not only Plaintiff, but U.S. consumers and cancer patients and U.S. market for oncology drugs, including:

g) Predatory and discriminatory pricing scheme used to finance anticompetitive conduct at the expense of U.S. cancer patients,

h) Sponsoring operations and profits of an "independent" third-party distributor, R-Farm;

i) Paying off hospitals, doctors and opinion leaders employed by foreign government to cause severe financial damage to Plaintiff and impede Plaintiff's ability and plan to enter the U.S. market;

j) Limiting the distribution network in the U.S. for the Drugs in anticipation of biosimilar entry and with the intent to restrain trade;

k) Registration of a non-existent drug through R-Farm, a third-party distributor and related illegal tying arrangements;

l) Submitting fraudulent bids at government auctions and tenders in Russia.

120. Defendants' scheme and conspiracy included both US and foreign conduct, where each Defendant played an integral role in the overall attempt

to restrict competition in the U.S. in the Relevant Markets, to prevent Plaintiff from selling cheaper lifesaving drugs in the U.S. and to maintain Roche's monopoly in the Relevant Markets. All Defendants acted and conspired together for the common goal – the ability to continue charging US cancer patients supra-competitive prices.

A. Predatory and Discriminatory Pricing Scheme Used to Finance Anticompetitive Conduct at the Expense of U.S. Cancer Patients

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

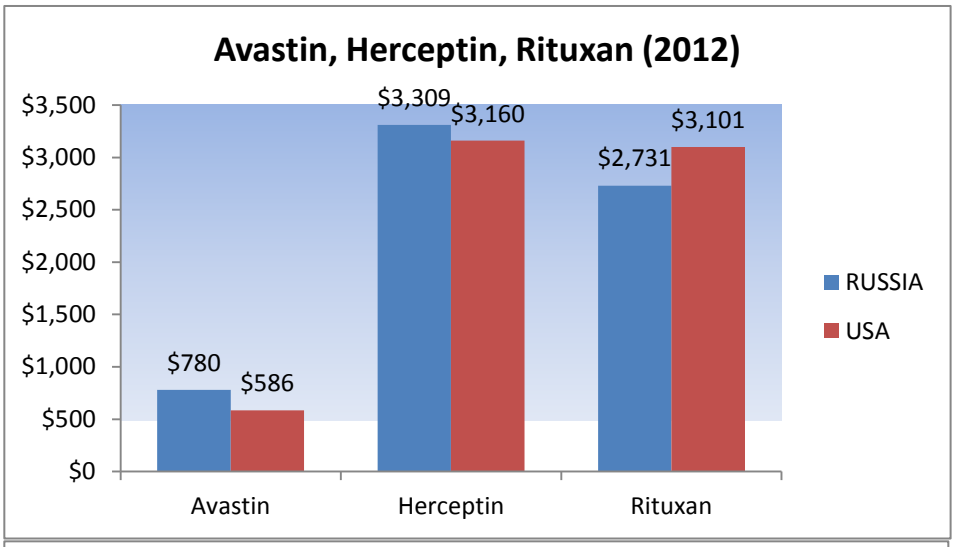
122. While Roche started selling its blockbuster drugs in Russia at prices higher than prices for the same drugs in the United States, over the past several years, Roche continued increasing the prices in the U.S. on average 19%, while dropping the prices in Russia on average 76%.

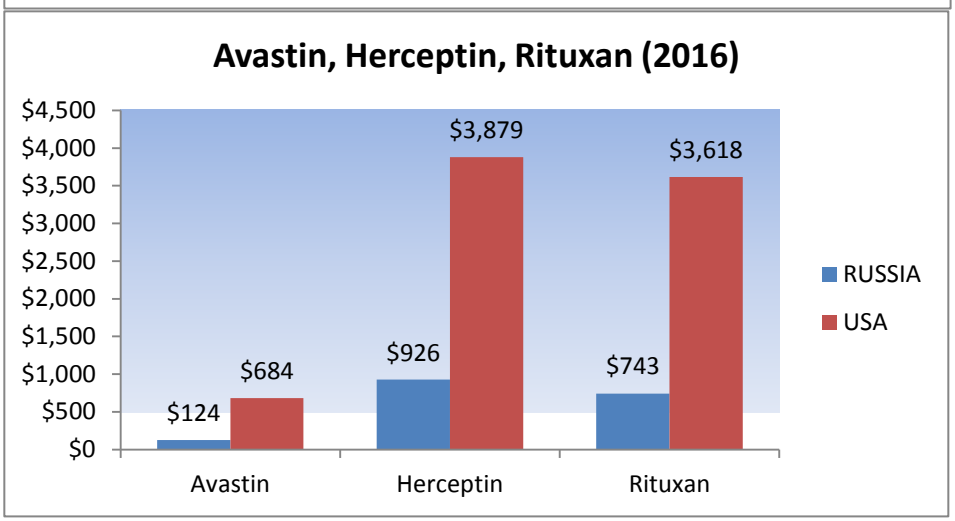
123. In addition, on October 1, 2014, shortly after Plaintiff received approval in Russia for its first biosimilar of Rituxan® and announced that significant progress is being made to copy Avastin® and Herceptin® but before the first sale of Plaintiff's biosimilar took place on October 13, 2014, Roche Defendants 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.[24]

124. The graphs below demonstrate the current price disparity with Avastin® costing 5.5 times cheaper in Russia than in the U.S.[25], Herceptin® – and Rituxan® – over 4 times cheaper.

Difference in Pricing of the Drugs between U.S. and Russia



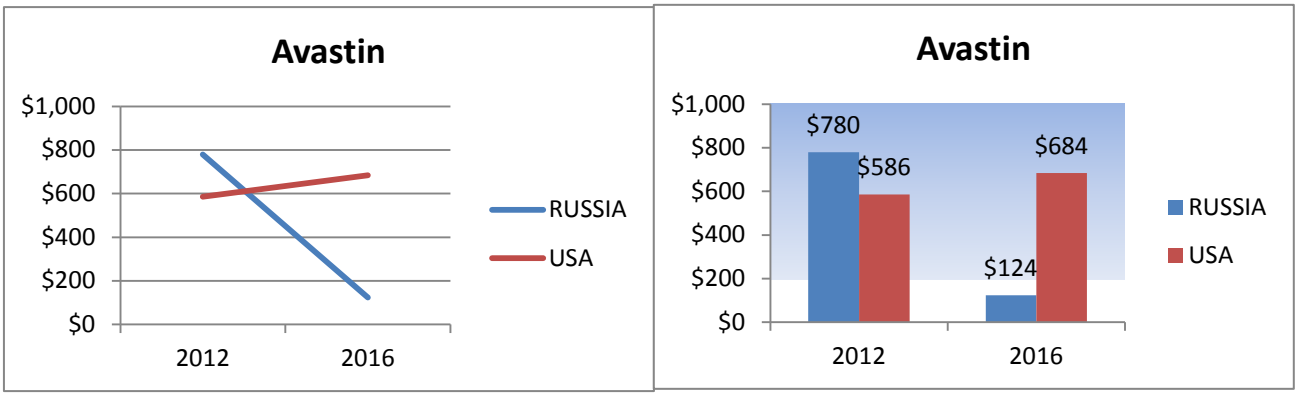


[24] Saporito, Bill (2014, October 27). *"Hospitals Furious at Cancer-Drug Price Hikes"*. Time. Retrieved from http://time.com/3541484/cancer-drug-price-hikes/

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

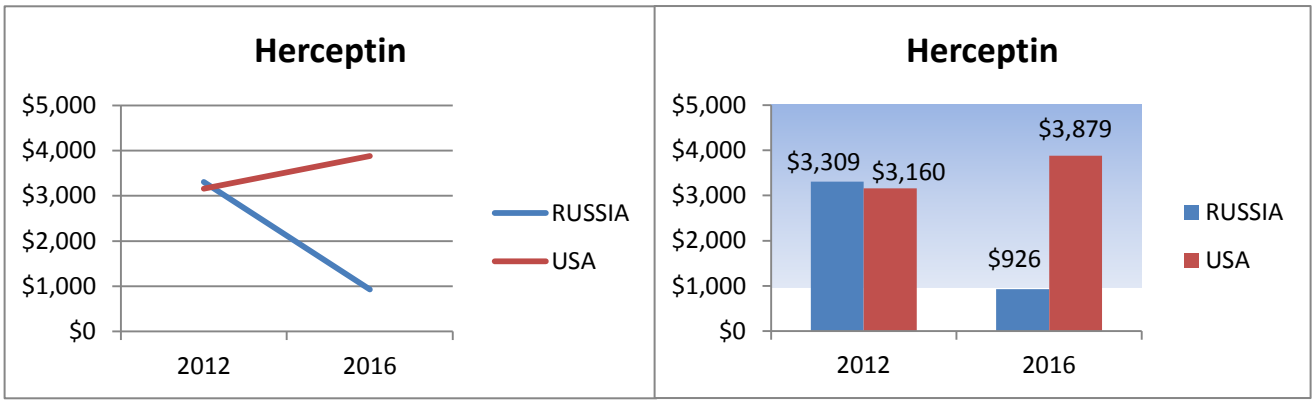
125. The average sales price of Avastin® 100mg increased substantially from 2012 to 2016 in the U.S. The increased pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Avastin® 100mg since 2012 84% or over 6 times.

Price History of Avastin® 100mg in the U.S. and Russia



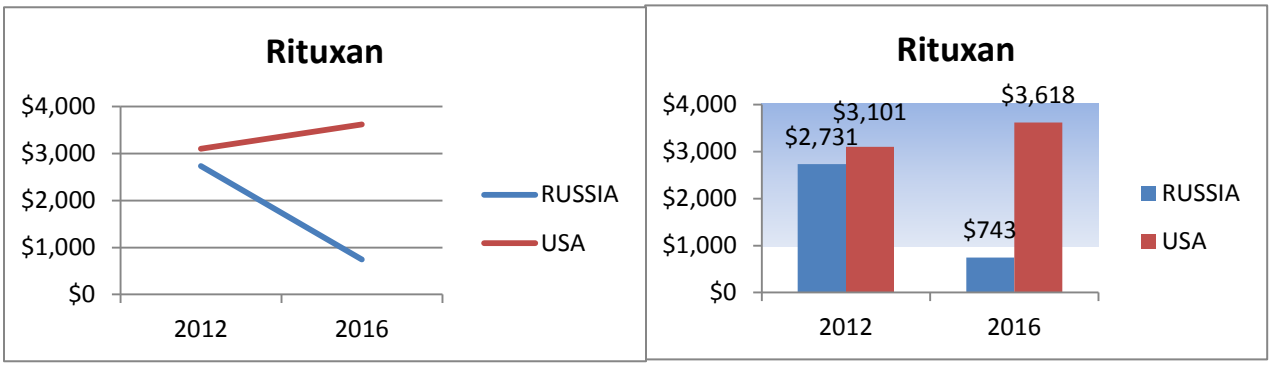
126. The average sales price of Herceptin® increased substantially from 2012 to 2016 in the U.S. The increased pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Herceptin® 72% since 2012 or almost 4 times.

Price History of Herceptin® in the U.S. and Russia



127. The average sales price Rituxan® increased substantially from 2012 to 2016 in the U.S. The increased 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.

Price History of Herceptin® in the U.S. and Russia



B. Sponsoring Operations and Profits of an "Independent" Distributor R-Farm

128. While the price disparity itself is apparent from the graphs above, Defendants conduct extended beyond predatory and discriminatory pricing scheme. Roche went as far as sponsoring operations and profits of its so-called "independent" distributor in Russia, Defendant R-Farm, to put Plaintiff out of business and preclude Plaintiff's entry on the U.S. market.

129. For example, Roche's price declared at customs upon entering Russia for bulk delivery of Avastin® 100mg is 20% higher than the price at which Avastin® 100mg is sold by R-Farm, an independent exclusive distributor of the Drugs, after the Drugs have been packaged, distributed, taxes/duties paid, including the profits of R-Farm. 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), 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.

130. A brief explanation of pricing mechanism is necessary:

> When a drug enters the country, Roche is required to declare the value of the drug at customs ("Entry Price"). Such price refers to the bulk value of the drug, without the duties, taxes, cost of packaging, etc.
>
> Then, Roche registers the price with the Russian Ministry of Health ("MOH Price"). Russian Law requires that the maximum manufacturer's price for a vital and essential drug be registered with the Ministry of Health as a prerequisite for placing such drug on the market. This price does not include taxes, special fees or distributor's profit margins. Manufacturers 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 actual price of a drug sold at auctions and tenders is referred to as "Actual Price".

131. Roche declares Entry Price of Avastin® 100mg at US$ 148. The MOH Price for Avastin® 100mg is registered by Roche at US$ 222.

132. Prior to Plaintiff's biosimilar of *bevacizumab* entering the market, Roche sold Avastin® 100mg at auctions and government tenders at about 16% over the MOH Price, sometimes as high as 120%.

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

Avastin 100mg	**Prior to 02.15.2016**	**After 15.02.2016**
Entry Price	US$ 148	US$ 148
MOH Price	US$ 222	US$ 222
Average Actual Price	US$ 257	US$ 124

134. More importantly, the average Actual Price of Avastin® 100mg is on average 20% lower than the Entry Price declared by Roche at customs. 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.

135. More disturbing is that hundreds of thousands of cancer patients 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. 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 and destroy Plaintiff's business and anticipated entry on the U.S. market.

C. Illegal Payoffs to Healthcare Professionals, Doctors and Opinion Leaders employed by foreign government

136. From 2010 and up to this day, Defendants have been engaging in improper and illegal transactions aimed at influencing doctors, pharmacies, hospitals and other healthcare professionals, employed by Russian government.

137. Roche went as far as paying doctors around $10 for each prescription and forced doctors to bring empty packages of Roche's medication as proof of prescribing and dispensing Roche's drugs.

138. Defendants further established various cash and travel reward programs for doctors, cash refund programs for pharmacies, and various sponsorship programs to pay for hospital renovations and to purchase medical and office equipment.

139. Roche made these improper and illegal payments to influence formulary approvals, purchase decisions and prescription decisions concerning Roche's drugs.

140. Defendants attempted to conceal the true nature of these transactions by improperly recording them on the books and records as legitimate expenses for promotional activities, marketing, training, travel and entertainment, clinical trials, freight, conferences and advertising.

Government Auctions – "Seven Nosologies Program"

141. In 2008, the Russian Department of Health developed a national "Seven Nosologies" insurance program ("Program") to reimburse terminally ill patients for the cost of expensive medications for treating rare diseases, including various oncological illnesses. The Program is one of the most funded federal projects in Russia. The Program has an annual budget exceeding US$ 1 Billion and currently covers more than 100,000 patients.

142. Throughout the year, the Ministry of Health collects information from regional hospitals and doctors that participate in the Program about the terminally ill patients and type of medications needed to treat such patients.

143. To encourage a fair play on the pharmaceutical market place, the government requires doctors and hospitals to submit medication formulary requests to the Program that describe medications only by their International Nonproprietary Names ("INN"). INN identifies active medication ingredients without referring to a specific brand name of such medication.

144. Based on the information received from doctors and hospitals, the government compiles formulary lists of medications needed for treating patients. The Program then schedules auctions for the purchase of medications listed on the formulary lists.

145. Using the network of doctors, opinion leaders and healthcare professionals employed by the Russian government, as well as government-sponsored hospitals, Defendants devised and executed a fraudulent scheme to

eliminate Plaintiff from participating in government auctions and tenders in connection with the Program.

146. Defendants maintained and paid-off a massive network of state-owned hospitals and state-employed healthcare officials to submit medication requests to the Program which were used for compiling auction formulary lists.

147. The medication requests were phrased in such a way that only Roche products could participate in the auctions. Namely, the hospitals and doctors paid by Defendants intentionally requested drug characteristics matching the specifications of medications produced by Roche, thus, eliminating all other competitors from participating in auctions in any given category. Such specifications were not based on drugs' active ingredients but were rather based on non-essential characteristics such as the product weight, packaging and form.

Payments to Hospitals in connection with the Program

148. In exchange for participation in the auctions and requesting specifications matching Roche's products, Roche supplied medical and office equipment to hospitals and paid for renovations.

149. According to the books and records meticulously maintained and updated by Defendants' employees, Roche made various improper and unsubstantiated payments to various hospitals throughout Russia, including $40,000 on renovating an oncological medical clinic in Belgorod; $7,000 for purchasing medical equipment for hospital in Vladimir; $7,000 for purchasing

medical equipment and chairs for a hospital in Kursk; $4,000 on renovating dispensary in one of the oncological hospitals in Kursk; $3,000 on purchasing notebooks for a hospital in Voronezh. Roche recorded these transactions in its books and records as Roche's legitimate business expenses.

150. In another instance, Roche spent more than $16,000 on renovating oncological clinic in Tula. In internal company's correspondence, one of the company's employees described this transaction as the reimbursement for the hospital processing a large order of Roche's medications.

Payments to Doctors in connection with the Program

151. To scale up Roche's participation in government auctions, the company provided direct financial incentives to leading oncological doctors and head of hospital departments.

152. On the books and records, Roche documented payments to doctors by region, place of employment, payment history and each doctor's sphere of influence in oncological field.

153. Some examples include:

> Dr. Svetlana Sheko, Head of Department at Smolensk Oncologic Dispensary
>
> *Forms requests within....7 N programs, and a hospital request. Practically independent in performing LPD-related therapy in Oncologic Dispensary. With the forecasted Chief Physician change (in 2011 according to unconfirmed information) will play even a bigger role in the medical and preventive institution*

(MPI). ***Loyal to [Roche], yet this loyalty was won with great difficulties.***

Dr. Aleksandr Pechony, Head of Hematology Department at Orel Oncological Dispensary

Pechony A. P - Head of hematology department, Orel Regional Clinical Hospital Purchases Neulastim at the in-patient clinic level. In 2010, Neulastim — 40 packages, Recormon 30 th. units — 93 packages, 10 th. units — 15 packages. Defends the requests at federal level

Dr. Elena Volodicheva, Regional Chief Hematologist at Tula Regional Clinical Hospital

Independently manages register of the patients with lymphoproliferative diseases (NHL + CLL) and defends requests at local and federal levels. Forms a request for the in-patient clinic.

Dr. Elena Borisenkova, Hematologist at Kaluga Regional Hospital

The Chief Hematologist (Tolstokoraya T. M.) "right hand", practical activities on preparing ALL the hematology-specific requests, has a significant influence on Chief Hematologist with a possibility to lobby [Roche] interests when preparing requests.

Dr. Irina Gushanskaia, Chief Medical Officer at Smolensk Oncologic Dispensary

Controls preparation of requests within FDC, BDCP and 7 N programs. Defends BDCP and 7 N requests. Enjoys more importance as Deputy Chief Physician on clinical care resulted from the personnel reshuffle (a new MPI Chief Physician), has a possibility to lobby the company interests when forming requests.

154. The list of doctors who received illegal kickbacks from Roche is endless.

155. Roche also paid for doctors' attendance of top international and regional oncological conferences and covered travel and lodging expenses.

156. For example, Roche sent Dr. Aleksandr Pechony, head of one of the local dispensaries, to Lugano Switzerland to attend 11th International Conference on Malignant Lymphoma. The Company sent Dr. Elena Volodicheva, Regional Chief Hematologist at Tula Regional Clinical Hospital to the United States to attend the 53rd American Society of Hematology Annual Meeting and Exposition.

157. As demonstrated in section above, both Dr. Aleksandr Pechony and Dr. Elena Volodicheva lobbied Roche interests when forming and submitting medication requests to the Program.

158. The doctors who participated in the fraudulent scheme to advance Roche interests in the Program also received direct payments from the company. The company paid these doctors substantial amounts in kickbacks.

159. Roche employees took steps to conceal the true nature of these improper payments by booking them as payments for "lectures".

160. To document illegal cash payments for "lectures", Roche employees went as far as creating the actual power point slides for the lectures as a proof.

161. For example, starting from 2010, Dr. Irina Gushanskaia and Elena Borisenkova have been assisting Roche in submitting falsified

medication formularies to the Program received substantial "cash" payments from Roche.

162. On the books and records, Roche recoded these transactions as the expense for "lectures" and documented the payments by creating themselves power point slide presentations for doctors:

> *"Modern Therapy for non-Hodkin lymphoma – reported prepared by the chief of hematological department of Bryansk Regional Hospital No. : Irina Gushanskaia"; and*
>
> *"Modern Therapy for non-Hodkin lymphoma – reported prepared by the chief of hematological department of The Kaluga Regional Hospital: Elena Borisenkova".*

163. Upon information and believe, Roche documented thousands of payments to doctors who participated in the Program using the recording system involving fake power point lecture slides.

"Doctor Reward" Program

164. To further boost sales and destroy Plaintiff's competing business, Roche paid doctors to prescribe Roche medications.

165. The company calculated payments to doctors based on the volume of prescribed medications. For each prescribed medication, Roche paid doctors approximately $10.

166. To keep track of payments and the volume of prescribed medications, doctors collected empty medication packages as the proof that he/she prescribed Roche medications to patients.

167. In the end of each month, Roche employees collected empty packages from doctors to calculate payments to doctors for an upcoming billing cycle and to distribute payments for the previous month.

168. On the books, Roche recorded illegal payments to doctors as legitimate business expenses for lectures. To document the payments, the company used the same system it used for documenting lecture payments to doctors who submitted falsified medication formularies to the Program – self-made power point slides.

169. Further, the company had a practice of collecting payment receipts from doctors who received payments in end of a billing cycle. There were instances when doctors who were late in receiving payments from Roche submitted written complaints to Roche requesting that the outstanding balances were paid.

"Pharmacy Bonus" Program

170. Under the "Pharmacy Bonus" program, Roche employees provided cash refunds to pharmacies that were calculated based on 5% of sales proceeds generated by pharmacies through selling drugs to public.

Defendants Knew And Approved The Illegal Payments To State-Employed Doctors And Hospitals

171. There is ample evidence demonstrating that Roche's global compliance department knew about the company's illegal business practices in Russia. Yet the company took no actions to prevent future misconduct and flagrant violations of law.

172. In 2013, Roche's global compliance team received several complaints

from Roche's employees in Moscow describing the company's illegal business practices that involved illegal kickback payments to doctors and hospitals for prescribing Roche drugs; the company's illegal participation in the government auctions for drug purchase; bonus programs to incentivize doctors and hospitals to purchase and to prescribe the company's drugs; and other violations of law.

173. For example, one of the company's regional managers submitted eleven page report to Roche discussing in detail the following conditions attributable to Roche business practices in Russia:

- company pays doctors and hospitals to prescribe medications;
- internal sales policies list fixed "kickback" amounts payable to doctors and hospitals for prescribing each class of medication – for example, 300 rubles for 1 prescribed package of intravenous Boniva;
- company conceals payments to doctor for prescribing medications as legitimate business expenses;
- regional management openly encourages and pushes employees to achieve sales goals through bribery of local health-care officials;
- there is a suicide history among the company's employees;
- management applies psychological pressure on employees to comply with illegally driven conduct aimed at achieving sales goals;
- management harasses and discriminates against those employees who refuse to participate in the bribery schemes to boost drug sales;
- management financially rewards employees who comply with the company's illegal sales techniques aimed at bribing doctors and hospitals by paying higher salaries to such employees, covering their living expenses and providing corporate perks that are otherwise unavailable to employees who refuse to comply with the illegal conduct;

174. Responding to the received complaints, in June of 2013 Roche sent international compliance managers Marie-Alix von Meiningen and Patrik Kronig to meet with Roche employees and to discuss the reports.

175. During the meetings, Kronig and Meiningen gathered countless reports establishing the company's illegal kickback activity, bonus programs, financing hospital renovations and supply of medical equipment in exchange for ordering Roche's drugs, accounting methods for concealing illegal payments and Roche's success on staged national and regional auctions for purchasing drugs.

176. Kronig and Meiningen assured employees that the global compliance team would investigate the company's business practices, take necessary actions to prevent future violations, and meet with Milosh Petrovic to discuss measures for addressing reported conditions.

177. However, months after the meetings with Kronig and Meiningen, several of Roche's employees contacted the compliance department expressing their bewilderment about why the company failed to undertake any steps to prevent reported misconduct and flagrant violations of law. For example, one of the employee who met with Kronig in Moscow emailed him on November 20th, 2013 the following letter:

> *Dear Partik,*
>
> *On June 18th we had a meeting at the Hotel Ararat Park Hyatt in Moscow. At that meeting you were provided with the evidence of regular laws violation by Elena Nikolaeva, RM department manager.*
>
> *During 4 months there are no changes in the department, there is still*

pressure under the employees and threats from Elena Nikolaeva. Due to this fact I am getting new requests from employees who were made to leave the Company.

Taking into account these circumstances, please inform us about your further actions, as it influences on our further ones.

Best regards,

Georgy

178. To this day, there is no evidence that the global compliance department of Roche took any steps to remediate past conduct or prevent future misconduct and violations of law, enhanced its internal controls and compliance functions, engaged in significant disciplinary measures or devised a new system of internal accounting controls that accurately reflect and fairly reflect the transactions.

179. Instead of completing a full-blown internal investigation of Roche business operations, the company applied pressure on employees, who met with Kronig and Meiningen, to voluntary quit their positions and to sign resignation statements confirming that they have not observed the company violating any laws or regulations concerning business activity in Russia.

180. The only obvious change that occurred in the company following Mr. Kronig's compliance visit to Moscow was his rapid career growth. In the beginning of 2014, the company promoted Kronig from the regional compliance officer to the head of business compliance program in China. In 2015, Mr. Kronig was appointed as the head of compliance office for the entire Asia Pacific region.

A. Limiting Distribution Networks In The U.S.

181. In order to further restrict competition in the U.S., raise barriers to entry and, thus, delay and preclude Plaintiff's entrance on the U.S. market, Roche substantially limited availability of samples necessary for FDA approval.

182. In September of 2014, Genentech, on behalf of Roche Holding and FHL Roche, announced substantial limitation of its distribution network for three drugs sold in the U.S. – Avastin®, Herceptin® and Rituxan®.

183. Genentech shifted distribution from eighty (80) wholesalers who had handled the Drugs to just six (6).

184. Such distribution change, which took place on October 1, 2014 shortly after Plaintiff received approval for its first biosimilar before the first sale of Plaintiff's biosimilar took place on October 13, 2014, 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.[26]

185. However, limiting distribution network in the U.S. did not only help Defendants finance their illegal conduct, but was also designed to slow down the entry of biosimilars on the U.S. market.

186. To receive FDA approval, competitors are required to conduct bioequivalence testing to demonstrate that formulation is therapeutically

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

equivalent to the brand drug (reference product). This testing requires access to samples or a limited amount of the brand product.

187. Limiting distribution networks is often used to thwart access to samples of reference drugs, delaying market entry and competition.

188. Thus, distribution restrictions are used by pharmaceutical companies to prevent competing firms from obtaining samples of the brand product for testing purposes with the FDA and to interfere with competitor's timely biosimilar development plans and FDA applications.

189. Roche implemented the distribution change shortly after Plaintiff's announcement of approval of its first biosimilar.

190. More importantly, Roche's plan to limit distribution network to a few specialty distributors not only limited Plaintiff's access to reference product but it also increased costs for patients and hospitals and forced hospitals to increase inventory and buy more drugs from Roche that they would normally order.

191. When hospitals contract with wholesalers, drugs are delivered daily from distributors at specific times. But with limited specialty distributors, drugs are shipped via other courier services such as FedEx, 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 cancer patients.

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

192. Shortly after Plaintiff obtained approval for biosimilar *trastuzumab*, Roche, with the help of Defendant R-Farm, once again hatched a scheme to prevent Plaintiff from sellig biosimlar *trastuzumab*.

193. Roche organized and orchestrated a classic tying and bundling scheme, where Roche forced Russian cancer patients in need of Perjeta® (another cancer drug produced by Roche), to purchase Roche's Herceptin®.

194. 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[27]. Thus, patients often require both drugs.

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

196. First, Roche stopped selling Perjeta® in Russia. Then, on October 10, 2014, R-Farm, at the direction and full knowledge of FHL Roche and Genentech, registered a new drug under the name "Beyodaim"[28] with the Russian Ministry of Health.

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[27] Genentech, *Genentech's Perjeta Significantly Extends Survival in People With HER2-Positive Metastatic Breast Cancer*, available at http://www.gene.com/media/press-releases/14267/2012-12-07/genentechs-perjeta-significantly-extends

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

197. 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.

198. Beyodaim is not recognized as an active ingredient by the World Health Organization[29] and is not listed as a product on FHL Roche's or Genentech's global websites or product lists. The only reference to "Beyodaim" can be found on FHL Roche's Russian version of the website.

199. Moreover, "Beyodaim" was registered as a new drug in the name of 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.

200. FHL Roche and Genentech knew and approved such registration and illegal tying scheme as, according to the registration statement, Herceptin® inside the "Beyodaim" box was produced and supplied by Genentech, and Perjeta® - by FHL Roche. Both drugs were then re-packaged into "Beyodaim" by "Ortat" JSC, R-Farm's wholly owned subsidiary.

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

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

[29] 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.

203. 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®.

204. Patients are, thus, forced to purchase Herceptin® from Roche in order to obtain the necessary Perjeta®.

205. As the only seller of Perjeta® on the Russian market[30], Roche has monopoly power and has exercised such power to force patients fighting with cancer to buy Genentech's Herceptin® from Defendants[31].

E. Fraudulent Bids For Avastin®

206. At the end of 2015, Biocad obtained approval for the manufacturing and sale of biosimilar *bevacizumab*. Until that time, *bevacizumab* was sold in Russia exclusively by Roche under the brand name Avastin®.

207. 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.

208. Once Plaintiff's biosimilar of *bevacizumab* became available on the Russian market, Roche dropped prices and even sponsored R-Farm's operations and profits, as discussed above.

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

[31] "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.

209. In addition, 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.

210. On March 10, 2016, "Ortat" JSC, a fully owned subsidiary of Defendant R-Farm and the 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.

211. Despite knowing that the drug is not 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.

212. With full knowledge that Defendants will not be able to perform, R-Farm entered into numerous government and municipal contracts on behalf of Roche that called for delivery of Avastin® before the second half of 2016.

213. R-Farm and Roche, knowingly and intentionally misrepresented the availability of Avastin® and participated in the 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 Plaintiff's biosimilar of Avastin®.

214. R-Farm and Roche succeeded in winning the fraudulent bids with no intention of delivering Avastin® pursuant to the contracts. Defendants did in fact default on numerous contracts and failed to deliver the drug, yet prevented Plaintiff from selling its product.

F. Dosage of Herceptin®

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

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

217. 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.

218. Each vial contains 440 mg of Herceptin® as a lyophilized sterile powder[32]. Before Herceptin® can be administered, it must be mixed with a liquid contained in the package and also provided by Roche.

219. According to Roche and Genentech, the mixed solution should

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

have a concentration of Herceptin® of 21mg/mL[33]. However, as described in a recent Class Action Suit filed against Roche and Genentech in California, Genentech 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[34].

220. More importantly, once dissolved as a solution, Herceptin® can lose its potency and must be discarded after 28 days[35].

221. 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[36].

222. 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[37].

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[33] *Id.*

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

[35] *Id.*

[36] *Id.*

[37] 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 accessed, June 3, 2016).

X. DEFENDANTS' CONDUCT WAS DESIGNED TO CAUSE AND DID IN FACT CAUSE SUBSTANTIAL ANTICOMPETITIVE EFFECT ON THE U.S. MARKET

223. 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 competition and unlawfully maintain its monopoly in the Relevant Markets.

224. Defendants conduct and conspiracy was meant to produce and did in fact produce some substantial effect on the interstate commerce, as well as import commerce to the United States.

225. Defendants' scheme affected price, quantity and competitive nature of the Relevant Markets and, thus, had direct, substantial and reasonably foreseeable effect on U.S. commerce precisely in ways that the antitrust laws were created to prevent.

226. Defendants' anti-competitive conduct was aimed to stabilize and maintain the monopoly in the U.S. beyond the 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.

227. As a direct and proximate result of Defendants' anti-competitive and unlawful tactics, competition in the Relevant Markets was improperly diminished and restrained, the barriers to entry were raised, a viable competitor is threatened with complete exclusion and the consumers are paying higher prices for life-saving cancer drugs.

228. The overall effect of Defendants' anticompetitive, exclusionary scheme has been to substantially foreclose and impair competition (and the threat of such competition) from lower priced biosimilars.

XI. DEFENDANTS HAVE DAMAGED COMPETITION IN THE RELEVANT MARKETS AND HAVE CAUSED PLAINTIFF TO SUFFER BOTH INJURY-IN-FACT AND ANTITRUST INJURY

229. As a direct and proximate result of the foregoing anticompetitive effects on the U.S. market, including restriction of competition and raised barriers to entry, Plaintiff has suffered antitrust injury including by being deprived of the ability to effectively compete in the United States.

230. In addition, as a direct and proximate result of the foregoing anticompetitive effects, Plaintiff has suffered injury to their business and property, including by being deprived of the ability to realize its substantial investments into the preparations undertaken to import biosimilars into the U.S. and to effectively compete in the United States.

231. In addition, Defendants actions both in the U.S. and abroad have materially impaired Plaintiff's ability to produce and export biosimilars of *bevacizumab*, *trastuzumab* and *rituximab* into the United States.

232. Plaintiff has suffered and continues to suffer injury-in-fact from Defendants' conduct, the anti-competitive effect on the U.S. market and the preservation of Roche's monopoly.

233. Plaintiff has antitrust standing because Plaintiff is a direct

competitor of Defendants who was excluded from the US market, suffered and will continue to suffer from restricted competition if Defendant's behavior persists and succeeds. Plaintiff's injury is of the type the antitrust laws were intended to prevent.

234. Plaintiff is the proper party to bring this action because Plaintiff is most directly impacted by Defendants' anticompetitive behavior, as Plaintiff is the largest competitor in offering competitively-priced biosimilar drugs. Plaintiff's interest is aligned with consumers' interest in promoting competition, and Plaintiff's self-interest would most motivate Plaintiff to vindicate the public interest in the antitrust enforcement.

CONCLUSION

235. When threatened with imminent competition to its blockbuster drugs, Roche Defendants designed and implemented a scheme with the help and active participation R-Farm 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 patients within the United States.

236. Defendants' conduct has delayed, and may completely foreclose, Plaintiff's entry into the Relevant Markets. It will delay, and may continue prevent, Plaintiff from competing against Roche Defendants in the U.S. Plaintiff brings this lawsuit to recover damages it has incurred as a result of Defendants' anticompetitive and monopolistic conduct. It also seeks injunctive

relief against defendants' continuation of such conduct.

FIRST CLAIM FOR RELIEF

Monopolization in Violation of Section 2 of the Sherman Act

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

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

239. At all relevant times Defendants' business activities and anticompetitive conduct that are the subject of this Amended Complaint were within the flow of and had a direct, substantial and reasonably foreseeable effect on domestic commerce, import commerce and foreign trade and commerce.

240. At all relevant times, Roche possessed monopoly power in the Relevant Markets.

241. At all relevant times, Roche used its monopoly power and raised prices in the U.S. forcing U.S. consumers to pay supra-competitive prices for life-saving cancer treatments

242. Through the anticompetitive conduct described herein, Defendants have willfully maintained monopoly power in the Relevant

Markets.

243. Defendants' anticompetitive conduct both in the U.S. and abroad included predatory and discriminatory pricing scheme (including sponsoring operations and profits of an "independent" distributor R-Farm), illegal kickback schemes to influence purchase decisions of hospitals, doctors and healthcare professional employed by foreign government and to prevent Plaintiff from selling its biosimilars, limitation of distribution network in the U.S. to prevent competitors from obtaining reference samples, registration of a non-existent drugs and illegal tying and bundling scheme, participation in auctions and tenders with fraudulent bids, and as otherwise described in this Amended Complaint.

244. There are no legitimate business justifications for Defendants' conduct, and any purported legitimate business justifications are mere pretexts. Roche went as far as fully sponsoring operations of a third-party distributor in order to achieve their anticompetitive goals.

245. The sole purpose of Defendants' conduct was to gain or maintain Roche's monopoly position in the Relevant Markets and to block Plaintiff's entrance on the U.S. market.

246. Defendants' conduct had direct effect of foreclosing the U.S. market to biosimilar competition, and Plaintiff was injured in their business or property as a direct and foreseeable result of such effect and Roche's monopolistic and predatory practices.

247. Defendants' anticompetitive activities and their effects have caused injury to the Plaintiff both inside the United States and in foreign nations.

248. Plaintiff has not only been delayed and excluded from entering the Relevant Markets, but will continue to be delayed and excluded from entering the Relevant Markets unless Defendants are enjoined.

249. Defendants' violation of Section 2 of the Sherman Act has caused, and will causes damages to Plaintiff in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C §15.

SECOND CLAIM FOR RELIEF

Attempted Monopolization in Violation of Section 2 of the Sherman Act

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

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

252. At all relevant times Defendants' business activities and anticompetitive conduct that are the subject of this Amended Complaint were within the flow of and had a direct, substantial and reasonably foreseeable effect on domestic commerce, import commerce and foreign trade and

commerce.

253. Defendants' anticompetitive conduct both in the U.S. and abroad included predatory and discriminatory pricing scheme (including sponsoring operations and profits of an "independent" distributor R-Farm), illegal kickback schemes to influence purchase decisions of hospitals, doctors and healthcare professional employed by foreign government and to prevent Plaintiff from selling its biosimilars, limitation of distribution network in the U.S. to prevent competitors from obtaining reference samples, registration of a non-existent drugs and illegal tying and bundling scheme, participation in auctions and tenders with fraudulent bids, and as otherwise described in this Amended Complaint.

254. Defendants specifically intended that the overarching anticompetitive scheme would maintain and achieve Roche's monopoly in the Relevant Markets beyond the statutory period, and their illegal conduct described herein enabled them to do so, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

255. If allowed to continue, Defendants have strong probability of achieving monopoly power in the Relevant Markets beyond statutory permitted period.

256. The Relevant Markets have very high barriers to entry, including regulatory approval process and high start-up costs.

257. Defendants' acts of attempted monopolization has unlawfully

prevented and delayed Plaintiff from entering the Relevant Markets and otherwise injure competition by reducing choice, inflating prices, lessening innovation and raising barriers to entry.

258. A dangerous probability exists that Roche Defendants have succeeded, and if not restrained, will continue to succeed in monopolizing the Relevant Markets.

259. There are no legitimate business justifications for Defendants' conduct, and any purported legitimate business justifications are mere pretexts. Roche Defendants went as far as fully sponsoring operations of a third-party distributor in order to achieve their anti-competitive goals.

260. The sole purpose of Defendants' conduct was to achieve Roche's monopoly position in the Relevant Markets beyond the statutory permitted period and to block Plaintiff's entrance on the U.S. market.

261. Defendants' conduct had direct effect of foreclosing the U.S. market to biosimilar competition, and Plaintiff was injured in their business or property as a direct and foreseeable result of such effect and Roche's monopolistic and predatory practices.

262. Defendants' anticompetitive activities and their effects have caused injury to the Plaintiff both inside the United States and in foreign nations.

263. Plaintiff has not only been delayed and excluded from entering

the Relevant Markets, but will continue to be delayed and excluded from entering the Relevant Markets unless Defendants are enjoined.

264. Defendants' attempted monopolization in violation of Section 2 of the Sherman Act has caused, and will causes damages to Plaintiff in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C §15.

THIRD CLAIM FOR RELIEF

Conspiracy to Monopolize in Violation of Section 2 of the Sherman Act

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

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

267. At all relevant times Defendants' business activities and anticompetitive conduct that are the subject of this Amended Complaint were within the flow of and had a direct, substantial and reasonably foreseeable effect on domestic commerce, import commerce and foreign trade and commerce.

268. Defendants conspired to extend Roche's monopoly in the Relevant Markets beyond the statutory permitted period by delaying and blocking entry of Plaintiff's biosimilars.

269. Defendants' anticompetitive conduct both in the U.S. and abroad included predatory and discriminatory pricing scheme (including sponsoring operations and profits of an "independent" distributor R-Farm), illegal kickback schemes to influence purchase decisions of hospitals, doctors and healthcare professional employed by foreign government and to prevent Plaintiff from selling its biosimilars, limitation of distribution network in the U.S. to prevent competitors from obtaining reference samples, registration of a non-existent drugs and illegal tying and bundling scheme, participation in auctions and tenders with fraudulent bids, and as otherwise described in this Amended Complaint.

270. Defendants specifically intended to conspire to monopolize the Relevant Markets beyond the statutory period, and their illegal conduct described herein enabled them to do so, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

271. The conspiracy involved an elaborate scheme and included both U.S. and foreign conduct, where each Defendant played an integral role in the overall attempt to restrict competition in the U.S. for monoclonal antibodies and prevent Plaintiff from selling cheaper lifesaving drugs in the U.S.

272. All Defendants acted together for the common goal – the ability to continue charging U.S. cancer patients supra-competitive prices in the U.S. after Roche's exclusivity rights expire.

273. Each Defendant committed at least one overt act in furtherance of the conspiracy.

274. There are no legitimate business justifications for Defendants' conduct, and any purported legitimate business justifications are mere pretexts. Roche Defendants went as far as fully sponsoring operations of a third-party distributor in order to achieve their anti-competitive goals.

275. The sole purpose of Defendants' conduct was to achieve Roche's monopoly position in the Relevant Markets beyond the statutory permitted period and to block Plaintiff's entrance on the U.S. market.

276. Defendants' conduct had direct effect of foreclosing the U.S. market to biosimilar competition, and Plaintiff was injured in their business or property as a direct and foreseeable result of such effect and Roche's monopolistic and predatory practices.

277. Defendants' anticompetitive activities and their effects have caused injury to the Plaintiff both inside the United States and in foreign nations.

278. Plaintiff has not only been delayed and excluded from entering the Relevant Markets, but will continue to be delayed and excluded from entering the Relevant Markets unless Defendants are enjoined.

279. Defendants' attempted monopolization in violation of Section 2 of the Sherman Act has caused, and will causes damages to Plaintiff in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C §15.

FORTH CLAIM FOR RELIEF

Unreasonable Restraint of Trade in Violation of Section 1 of the Sherman Act

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

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

282. At all relevant times Defendants' business activities and anticompetitive conduct that are the subject of this Amended Complaint were within the flow of and had a direct, substantial and reasonably foreseeable effect on domestic commerce, import commerce and foreign trade and commerce.

283. Roche holds monopoly in the Relevant Markets and maintains supra-competitive monopoly pricing in the Relevant Markets.

284. Plaintiff is Roche's competitor in the Relevant Markets.

285. Eliminating Plaintiff as competitor would increase Roche ability to gain profits from U.S. consumers, allowing it to control prices for life saving cancer treatments drugs over which the cross-price elasticity of demand is absent.

286. Roche could and did impose significant non-transitory price

increases in the Relevant Markets without losing sufficient sales.

287. Defendants contracted, combined or conspired to restrain trade in the Relevant Markets.

288. Defendants' anticompetitive conduct both in the U.S. and abroad included predatory and discriminatory pricing scheme (including sponsoring operations and profits of an "independent" distributor R-Farm), illegal kickback schemes to influence purchase decisions of hospitals, doctors and healthcare professional employed by foreign government and to prevent Plaintiff from selling its biosimilars, limitation of distribution network in the U.S. to prevent competitors from obtaining reference samples, registration of a non-existent drugs and illegal tying and bundling scheme, participation in auctions and tenders with fraudulent bids, and as otherwise described in this Amended Complaint.

289. Defendants conduct constitutes an agreement and/or conspiracy that substantially, unreasonably and unduly restrains trade in the Relevant Markets, and harms competition in the Relevant Markets in violation of Section 1 of the Sherman Act.

290. There are no legitimate business justifications for Defendants' conduct, and any purported legitimate business justifications are mere pretexts. Roche Defendants went as far as fully sponsoring operations of a third-party distributor in order to achieve their anti-competitive goals.

291. The sole purpose of Defendants' conduct was to achieve Roche's

monopoly position in the Relevant Markets beyond the statutory permitted period and to block Plaintiff's entrance on the U.S. market.

292. Defendants' conduct had direct effect of foreclosing the U.S. market to biosimilar competition, and Plaintiff was injured in their business or property as a direct and foreseeable result of such effect and Roche's monopolistic and predatory practices.

293. Defendants' anticompetitive activities and their effects have caused injury to the Plaintiff both inside the United States and in foreign nations.

294. Plaintiff has not only been delayed and excluded from entering the Relevant Markets, but will continue to be delayed and excluded from entering the Relevant Markets unless Defendants are enjoined.

295. Defendants' conduct constitute unreasonable restraint of trade in violation of Section 1 of the Sherman Act has caused, and will causes damages to Plaintiff in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C §15.

FIFTH CLAIM FOR RELIEF

Violation of Section 4 of the Clayton Act 15 U.S.C. §15

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

297. Defendants have combined and conspired to unreasonably restrain interstate trade and commerce, as well as monopolize the Relevant Markets, constituting violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

298. Defendants' anticompetitive conduct both in the U.S. and abroad included predatory and discriminatory pricing scheme (including sponsoring operations and profits of an "independent" distributor R-Farm), illegal kickback schemes to influence purchase decisions of hospitals, doctors and healthcare professional employed by foreign government and to prevent Plaintiff from selling its biosimilars, limitation of distribution network in the U.S. to prevent competitors from obtaining reference samples, registration of a non-existent drugs and illegal tying and bundling scheme, participation in auctions and tenders with fraudulent bids, and as otherwise described in this Amended Complaint.

299. Defendants' monopolization, conspiracy and other unlawful antitrust activities were meant to eliminate price competition among producers of biosimilars, including Plaintiff.

300. Defendants conspiracy and unlawful anticompetitive actions have resulted in anticompetitive effects on consumers in the cancer biological drug market by setting supra competitive prices and by depriving cancer patients of the benefits of price competition and innovation among the biosimilars' producers, including Plaintiff.

301. Plaintiff, as well as consumers, have suffered antitrust injury from

Defendants' conduct.

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

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

SIXTH CLAIM FOR RELIEF

Injunctive Relief Under Section 16 of Clayton Act 15 U.S.C. § 26

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

305. Plaintiff's allegations described in this Amended Complaint and in Claims I-V comprise violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

306. Plaintiff seeks equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. §26, to correct for the anticompetitive effects caused by Defendants' unlawful conduct and to assure that similar anticompetitive conduct does not occur in the future.

307. Defendants' antitrust violations are likely to recur presenting significant threat of injury to Plaintiff.

308. Because of Defendants' unlawful conduct, Plaintiff is at significant risk of not being able to offer, and consumers not being able to purchase Plaintiff's biosimilars.

309. Moreover, because Defendants' contemporary violations of antitrust laws likely to continue or recur, Plaintiff is at significant threat of not only losing its substantial investment into U.S. market entry and its profits from selling biosimilars but also of inability to compete in the Relevant Markets.

310. Plaintiff, as well as U.S. consumers, is at risk of suffering antitrust injury from Defendants' conduct. Plaintiff's interest is aligned with public interest in promoting price competition in the Relevant Markets.

SEVENTH CLAIM FOR RELIEF

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

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

312. 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.

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

314. The effect of such conduct is to substantially lessen and harm competition in the Relevant Markets.

315. The sales by Defendants Roche and Genentech were and are being made in interstate commerce.

316. The differences in prices charged by Roche 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.

317. 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.

318. 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.

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

EIGHTH CLAIM FOR RELIEF

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

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

321. Defendants have engaged in anticompetitive conduct as alleged in this Amended Complaint that unreasonably restrained trade in the Relevant Markets.

322. 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 maintaining Roche's monopoly in the Relevant Markets.

323. As a direct and proximate result of Defendants' conduct, Plaintiff has been injured in their business and property in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

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

B. For treble damages pursuant to Section 4 of the Clayton Act (5 U.S.C. § 15);

C. For reasonable attorney's fees and costs of litigation in accordance with Section 4 of the Clayton Act (15 U.S.C. § 15);

D. On the SIXTH claim for relief for Defendants being enjoined from continuing the unlawful and anticompetitive conduct alleged herein and other appropriate injunctive relief in accordance with Section 16 of the Clayton Act (15 U.S.C. § 26);

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

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

C. 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: October 24, 2016
New York, New York

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