17-3486

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BIOCAD JSC,
Plaintiff-Appellant,
v.

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

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

JOINT APPENDIX

Paul Spagnoletti
Andrew S. Gehring
DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
(212) 450-4000

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

David C. Frederick
Gregory G. Rapawy
Julius P. Taranto
KELLOGG, HANSEN, TODD,
FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036
(202) 326-7900

Counsel for Plaintiff-Appellant

February 8, 2018

(Additional Counsel Listed On Inside Cover)

Daniel M. Wall
LATHAM & WATKINS LLP
505 Montgomery Street
Suite 2000
San Francisco, CA 94111-6538
(415) 395-8240

Lawrence E. Buterman
LATHAM & WATKINS LLP
885 Third Avenue
New York, N.Y. 10022-4834
(212) 906-1264

Amanda P. Reeves
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2207

Counsel for Defendant-Appellee Genentech, Inc.

Caitlin J. Halligan
Eric J. Stock
Alejandro A. Herrera
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, New York 10166
(212) 351-4000

Counsel for Defendant-Appellee R-Pharm JSC

Albert Feinstein
FEINSTEIN & PARTNERS, P.L.L.C.
54 East 66th Street
New York, New York 10065
(212) 224-0224

Counsel for Plaintiff-Appellant

TABLE OF CONTENTS

CLOSED,APPEAL,ECF

U.S. District Court
Southern District of New York (Foley Square)
CIVIL DOCKET FOR CASE #: 1:16−cv−04226−RJS

Biocad JSC v. F. Hoffman La−Roche Ltd. et al
Assigned to: Judge Richard J. Sullivan
Cause: 15:1 Antitrust Litigation (Monopolizing Trade)

Date Filed: 06/07/2016
Date Terminated: 09/30/2017
Jury Demand: Plaintiff
Nature of Suit: 410 Anti−Trust
Jurisdiction: Federal Question

Plaintiff

Biocad JSC represented by **Albert Feinstein**
Law Offices of Albert Feinstein
216 East 49 Street 4 Floor
New York, NY 10017
(212) 224−0224
Fax: (212) 202−4069
Email: albert.feinstein@feinsteinpartners.com
ATTORNEY TO BE NOTICED

Arevik Khurdayan
Feinstein & Partners PLLC
54 East 66 Street
New York, NY 10065
(646)−764−1630
Email: rk@feinsteinpartners.com
ATTORNEY TO BE NOTICED

V.

Defendant

F. Hoffman La−Roche Ltd. represented by **Paul Spagnoletti**
Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017
(212)−450−4577
Fax: (212)−450−5649
Email: paul.spagnoletti@dpw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Andrew Scott Gehring
Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017
(212) 450−4197
Fax: (212) 701−5197
Email: andrew.gehring@davispolk.com
ATTORNEY TO BE NOTICED

Defendant

Genentech, Inc. represented by **Amanda P Reeves**
Latham & Watkins LLP (DC)
555 Eleventh Street, Nw, Suite 1000
Washington, DC 20004
(202) 637−2183
Fax: (202) 637−2201
Email: amanda.reeves@lw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Daniel Murray Wall
Latham & Watkins, LLP(SanFran)
505 Montgomery Street, Ste. 2000
San Francisco, CA 94111
(415)−395−8240
Fax: (415)−395−8095
Email: dan.wall@lw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Lawrence Edward Buterman
Latham & Watkins LLP (NY)
885 Third Avenue
New York, NY 10022
212− 906−1200
Fax: 212−751−4864
Email: lawrence.buterman@lw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Thomas James Giblin
Latham & Watkins LLP
885 Third Avenue, Suite 1000
New York, NY 10022
(212) 906−1665
Fax: (212) 751−4864
Email: thomas.giblin@lw.com
ATTORNEY TO BE NOTICED

Defendant

R−Farm JSC represented by

Eric Jonathan Stock
Gibson, Dunn & Crutcher, LLP (NY)
200 Park Avenue, 48th Floor
New York, NY 10166
212−351−2346
Fax: 212−351−6345
Email: estock@gibsondunn.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Roche Holding AG represented by

Paul Spagnoletti
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Andrew Scott Gehring
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
06/07/2016	1	COMPLAINT against F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC. (Filing Fee $ 400.00, Receipt Number 0208−12388246)Document filed by Biocad JSC.(Feinstein, Albert) (Entered: 06/07/2016)
06/07/2016	2	REQUEST FOR ISSUANCE OF SUMMONS as to F. HOFFMAN LA−ROCHE LTD., GENENTECH, INC. and R−FARM JSC, re: 1 Complaint. Document filed by F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC. (Feinstein, Albert) (Entered: 06/07/2016)

06/07/2016	3	**FILING ERROR − DUPLICATE DOCKET ENTRY** REQUEST FOR ISSUANCE OF SUMMONS as to F. HOFFMAN LA−ROCHE LTD., GENENTECH, INC. and R−FARM JSC, re: 1 Complaint. Document filed by Biocad JSC. (Feinstein, Albert) Modified on 6/8/2016 (pc). (Entered: 06/07/2016)
06/07/2016	4	CIVIL COVER SHEET filed. (Feinstein, Albert) (Entered: 06/07/2016)
06/07/2016	5	RULE 7.1 CORPORATE DISCLOSURE STATEMENT. Identifying Corporate Parent Biocad Holding Limited for Biocad JSC. Document filed by Biocad JSC.(Feinstein, Albert) (Entered: 06/07/2016)
06/08/2016		*****NOTICE TO ATTORNEY REGARDING CASE OPENING STATISTICAL ERROR CORRECTION: Notice to attorney Albert Feinstein. The following case opening statistical information was erroneously selected/entered: County code New York; Fee Status code due (due). The following correction(s) have been made to your case entry: the County code has been modified to XX Out of U.S.; the Fee Status code has been modified to pd (paid). (pc)** (Entered: 06/08/2016)
06/08/2016		*****NOTICE TO ATTORNEY REGARDING PARTY MODIFICATION. Notice to attorney Albert Feinstein. The party information for the following party/parties has been modified: Biocad JSC. The information for the party/parties has been modified for the following reason/reasons: party role was entered incorrectly. (pc)** (Entered: 06/08/2016)
06/08/2016		CASE OPENING INITIAL ASSIGNMENT NOTICE: The above−entitled action is assigned to Judge Richard J. Sullivan. Please download and review the Individual Practices of the assigned District Judge, located at http://nysd.uscourts.gov/judges/District. Attorneys are responsible for providing courtesy copies to judges where their Individual Practices require such. Please download and review the ECF Rules and Instructions, located at http://nysd.uscourts.gov/ecf_filing.php. (pc) (Entered: 06/08/2016)
06/08/2016		Magistrate Judge James L. Cott is so designated. (pc) (Entered: 06/08/2016)
06/08/2016		Case Designated ECF. (pc) (Entered: 06/08/2016)
06/08/2016	6	ELECTRONIC SUMMONS ISSUED as to F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC. (pc) (Entered: 06/08/2016)
07/31/2016	7	NOTICE OF APPEARANCE by Lawrence Edward Buterman on behalf of Genentech, Inc.. (Buterman, Lawrence) (Entered: 07/31/2016)
07/31/2016	8	RULE 7.1 CORPORATE DISCLOSURE STATEMENT. Identifying Corporate Parent Roche Holdings, Inc., Corporate Parent Roche Holding Ltd., Other Affiliate Novartis AG for Genentech, Inc.. Document filed by Genentech, Inc..(Buterman, Lawrence) (Entered: 07/31/2016)
07/31/2016	9	CONSENT LETTER MOTION for Extension of Time to File Answer re: 1 Complaint *or to file a request for a pre−motion conference in anticipation of moving to dismiss plaintiff's complaint* addressed to Judge Richard J. Sullivan from Lawrence E. Buterman dated July 31, 2016. Document filed by Genentech, Inc..(Buterman, Lawrence) (Entered: 07/31/2016)
08/01/2016	10	ORDER granting 9 Letter Motion for Extension of Time to Answer. IT IS HEREBY ORDERED THAT Defendant Genentech's time to answer or otherwise respond to the complaint is extended to September 9, 2016. The Clerk of the Court is respectfully directed to terminate the motion pending at docket number 9. Genentech, Inc. answer due 9/9/2016. (Signed by Judge Richard J. Sullivan on 8/1/2016) (mro) (Entered: 08/01/2016)
08/01/2016	11	AFFIDAVIT OF SERVICE. R−Farm JSC served on 7/6/2016, answer due 7/27/2016. Service was accepted by Konstantin Gavrilenko. Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 08/01/2016)
08/01/2016	12	AFFIDAVIT OF SERVICE. F. Hoffman La−Roche Ltd. served on 7/22/2016, answer due 8/12/2016. Service was accepted by Patricia Oscilowski. Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 08/01/2016)

08/01/2016	13	MOTION for Daniel M. Wall to Appear Pro Hac Vice . Filing fee $ 200.00, receipt number 0208−12601920. **Motion and supporting papers to be reviewed by Clerk's Office staff.** Document filed by Genentech, Inc.. (Attachments: # 1 Exhibit − Certificate of Good Standing, # 2 Text of Proposed Order)(Wall, Daniel) (Entered: 08/01/2016)
08/02/2016		**>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. 13 MOTION for Daniel M. Wall to Appear Pro Hac Vice . Filing fee $ 200.00, receipt number 0208−12601920. Motion and supporting papers to be reviewed by Clerk's Office staff.. The document has been reviewed and there are no deficiencies. (wb)** (Entered: 08/02/2016)
08/03/2016	14	ORDER FOR ADMISSION PRO HAC VICE granting 13 Motion for Daniel M. Wall to Appear Pro Hac Vice. (Signed by Judge Richard J. Sullivan on 8/3/2016) (mro) (Entered: 08/03/2016)
08/03/2016	15	ORDER: Initial Conference set for 9/23/2016 at 11:00 AM in Courtroom 905 of the Thurgood Marshall United States District Court for the Southern District of New York, 40 Centre Street, New York, NY 10007 before Judge Richard J. Sullivan. In addition, the Court notes that, based on affidavits of service filed by Plaintiff on August 1, 2016 (Doc. Nos. 11, 12), Defendant R−Farm JSC's response to the complaint was due on July 27, 2016, and Defendant F. Hoffman La−Roche Ltd.'s response to the complaint is due on August 12, 2016. Because the Court previously extended Defendant Genentech, Inc.'s time to respond to the complaint to September 9, 2016 (Doc. No. 10), IT IS FURTHER ORDERED THAT Defendants R−Farm JSC's and F. Hoffman La−Roche Ltd.'s time to respond to the complaint is similarly extended to September 9, 2016. (As further set forth in this Order.) (Signed by Judge Richard J. Sullivan on 8/3/2016) (mro) (Entered: 08/04/2016)
08/03/2016		Set/Reset Deadlines: F. Hoffman La−Roche Ltd. answer due 9/9/2016; R−Farm JSC answer due 9/9/2016. (mro) (Entered: 08/04/2016)
08/04/2016	16	MOTION for Amanda P. Reeves to Appear Pro Hac Vice . Filing fee $ 200.00, receipt number 0208−12613673. **Motion and supporting papers to be reviewed by Clerk's Office staff.** Document filed by Genentech, Inc.. (Attachments: # 1 Exhibit − Certificates of Good Standing, # 2 Text of Proposed Order)(Reeves, Amanda) (Entered: 08/04/2016)
08/04/2016		**>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. 16 MOTION for Amanda P. Reeves to Appear Pro Hac Vice . Filing fee $ 200.00, receipt number 0208−12613673. Motion and supporting papers to be reviewed by Clerk's Office staff.. The document has been reviewed and there are no deficiencies. (bcu)** (Entered: 08/04/2016)
08/05/2016	17	ORDER FOR ADMISSION PRO HAC VICE granting 16 Motion for Amanda P. Reeves to Appear Pro Hac Vice. (As further set forth in this Order.) (Signed by Judge Richard J. Sullivan on 8/5/2016) (cf) (Entered: 08/05/2016)
09/09/2016	18	NOTICE OF APPEARANCE by Paul Spagnoletti on behalf of F. Hoffman La−Roche Ltd.. (Spagnoletti, Paul) (Entered: 09/09/2016)
09/09/2016	19	RULE 7.1 CORPORATE DISCLOSURE STATEMENT. Identifying Corporate Parent Roche Holding Ltd. for F. Hoffman La−Roche Ltd.. Document filed by F. Hoffman La−Roche Ltd..(Spagnoletti, Paul) (Entered: 09/09/2016)
09/09/2016	20	LETTER addressed to Judge Richard J. Sullivan from Paul Spagnoletti dated 9/9/2016 re: requests a pre−motion conference regarding a motion pursuant to Federal Rules of Civil Procedure 12(b)(5) and (6) to dismiss the claims brought against it by plaintiff BIOCAD JSC (BIOCAD).. Document filed by F. Hoffman La−Roche Ltd..(Spagnoletti, Paul) (Entered: 09/09/2016)
09/09/2016	21	NOTICE OF APPEARANCE by Andrew Scott Gehring on behalf of F. Hoffman La−Roche Ltd.. (Gehring, Andrew) (Entered: 09/09/2016)
09/09/2016	22	LETTER MOTION for Conference *pursuant to Rule 2.A. of the Individual Rules and Practices of Richard J. Sullivan* addressed to Judge Richard J. Sullivan from Daniel M. Wall dated September 9, 2016. Document filed by Genentech, Inc..(Wall, Daniel) (Entered: 09/09/2016)

09/09/2016	23	LETTER MOTION for Conference *Regarding Anticipated Motion to Dismiss the Complaint* addressed to Judge Richard J. Sullivan from Eric J. Stock dated 9/9/2016. Document filed by R−Farm JSC.(Stock, Eric) (Entered: 09/09/2016)
09/09/2016	24	AFFIDAVIT OF SERVICE. F. Hoffman La−Roche Ltd. served on 7/21/2016, answer due 9/9/2016. Service was accepted by Gail Goldman, Paralegal. Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 09/09/2016)
09/09/2016	25	ORDER granting 22 Letter Motion for Conference; granting 23 Letter Motion for Conference. IT IS HEREBY ORDERED THAT the initial conference previously scheduled for September 23, 2016 at 11:00 a.m. is adjourned to 12:00 p.m. the same day and shall also serve as a pre−motion conference on Defendants' anticipated motions to dismiss. Pursuant to Rule 2.A of the Court's Individual Rules and Practices, Plaintiff shall respond to Defendants' letters by September 14, 2016. The Clerk of the Court is respectfully directed to terminate the motions pending at docket numbers 22 and 23. Initial Conference set for 9/23/2016 at 12:00 PM before Judge Richard J. Sullivan. Pre−Motion Conference set for 9/23/2016 at 12:00 PM before Judge Richard J. Sullivan. (Signed by Judge Richard J. Sullivan on 9/9/2016) (mro) Modified on 9/14/2016 (mro). (Entered: 09/12/2016)
09/12/2016	26	NOTICE OF APPEARANCE by Paul Spagnoletti on behalf of F. Hoffman La−Roche Ltd.. (Spagnoletti, Paul) (Entered: 09/12/2016)
09/12/2016	27	NOTICE OF APPEARANCE by Andrew Scott Gehring on behalf of F. Hoffman La−Roche Ltd.. (Gehring, Andrew) (Entered: 09/12/2016)
09/12/2016	28	RULE 7.1 CORPORATE DISCLOSURE STATEMENT. Identifying Corporate Parent Roche Holding Ltd., Other Affiliate Novartis AG for F. Hoffman La−Roche Ltd.. Document filed by F. Hoffman La−Roche Ltd..(Spagnoletti, Paul) (Entered: 09/12/2016)
09/12/2016	29	NOTICE OF APPEARANCE by Thomas James Giblin on behalf of Genentech, Inc.. (Giblin, Thomas) (Entered: 09/12/2016)
09/13/2016	30	RULE 7.1 CORPORATE DISCLOSURE STATEMENT. No Corporate Parent. Document filed by R−Farm JSC.(Stock, Eric) (Entered: 09/13/2016)
09/14/2016	31	LETTER addressed to Judge Richard J. Sullivan from Daniel M. Wall dated September 14, 2016 re: information requested pursuant to August 3, 2016 Order (Dkt. No. 15). Document filed by Genentech, Inc.. (Attachments: # 1 Text of Proposed Order)(Wall, Daniel) (Entered: 09/14/2016)
09/14/2016	32	LETTER RESPONSE to Motion addressed to Judge Richard J. Sullivan from Albert Feinstein dated September 14, 2016 re: 22 LETTER MOTION for Conference *pursuant to Rule 2.A. of the Individual Rules and Practices of Richard J. Sullivan* addressed to Judge Richard J. Sullivan from Daniel M. Wall dated September 9, 2016., 23 LETTER MOTION for Conference *Regarding Anticipated Motion to Dismiss the Complaint* addressed to Judge Richard J. Sullivan from Eric J. Stock dated 9/9/2016. . Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 09/14/2016)
09/23/2016		Minute Entry for proceedings held before Judge Richard J. Sullivan: Pre−Motion Conference held on 9/23/2016 at 12:09 p.m. Attorneys Albert Feinstein, Rika Khurdayan, and Max Dilendorf present for Plaintiff. Attorneys Paul Spagnoletti and Andrew Gehring present for Defendant F. Hoffman La−Roche Ltd., Attorney Erick Stock present for Defendant R−Pharm JSC, and Attorney Daniel Wall present for Defendant Genentech, Inc. Court reporter present. The Court ordered Plaintiff to file its amended complaint by 10/24/2016 and ordered Defendants to file by 11/7/2016 a joint letter regarding their intent with respect to any motions to dismiss the amended complaint. (Ruff, Robert) (Entered: 09/23/2016)
10/07/2016	33	TRANSCRIPT of Proceedings re: CONFERENCE held on 9/23/2016 before Judge Richard J. Sullivan. Court Reporter/Transcriber: Khristine Sellin, (212) 805−0300. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 10/31/2016. Redacted Transcript Deadline set for 11/10/2016. Release of Transcript Restriction set for 1/8/2017.(McGuirk, Kelly) (Entered: 10/07/2016)

10/07/2016	34	NOTICE OF FILING OF OFFICIAL TRANSCRIPT Notice is hereby given that an official transcript of a CONFERENCE proceeding held on 9/23/16 has been filed by the court reporter/transcriber in the above−captioned matter. The parties have seven (7) calendar days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript may be made remotely electronically available to the public without redaction after 90 calendar days...(McGuirk, Kelly) (Entered: 10/07/2016)
10/13/2016	35	TRANSCRIPT of Proceedings re: CONFERENCE held on 9/23/2016 before Judge Richard J. Sullivan. Court Reporter/Transcriber: Khristine Sellin, (212) 805−0300. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 11/7/2016. Redacted Transcript Deadline set for 11/17/2016. Release of Transcript Restriction set for 1/14/2017.(McGuirk, Kelly) (Entered: 10/13/2016)
10/13/2016	36	NOTICE OF FILING OF OFFICIAL TRANSCRIPT Notice is hereby given that an official transcript of a CONFERENCE proceeding held on 9/23/16 has been filed by the court reporter/transcriber in the above−captioned matter. The parties have seven (7) calendar days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript may be made remotely electronically available to the public without redaction after 90 calendar days...(McGuirk, Kelly) (Entered: 10/13/2016)
10/24/2016	37	FIRST AMENDED COMPLAINT amending 1 Complaint against F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC, Roche Holding AG with JURY DEMAND.Document filed by Biocad JSC. Related document: 1 Complaint filed by Biocad JSC.(Khurdayan, Arevik) (Entered: 10/24/2016)
10/24/2016	38	NOTICE OF APPEARANCE by Arevik Khurdayan on behalf of Biocad JSC. (Khurdayan, Arevik) (Entered: 10/24/2016)
11/07/2016	39	NOTICE OF APPEARANCE by Paul Spagnoletti on behalf of Roche Holding AG. (Spagnoletti, Paul) (Entered: 11/07/2016)
11/07/2016	40	NOTICE OF APPEARANCE by Andrew Scott Gehring on behalf of Roche Holding AG. (Gehring, Andrew) (Entered: 11/07/2016)
11/07/2016	41	RULE 7.1 CORPORATE DISCLOSURE STATEMENT. Identifying Other Affiliate Novartis AG for Roche Holding AG. Document filed by Roche Holding AG.(Spagnoletti, Paul) (Entered: 11/07/2016)
11/07/2016	42	JOINT LETTER addressed to Judge Richard J. Sullivan from Paul Spagnoletti, Daniel M. Wall, and Eric J. Stock dated November 7, 2016 re: In Response to The Court's September 23, 2016 Order. Document filed by F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC, Roche Holding AG.(Spagnoletti, Paul) (Entered: 11/07/2016)
11/07/2016	43	MEMO ENDORSEMENT on re: 42 Letter, filed by F. Hoffman La−Roche Ltd., Genentech, Inc., Roche Holding AG, R−Farm JSC. ENDORSEMENT: IT IS HEREBY ORDERED THAT Defendants shall file their opening briefs in support of their motions to dismiss by December 12, 2016; Plaintiff shall file its response by January 11, 2017; and Defendants shall file their replies by January 26, 2017. The parties' submissions shall comply with Rule 2 of the Court's Individual Rules and Practices. Plaintiff shall submit only one brief; however, Plaintiff may seek leave to exceed the page limit set forth in Rule 2.B upon reviewing Defendants' opening briefs. Any such request must be made at least 48 hours before the deadline for Plaintiff's response. (Motions due by 12/12/2016., Responses due by 1/11/2017, Replies due by 1/26/2017.) (Signed by Judge Richard J. Sullivan on 11/7/2016) (mro) (Entered: 11/09/2016)
11/22/2016	44	**FILING ERROR − DEFICIENT PLEADING −PDF ERROR** REQUEST FOR ISSUANCE OF AMENDED SUMMONS as to ROCHE HOLDING AG, F. HOFFMAN LA−ROCHE LTD., GENENTECH, INC. AND R−FARM JSC, re: 37 Amended Complaint,. Document filed by Biocad JSC. (Feinstein, Albert) Modified on 11/23/2016 (dgo). (Entered: 11/22/2016)
11/23/2016		***NOTICE TO ATTORNEY REGARDING DEFICIENT REQUEST FOR ISSUANCE OF SUMMONS. Notice to Attorney to RE−FILE Document No. 44

		Request for Issuance of Amended Summons,. The filing is deficient for the following reason(s): PDF should read out AMENDED SUMMONS IN A CIVIL ACTION. Get the word AMENDED on it. Also, request Roche Holdings AG on its own as a regular summons because this party has not been issued a summons yet;. Re−file the document using the event type Request for Issuance of AMENDED Summons found under the event list Service of Process − select the correct filer/filers − and attach the correct summons form PDF. (dgo) (Entered: 11/23/2016)
11/23/2016	45	REQUEST FOR ISSUANCE OF SUMMONS as to ROCHE HOLDING AG, re: 37 Amended Complaint,. Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 11/23/2016)
11/23/2016	46	REQUEST FOR ISSUANCE OF AMENDED SUMMONS as to F. HOFFMAN LA−ROCHE LTD., re: 37 Amended Complaint,. Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 11/23/2016)
11/28/2016	47	ELECTRONIC SUMMONS ISSUED as to Roche Holding AG. (dgo) (Entered: 11/28/2016)
11/28/2016	48	ELECTRONIC AMENDED SUMMONS ISSUED as to F. Hoffman La−Roche Ltd.. (dgo) (Entered: 11/28/2016)
12/08/2016	49	CERTIFICATE OF SERVICE of Summons and Amended Complaint,. Roche Holding AG served on 12/7/2016, answer due 12/28/2016. Service was accepted by Robert Ferraro, Counsel. Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 12/08/2016)
12/08/2016	50	CERTIFICATE OF SERVICE of Summons and Amended Complaint,. F. Hoffman La−Roche Ltd. served on 12/7/2016, answer due 12/28/2016. Service was accepted by Robert Ferraro, Counsel. Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 12/08/2016)
12/12/2016	51	MOTION to Dismiss *The Amended Complaint*. Document filed by F. Hoffman La−Roche Ltd., Roche Holding AG.(Spagnoletti, Paul) (Entered: 12/12/2016)
12/12/2016	52	MEMORANDUM OF LAW in Support re: 51 MOTION to Dismiss *The Amended Complaint*. . Document filed by F. Hoffman La−Roche Ltd., Roche Holding AG. (Spagnoletti, Paul) (Entered: 12/12/2016)
12/12/2016	53	MOTION to Dismiss */ Notice of Motion to Dismiss Plaintiff's Amended Complaint*. Document filed by R−Farm JSC.(Stock, Eric) (Entered: 12/12/2016)
12/12/2016	54	DECLARATION of Eric J. Stock in Support re: 53 MOTION to Dismiss */ Notice of Motion to Dismiss Plaintiff's Amended Complaint*.. Document filed by R−Farm JSC. (Attachments: # 1 Exhibit 1 − excerpts of transcript)(Stock, Eric) (Entered: 12/12/2016)
12/12/2016	55	MEMORANDUM OF LAW in Support re: 53 MOTION to Dismiss */ Notice of Motion to Dismiss Plaintiff's Amended Complaint*. . Document filed by R−Farm JSC. (Stock, Eric) (Entered: 12/12/2016)
12/12/2016	56	MOTION to Dismiss *the Amended Complaint*. Document filed by Genentech, Inc..(Wall, Daniel) (Entered: 12/12/2016)
12/12/2016	57	MEMORANDUM OF LAW in Support re: 56 MOTION to Dismiss *the Amended Complaint*. . Document filed by Genentech, Inc.. (Wall, Daniel) (Entered: 12/12/2016)
12/12/2016	58	DECLARATION of Lawrence E. Buterman in Support re: 56 MOTION to Dismiss *the Amended Complaint*.. Document filed by Genentech, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C)(Buterman, Lawrence) (Entered: 12/12/2016)
01/05/2017	59	LETTER MOTION for Extension of Time to File Response/Reply as to 43 Memo Endorsement, Set Deadlines,,,,,, addressed to Judge Richard J. Sullivan from Albert Feinstein dated January 5, 2017., LETTER MOTION for Leave to File Excess Pages addressed to Judge Richard J. Sullivan from Albert Feinstein dated January 5, 2017. Document filed by Biocad JSC.(Feinstein, Albert) (Entered: 01/05/2017)

01/05/2017	60	LETTER RESPONSE to Motion addressed to Judge Richard J. Sullivan from Paul Spagnoletti; Daniel M. Wall; and Eric J. Stock dated January 5, 2017 re: 59 LETTER MOTION for Extension of Time to File Response/Reply as to 43 Memo Endorsement, Set Deadlines,,,,,,, addressed to Judge Richard J. Sullivan from Albert Feinstein dated January 5, 2017. LETTER MOTION for Leave to File Excess Pages addressed to Judge Richard J. Sullivan from Albert Feinstein dated January 5, 2017. . Document filed by F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC, Roche Holding AG. (Spagnoletti, Paul) (Entered: 01/05/2017)
01/05/2017	61	ORDER terminating 59 Letter Motion for Extension of Time to File Response/Reply; terminating 59 Letter Motion for Leave to File Excess Pages. Given the length of Defendants' briefs but accounting for the fact that the briefs cover several of the same grounds for dismissal, the Court grants Plaintiff's request to exceed the page limit for its opposition brief, but Plaintiff shall be limited to 50 pages. With respect to Plaintiff's extension request, while the extra pages warrant some extension of the deadline, the Court finds that an extra month is excessive. Accordingly, Plaintiff's deadline to file its opposition brief is extended to January 31, 2017, and Defendants' deadline to file their reply briefs is extended to February 15, 2017. (Signed by Judge Richard J. Sullivan on 1/5/2017) (mro) (Entered: 01/06/2017)
01/05/2017		Set/Reset Deadlines: Responses due by 1/31/2017 Replies due by 2/15/2017. (mro) (Entered: 01/06/2017)
01/31/2017	62	DECLARATION of Albert Feinstein in Opposition re: 56 MOTION to Dismiss *the Amended Complaint*., 53 MOTION to Dismiss */ Notice of Motion to Dismiss Plaintiff's Amended Complaint*., 51 MOTION to Dismiss *The Amended Complaint*.. Document filed by Biocad JSC. (Attachments: # 1 Exhibit A − Repik's Interview, # 2 Exhibit B − Ignatiev's Presentation, # 3 Exhibit C − Expense Report, # 4 Exhibit D − Internal Memo, # 5 Exhibit E − Roche's Payment Schedule, # 6 Exhibit F − Roche's Payment Schedule 2, # 7 Exhibit G − Explanatory Statement, # 8 Exhibit H − Roche Complaint Report, # 9 Exhibit I − Roche's Email Correspondence, # 10 Exhibit J − Roche's Email Correspondence 2)(Feinstein, Albert) (Entered: 01/31/2017)
01/31/2017	63	MEMORANDUM OF LAW in Opposition re: 56 MOTION to Dismiss *the Amended Complaint*., 53 MOTION to Dismiss */ Notice of Motion to Dismiss Plaintiff's Amended Complaint*., 51 MOTION to Dismiss *The Amended Complaint*. . Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 01/31/2017)
02/14/2017	64	LETTER addressed to Judge Richard J. Sullivan from Paul Spagnoletti; Daniel M. Wall; and Eric J. Stock dated February 14, 2017 re: Waive the Requirement for Pre−Motion Conference. Document filed by F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC, Roche Holding AG.(Spagnoletti, Paul) (Entered: 02/14/2017)
02/15/2017	65	REPLY MEMORANDUM OF LAW in Support re: 51 MOTION to Dismiss *The Amended Complaint*. . Document filed by F. Hoffman La−Roche Ltd., Roche Holding AG. (Spagnoletti, Paul) (Entered: 02/15/2017)
02/15/2017	66	REPLY MEMORANDUM OF LAW in Support re: 53 MOTION to Dismiss */ Notice of Motion to Dismiss Plaintiff's Amended Complaint*. . Document filed by R−Farm JSC. (Stock, Eric) (Entered: 02/15/2017)
02/15/2017	67	REPLY MEMORANDUM OF LAW in Support re: 56 MOTION to Dismiss *the Amended Complaint*. . Document filed by Genentech, Inc.. (Wall, Daniel) (Entered: 02/15/2017)
02/16/2017	68	MEMO ENDORSEMENT on re: 64 Letter re: Waive the Requirement for Pre−Motion Conference, filed by F. Hoffman La−Roche Ltd., Genentech, Inc., Roche Holding AG, R−Farm JSC. ENDORSEMENT: In light of the facts that (1) the motion to dismiss will soon be fully briefed, and (2) Defendants' contemplated sanctions motion is closely associated with that motion, the Court is persuaded that a pre− motion conference on Defendants' sanctions motion is unwarranted. Accordingly, IT IS HEREBY ORDERED that Defendants shall file their motion no later than March 7, 2017, and Plaintiff shall file its response by March 21, 2017. The Court does not require a reply brief. (Motions due by 3/7/2017., Responses due by 3/21/2017) (Signed by Judge Richard J. Sullivan on 2/15/2017) (cla) (Entered: 02/16/2017)

02/21/2017	69	LETTER addressed to Judge Richard J. Sullivan from Albert Feinstein dated February 21, 2017 re: the Court's Leave to File a Sur−Reply. Document filed by Biocad JSC.(Feinstein, Albert) (Entered: 02/21/2017)
02/22/2017	70	MEMO ENDORSEMENT on re: 69 Letter filed by Biocad JSC. ENDORSEMENT: IT IS HERBY ORDERED that Plaintiff's request to file a sur−reply in connection with Defendant's motion to dismiss the Complaint is DENIED. (Signed by Judge Richard J. Sullivan on 2/22/2017) (jwh) (Entered: 02/22/2017)
03/07/2017	71	MOTION for Sanctions *Notice of Motion to Sanction Biocad and Its Counsel*. Document filed by F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC, Roche Holding AG.(Spagnoletti, Paul) (Entered: 03/07/2017)
03/07/2017	72	MEMORANDUM OF LAW in Support re: 71 MOTION for Sanctions *Notice of Motion to Sanction Biocad and Its Counsel*. . Document filed by F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC, Roche Holding AG. (Spagnoletti, Paul) (Entered: 03/07/2017)
03/07/2017	73	DECLARATION of Andrew S. Gehring in Support re: 71 MOTION for Sanctions *Notice of Motion to Sanction Biocad and Its Counsel*.. Document filed by F. Hoffman La−Roche Ltd., Genentech, Inc., R−Farm JSC, Roche Holding AG. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C − Part 1 of 3, # 4 Exhibit C− Part 2 of 3, # 5 Exhibit C − Part 3 of 3, # 6 Exhibit D)(Spagnoletti, Paul) (Entered: 03/07/2017)
03/21/2017	74	MEMORANDUM OF LAW in Opposition re: 71 MOTION for Sanctions *Notice of Motion to Sanction Biocad and Its Counsel*. . Document filed by Biocad JSC. (Feinstein, Albert) (Entered: 03/21/2017)
09/30/2017	75	OPINION AND ORDER re: 56 MOTION to Dismiss *the Amended Complaint* filed by Genentech, Inc., 53 MOTION to Dismiss */ Notice of Motion to Dismiss Plaintiff's Amended Complaint* filed by R−Farm JSC, 51 MOTION to Dismiss *The Amended Complaint* filed by F. Hoffman La−Roche Ltd., Roche Holding AG. Because Plaintiff has failed to plead an antitrust injury, because the foreign locus of Plaintiff's claims place them outside the reach of U.S. antitrust law, and because Plaintiff has not demonstrated a significant threat of injury from an impending violation of the antitrust laws, Defendants' motions to dismiss are GRANTED, and Plaintiff's request for leave to amend the First Amended Complaint is DENIED. The Clerk of Court is respectfully directed to terminate the motions pending at docket numbers 51, 53, and 56, and to close this case. (Signed by Judge Richard J. Sullivan on 9/30/2017) (mro) (Entered: 10/02/2017)
09/30/2017		Transmission to Judgments and Orders Clerk. Transmitted re: 75 Memorandum & Opinion to the Judgments and Orders Clerk. (mro) (Entered: 10/02/2017)
09/30/2017	76	CLERK'S JUDGMENT: It is, ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Opinion and Order dated September 30, 2017, Defendants' motions to dismiss the First Amended Complaint are granted and Plaintiff's request for leave to amend the First Amended Complaint is denied; accordingly, the case is closed. (Signed by Clerk of Court Ruby Krajick on 9/30/2017) (Attachments: # 1 Right to Appeal, # 2 Right to Appeal)(km) (Entered: 10/02/2017)
09/30/2017		Terminate Transcript Deadlines (km) (Entered: 10/02/2017)
10/27/2017	77	NOTICE OF APPEAL from 75 Memorandum & Opinion,,, 76 Clerk's Judgment,. Document filed by Biocad JSC. Filing fee $ 505.00, receipt number 0208−14296398. Form C and Form D are due within 14 days to the Court of Appeals, Second Circuit. (Feinstein, Albert) (Entered: 10/27/2017)
10/27/2017		Transmission of Notice of Appeal and Certified Copy of Docket Sheet to US Court of Appeals re: 77 Notice of Appeal. (tp) (Entered: 10/27/2017)
10/27/2017		Appeal Record Sent to USCA (Electronic File). Certified Indexed record on Appeal Electronic Files for 77 Notice of Appeal, filed by Biocad JSC were transmitted to the U.S. Court of Appeals. (tp) (Entered: 10/27/2017)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

Contents

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

NATURE AND SUMMARY OF THE ACTION

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

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

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

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

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

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

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

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

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

inflated prices for oncology medication.

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

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

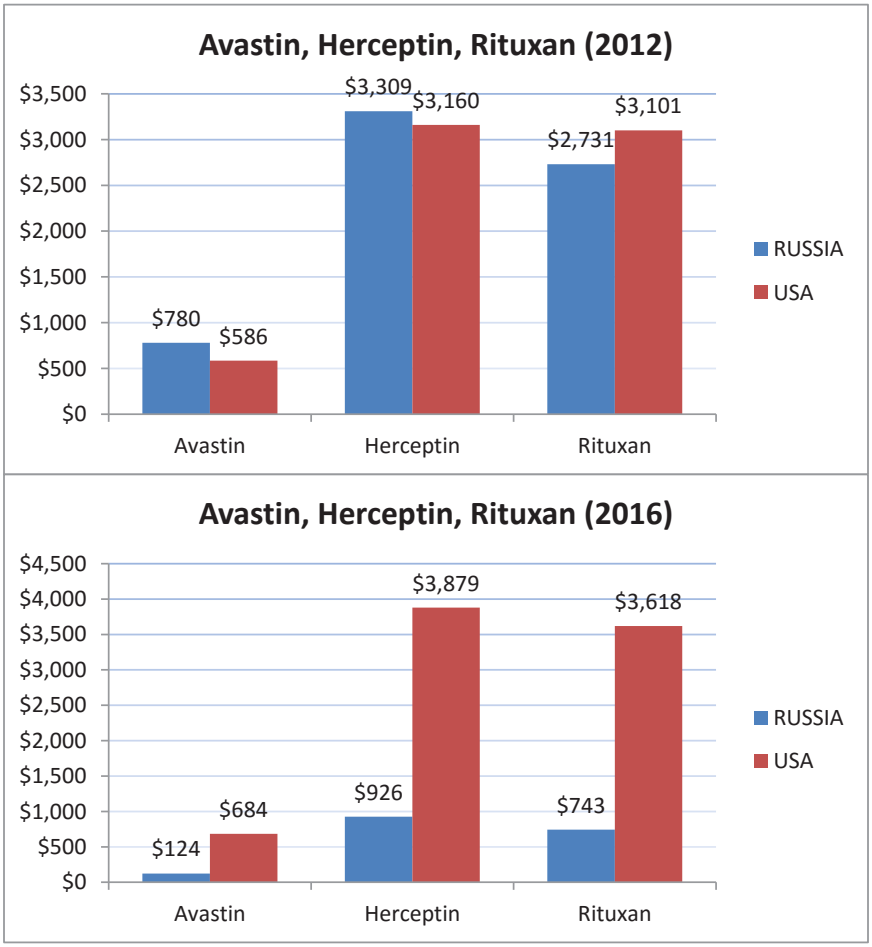
11. For example, Roche's officially declared price for bulk delivery of Avastin® 100mg upon entry to Russia is 20% higher than the price at which Avastin® 100mg is sold by Defendant R-Farm JSC ("R-Farm"), an independent exclusive distributor of the Drugs, after being packaged, distributed, taxes/duties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

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

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

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

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



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

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

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

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

JURISDICTION AND VENUE

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

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

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

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

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

PARTIES

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

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

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

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

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

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

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

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

FACTUAL ALLEGATIONS RELEVANT TO ALL CAUSES OF ACTIONS

I. CANCER AND THE ONCOLOGY DRUGS MARKET

A. General Overview

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

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

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

30. Geographically, the United States dominates the market and

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

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

B. The Use Of Monoclonal Antibodies In Treating Cancer

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

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

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

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

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

[6] *Id.*

C. Market for Cancer Monoclonal Antibodies

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

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

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

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

---

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

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

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

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

III. ROCHE'S BLOCKBUSTER ONCOLOGY DRUGS

A. Avastin®

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

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

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

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

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

[12] *Id.*

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

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

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

C. Herceptin®

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

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

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

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

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

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

1998.

A. Rituxan®

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

engineering to large-scale commercial manufacturing and marketing support.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VII. RELEVANT MARKETS FOR ANTITRUST PURPOSES

A. Relevant Market for Bevacizumab

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

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

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

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

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

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

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

B. Relevant Market for Trastuzumab

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

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

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

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

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

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

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

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

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

C. Relevant Market for Rituximab

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a) Predatory and discriminatory pricing;

b) Limiting output followed by illegal tying arrangements;

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

d) Participation in auctions and contests with fraudulent bids;

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

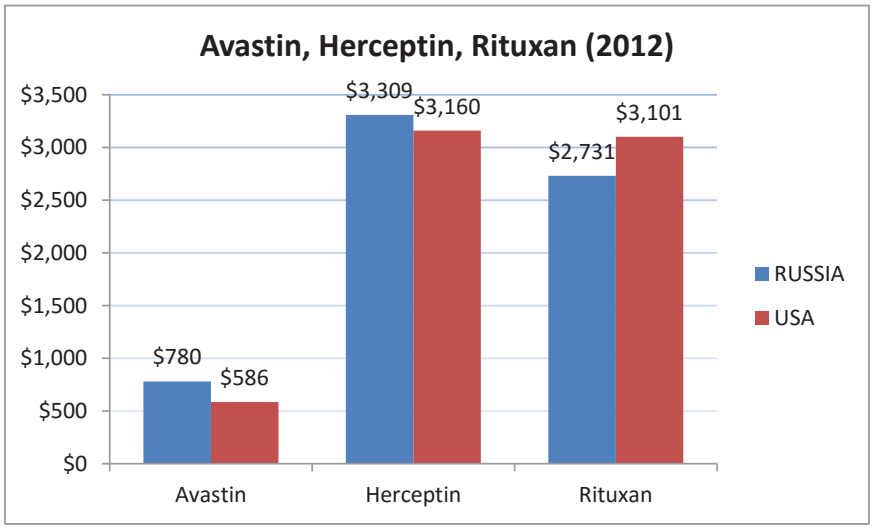
99. Roche used its monopoly position in the U.S. and its ability to charge American cancer patients supra competitive prices to finance its illegal scheme to destroy Plaintiff's business both in the U.S. and Russia, and to foreclose the U.S. market to generic alternatives to Roche's blockbuster drugs.

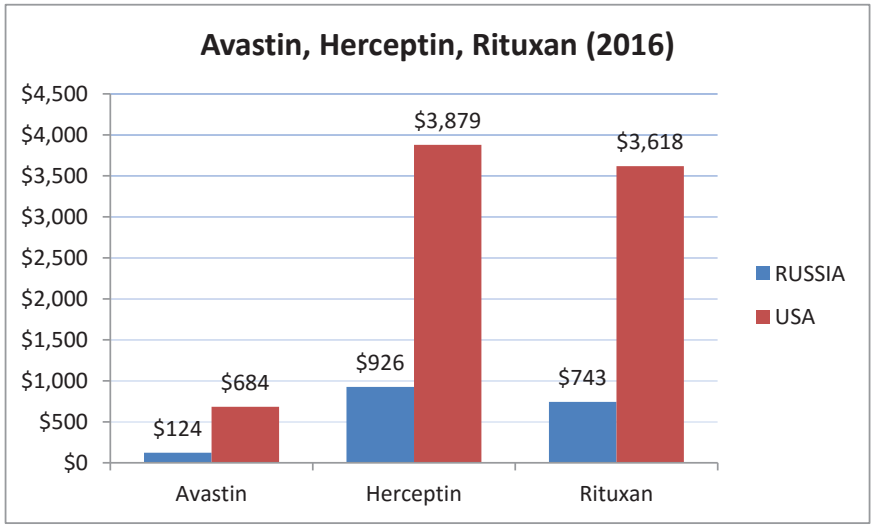
100. While Roche started selling its blockbuster drugs in Russia at prices higher than prices for the same drugs in the United States, over the past several years, Roche continued increasing the prices in the U.S. on average 19%, while dropping the prices in Russia on average 76%. In addition, shortly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

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

[17] *Id.*

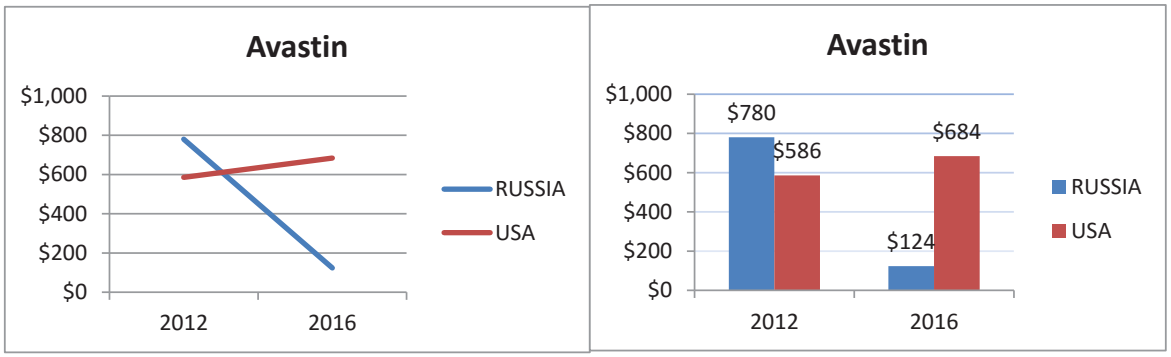
101. The graphs below demonstrate the current price disparity with Avastin® costing 5.5 times cheaper in Russia than in the U.S.[18], Herceptin® – and Rituxan® – over 4 times cheaper.



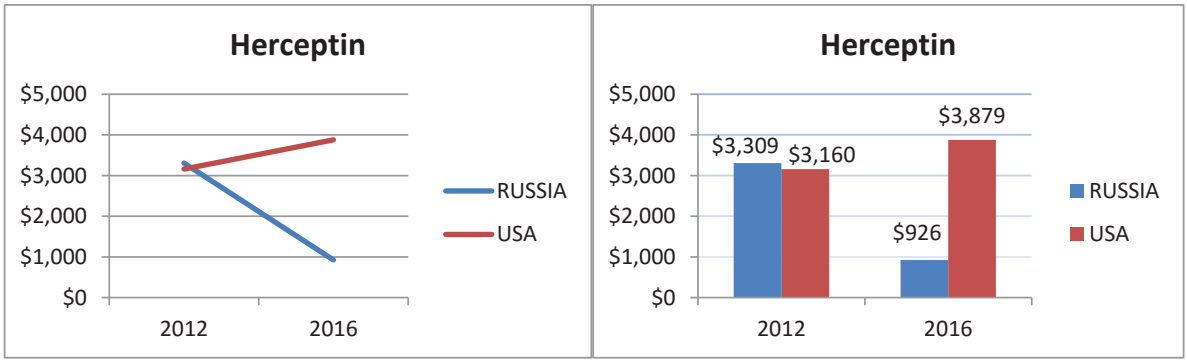


[18] The price disparity for Avastin® reached 14 times at certain auctions and tenders, with Avastin® sold by Roche for as low as US$ 46.

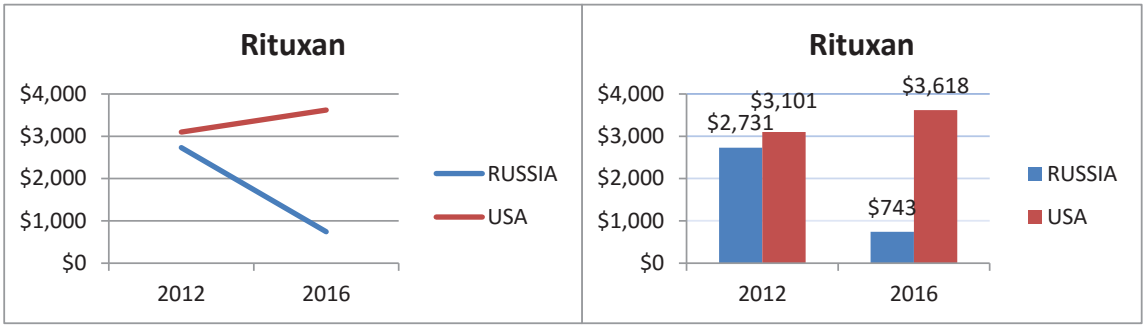
102. The average sales price of Avastin® 100mg increased substantially from 2012 to 2016 in the U.S. At the same time, the supra competitive pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Avastin® 100mg since 2012 84% or over 6 times.



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



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



A. Predatory And Discriminatory Pricing Scheme

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

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

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

financed by the price hikes in the U.S.

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

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

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

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

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

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

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

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

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

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

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

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

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

require both drugs.

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Dosage of Herceptin®

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

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

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

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

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

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

[26] *Id.*

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

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

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

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

D. Fraudulent Bids For Avastin®

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

---

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

[28] *Id.*

[29] *Id.*

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

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

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

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

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

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

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

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

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

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

D. Limiting Distribution Networks In The U.S.

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

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

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

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

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

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

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

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

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

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

the cancer patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

patients within the United States and abroad.

FIRST CLAIM FOR RELIEF

Violation of Section 2 of the Sherman Act

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

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

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

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

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

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

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

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

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

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

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

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

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

SECOND CLAIM FOR RELIEF

Violation of Section 1 of the Sherman Act

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

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

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

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

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

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

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

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

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

THIRD CLAIM FOR RELIEF

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

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

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

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

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

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

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

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

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

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

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

FOURTH CLAIM FOR RELIEF

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

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

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

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

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

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

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

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

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

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

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

FIFTH CLAIM FOR RELIEF

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

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

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

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

SIXTH CLAIM FOR RELIEF

Tortious Interference With Business Relationships

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

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

212. Defendants had full knowledge of Plaintiff's business

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

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

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

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

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

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

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

JURY DEMAND

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

Dated: June 6, 2016
New York, New York

Albert Feinstein

Albert Feinstein, Esq. (AF5591)
Rika Khurdayan, Esq. (AK9122)
FEINSTEIN & PARTNERS, PLLC
Attorneys for Plaintiff
54 East 66th Street
New York, NY 10065
tel: 212.224.0224

OF COUNSEL:

Oleg Rivkin (OR1331)
RIVKIN LAW GROUP pllc
800 Third Avenue, Suite 2501
New York, New York 10022
t. 212.231.9776
or@rivkinlawgroup.com

Davis Polk

Paul Spagnoletti

Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017

212 450 4577 tel
212 701 5577 fax
paul.spagnoletti@davispolk.com

September 9, 2016

Re: *BIOCAD JSC v. F. Hoffman La-Roche Ltd., et al.*, Case No. 16 Civ. 4226 (RJS)

The Honorable Richard J. Sullivan
United States District Court for the Southern District of New York
40 Foley Square, Room 2104
New York, New York 10007

Dear Judge Sullivan:

Defendant F. Hoffmann-La Roche Ltd ("FHLR") respectfully requests a pre-motion conference regarding a motion pursuant to Federal Rules of Civil Procedure 12(b)(5) and (6) to dismiss the claims brought against it by plaintiff BIOCAD JSC ("BIOCAD").

I. Overview of the Motion

FHLR is a Swiss pharmaceutical corporation with its principal place of business in Switzerland. Defendant Genentech Inc. ("Genentech") is an affiliate of FHLR that markets and sells the Roche Group's drugs in the United States. BIOCAD, a Russian company, has brought this suit—in a U.S. court under U.S. antitrust laws—alleging that FHLR, Genentech, and an independent distributor of the Roche Group's products in Russia, R-Pharm JSC ("R-Pharm"), committed wrongful acts in Russia.

As an initial matter, BIOCAD has not properly effected service on FHLR. Neglecting the dictates of the Hague Convention, BIOCAD's purported service was made on an independent affiliate of FHLR that is neither authorized to accept service nor an instrumentality of FHLR through which the law permits service to be made. BIOCAD should not be permitted to ignore the well-established rules governing service on a foreign entity simply because it finds them inconvenient.

Even if service had been properly made, BIOCAD's Complaint should still be dismissed for failure to state a claim against FHLR. BIOCAD's central allegation of wrongdoing is that, after BIOCAD brought generic competitors to market in Russia, R-Pharm lowered the prices of certain of FHLR's drugs in Russia to prices below what they are sold for in the United States. Ignoring that this alleged conduct is simply a reflection of how competitive markets operate, BIOCAD has alleged that this conduct constitutes predatory pricing in violation of the U.S. antitrust laws. In order to create a domestic hook for its claims, BIOCAD has asserted a strained and speculative chain of causation whereby a reduction in its Russian profits has allegedly harmed BIOCAD's business generally, which in turn has set back BIOCAD's purported future plans to enter the American market, after Genentech's U.S. patents expire in 2018 and 2019.

BIOCAD has also padded its Complaint with other meritless allegations: (i) R-Pharm, purportedly at FHLR's direction, sells two of FHLR's drugs in a bundle in Russia; (ii) R-Pharm, purportedly at

FHLR's direction, submitted bids in Russian government auctions for the sale of drugs after publicly disclosing that there was a delay in the production of those drugs; (iii) FHLR and Genentech have mislabeled the correct dosage of a drug; and (iv) Genentech has changed the drug distribution channels it uses in the United States.

Even assuming the truth of these allegations, BIOCAD's claims are all subject to dismissal. First, the U.S. antitrust statutes categorically bar claims predicated on foreign conduct with only tangential impact on American commerce. To the extent BIOCAD has made allegations regarding conduct in the United States, it has not, as required, alleged any injury at all arising therefrom. Second, BIOCAD does not participate in any U.S. pharmaceutical market and is not imminently entering the American market, and thus it has no standing to bring these antitrust claims. Third, BIOCAD fails to allege essential elements of its claims.

II. Bases for Dismissal

A. BIOCAD has failed to serve process upon FHLR.

Federal Rule of Civil Procedure 4(f) is clear that service on a foreign entity must take place through an "internationally agreed means of service." Here, that internationally agreed means of service is the Hague Convention, to which Switzerland is a party. But BIOCAD has ignored the requirements of both Rule 4(f) and the Hague Convention. Instead, it has attempted to serve process upon FHLR through service on Roche TCRC, Inc. ("TCRC"), an independent affiliate of FHLR in New York. BIOCAD's attempted service is impermissible and ineffective because TCRC is neither authorized to accept service on FHLR's behalf nor a "mere department" of FHLR. *Darden v. DaimlerChrysler N. Am. Holding Corp.*, 191 F. Supp. 2d 382, 387-88 (S.D.N.Y. 2002). Moreover, BIOCAD's attempted service violated this Court's August 3, 2016 order (the "Order"), which required BIOCAD to serve a copy of the Order on FHLR. Neither FHLR nor any of its affiliates received a copy of the Order from BIOCAD. FHLR was made aware of the Court's deadline to respond to the Complaint solely through its own diligence.

B. BIOCAD's antitrust claims are based on foreign conduct and do not implicate U.S. antitrust law.

The core of BIOCAD's antitrust claims against FHLR—for predatory pricing, tying, and misrepresentation—exclusively involves alleged conduct in Russia. U.S. antitrust law does not provide a cause of action based on such allegations.[1]

First, the Foreign Trade Antitrust Improvements Act (the "FTAIA") bars application of the Sherman Act to claims based on foreign conduct where (i) there is not a "direct, substantial, and reasonably foreseeable effect" on U.S. commerce that (ii) "gives rise to" the plaintiff's antitrust claims. 15 U.S.C. § 6a. To demonstrate the requisite connection between foreign conduct and an effect on U.S. commerce, the Second Circuit requires "a reasonably proximate causal nexus" between the two. *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 398 (2d Cir. 2014). While BIOCAD alleges that FHLR raised prices of its drugs in the United States, it does not allege that those changes in price were caused by the alleged foreign conduct. Instead, BIOCAD's claimed domestic effect is eventual harm to U.S. consumers based on its purported inability to enter the U.S. market. (Compl. ¶¶ 154, 156.) The chain of causation between that supposed effect and the alleged conduct in Russia—which requires assumptions that, among other things, BIOCAD would eventually obtain FDA approval to market its drugs in the United States and no other generics or biosimilars would enter the U.S. market after FHLR's exclusivity period ends—is far too convoluted

[1] To the extent BIOCAD has alleged anticompetitive acts by FHLR in the United States, it has not alleged that any of those acts have caused it any damages.

and speculative to be considered "proximate." Moreover, that claimed effect on U.S. commerce does not give rise to BIOCAD's alleged injury, the supposed detriment to BIOCAD's Russian business; rather BIOCAD's alleged injury precedes any such effect, such that "the direction of causation runs the wrong way." *Id.* at 414. Either of these reasons—the lack of proximate causation between the alleged conduct and a domestic effect or the lack of an injury caused by the alleged domestic effect—requires dismissal of BIOCAD's Sherman Act claims.

Second, BIOCAD's remaining federal claims are based on the Clayton Act and the Robinson-Patman Act, both of which extend only to conduct involving products sold for "use, consumption, or resale within the United States." 15 U.S.C. §§ 13(a) (Robinson-Patman Act), 14 (Clayton Act). Neither statute applies to conduct involving the sale of goods outside the United States, but that is exactly what BIOCAD's allegations pertain to. These claims should also be dismissed.

C. BIOCAD has no antitrust standing.

Any plaintiff seeking to bring an antitrust claim must demonstrate that it has suffered an antitrust injury, which requires a showing of "(1) an injury-in-fact; (2) that has been caused by the [alleged] violation; and (3) that is the type of injury contemplated by the statute." *Blue Tree Hotels Inv. (Can), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 220 (2d Cir. 2004). BIOCAD can show none of these elements. Most acutely, BIOCAD's primary alleged injury is a detriment to its Russian business, but "foreign injuries that occurred in foreign markets" "are not the type of injury Congress intended to prevent." *In re Intel Corp. Microprocessor Antitrust Litig.*, 452 F. Supp. 2d 555, 563 (D. Del. 2006). And BIOCAD has suffered no injury in the United States, where it does not participate in the market and can only do so if, after FHLR's patents expire, BIOCAD can itself obtain FDA approval. BIOCAD is thus at best a potential market entrant, in which case it must allege its intent and preparedness to enter the market, including that it has taken steps to attain, and anticipates receiving, FDA approval. *See Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 807 (D.C. Cir. 2001). BIOCAD has made no such allegations, and can make no such allegations, and therefore its claims should be dismissed.

D. BIOCAD fails to plead essential elements of its claims.

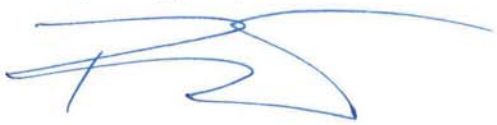
In addition to the fatal deficiencies in BIOCAD's Complaint discussed above, the anticompetitive acts alleged by BIOCAD also fail as a matter of law. For instance, the gravamen of a predatory pricing claim is that "the prices complained of are below an appropriate measure of [the defendant's] costs," *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 451 (2009), but BIOCAD's allegations are based solely on differences between Russian and American drug *prices*, with no reference whatsoever to those drugs' *costs*. Such allegations are unsustainable as a matter of law. *See, e.g.*, *Affinity LLC v. GFK Mediamark Research Intelligence, LLC*, No. 12 Civ. 1728, 2013 WL 1189317, at *3-4 (S.D.N.Y. Mar. 25, 2013) (Sullivan, J.), *aff'd* 547 F. App'x 54 (2013).

Likewise, BIOCAD has utterly failed to allege that it was injured in any way by the alleged fraudulent auction bids, misrepresentations regarding dosage amounts, or change in distribution channels. With respect to the allegations of tying and fraudulent auction bids, BIOCAD has made only conclusory allegations of FHLR's involvement, which are plainly insufficient to sustain a claim. Accordingly, none of BIOCAD's allegations can support its claims.

III. Conclusion

For the reasons discussed above, FHLR intends to file a motion to dismiss on the grounds that (1) BIOCAD has failed to serve process upon FHLR; and (2) BIOCAD's Complaint fails to state any claims against FHLR upon which relief may be granted. Given the merits of its proposed motion, FHLR requests that discovery be stayed until the motion has been resolved.

Respectfully yours,



Paul Spagnoletti
Counsel for Defendant
F. Hoffmann-La Roche Ltd

505 Montgomery Street, Suite 2000
San Francisco, California 94111-6538
Tel: +1.415.391.0600 Fax: +1.415.395.8095
www.lw.com

LATHAM & WATKINS LLP

September 9, 2016

VIA ECF AND E-MAIL

The Honorable Richard J. Sullivan
United States District Judge
Southern District of New York
Thurgood Marshall United States Courthouse
40 Foley Square
New York, NY 10007

Re: *Biocad JSC v. F. Hoffman La-Roche Ltd., et al.*, Civ. No. 1:16-cv-04226

Dear Judge Sullivan:

Defendant Genentech, Inc. ("Genentech") respectfully requests a pre-motion conference on a Rule 12(b)(6) motion to dismiss Plaintiff BIOCAD JSC's ("BIOCAD") Complaint.

This case centers primarily on pharmaceutical competition in Russia. Plaintiff BIOCAD is a Russian company based in Saint Petersburg, Russia, that has developed "biosimilar" copies of three branded cancer-fighting drugs—Avastin, Herceptin and Rituxan—developed and manufactured by Genentech, but which F. Hoffmann-La Roche Ltd ("FHLR"), an affiliate Swiss company, commercializes outside the U.S. Since 2009, Genentech has been a wholly-owned subsidiary of Roche Holdings, Inc., which is also an FHLR affiliate.

BIOCAD alleges that "at some point after [it] started working on biosimilars to [FHLR's] star drugs," FHLR sought to undermine BIOCAD's business in its "main and largest market—Russia." (Compl. ¶¶ 95, 97). This was allegedly intended to keep BIOCAD from expanding to other countries, including but not limited to the U.S. The Complaint attacks an "array" of conduct occurring almost exclusively in Russia, including predatory pricing, illegal tying, misrepresentations and fraudulent bidding. (Compl. ¶ 98). The Complaint contains causes of action under: Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2 (Compl. ¶¶ 166-87); Section 3 of the Clayton Act, 15 U.S.C. § 14 (Compl. ¶¶ 188-97); the Robinson-Patman Act, 15 U.S.C. § 13 (Compl. ¶¶ 198-206); the Donnelly Act, N.Y. Gen. Bus. Law §§ 340 *et seq.* (Compl. ¶¶ 207-09); and the common law of tortious interference (Compl. ¶¶ 210-16).

Plaintiff's Complaint is fatally defective as a matter of law. Genentech currently anticipates moving to dismiss all causes of action on the following grounds:

1. The Claims Are Barred by the Foreign Trade Antitrust Improvements Act: This case belongs in Russia (if anywhere). BIOCAD complains of conduct carried out almost

exclusively in Russia that has allegedly stifled its ability to compete in that country with its copies of Genentech's drugs. That conduct has had zero effect to date on competition in the U.S., where BIOCAD does not compete and the three drugs are still under patent.

The Foreign Trade Antitrust Improvements Act ("FTAIA"), 15 U.S.C. § 6a, bars claims brought pursuant to the Sherman Act for foreign conduct unless the plaintiff can demonstrate that the conduct had a "direct, substantial, and reasonably foreseeable effect" on commerce in the U.S. and that "such effect gives rise to a claim" under the Sherman Act. *See generally F. Hoffmann-La Roche Ltd. v. Empagran*, 542 U.S. 155 (2004). The Second Circuit has interpreted "direct effect" under the Sherman Act to require a showing of proximate cause between the conduct and the effect on U.S. commerce. *Lotes Co., Ltd. v. Hon Hai Precision Indus. Co., Ltd.*, 753 F.3d 395 (2d Cir. 2014). So-called "ripple effects" in the U.S. from foreign anticompetitive conduct do not give rise to a U.S. cause of action. *See Latino Quimica-Amtex S.A. v. Akzo Nobel Chemicals B.V.*, No. 03 Civ. 10312, 2005 WL 2207017, *8 (S.D.N.Y. Sep. 8, 2005) (citing *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 477 (1982)).

BIOCAD clearly asserts that the alleged conduct was aimed at directly affecting its business in Russia. (Compl. ¶ 97). At most, BIOCAD alleges ripple effects in the U.S., and exceedingly speculative ones at that. No FTAIA case that Genentech is aware of has permitted a U.S. action to go forward on BIOCAD's theory that foreign "predation" foreclosed a foreign company's future international expansion to the U.S. But even if that were possible, BIOCAD's version of the theory depends on too many uncertain intervening events. Courts refuse to accept U.S. effects theories "premised on a multitude of speculative and changing factors affecting business and investment decisions." *In re Intel Corp. Microprocessor Antitrust Litig.*, 452 F. Supp. 2d 555, 560-61 (D. Del. 2006). This is such a case.

2. BIOCAD Does Not Have Standing: A plaintiff seeking to bring an antitrust claim must demonstrate, *inter alia*, that it has suffered an "antitrust injury." *Gatt Commc'ns, Inc. v. PMC Assocs., L.L.C.*, 711 F.3d 68, 76 (2d Cir. 2013). Demonstration of an antitrust injury requires "(1) an injury-in-fact; (2) that has been caused by the [alleged] violation; and (3) that is the type of injury contemplated by the statute." *Blue Tree Hotels Inv., Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 220 (2d Cir. 2004) (internal citation omitted).

Plaintiffs such as BIOCAD who are at best *potential competitors* face special challenges in establishing standing. To plead an injury-in-fact, BIOCAD must allege facts showing "intent and preparedness" to enter the U.S. market. *See Andrx Pharm., Inc. v. Biovial Corp. Int'l*, 256 F.3d 799, 806-07 (D.C. Cir. 2001). In the highly analogous context of claims involving generic drug competition, "intent and preparedness" means that the plaintiff must plead, *inter alia*, that it has taken steps to attain FDA approval for its products and that it anticipates receiving FDA approval. *Id.* BIOCAD has failed to do so. It pleads nothing regarding any efforts to attain FDA approval for its drug copies. This deficiency, moreover, appears to be incurable. There is no public indication the BIOCAD has even begun the process of attaining FDA approval for any of the three alleged biosimilar copies at issue.

3. BIOCAD Has Failed to Plead Substantive Elements of its Claims: For each of the asserted causes of action, BIOCAD has failed to plead critical elements.

First Claim for Relief (violation of Section 2 of the Sherman Act). Plaintiff's primary conduct claim is for predatory pricing (in Russia). It fails as a matter of law because BIOCAD has not alleged that the prices at which Defendants' products were sold in Russia were below cost—which is what makes prices "predatory." *See Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 451 (2009); *Affinity LLC v. GFK Mediamark Research & Intelligence, LLC*, No. 12-cv-1728, 2013 WL 1189317 (S.D.N.Y. Mar. 25, 2013), *aff'd* 547 F. App'x 54 (2013).

Second Claim for Relief (violation of Section 1 of the Sherman Act). Section 1 only proscribes conspiracy or other "concerted action" that restrains trade. *See generally Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556-57 (2007); *In re Zinc Antitrust Litig.*, 155 F. Supp. 3d 337 (S.D.N.Y. 2016). BIOCAD clearly does not allege conspiracy among competitors, and it is impossible to tell whether it is alleging any other kind of conspiracy.

Third Claim for Relief ("tying" in violation of Section 3 of the Clayton Act). Plaintiff's tying claim must be dismissed because the only tying alleged in the Complaint took place solely in Russia, and did not involve a product for use within the U.S. *See United States v. Int'l Bus. Machines Corp.*, 163 F.3d 737, 741 (2d Cir. 1998).

Fourth Claim for Relief ("price discrimination" in violation of the Robinson-Patman Act). Plaintiff's claim a Robinson-Patman Act violation based on differences between the U.S. and Russian prices for the three cancer drugs. But by definition, price discrimination must occur within the same geographic market, not as between two nations with separate market conditions, regulations and competitors. *See George Haug Co., Inc. v. Rolls Royce Motor Cars Inc.*, 148 F.3d 136, 142 (2d Cir. 1998).

Fifth Claim for Relief (violation of the Donnelly Act). Because BIOCAD cannot maintain its antitrust claims, its Donnelly Act claim must fail as well. *See Bilinski v. Keith Haring Found., Inc.*, 96 F. Supp. 3d 35, 42 n.6 (S.D.N.Y. 2015), *aff'd* 632 F. App'x 637 (2d Cir. 2015) ("Except when state policy or legislative history dictates otherwise, the Donnelly Act is generally coextensive with the Sherman Act.").

Sixth Claim for Relief (tortious interference with business relationships). BIOCAD's claim for tortious interference must be dismissed because it contains only a general allegation of interference with customers without any sufficiently particular allegation of interference with a specific contract or business relationship. *16 Casa Duse, LLC v. Merkin*, 791 F.3d 247, 262 (2d Cir. 2015) quoting *McGill v. Parker*, 179 A.D. 2d 98, 105 (N.Y. 1st Dep't 1992).

4. BIOCAD Has Failed to Plead Any Illegal Conduct by Genentech: Finally, BIOCAD simply has failed to allege any conduct of any kind committed *by Genentech* that could subject it to liability in this case. The references to Genentech are mostly background for the allegations of wrongdoing by others, which is insufficient to state a claim against Genentech.

* * *

For the foregoing reasons, Genentech respectfully requests that it be granted leave to file a motion to dismiss the Complaint.

Respectfully submitted,

/s/ Daniel M. Wall
Daniel M. Wall (*admitted pro hac vice*)
of LATHAM & WATKINS LLP

cc: All counsel of record (via ECF)

GIBSON DUNN

Gibson, Dunn & Crutcher LLP

200 Park Avenue
New York, NY 10166-0193
Tel 212.351.4000
www.gibsondunn.com

Eric J. Stock
Direct: +1 212.351.2301
Fax: +1 212.716.0801
EStock@gibsondunn.com

Client: 80036-00001

September 9, 2016

VIA ECF

Hon. Richard J. Sullivan
United States District Court, Southern District of New York
40 Foley Square
New York, NY 10007

Re: Biocad JSC v. F. Hoffmann-La-Roche Ltd., et al., Case No. 16 Civ. 4226 (RJS)

Dear Judge Sullivan:

We represent defendant R-Pharm JSC ("R-Pharm") in the above-captioned action. We respectfully request a Pre-Motion Conference for R-Pharm's contemplated motion to dismiss the Complaint. Without waiving any of R-Pharm's legal rights or objections, including with respect to service and jurisdiction, we are prepared to appear and discuss these issues at the conference already scheduled by the Court for September 23, 2016.

R-Pharm and the Instant Dispute

R-Pharm (which Plaintiff mistakenly refers to as "R-Farm" in the Complaint) is a pharmaceutical company organized under the laws of the Russian Federation, and based in Moscow, Russia. *R-Pharm does no business at all in the United States*.[1] Plaintiff Biocad JSC, also a Russian company, alleges that R-Pharm's competitive activities *in Russia* weakened Plaintiff financially and that this financial weakness, in turn, impeded Plaintiff from entering the U.S. market. (*See, e.g.*, Compl. ¶¶ 10-12, 112-27, 181). That is the purported basis of Plaintiff's U.S. antitrust claims against R-Pharm.

R-Pharm's Proposed Motion to Dismiss

We respectfully request permission to move to dismiss on at least the following grounds: (1) improper service of process; (2) lack of personal jurisdiction; (3) failure to state a claim, including pursuant to the Foreign Trade Antitrust Improvements Act ("FTAIA"); and (4) comity/forum non conveniens.

[1] R-Pharm does own two very small subsidiaries in the U.S. (neither of which operates out of New York). Plaintiff does not (and could not) allege that either has any connection to the facts alleged in the Complaint.

Service of Process. Plaintiff has not served R-Pharm properly under Fed. R. Civ. P. 4. Plaintiff sought to serve R-Pharm through personal delivery overseas and registered mail (*see* Dkt # 11), but these means are not permitted by Rule 4 for service on a foreign corporation in Russia. Rule 4(h)(2) expressly declines to authorize personal service on foreign companies overseas.[2] *See Bidonthecity.com LLC v. Halverston Holdings Ltd*., No. 12 Civ. 9258, 2014 WL 1331046 at *7 (S.D.N.Y. Mar. 31, 2014) (Carter, J.).

Service by registered mail is also not permitted because Russia is a party to the Hague Convention. Russian companies must ordinarily be served pursuant to that treaty's procedures. *See id.*; Fed. R. Civ. P. 4(f). The Russian government has apparently suspended cooperation with the U.S. under that treaty, and some courts have accordingly granted motions by plaintiffs to serve Russian defendants by "alternative means not prohibited by international agreement" under Rule 4(f)(3). 2014 WL 1331046 at *10. But Plaintiff has not sought such an order. If Plaintiff files such a motion, it must propose a means of service that complies with Rule 4 and U.S. treaty obligations. R-Pharm is likely to oppose such motion.

Personal Jurisdiction. As noted, R-Pharm is a Russian entity that does no business in the United States. As such, it lacks the requisite "minimum contacts"—and none are alleged—with New York or the United States to support personal jurisdiction. *See, e.g., Lewis v. Madej*, No. 15-cv-2676, 2015 WL 6442255 at *6 (S.D.N.Y. Oct. 23, 2015). R-Pharm is not alleged to have made any sales in the United States, engaged in any marketing in the United States, or otherwise purposely availed itself of U.S. laws or legal protection.[3]

The Complaint challenges R-Pharm's conduct in connection with its sale of cancer drugs in Russia—drugs that R-Pharm is not alleged to be able to sell in the U.S. (Compl. ¶¶ 12, 26). A company in such a position would not reasonably expect its business activities, such as the pricing and packaging of its drugs in Russia, to be governed by U.S. antitrust laws, and would not "reasonably anticipate being haled into" into a faraway U.S. court based on such conduct. *Lewis*, 2015 WL 6442255 at *6 (citation and quotations omitted).

FTAIA. Plaintiff attempts to "dress up" this action as involving U.S. commerce, but the factual allegations underlying its purported claims against R-Pharm relate exclusively to

[2] Rule 4(h) provides that service on a foreign company overseas may be "in any manner prescribed by Rule 4(f) for serving an individual, *except personal delivery* . . . ." Fed. R. Civ. P. 4(h)(2) (emphasis added).

[3] As noted, R-Pharm does have two small U.S. subsidiaries, but under well-established jurisprudence a subsidiary's activities in the United States cannot be attributed to the parent for the purposes of exercising personal jurisdiction over the parent. *See Daimler AG v. Bauman*, 134 S. Ct. 746, 758-60 (2013).

commerce in Russia. (Compl. ¶¶ 12, 26, 112-43). Plaintiff's allegation that R-Pharm's conduct in Russia harmed Plaintiff in Russia—but resulted in financial weakness that in turn impeded Plaintiff's ability to enter the U.S. market—is a paradigmatic example of foreign-market conduct with at most allegedly *indirect* ripple effects in the U.S. Congress expressly foreclosed U.S. jurisdiction over claims based on such indirect effects. *See* 15 U.S.C. § 6a (Sherman Act does not apply to conduct involving foreign commerce unless "such conduct has a direct, substantial, and reasonably foreseeable effect" on U.S. commerce); *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 409-13 (2d Cir. 2014) (requiring "reasonably proximate causal nexus" between the alleged conduct and U.S. effect under FTAIA).

For the reasons explained in the letters separately submitted by co-defendants Genentech and FHLR, the claims against all Defendants in this action are precluded by the FTAIA because they rely on the indirect and speculative effects (relating to entry that has not occurred) of alleged anticompetitive conduct concerning commerce and competition within Russia. But the case for dismissal is even stronger for R-Pharm. R-Pharm is not alleged to have participated in or profited from any sales made by any party in the U.S. There are no facts pled even remotely suggesting that R-Pharm has any stake in competition in the U.S. for the drugs subject to the Complaint; its conduct and profits for those drugs relate solely to the Russian market.

Plaintiff's claims are also deficient for numerous other reasons. To avoid repetition, R-Pharm incorporates by reference the defects noted by its co-defendants in their letters being filed concurrently with the Court, including as to standing and the elements of claims for predatory pricing, price discrimination, tying, and tortious interference.

Comity/Forum Non Conveniens. Plaintiff's claims against R-Pharm also improperly seek to litigate what is essentially a Russian dispute in a U.S. court. To the extent that R-Pharm's competitive activities in Russia were lawful under Russian law, Plaintiff's attempt to challenge them under U.S. antitrust law would impinge on Russian sovereignty. It is one thing for U.S. courts to provide a cause of action where competitors acting outside of the U.S. collude in an effort to fix prices or allocate the U.S. market. It is quite another for U.S. antitrust standards to dictate how Russian companies must compete within Russia for sales in that country. *See, e.g., In re Foreign Exchange Benchmark Rates Antitrust Litigation*, 74 F. Supp. 3d 581, 599 (S.D.N.Y. 2015). Plaintiff challenges, among other things, *the prices R-Pharm charges for its drugs in Russia* and *how R-Pharm packages its drugs for the Russian market*. (*See, e.g.,* Compl. ¶¶ 124, 140). Further, it would be inconvenient from the standpoint of evidence and witnesses for two Russian companies to litigate such a dispute in a U.S. court. *See, e.g.*, *Wallert v. Atlan*, 141 F. Supp. 3d 258, 281 (S.D.N.Y. 2015).

Respectfully submitted,

/s/ Eric Stock
Eric Stock

G9n1bioc

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x

BIOCAD JSC,

Plaintiff,

v. 16 Civ. 4226 (RJS)

F. HOFFMAN LA-ROCHE LTD., GENENTECH, INC., R-FARM JSC,

Defendants. Premotion Conference

----------x

New York, N.Y.
September 23, 2016
12:10 p.m.

Before:

HON. RICHARD J. SULLIVAN,

District Judge

APPEARANCES

FEINSTEIN PARTNERS
Attorneys for Plaintiff
BY: ALBERT FEINSTEIN, ESQ.
RIKA KHURDAYAN, ESQ.
MAX DILENDORF, ESQ.

DAVIS POLK & WARDWELL LLP
Attorneys for Defendant "F. Hoffman La-Roche Ltd."
BY: PAUL SPAGNOLETTI, ESQ.
ANDREW S. GEHRING, ESQ.

LATHAM & WATKINS LLP
Attorneys for Defendant Genentech, Inc.
BY: DANIEL M. WALL, ESQ.

GIBSON, DUNN & CRUTCHER, LLP
Attorneys for Defendant "R-Farm JSC"
BY: ERIC J. STOCK, ESQ.

(Case called)

MR. FEINSTEIN: Good afternoon, Judge. Albert Feinstein of Feinstein Partners, for the plaintiff, 54 East 66th Street, New York, New York 10065.

THE COURT: Okay. And with you at counsel table?

MR. FEINSTEIN: I'm joined by two of my associates, Rika Khurdayan and Max Dilendorf.

THE COURT: Say those names again, because neither is on the docket sheet, I don't think.

MR. FEINSTEIN: Rika, R-I-K-A, Khurdayan, K-H-U-R-D-A-Y-A-N, and Max Dilendorf, D-I-L-E-N-D-O-R-F.

THE COURT: Okay. And are they going to be proceeding in this case going forward?

MR. FEINSTEIN: It's my name, Judge, on the complaint, and my associate Rika Khurdayan.

THE COURT: Okay. Let's have each of them file notices of appearance. Any lawyer who's going to be participating I think should be on the docket sheet, okay?

MR. FEINSTEIN: We are. Thank you.

THE COURT: Well, the firm is, but make sure the individual lawyers are.

MR. FEINSTEIN: All right. Thank you.

THE COURT: For the defendants, let's start with FHLR, as we've been calling it, I think.

MR. SPAGNOLETTI: Good afternoon, your Honor. Paul

Spagnoletti, Davis Polk & Wardwell, on behalf of FHLR.

THE COURT: Okay. Good. Mr. Spagnoletti. And then for Genentech? Oh, wait. Do you have somebody with you?

MR. GEHRING: Andrew Gehring, also from Davis Polk.

THE COURT: Okay. You're on there too. Okay, Mr. Gehring. Good afternoon.

Genentech?

MR. WALL: Good afternoon, your Honor. Dan Wall from Latham & Watkins.

THE COURT: Yes. All right. Mr. Wall. Good afternoon.

And then R-Pharm.

MR. STOCK: Your Honor, Eric Stock from Gibson, Dunn & Crutcher.

THE COURT: Okay. Good afternoon to you, Mr. Stock.

So we're here in connection with the defendants' assorted contemplated motions to dismiss this complaint. And so there are a lot of different grounds. I've gotten premotion letters from all of the defendants and I have a response from the plaintiffs.

And so let me just sort of tell you the ground rules. Premotion conferences are for my benefit. I have a requirement of premotion letters and conferences because I think they help me get my head around issues and motions better than just sort of getting 25 pages dumped in my lap. And so that's the reason

why I require it. I don't do it as an extra burden or an extra hurdle on the lawyers. I think it's ultimately beneficial, and I think it can streamline the process, it can make things more efficient when you have a sense of my own at least preliminary views of things. I'm not ruling. I never tell a party they can't make a motion. You have a right to make a motion. But I do think it can be valuable to at least get the judge's gut reaction out of the gate as to whether the thing has any legs or whether it's not worth doing.

And so with that in mind, I want to address some of the issues that have been raised.

Let's begin with the service issue. And that pertains to two of the defendants, I guess; not Genentech, right? Genentech was properly served. The other two entities were not served through the Hague Convention, right? I guess in the case of R-Pharm, they were served through a subsidiary here in the U.S., and in the case of FHLR -- am I saying that right?

MR. SPAGNOLETTI: Yes, your Honor.

THE COURT: -- they were served by some alternate service in Russia, is that correct?

MR. SPAGNOLETTI: I don't believe so, your Honor. I believe, with respect to FHLR, the service was attempted through two entities in the United States. One was Genentech and the other was another entity in New York.

THE COURT: Okay. So I think that is a problem here,

Mr. Feinstein. So I want to hear from you on that. It is not the case that a parent can be automatically served through their subs, right? You don't suggest that's the case, do you?

MR. FEINSTEIN: No, your Honor, we do not.

THE COURT: Okay. So then what's your basis for thinking that you can serve these two entities through their U.S. subsidiaries? Or Genentech is not even a subsidiary, right?

MR. SPAGNOLETTI: That's right. Neither of those entities is a subsidiary of FHLR.

MR. STOCK: Your Honor, just to clarify, I think you got it reversed, the issues. It's Hoffmann-La Roche that was served throughs its U.S. subsidiary. R-Pharm, they attempted service in Russia.

THE COURT: Okay. So I did invert them. In any event, so --

MS. KHURDAYAN: Your Honor, if I may clarify service.

THE COURT: Okay.

MS. KHURDAYAN: Roche, defendant Roche, Hoffmann-La Roche, was served in the U.S. for Genentech because Genentech is official headquarters for Roche operations in the U.S. They used to maintain separate companies for U.S. operations purposes in Nutley, New Jersey. Now their official website states that that company was closed after they acquired Genentech and Genentech is now the official headquarters for

Roche and for all operations for Roche in the U.S.

THE COURT: Do you want to respond to that, Mr. Spagnoletti?

MR. SPAGNOLETTI: Yes, yes. Thank you, your Honor.

Just to be clear here, I think there's a misimpression that the plaintiffs have that Hoffmann-La Roche is somehow a parent company of either Genentech or TCRC, which is the name of the New York entity that they attempted to serve. Hoffmann-La Roche is not a parent company, an ultimate parent company of either of those two entities. They're sort of in a family tree and they're cousins, if you will, distant cousins. But Hoffmann-La Roche is not a parent of those companies, doesn't control those entities.

THE COURT: All right. And so the reference to a website, do you understand what's being referred to?

MR. SPAGNOLETTI: I think there's some confusion. I don't believe that website is referring to Hoffmann-La Roche.

THE COURT: All right. Well, that's not something I'm going to be able to resolve today, but it's easily enough resolved, I suppose. I would take declarations and I'd get --

MS. KHURDAYAN: Your Honor, if I may respond to that. We've never alleged that F. Hoffmann-La Roche was a parent of Genentech. They're both owned by a holding company that does not do any business and has no operations. Now defendant F. Hoffmann-La Roche is an operational company and all of the

operations of defendant Roche are done in the U.S. through Genentech.

THE COURT: Well, is Genentech an authorized agent for service of Hoffmann-La Roche?

MS. KHURDAYAN: No, but there's case law that suggests that it is not necessary to invoke the Hague Convention if a foreign defendant maintains an agent in the United States.

THE COURT: I think that's what's being disputed here, right?

MR. FEINSTEIN: Yes, Judge. But for all of our purposes, we believe that this company, Genentech and Roche, Roche operates solely through Genentech in the United States, and openly states so.

THE COURT: Do you want to say something?

MR. SPAGNOLETTI: Yes, your Honor. There are no cases that the plaintiff cites that support the proposition that service on Genentech, for example, would be sufficient service on F. Hoffmann-La Roche under these circumstances. The one case that plaintiff cites on service relates to a situation where the entity that had been served was, by operation of law, the agent for service for the parent company. Here, as I mentioned, we're not even a parent company of the entities that received the service. We only found out about the litigation through our own diligence and reviewing the court's docket. We still haven't received service through the Hague Convention. I

believe it's critical that the plaintiffs go through that process. Otherwise, we'll be in the situation where it would just eviscerate the protections afforded by the Hague Treaty.

THE COURT: Yes. I think it is a problem. I mean, I think I'm going to have to take a declaration or two to make sure who's a parent of whom and who's a sub of whom and who's an agent of whom is delineated. I can't do that based on just what's in the complaint, or what's in a premotion letter. But it seems to me that there really is a problem, potentially, with service of process here.

So let's put that to one side, because I don't think we're going to be able to resolve that right now. But it would be a showstopper if it is in fact the case that those entities have not been served.

Now we also have a lack of personal jurisdiction over R-Pharm which is being asserted here, and this turns on whether or not the existence of what are described by the defendants as two small subsidiaries is enough to establish the kind of minimum contacts that are contemplated for personal jurisdiction. So let me hear from R-Pharm on that question.

MR. STOCK: Yes, your Honor. And I don't know if you intentionally meant to skip the service issue for R-Pharm as well or --

THE COURT: I think it's the same. Well, the R-Pharm issue is, they were served in Russia through sort of informal

means and cases cited are cases in which courts have authorized alternative service.

Also, the plaintiffs cite a case, an opinion that I wrote, which I guess that's more about personal jurisdiction. We'll get to that in a minute.

So I think that the cases cited don't really stand for the propositions for which they're being offered. Is there anything else you wanted to say on that?

MR. STOCK: What I would add, your Honor, is that there's an additional wrinkle with respect to Russia under the Hague Convention. I mean, I think it's very clear that Roche needs to be served under the Hague Convention. I think it's also clear that under the treaty, R-Pharm needs to be served under the Hague Convention. What I know that plaintiffs are going to argue, which other plaintiffs have argued, is that because of the status of Russia-United States, you know, relations in connection with that treaty, they should be entitled to request the Court's permission for a different type of service.

THE COURT: Right. I get that. But nobody asked before they served in this case.

MR. STOCK: Right. They did not obtain that.

THE COURT: That's usually the way it's done.

MR. STOCK: Exactly. So if you'd like to discuss the personal jurisdiction issue --

THE COURT: Yes.

MR. STOCK: So just so it's absolutely clear, the defendant in the case is the parent company, R-Pharm, JSC, even though they spelled it wrong. This company has absolutely no operations or sales in the United States. And it's absolutely the quintessential type of foreign entity that does not have minimum contacts with the United States to allow jurisdiction under the Constitution. I believe what the plaintiffs are arguing is that because in 2014 this R-Pharm company opened up a subsidiary in New Jersey -- and I put in my letter that in fact we have two subsidiaries in the United States -- that that's some sort of basis for hauling the parent company to the United States. But as the Supreme Court has made absolutely clear, you cannot use the fact that a company has a subsidiary in the U.S. as a basis for establishing minimum contacts on the parent. So that I think is the issue teed up for the personal jurisdiction motion.

THE COURT: Yes. I think this is a problem too.

Now plaintiffs cited my opinion in *SEC v. Straub* for the proposition that minimum contacts may be established when the plaintiff adequately pleaded defendant's conduct was designed to violate U.S. laws, and that's actually not what it says at all. So I don't think that was a very careful reading of my opinion. That's a case in which the defendants were basically making public filings with the SEC in New York, and

they were selling ADRs on U.S. exchanges, and so that's what was going on in that case, but I didn't say, and certainly didn't intend to say, that pleading that somebody was engaged in or intended to violate U.S. laws is enough to establish minimum contacts for purposes of finding personal jurisdiction. That's just not what it says. So I think that's a problem.

I'm happy to hear a response from plaintiffs on that.

MS. KHURDAYAN: Your Honor, first of all, in regards to the subsidiary in the U.S., R-Pharm subsidiary, again, the website, the front page directory says they've established a subsidiary in 2013 to expand Russian company into the North America. Not only this, they're selling two drugs within the United States. One is Ixempra, that they've acquired from Bristol-Myers and they're selling actually in the United States. I think that --

THE COURT: But so what? I mean, how does that make the parent subject to personal jurisdiction here?

MS. KHURDAYAN: Because the parent conducts business in the U.S. through its subsidiary.

THE COURT: Well, I mean, it seems to me, both here and previously with respect to service, you seem to be ignoring the corporate form and seem to think that you can do that, when the case law doesn't make it that simple.

So I think this is an uphill climb for you, I have to say. I guess maybe I'll see what declarations we have for that

too because, once again, I'm not limited to what's in the complaint. The complaint doesn't say much.

MS. KHURDAYAN: Your Honor, we also believe that the Court has jurisdiction over the Russian entity because R-Pharm's conduct in the U.S., or in Russia, was designed to have effect in the U.S.

THE COURT: Well, I mean, that's really I think sort of the merits-based arguments about whether you've stated a claim or not, so we will talk about that as well. But I think personal jurisdiction, you know, there is a standard that has to be complied with, and I don't think saying that they intended to violate a U.S. law automatically gives U.S. courts the power to haul people into the Southern District of New York.

All right. But then let's get to sort of the main argument here, and that is that there's really no claim here, and that's because what's really being alleged are violations for acts of Russian antitrust law but all this conduct is in Russia and what you're really arguing is that by virtue of what was done in Russia, it prevented the plaintiff from developing into a viable competitor in the United States.

Now there's a standing issue. We can talk about that first, I guess. If I were doing an opinion, I'd deal with standing before I would deal with the merits, or the merits of what's been pled under 12(b)(6).

But why don't we just get to the meat and potatoes here, because it does seem to me that this is an extremely aggressive theory of antitrust liability that I don't see any precedent for and I think, frankly, the precedent really is going the other way here.

So I don't know who's carrying the ball on this. Is it you, Mr. Feinstein, or --

MR. FEINSTEIN: Yes, Judge.

Your Honor, I totally agree with you that it's probably one of the first cases, but I believe we should be able to do the following. We are not saying that the conduct in Russia prevents the competitor to enter the market. It's just part of our theory. What we're saying is something else. Roche, through its own company in the U.S., Genentech, and through another company, which is supposedly independent distributor in Russia, R-Pharm, designed a whole scheme where they're making in the U.S. consumer foot the bill to do certain steps which are completely, we believe, illegal and improper and unethical, not only to destroy the competitor from entering the U.S. market but pretty much to maintain the monopoly for themselves. So at the end of the day, it's not the plaintiff which will suffer; it's the defendant Roche which will continue its monopoly beyond the permitted time and there is consumer which will continue paying higher and higher premiums to allow Roche to do whatever they've been doing.

THE COURT: Well, that's great. My mother might be very upset about stuff like that too, but I don't think she has standing and I don't think she has the ability to come in and bring a claim based on that.

MR. FEINSTEIN: In order to establish the standing, based on the law, we have to show steps, which steps we've taken to enter the U.S. market.

THE COURT: I think you have to show that you've got an injury.

MR. FEINSTEIN: We've got an injury, Judge.

THE COURT: What's the injury?

MR. FEINSTEIN: The injury is, because of the acts of all the defendants, we are being closed, being shut down, financially and everything else, because the --

THE COURT: In Russia.

MR. FEINSTEIN: Not in Russia, Judge. It's beyond Russia. In the United States. We have a company in the United States, we've transferred people, we've done contracts to develop and distribute all the same drugs that the company Roche is now --

THE COURT: You're saying all these injuries predated your arrival in the United States, right?

MR. FEINSTEIN: No.

THE COURT: No?

MR. FEINSTEIN: No. They're all occurring, Judge, at

the same time. They're all occurring, Judge, at the same time. And I understand this Court's predicament in looking at this case.

THE COURT: I'm just looking at your complaint, and I don't think your complaint states a cause of action. But go ahead.

MR. FEINSTEIN: So at this time I think what's happening, we've managed to manufacture all three biosimilars. Every single time, Judge, we prepare and launch these biosimilars --

THE COURT: In the United States.

MR. FEINSTEIN: No. In Russia.

THE COURT: Okay.

MR. FEINSTEIN: -- Roche and other defendants take steps in the United States to finance and subsidize the destruction of their competitor so the competitor will not act in the United States or not continue to act in the United States. So this time, Judge, because we open up the subsidiary and all the steps that we've taken, so far, to offer the same products that Roche is offering to the U.S. consumer, it becomes impossible financially and from any other perspective, and at the end of the day, Judge, it's not the plaintiff that will be destroyed. Again, the question is about Roche maintaining its monopoly beyond the permitted time. So it's broader, Judge, than just competitor just asking for the Court

to help out the competitor to stay in business. Absolutely not. I think we've discovered, and continue to discover, Judge -- we're doing very active investigations. Our foreign and local colleagues are doing a lot of investigation and possibly we'll be amending the complaint to provide additional facts and references to defendants' improper actions both in the U.S. and outside of the U.S. But at this time I think that it's just beyond that a competitor is about to pull out outside of the United States. It's much more. It's the conduct in the United States which causes the injury to U.S. consumer.

THE COURT: The injury to the U.S. consumer is what?

MR. FEINSTEIN: That U.S. consumer is paying higher and higher premiums to Roche and Genentech to finance Roche illegal conduct right now and beyond its monopoly time. I'm talking about 2018, when their patents expire, the last one should expire. So the injuries today --

THE COURT: The injury is what?

MR. FEINSTEIN: The injury is today, on both hand, the U.S. consumer and plaintiff. Plaintiff has standing because plaintiff has expanded in the United States to do such operations; specifically, to sell its product in the United States. As of today, Judge, not as of tomorrow. As of today. And we believe the case law shows that we've done enough steps to show the standing to be in the lawsuit --

THE COURT: Wait. What does the complaint show in

terms of your being a viable competitor in the United States?

MR. FEINSTEIN: Judge, I don't believe we have to show that we're a viable competitor in the United States.

THE COURT: You have to show something more than a speculative injury here. So that turns on you being in a position to undercut or undersell the defendants here. So what is the basis in the complaint, what are the facts alleged, to suggest that that's what's going on here?

MR. FEINSTEIN: Judge, as I understand, you're referring to the standing, because we have to show the viable competitor under the Sherman Act, if we're talking about the monopoly, improper monopoly on the defendants' part. But from the standing perspective, plaintiff did take the steps to enter the U.S. market.

THE COURT: What steps have you taken to enter the U.S. market?

MR. FEINSTEIN: Plaintiff opened up a subsidiary in the United States, actually an office in the United States, transferred its personnel to the United States, began soliciting and obtaining contracts for the distribution, development, and obtaining the approvals in the United States for the biosimilars that plaintiff is manufacturing. Plaintiff is sampling the market, plaintiff is discussing and negotiating the contracts with all relevant parties for the distribution, and all other steps that any company that plans to sell their

product in the United States will be taking.

THE COURT: But you're not authorized to sell in the United States yet, right?

MR. FEINSTEIN: No, not yet, Judge, but there's no requirement to have --

THE COURT: What steps have you taken to do that?

MR. FEINSTEIN: What steps we've taken to do that?

THE COURT: Yes.

MR. FEINSTEIN: We've acquired the companies, Judge, that will assist us to obtain all the necessary approvals and complete the process to permit us to sell the drugs as soon as the Roche's patents expire in 2018.

THE COURT: In 2018, right? So we're talking about 2018 and we're talking about you getting approvals to sell, which is a pretty lengthy process that you haven't even started yet, right?

MR. FEINSTEIN: Yes, Judge, but I don't believe there is a requirement that we have to obtain the FDA approval before we can file the claim if we have the injuries already. We don't have to wait for the injury in 2018.

THE COURT: What is your injury today? You're only injured if you in fact would be able to sell here, right? You're asking me to assume that you'd be able to sell here when there's no reason to think that that's the case.

MR. FEINSTEIN: Your Honor, I do not believe that the

case law requires us to obtain the FDA approval and start selling in order for us to have an injury.

THE COURT: You have to establish a nonspeculative injury, right?

MR. FEINSTEIN: And the injury is, we will not be able to, Judge, to sustain our operations and development if defendants continue their illegal and improper monopolistic conduct. That's what we're saying.

THE COURT: I don't think that's really what the complaint is saying.

All right. Let me give the defendants an opportunity to address this. I'm carrying their water for them and I'm not getting paid nearly as much. So go ahead. Who's carrying the ball on this one?

Mr. Wall.

MR. WALL: Your Honor, we've sort of divided standing and FTAIA, so I'll start off on the standing aspects. They're obviously related because --

THE COURT: They are related. I think it's almost the same. It's a different legal analysis, but it's the same factual analysis.

MR. WALL: So certainly one of the things that you just heard here is a strong indication that, to the extent that there has been any injury or effect on what they're doing in the U.S., it is because of the plot to undermine them in

Russia, and that's the particular issue that I'll hold off on.

But what our motion on standing is about, as you know, there's a relationship, legally and logically, between the idea of a speculative injury and what the courts have referred to as this intent and preparedness, and there's a doctrine which was developed in actually quite a few of these generic pharmaceutical cases that hasn't been applied to this slightly different regulatory setting of biosimilars yet, having to do with how far or how close to the finish line of having a product on the market you need to be. And I think it's safe to say that when that was briefed, we would find that if you sort of lined up the different cases, that this one is on the far end of the spectrum away from intent and preparedness. Because what we just essentially heard is that the tangible step in the United States is that they have a subsidiary, then they opened in August in order to start making contracts to start the approval process. That's not a fact pattern you're going to find in any of the prior disputes that occurred in the generic pharmaceutical case. There's a specific biosimilar pathway that Congress established in 2009. It requires a lot of scientific showings, of literal biosimilarities, safety, efficacy, certain studies. None of that is pleaded. Even what's been heard here, or what's been said here, rather, is new. We heard it for the first time in the letter. And I must say that if they are going to amend to put that or anything

else in about their intent and preparedness, I hope that that happens before we have to file a motion so that we don't just kind of pass like ships in the night on this.

THE COURT: Well, the complaint I guess, at page 20 and 21, sort of speaks very generally but says plaintiff has signed a dozen agreements with manufacturing companies; it says that they concluded contracts for sale and delivery of AcellBia; and, in paragraph 68, that they've established and grown operations in the U.S. in the past several years, hired new people, and transferred business development personnel from Russia to the U.S. Pretty vague. But that's, I guess, some of what was said today by Mr. Feinstein.

MR. WALL: Right. What's not alleged, anywhere, is what steps have they made on the regulatory pathway. Those to me would be sort of --

THE COURT: Nothing about that.

MR. WALL: -- pre-pre-entry types of steps that, we've arrived here, we have a sub, we've entered into some contracts. We know they've filed a lawsuit. We don't know that they've done anything with respect to that FTAIA process. And the case law that was developed in the generic pharm case, at a very broad level, is trying to make a judgment call about whether you're close enough to the finish line that we can rule out that this is a speculative injury.

And nothing is dispositive. We are not saying that

they have to have FDA approval. That's not our position. But we are saying that they have to plead a lot more than this. And, you know, I do think that, again, that the logical thing is, if they intend to amend because they think they have more, and of course they should be able to plead everything there is to know about their own efforts to enter the market, they ought to do that, and then we ought to be able to take our shot at it under the various authorities that have decided.

THE COURT: So that's standing.

MR. WALL: That's standing.

THE COURT: And then Mr. Spagnoletti is going to talk about the antitrust laws and --

MR. SPAGNOLETTI: On the FTAIA, your Honor, just briefly, it does overlap substantially with what Mr. Wall said, but let me just make a couple of points.

It's not just about intent and preparedness. The plaintiff just simply has not pled sufficient facts in order to meet the exceptions under the FTAIA. Their claim is barred under the Sherman Act unless they plead a direct, substantial, and reasonably foreseeable effect on U.S. commerce, and that effect on U.S. commerce gives rise to their claim. They fail under each of those prongs, your Honor.

If you look at their complaint, all they say about the effect on U.S. commerce is in paragraph 154, which says, "As a direct and proximate result of defendants' anticompetitive and

unlawful tactics, competition in the sale of monoclonal antibodies in the United States was improperly diminished and restrained." That's just much too conclusory for purposes of satisfying the rigid requirements of the FTAIA. In order for the plaintiffs to prevail on the motion to dismiss here, the Court and the parties would have to engage in a massive speculation effort, of a number of attenuated facts.

And let me just give the Court an example. You'd have to assume that the allegedly anticompetitive conduct in Russia had a negative impact on Biocad's revenues or profits. You'd have to assume that that negative impact on their profits undermined Biocad's nascent U.S. efforts to launch their generic drugs. You'd have to assume that Biocad applies for FDA approval in the United States. You have to assume that FDA approval was secured. You have to assume that there is no other competitors in the market. You have to assume that, after all that, the prices in the U.S. rise when Roche's patents expire in 2018 and '19 and, as a result, there's a harm to U.S. commerce. That's just much too attenuated, much too speculative to satisfy the requirements of the FTAIA.

Moreover, I think it's obvious that Biocad cannot satisfy the second prong, which is to show that their claim arises from the anticompetitive effects in the United States, because you would only get to that after all that long parade of horribles happened. What they're really complaining about

is how they're being harmed now in Russia.

THE COURT: I think that was clear from your letter.

So I'm not sure what the response is though, to that, Mr. Feinstein.

MR. FEINSTEIN: Judge, if I may, I'm not so sure, Judge, that we have to take all of those assumptions as assumptions for the purpose of sustaining the complaint. For example, we don't have to establish today, Judge, or speculate that we will get the FDA approval for our purposes. We don't have to, Judge, speculate today that Biocad is suffering financial loss, because that can be established --

THE COURT: Oh, wait. But the only financial loss that you're suffering today is in Russia. You're not in a position to sell anything in the United States yet, right?

MR. FEINSTEIN: Right, Judge, but we're not discussing the standing claim. If we're discussing the standing claim, that's one thing. If we're discussing if we can establish our claim under Foreign Trade Antitrust Improvements Act, that's a bit different, Judge, because if we are to establish the standing and switch to the requirements under Foreign Trade Antitrust Improvements Act, I think we can sustain our claims under that act. And again, Judge --

THE COURT: Well, you have to prove an injury, right?

MR. FEINSTEIN: We have to prove the injury.

THE COURT: So what is the injury in the United States

that you're talking about here? You're really complaining about being sort of snuffed out in your infancy in Russia and that has an ultimate effect, in Russia. It's prevented you from growing as large as you would have grown --

MR. FEINSTEIN: No.

THE COURT: -- outside of the United States, which then would have allowed you to take your business on the road and be a player in the United States. That seems to be what you're saying. You're not a player yet in the United States, right?

MR. FEINSTEIN: May I rephrase what I think we're saying?

THE COURT: Go ahead.

MR. FEINSTEIN: Or restate? I'm sorry. We're not saying that we are going to be small in Russia. That's not what we're saying. We're saying we will not exist in the United States because of defendants' illegal improper practices because they want to maintain that monopoly, and there is no way to go around that monopoly because they're acting illegally and improperly today. That's our claim, Judge. We are not saying we're small in Russia or we are going to become small in Russia. We will never become -- our drugs will never get to the United States. The monopolist, which is the monopolist today, will maintain its monopoly beyond its permitted time frame, and it's improper and illegal, and we're showing the

facts how they're doing it today through continuing the monopoly beyond the applicable time. So the injury is occurring today, Judge, from our perspective, and the effect of that conduct -- because I heard there is no effect on U.S. commerce, so I think it's a bit, you know, questionable statement, because our complaint details what steps defendants take every single time we come up with the biosimilar, or, I'm sorry, we manufacture the biosimilar, we see what they do in the United States to maintain their monopoly, including controlling the chain of distribution, money, and everything else.

THE COURT: But why are we doing this now? I mean, it's two years before this patent ends, right? 2018 is the earliest date in which you can start selling your biosimilars, is that correct?

MR. FEINSTEIN: Yes. We're doing it today, Judge, because, first of all, there will be nothing in 2018, to begin with. There will be no 2018 for us.

THE COURT: Is that the Aztec calendar you're referring to or what?

MR. FEINSTEIN: No, Judge. 2018 for us will not exist because if we cannot do what we're supposed to do before 2018, 2018 will not --

THE COURT: What will you be prevented from doing now? What are they preventing you from doing now?

MR. FEINSTEIN: There is no way, Judge, we will get to the stage where we're going to get the FDA approvals for our drugs if they continue their conduct as they're doing today.

Judge, in essence, defendant Roche openly, openly delivers their product below the cost and openly declares it at the Russian customs, and then it has R-Pharm, which is supposedly independent distributor, sell it even at lower price than declared as the cost at the border.

Judge, we are talking about such an open and improper conduct, and once we amend the complaint, your Honor will see that Roche and other defendants have gone beyond acting improperly. I think we'll have tremendous evidence to show that it's been a very active plan for years in question involving all the higher-ups at Roche and other defendants participating in this scheme. So it's not artificial, Judge, that something occurs in Russia and we cannot establish the effect in the United States. We have the company in Switzerland, La Roche, we have the account in Genentech in the U.S., and their company, R-Pharm, in Russia. They're all acting together. And the only effect we see, Judge, is in the United States. It's not even in Russia. Actually, there's almost no effect. If anything, the effect in Russia is rather small. In the United States, we can definitely see the effect, what's happening. They're expanding and maintaining their monopoly. That's all. And we will never get there, Judge. We

will never get the approvals for our drugs here if they continue what they're doing today.

THE COURT: Why will you not get approvals for your drugs if they continue what they're doing? I don't understand that.

MR. FEINSTEIN: Because they are not only destroying us financially, they're doing all these things that --

THE COURT: They're destroying you financially where? Here in the United States?

MR. FEINSTEIN: Here, of course, in the United States.

THE COURT: So all the things that you would sell here now, you're not able to sell? You're not selling anything. What are you doing in the United States that's generating revenue?

MR. FEINSTEIN: Actually, no. We're expending the money to set up our presence in the United States as required for any company entering the U.S. market.

THE COURT: Right. So again, the question is, what are they doing that would prevent you from getting the approvals you need to be a competitor in the United States?

MR. FEINSTEIN: The short answer, Judge, would be, they have the financial means to maintain their monopoly to destroy us financially.

THE COURT: That's a circular statement. You just said, if they keep doing what they're doing, we will never get

approval here.

MR. FEINSTEIN: Because they financially destroy us. They have the means to financially destroy us.

THE COURT: What does that mean, "to financially destroy us"?

MR. FEINSTEIN: We have no means, Judge, to maintain, sustain our operations in the United States --

THE COURT: But you have no operations in the United States, right?

MR. FEINSTEIN: We do. We don't have the --

THE COURT: Are you generating revenue in the United States?

MR. FEINSTEIN: No. Of course not, Judge.

THE COURT: So what does that mean to say that they're destroying you financially if you're getting zero revenue regardless?

MR. FEINSTEIN: Absolutely, in the United States, yes. In order for us to expand and maintain our presence in the United States, we have to invest the money. In order for us to invest the money, we have to be viable company.

THE COURT: Generating revenue where?

MR. FEINSTEIN: Everywhere, around the globe.

THE COURT: Okay. And so that's really what you're arguing, right, is they're preventing you from generating revenue around the globe, which is then preventing you from

getting large enough and competitive enough that you could later, no earlier than 2018, become a competitor to them in the United States market. Is that what you're saying?

MR. FEINSTEIN: Not large enough, Judge. We're as good as it gets. They're preventing us from completing the steps to compete with them in the United States. We're the only company which has the same drugs as they do.

THE COURT: Right. But again, you keep saying they're going to destroy you financially, and I don't know what that means if you're large enough.

MR. FEINSTEIN: If they're capable to do illegal steps to sell their drugs below the cost and below any possible prices for us, the whole production, manufacturing, and expansion makes no sense.

THE COURT: Well, that's just basically saying that you would like to be able to just bring antitrust claims in any country where you'd like to come in and do business. But you don't get to do that, right?

MR. FEINSTEIN: I know, Judge, but we're talking about only the United States in this case. The United States has a very specific market where, for the first time, we can see how they do it. We can connect the dots between the United States market and what they do outside the United States market to maintain this monopoly, Judge. If we could come back to your Honor in 2018, it wouldn't make any sense. There would be

nothing to target in 2018.

THE COURT: What do you mean there would be nothing to target?

MR. FEINSTEIN: From our perspective, there would be no presence, no FDA process, because by 2018, defendants will do everything to destroy us. We're not going to exist by then.

THE COURT: But you don't get to just say things like "they will do everything to destroy us." That's not actionable, okay? You have to have facts. First, you have to have standing, then you have to have facts. You have to be able to establish an injury, and you have to show where that injury is taking place.

So I think we're kind of going in circles here. You've said several times that you intend to amend.

MR. FEINSTEIN: Yes.

THE COURT: And I guess it's not clear to me what the amendments are going to look like that would even make a difference here.

But let me see if the defendants wanted to say anything else. Did you want to say anything?

MR. STOCK: No, your Honor.

THE COURT: R-Pharm? No?

Mr. Wall?

MR. WALL: Just one point, because it does relate to any amendment that might come out. We've put a line at the end

of our letter noting the fact that there's actually hardly anything in this complaint about Genentech itself. Now in the context of this conversation, that's an important point, because if what they're going to say is that there's actually things happening in the United States, those would be done by Genentech. That's who would do them. That's the way the company is organized. Those would be things that would be done by Genentech. And there's no allegations of anything that's done by Genentech that is going to contribute in any logical way to preventing them from going through the regulatory process, which is the big hurdle for them to actually getting on the market. So I would just hope that that just doesn't get glossed over and then we hear more and more about what F. Hoffmann-La Roche is doing in other parts of the world, because that's just going to close the circle right back to the point you made about a theory which right now is about doing things elsewhere to sort of snuff them in their infancy, as you put it.

THE COURT: All right. So what do you intend to add to this complaint, Mr. Feinstein?

MR. FEINSTEIN: Judge, from the point of view of the standing, as I've heard from the Court today, we will add the facts and allegations pertaining to all the steps and everything else that the company has taken to expand to the U.S. market.

THE COURT: Okay. Anything else?

MR. FEINSTEIN: From what I've heard from the defense side, we're going to amend the complaint to provide more facts, what's been occurring in the United States from our standpoint, we'll show that effect on the U.S. market in more detail, we'll add the facts, what's occurring in the U.S. market. We'll also show the steps that all the defendants have been taking and the factual allegations, what's been occurring for the past number of years. And I'm talking about acting together by all three defendants.

In terms of jurisdiction, Judge, we'll add the facts to establish the jurisdiction.

From the service standpoint, Judge, I believe Russia suspended Hague Convention service, and we've done several times before, so even though the Court mentioned that we have to ask for the permission to effectuate the different service, we'll double-check on that part, your Honor. I believe the service to be completed in Russia on R-Pharm has been found sufficient before by the courts of this district. But we'll definitely investigate this matter. As well as the service on the defendant Roche, even though we believe they operate, as we just heard, through Genentech, solely through Genentech, not as a parent company but actually I believe it's the same company for all purposes in the United States.

Now, your Honor, we'll add allegations pertaining to

Foreign Trade Antitrust Improvements Act. I've noted what defense side was saying. We do have a number of facts that we'll supplement in our complaint.

THE COURT: Well, I think you have to establish what is going on here, because I think at paragraph 97 is really what you're talking about. I think this is your theory: "To perpetuate its monopoly profits for several more years and to continue charging U.S. consumers supracompetitive prices, Roche knew that plaintiff's business had to be destroyed before plaintiff's cheaper generic versions of Roche's star drugs could become available in the U.S. Defendants started with plaintiff's main and largest market, Russia." So it seems to me this is exactly what you're alleging, which is that they tried to snuff you out in Russia, and that might well have been a violation of Russian antitrust law, I don't know, but you're arguing that by doing that in Russia, it would have had the predictable and inevitable effect of preventing you from coming into the United States and being their competitor here. That's really your theory, right?

MR. FEINSTEIN: Judge --

THE COURT: You several times seem to deny that as your main theory, and I've just read you this paragraph. Isn't that your theory?

MR. FEINSTEIN: Judge, it's part of the theory. What we're saying, the fact is totally in the United States. They

use the means in the United States and the process in the United States to prevent things from happening in the United States. Russia is just one of the battlegrounds where they do this, but it's not in Russia. The effect is not in Russia, Judge. The entire effect, from the consumer standpoint and from plaintiff's standpoint, is in the United States, not in Russia. So that's part of the theory, just to show how they do it. But then again, Judge --

THE COURT: Well, this is what you said. "Roche continued increasing the prices in the U.S. --"

MR. FEINSTEIN: Yes.

THE COURT: "-- on average by 19 percent," I guess per year, "over a period of time, while dropping prices in Russia 76 percent."

MR. FEINSTEIN: Yes.

THE COURT: So that's what you're saying they're undercutting. They're doing things in Russia that would be arguably violations of Russian antitrust law. But you're then saying that it should be in the U.S. court because ultimately, if they hadn't done these things to you in Russia, then you might have blossomed to the point where you could compete in the United States.

MR. FEINSTEIN: Judge, the reason why we're saying that, as your Honor knows, in a normal monopoly case, we have to show that somebody decreases the prices to the point below

cost and then they maintain the monopoly to recoup all of those monies that the monopolist has lost. In our case the reason why it's different -- and that's why there are very few, if any, cases on point -- is, we know today what Roche and other defendants are doing in the United States, and there is damage and injury to the consumer today, who finance this whole monopolistic movement, to decrease the prices below cost. So it's happening today. We have given proof that they have the means to maintain the monopoly.

THE COURT: What's happening today is that they're undercutting you in Russia, right? That's what's happening today. Is there something that prohibits them from selling this drug for what they're selling it for in the United States? You're saying that they're charging too much in the United States and that's to enable them to undercut you in Russia in order to prevent you from competing with them in the United States. But you're not suggesting that it's illegal for them to charge what they're charging in the United States.

MR. FEINSTEIN: No, we're not. We're just showing why they're doing it and how they're using these extra profits and money to maintain their monopoly.

And I think we've looked at hundreds of cases, Judge, and the reason why all other cases, you know, we saw being dismissed is just nobody could establish that somebody, or Roche, was selling the drugs below the cost, or how they were

selling the drugs below the cost.

THE COURT: But they're not selling them below their cost here in the United States, right?

MR. FEINSTEIN: No. No.

THE COURT: Yes. So --

MR. FEINSTEIN: They're selling below the cost --

THE COURT: It seems to me you want U.S. antitrust law to stop them from doing what they're doing in Russia. And I think it's sort of the reverse ripple effect that is what makes this such a problematic theory.

Okay. If you're going to amend, you should amend. When do you think you want to amend by?

MR. FEINSTEIN: Today is the 23rd, Judge.

THE COURT: Yes.

MR. FEINSTEIN: Can we have 30 days, Judge, to amend?

THE COURT: That's fine with me. I assume defendants don't care.

MR. WALL: That's fine.

THE COURT: So 30 days puts us at October 23rd or thereabouts. What day of the week is that? That's a Sunday? All right. So the 24th is Monday. So the 24th of October for the amended complaint.

And then maybe I'll just ask the defendants to look at it and then send me a letter indicating whether you still intend to go forward with your motions or whether there are

certain motions you no longer wish to make or certain motions that you now intend to make in light of new pleadings. Okay? But I assume otherwise everything that you've already told me about is still going to be a basis on which you intend to move. All right?

MR. WALL: I think so, your Honor, but I will say that one of the things that we're wondering we might get guidance on is, we've discussed some sort of, to use your phrase, showstopper arguments potentially about FTAIA standing and so forth. There are also various deficiencies with the individual causes of action. Do you want us to do everything at once if we were to file a motion, or would you prefer us to focus on just those sort of --

THE COURT: I guess I'd just as soon do this all at once. You may have multiple grounds for dismissing this thing.

MR. WALL: Right. That's fine. That's all we wanted to know.

THE COURT: I've exhibited some skepticism here. I don't think that should be lost on anyone. I do think that this is not a viable cause of action, at least as currently pled, and it doesn't sound to me like what you're going to add is going to fix this. I think there's arguably a Rule 11 motion to be made here, but nobody's indicated they intend to do that and I guess I'm not going to push it, but this strikes me as a really fanciful application of the U.S. antitrust laws

in order to get a result that might be beneficial, ultimately, to the plaintiffs and to other would-be competitors, but I don't think that it's a proper use of the U.S. antitrust laws. I mean, if you want to write a Congressman or you want to write an op-ed piece, I think you can probably do that, but I don't think that you've got much of a shot here, as currently pled, of an antitrust claim, seems to me. Or maybe you should bring an antitrust claim in Russia, which will stop them from doing there what would prevent you from becoming a market competitor elsewhere.

So how long do you think, defendants, you're going to need to review the new complaint and then just write me a short letter telling me what you intend to move on?

MR. SPAGNOLETTI: Your Honor, could we have two weeks after we get the new complaint?

THE COURT: That's fine. Okay. So that's November 8th, I think, right? That's the day before Election Day. Oh, the 7th. November 7th, the day before Election Day.

All right. And then once I have that, I'll issue an order either setting a briefing schedule or doing something else, depending on what you tell me, okay?

All right. Well, this was interesting. Thank you very much. I appreciate the time and effort. Everybody have a nice weekend.

Let me thank the court reporter for her time, and if anyone needs a copy of this transcript, you can take that up with her now or later through the website.

Okay. Have a good day. Thank you.

ALL COUNSEL: Thank you, your Honor.

(Adjourned)

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®.

[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,

[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,

[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.

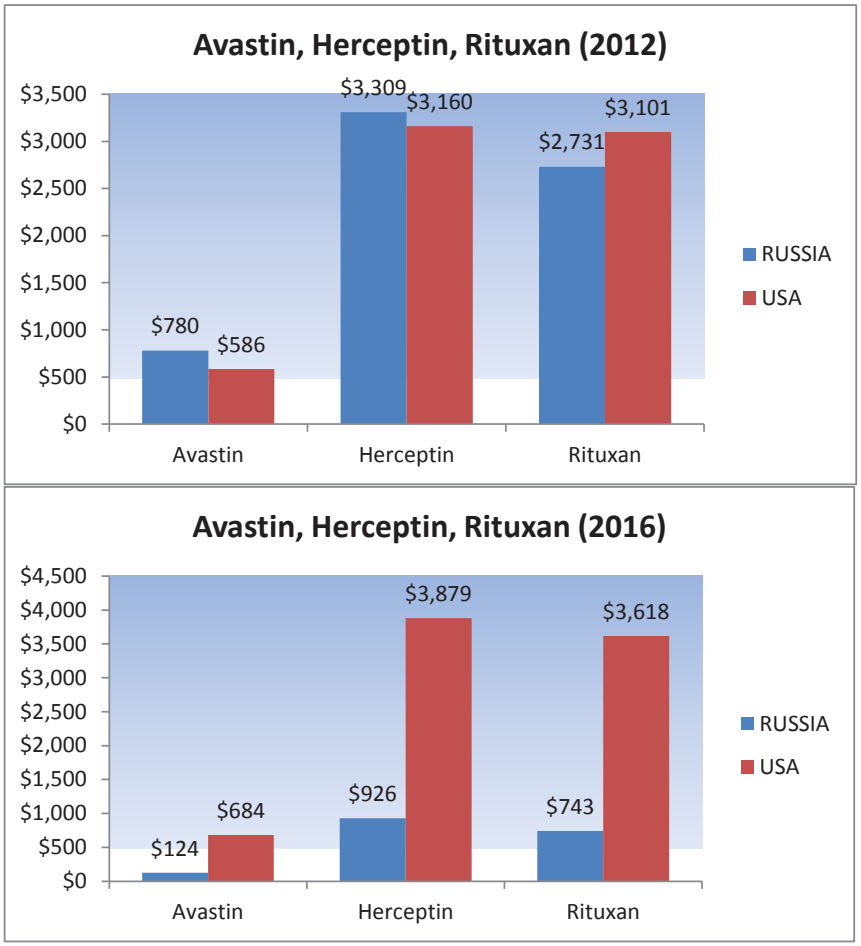
122. While Roche started selling its blockbuster drugs in Russia at prices higher than prices for the same drugs in the United States, over the past several years, Roche continued increasing the prices in the U.S. on average 19%, while dropping the prices in Russia on average 76%.

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

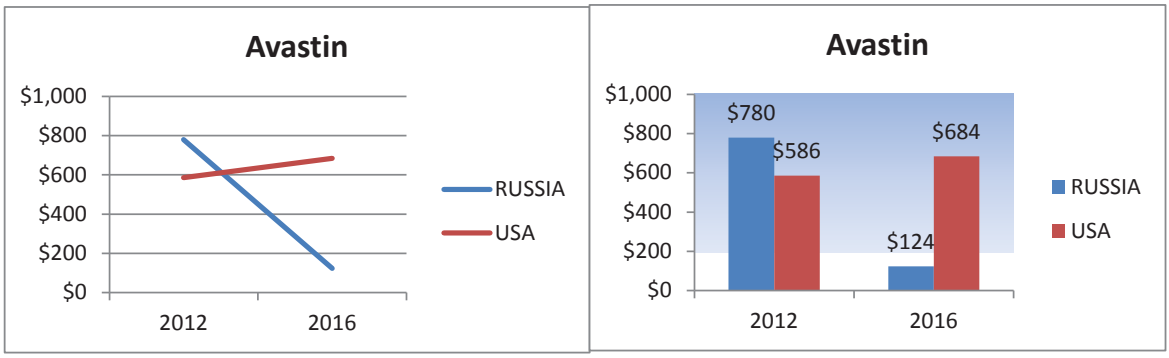


[24] Saporito, Bill (2014, October 27). "*Hospitals Furious at Cancer-Drug Price Hikes*". Time. Retrieved from http://time.com/3541484/cancer-drug-price-hikes/

[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.

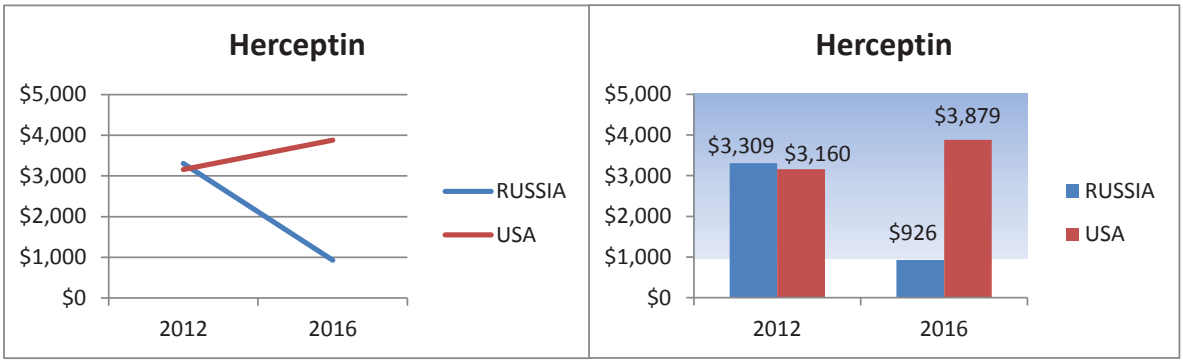
125. The average sales price of Avastin® 100mg increased substantially from 2012 to 2016 in the U.S. The increased pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Avastin® 100mg since 2012 84% or over 6 times.

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



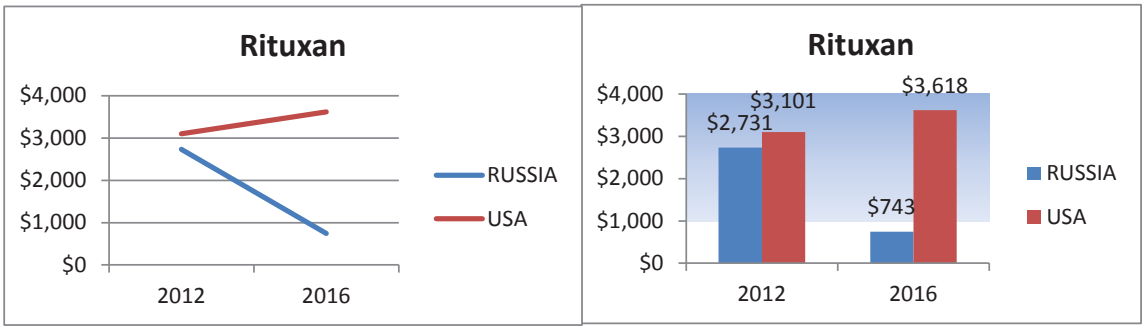
126. The average sales price of Herceptin® increased substantially from 2012 to 2016 in the U.S. The increased pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Herceptin® 72% since 2012 or almost 4 times.

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.

[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.

[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].

[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

_____
Albert Feinstein, Esq. (AF5591)
Rika Khurdayan, Esq. (AK9122)
FEINSTEIN & PARTNERS, PLLC
Attorneys for Plaintiff
54 East 66th Street
New York, NY 10065
tel: 212.224.0224

OF COUNSEL:

Oleg Rivkin (OR1331)
RIVKIN LAW GROUP pllc
800 Third Avenue, Suite 2501
New York, New York 10022
t. 212.231.9776
or@rivkinlawgroup.com

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. 16-CV-04226 (RJS) ECF Case **NOTICE OF APPEAL**

Notice is hereby given that Plaintiff BIOCAD JSC appeals to the United States Court of Appeals for the Second Circuit from the final Judgment and Order, entered in this action by Honorable Judge Richard J. Sullivan of this Court on September 30, 2017, dismissing Plaintiff's First Amended Complaint for failure to plead an antitrust injury and closing the case. Plaintiff also hereby appeals from any and all orders and rulings that were adverse to it, whether or not subsumed within the September 30, 2017 final Order and Judgment.

Dated: October 27, 2017
New York, New York

Albert Feinstein

Albert Feinstein, Esq. (AF5591)
FEINSTEIN & PARTNERS, PLLC
Attorneys for Plaintiff
54 East 66th Street
New York, NY 10065
tel: 212.224.0224
AF@FeinsteinPartners.com

CERTIFICATE OF SERVICE

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

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