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GENENTECH, INC. and CITY OF HOPE

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

GENENTECH, INC. and CITY OF HOPE,

Plaintiffs,

v.

GLAXO GROUP LIMITED, GLAXOSMITHKLINE LLC, HUMAN GENOME SCIENCES, INC., LONZA BIOLOGICS PLC, and LONZA BIOLOGICS INC.,

Defendants.

Case No. CV11 03065 SVW FMOx

COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

JURY TRIAL DEMAND

COMPLAINT FOR PATENT INFRINGEMENT

For their Complaint against Defendants Glaxo Group Limited and GlaxoSmithKline LLC (collectively, "GSK"), Human Genome Sciences, Inc. ("HGS"), Lonza Biologics plc, and Lonza Biologics Inc. (collectively, "Defendants"), Plaintiffs Genentech, Inc. and City of Hope allege as follows:

PARTIES

1. Plaintiff Genentech, Inc. is a corporation organized under the laws of Delaware, with its principal place of business in South San Francisco, California.

2. Plaintiff City of Hope is a California not-for-profit organization with its principal place of business in Duarte, California.

3. Defendant Glaxo Group Limited does business as GlaxoSmithKline, and is an English corporation having a principal place of business at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom.

4. Defendant GlaxoSmithKline LLC is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102.

5. Defendant Human Genome Sciences, Inc., is a Delaware Corporation having a principal place of business at 14200 Shady Grove Rd., Rockville, MD.

6. Defendant Lonza Biologics plc is a public limited company organized under the laws of Great Britain having a principal place of business at 228 Bath Road, in Slough, Berkshire, SL1 4DX, United Kingdom.

7. Defendant Lonza Biologics Inc. is a Delaware corporation having a principal place of business at 101 International Drive in Portsmouth, New Hampshire.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 1 *et seq.* and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* Subject matter jurisdiction is proper pursuant to Title 35 of the United States Code, § 271 and Title 28 of the United States Code, §§ 1338(a), 2201(a) and 2202.

9. This Court has personal jurisdiction over Glaxo Group Limited by virtue of, *inter alia*, its having conducted business inside the State of California, including in the Central District of California, having availed itself of the rights and benefits of California law, and having systematic and continuous contacts with the State of California, including with the Central District of California.

10. This Court has personal jurisdiction over GlaxoSmithKline LLC by virtue of, *inter alia*, its having conducted business inside the State of California, including the Central District of California, having availed itself of the rights and benefits of California law, and, on information and belief, having systematic and continuous contacts with the State of California, including with the Central District of California.

11. GSK continuously and systematically markets and sells its products in the State and in this District.

12. HGS and GSK entered into a co-development and commercialization agreement for the development, manufacturing, and sale of Benlysta® (belimumab). On information and belief, pursuant to GSK's request and direction, HGS has manufactured and is currently manufacturing Benlysta® for GSK in Rockville, MD, for commercial sale by GSK throughout the United States, including in the State of California and the Central District of California. On information and belief, on March 9, 2011, the U.S. Food and Drug Administration ("FDA") approved the Biologics License Application for Benlysta®, and GSK and HGS began selling Benlysta® throughout the United States, including the State of California and the Central District of California, that is supplied by HGS. On information and belief, HGS introduces Benlysta® into the stream of commerce in the United States knowing that Benlysta® will be sold in the State of California, including in the Central District of California. By virtue of these activities, this Court has personal jurisdiction over HGS.

13. Lonza Biologics plc and/or one or more of its affiliated companies developed a commercial process for manufacturing ofatumumab. Pursuant to an agreement between Lonza Biologics plc (or an affiliated company of Lonza Biologics

plc) and GSK, Lonza Biologics plc manufactures ofatumumab in the United Kingdom and supplies said ofatumumab to GSK, and introduces ofatumumab into the stream of commerce while knowing that GSK will and does incorporate ofatumumab into the final product Arzerra™, import Arzerra™ into the United States, and markets, distributes, and sells Arzerra™ throughout the United States, including in the State of California and within the Central District of California. By virtue of these activities, this Court has personal jurisdiction over Lonza Biologics plc.

14. On information and belief, Lonza Biologics Inc. has imported cells from Lonza Biologics plc and supplied cells to Lonza Biologics plc for use in manufacturing Arzerra™ for supply to GSK while knowing that GSK will and does import Arzerra™ into the United States, and markets, distributes, and sells Arzerra™ throughout the United States, including in the State of California and the Central District of California. Lonza Biologics Inc. has entered into and performed under contracts with entities in the State of California and, on information and belief, engages in business activities in California, including the Central District of California, with and/or through one or more of its affiliated companies doing business in California, including the Central District of California. By virtue of these activities, this Court has personal jurisdiction over Lonza Biologics Inc.

15. Venue is proper in this District pursuant to Title 28, United States Code, §§ 1391 and 1400(b).

THE CABILLY III PATENT

16. On April 12, 2011, U.S. Patent No. 7,923,221 ("the Cabilly III patent") was issued by the PTO, entitled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen." A true and correct copy of the Cabilly III patent is attached hereto as Exhibit A.

17. Genentech and COH are the co-owners by assignment of the right, title, and interest in the Cabilly III patent.

18. GSK has known of the Cabilly III patent and/or its imminent issue as a

patent from U.S. Patent Application No. 08/422,187 since at least January 28, 2011, when Genentech and COH filed a Notice of the Notice of Allowance and Fee(s) Due with respect to the Cabilly III application in litigation currently pending before this court, *Glaxo Group Ltd. and Glaxosmithkline LLC v. Genentech, Inc. and City of Hope*, Case No. CV-10-2764 MRP (FMOx) (the "*GSK* action").

19. On information and belief, HGS has known of the Cabilly III patent and/or its imminent issue as a patent from U.S. Patent Application No. 08/422,187 since at least January 28, 2011, by virtue of its monitoring the pleadings in the *GSK* action, as evidenced by its reference to the *GSK* action in pleadings filed in actions in Delaware related to the Cabilly II patent.

20. On information and belief, Lonza Biologics plc and Lonza Biologics Inc. have known of the Cabilly III patent and/or its imminent issue as a patent from U.S. Patent Application No. 08/422,187 since at least January 28, 2011, when Genentech and COH moved to add Lonza Biologics plc and Lonza Biologics Inc. as Counter-Defendants in the *GSK* action.

BELIMUMAB, A/K/A BENLYSTA®

21. Benlysta® (belimumab) is a recombinantly engineered monoclonal antibody that purportedly aims to target BlyS. BlyS is a naturally occurring protein required for the survival and development of B-lymphocyte cells into mature plasma B cells that is believed to be involved in the mediation of systemic lupus erythematosus. Benlysta® (belimumab) is indicated for the treatment of adult patients with active autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

22. On information and belief, GSK and HGS began marketing, distributing, and selling Benlysta® in the United States, including in the State of California, on or about March 9, 2011, the date that the FDA approved the Biologics License Application for Benlysta®. On information and belief, GSK began offering for sale and selling Benlysta® made by HGS for GSK in the United States, including in the State of California.

23. On information and belief, HGS has made and makes and/or has used and

uses recombinant host cells for use in manufacturing Benlysta® (belimumab) and has supplied or supplies Benlysta® (belimumab) to GSK for commercial sale.

24. On information and belief, GSK and HGS offer for sale and sell Benlysta® in the United States, including in the State of California, that is made by HGS.

OFATUMUMAB, A/K/A ARZERRA™

25. GSK is marketing and selling a human monoclonal antibody, ofatumumab, under the name Arzerra™. Arzerra™ purportedly aims to target CD20, a naturally occurring protein present on B- lymphocytes, which is believed to be involved in the mediation of lymphoproliferative and autoimmune diseases.

26. On information and belief, Arzerra™ is the 2F2 monoclonal antibody produced in a recombinant murine cell line that is described in the World Intellectual Property Organization patent application publication number WO 2004/035607.

27. On October 26, 2009, the United States Food & Drug Administration issued Department of Health and Human Services U.S. License No. 1809 to GSK, authorizing GSK to market Arzerra™ with an indication for the treatment of chronic lymphocytic leukemia refractory to fludarabine and alemtuzumab, allowing GSK to manufacture Arzerra™, market it in the United States, and introduce it into interstate commerce inside the United States.

28. GSK is actively marketing Arzerra™ in the United States.

29. GSK or its agents have and/or are importing Arzerra™ into the United States from the United Kingdom, where ofatumumab is manufactured by Lonza Biologics plc for GSK and where the final Arzerra™ product is manufactured, filled, labeled, and packaged by a GSK affiliate.

30. GSK is selling and offering for sale Arzerra™ in the United States.

31. Lonza Biologics plc supplies ofatumumab to GSK knowing that GSK will and does import Arzerra™ containing Lonza Biologics plc-made ofatumumab into the United States and GSK will and does market, distribute, and sell Arzerra™ throughout

the United States, including in the State of California.

32. On information and belief, Lonza Biologics plc supplies cells from Lonza Biologics plc's working cell bank to its affiliate Lonza Biologics Inc., located in Portsmouth, New Hampshire, where Lonza Biologics Inc. maintains such cells and supplies Lonza Biologics plc with cells for making ofatumumab for GSK.

COUNT I

(Infringement and Declaratory Judgment of Infringement of The Cabilly III Patent by GSK and HGS)

33. Genentech and COH incorporate the allegations in Paragraphs 1 - 32 as if fully set forth herein.

34. By manufacturing Benlysta® in the United States to offer for sale and sell, and offering for sale and selling Benlysta® throughout the United States, HGS has infringed, is infringing, and/or will infringe, one or more claims of the Cabilly III patent, literally and/or under the doctrine of equivalents.

35. By causing HGS to manufacture Benlysta®, including manufacturing and/or using the cells used to manufacture Benlysta®, for supply to GSK for commercial sale throughout the United States, and by offering to sell and selling Benlysta® throughout the United States, GSK has actively induced, is actively inducing, and/or will actively induce the infringement of, and infringes and will infringe, one or more claims of the Cabilly III patent, literally and/or under the doctrine of equivalents.

36. GSK and HGS' infringement and active inducement of infringement have caused and will cause damage to Genentech and COH, and Genentech and COH are entitled to recover from GSK and HGS the damages sustained by Genentech and COH as a result of GSK and HGS' wrongful acts in an amount subject to proof at trial, but not less than a reasonable royalty.

37. GSK and HGS' infringement and active inducement of infringement have caused Genentech and COH to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until GSK and HGS' infringement

and active inducement of infringement are enjoined by this Court.

COUNT II

(Infringement and Declaratory Judgment of Infringement of The Cabilly III Patent by GSK, Lonza Biologics Inc., and Lonza Biologics plc)

38. Genentech and COH incorporate the allegations in Paragraphs 1 - 37 as if fully set forth herein.

39. By making, having made, marketing, preparing to sell, offering to sell, and selling Arzerra™ in the United States, importing Arzerra™ into the United States, and contracting with Lonza Biologics plc and/or one or more of its affiliated companies, to manufacture and supply ofatumumab intended for sale in and/or importation into the United States as the Arzerra™ product, GSK has infringed, is infringing, and/or will infringe one or more claims of the Cabilly III patent, literally and/or under the doctrine of equivalents.

40. By manufacturing and supplying ofatumumab to GSK in the United Kingdom, knowing that GSK will and does import Arzerra™ into the United States and will and does market, distribute, and sell Arzerra™ throughout the United States, Lonza Biologics plc has actively induced, is actively inducing, and/or will actively induce the infringement of one or more claims of the Cabilly III patent, literally and/or under the doctrine of equivalents.

41. By supplying cells capable of producing Arzerra™ to its affiliate in the United States, Lonza Biologics Inc., Lonza Biologics plc has actively induced, is actively inducing, and/or will actively induce the infringement of one or more claims of the Cabilly III patent, literally and/or under the doctrine of equivalents.

42. By maintaining cells in Portsmouth, New Hampshire, capable of making the ofatumumab contained in Arzerra™, and thereby using and/or making such cells, and supplying said cells to Lonza Biologics plc, Lonza Biologics Inc. has infringed, is infringing, and/or will infringe, and has actively induced, is actively inducing, and/or will actively induce the infringement of one or more claims of the Cabilly III patent, literally

and/or under the doctrine of equivalents.

43. GSK's, Lonza Biologics plc's and Lonza Biologics Inc.'s infringement and active inducement of infringement have caused damage to Genentech and COH, and Genentech and COH are entitled to recover from GSK, Lonza Biologics plc and Lonza Biologics Inc. the damages sustained by Genentech and COH as a result of GSK's, Lonza Biologics plc's and Lonza Biologics Inc.'s wrongful acts in an amount subject to proof at trial, but not less than a reasonable royalty.

44. GSK's, Lonza Biologics plc's and Lonza Biologics Inc.'s infringement and active inducement of infringement have caused Genentech and COH to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until GSK's, Lonza Biologics plc's and Lonza Biologics Inc.'s infringement and active inducement of infringement are enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Genentech and COH request that judgment be entered in favor of Genentech and COH on Counts I and II and against Defendants GSK, HGS, Lonza Biologics plc and Lonza Biologics Inc.:

1. Finding GSK has infringed and actively induced the infringement of the Cabilly III patent;

2. Finding HGS has infringed the Cabilly III patent;

3. Finding Lonza Biologics plc has actively induced the infringement of the Cabilly III patent;

4. Finding Lonza Biologics Inc. has infringed and actively induced the infringement of the Cabilly III patent;

5. Finding Defendants will in the future infringe and actively induce the infringement of the Cabilly III patent;

6. Ordering Defendants to account for and pay to Genentech and COH all damages caused by their infringement and active inducement of infringement of the

Cabilly III patent;

7. Ordering an award of Genentech and COH's costs and expenses for this action, pre- and post-judgment interest on any money damages award, and other charges to the maximum extent permitted;

8. If appropriate, taking into account the interests of patients, ordering a permanent injunction, prohibiting Defendants, their officers, agents, servants, employees, attorneys, all parent, subsidiary and affiliate corporations and other business entities, and all other persons or entities acting in concert, participation or in privity with them, and their successors and assigns from infringing, and actively inducing the infringement of, the Cabilly III patent; and

9. Ordering such other future relief as the Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Genentech and COH demand trial by jury of all issues so triable.

Dated: April 12, 2011

Respectfully Submitted,

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