Doc. 388 Att. 12

Case 1:05-cv-12237-WGY

Document 388-13

Filed 04/13/2007

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Exhibit 11

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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AMGEN'S FOURTH NOTICE OF DEPOSITION TO DEFENDANTS PURSUANT TO FED. R. CIV. P. 30(B)(6)

TO ALL PARTIES HERETO AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, pursuant to Federal Rule of Civil Procedure 30(b)(6), plaintiff Amgen Inc. will take the deposition upon oral examination of Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann La Roche Inc. (collectively "Roche") commencing on March 19, 2007 at 9:00 a.m. at the offices of McDermott Will & Emery, 340 Madison Avenue, New York, NY, 10173-1922, and continuing from day to day thereafter, excluding weekends and holidays, until completed. The deposition will be recorded by a videographer and a certified court reporter.

PLEASE TAKE FURTHER NOTICE that, pursuant to Federal Rule of Civil Procedure 30(b)(6), Roche is required to designate one or more of its officers, directors, partners, managing agents or other such persons as are most qualified, knowledgeable, and competent to testify on behalf of the deponents as to all matters known or reasonably available to it to testify accurately and completely with respect to each of the following subjects, and for each person designated, to set forth all matters on which the person will testify on behalf of Roche in a written response to be served on or before March 13, 2007:

DEFINITIONS

- 1. As used herein, "all" means "any and all"; "any" means "any and all."
- 2. As used herein, "and" and "or" encompass both "and" and "or," and references shall be construed either as singular or plural, as necessary to bring within the scope of these requests any information or documents and things that might otherwise be construed to be outside their scope.
- 3. As used herein, "communication" means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise).

- **4.** As used herein, "concerning" means referring to, describing, evidencing, or constituting.
- 5. As used herein, "employee" means any director, trustee, officer, employee, partner, corporate parent, subsidiary, affiliate or servant of the designated entity, whether active or retired, full-time or part-time, current or former, and compensated or not.
- **6.** As used herein, "entity" means any individual and any other cognizable entity, including corporations, proprietorships, partnerships, joint ventures, businesses, consortiums, clubs, associations, foundations, governmental agencies or instrumentalities, societies, and orders.
 - 7. As used herein, "including" means "including but not limited to."
- **8.** As used herein, "human EPO" means any naturally occurring or recombinantly produced human erythropoietin, including (without limitation) epoetin alfa, epoetin beta, and endogenous gene activated EPO.
- **9.** As used herein, "pegylated human EPO" means any human EPO that has been pegylated, including (without limitation) the drug substance RO0503821.
- **10.** As used herein, "ESP" means any erythropoiesis-stimulating protein or polypeptide, including (without limitation) epoetin alfa, epoetin beta, darbepoetin, and endogenous gene activated EPO.
- 11. As used herein, "person" means any natural person and any other cognizable entity, including corporations, proprietorships, partnerships, joint ventures, businesses, consortiums, clubs, associations, foundations, governmental agencies or instrumentalities, societies, and orders, consistent with the definition set forth at Local Rule 26.5(c)(6).
- **12.** As used herein, "Amgen's Patents" means the patents-in-suit, including (without limitation) U.S. Patent No. 5,547,933; U.S. Patent No. 5,618,698; U.S. Patent No. 5,621,080;

U.S. Patent No. 5,441,868; U.S. Patent No. 5,955,422; or U.S. Patent No. 5,756,349.

- 13. As used herein, "relating to" shall mean relating to, referring to, concerning, mentioning, reflecting, pertaining to, evidencing, involving, describing, depicting, discussing, commenting on, embodying, responding to, supporting, contradicting, or constituting (in whole or part), as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.
- 14. As used herein, "characterize," "characterization," "comparison," and "evaluation" shall include a description of any experimental method used, an identification of persons involved, a description of any assumptions made, a description of any conclusions made, an identification of any documents that contain such characterization, comparison, or evaluation, and whether such documents have been searched for, collected and produced.
- Roche Inc., F. Hoffman-La Roche Ltd., or Roche Diagnostics GmbH, their directors, officers, employees, attorneys, accountants, consultants, representatives, agents, divisions, parents, subsidiaries, or affiliates, past or present, any partnership or joint ventures to which they are a party and all others acting on behalf of the named Defendants. References herein to activities conducted by, for, and/or on behalf of ROCHE includes, without limitation, activities conducted by, for, or on behalf of Chugai Pharmaceuticals Co., Ltd., Boehringer Mannheim GmbH, and/or any entity that directly, or indirectly controls at least fifty percent (50%) of the stock normally entitled to vote for election of directors of the named Defendants, any entity owned or directly controlled by the named Defendants through ownership of at least fifty percent (50%) of the stock normally entitled to vote for election of directors, and any entity under common control with the named Defendants; provided, however, that in the circumstance where the country of incorporation of such owned or controlled corporation requires the maximum ownership by a

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foreign entity be less than fifty percent (50%), the percentage of ownership required to make such an entity an affiliate, shall be equal to the maximum percentage of ownership permitted by such country, and/or any contract research organization or consultant retained by ROCHE.

As used herein, "characterize," "efforts to characterize," and "analyze" include 16. (without limitation) any isolation, purification, or determination of:

> Structure; Sequence; Composition; Conformation; Glycosylation; Carbohydrate structure or composition; Sialic acid content, linkages, chemical structure, number, and disposition; Sulfation; Actual or apparent molecular weight; In vitro biological activity; In vivo biological activity; Interaction with the human erythropoietin receptor (including the equilibrium constant, disassociation constant, association rate constant, change in free energy);

Pharmacodynamics;

Pharmacokinetics;

Immunogenicity and/or antigenicity;

Internalization and recycling by cells;

Manner of clearance: and

Results from any other analytical technique (including isoelectric focusing, MALDI mass spectroscopy, and HPLC chromatography).

DEPOSITION TOPICS

Examination is requested on the following matters:

- 1. Roche's planned or executed efforts (specifically including the efforts of its predecessors-in-interest Boehringer Mannheim GmbH, Genetics Institute, and Chugai Pharmaceutical Co. Ltd.) to characterize any human EPO that was relied on or referred to in opposition proceedings in Europe to Genetics Institute's European patents EP 411 678 ("the '678 patent") and EP 209 539 ("the '539 patent"), opposition proceedings in Europe involving Amgen's European patent EP 148 605 ("the '605 patent"), proceedings before the Federal Court of Australia in No. VG 868 of 1995 between Genetics Institute Inc. and Kirin-Amgen Inc., or proceedings before the Federal Court of Canada in T-2784-97 between Kirin-Amgen Inc. and Janssen-Ortho Inc and Hoffman-La Roche Ltd.
- 2. Roche's planned or executed efforts (specifically including the efforts of its predecessors-in-interest Boehringer Mannheim GmbH, Genetics Institute, and Chugai Pharmaceutical Co. Ltd.) to characterize any human EPO purified, isolated or otherwise derived from human urine, plasma or blood at any time from 1984 to the present, including any comparison between such human EPO and any recombinant human EPO.
- **3.** Roche's planned or executed efforts (specifically including the efforts of its predecessors-in-interest Boehringer Mannheim GmbH, Genetics Institute, and Chugai Pharmaceutical Co. Ltd.) to characterize any recombinant human EPO produced by a mammalian cell grown in culture at any time from 1984 to the present, including any comparison between such recombinant human EPO and human EPO purified, isolated or otherwise derived from human urine, plasma or blood.

- 4. Roche's planned or executed efforts (specifically including the efforts of its predecessors-in-interest Boehringer Mannheim GmbH, Genetics Institute, and Chugai Pharmaceutical Co. Ltd.) to identify, characterize or analyze any cell or tissue expressing, secreting and/or otherwise producing erythropoietin (other than the cells used to make the active drug product in Recormon, NeoRecormon, or Mircera), including (a) any characterization of human EPO produced by any such cell or tissue, (b) the source of any such cell or tissue, (c) any comparison between any human EPO produced by any such cell or tissue with any other human EPO; and (d) any communication by Roche with any third party concerning such efforts.
- 5. All facts and circumstances known to Roche concerning any effort by Edward Fritsch or those working with him to identify, clone, isolate, or express a DNA encoding human EPO, including specifically any publicly available information relied upon by him in that effort, and his conception and reduction to practice of any subject matter(s) described and/or claimed in U.S. patent applications Serial Nos. 06/688,622 and 06/693,258 or in any related application or related patent.
- 6. All facts and circumstances known to Roche concerning any effort (whether or not successful) by any person other than Fu-Kuen Lin and Edward Fritsch (including, for example, any effort by any person affiliated with Biogen, Genentech, New York University, Harvard University, or the University of Washington) to identify, clone, isolate, sequence, or express a DNA encoding human EPO prior to November 30, 1984.
- 7. All facts and circumstances known to Roche concerning the structural, immunological, and biological properties of any preparation of urinary human EPO.
- 8. All facts and circumstances known to Roche concerning any effort (whether or not successful) by any person to characterize any human EPO (including sequencing any EPO polypeptide or fragment thereof) before November 30, 1984.

- 9. All facts and circumstances known to Roche concerning the administration of any human EPO to any human being before November 30, 1984.
- **10.** All facts and circumstances known to Roche concerning each instance of the expression of a biologically active mammalian glycoprotein by a mammalian cell transformed or transfected with DNA encoding that protein and grown in culture before November 30, 1984.
- All facts and circumstances known to Roche concerning each instance of the 11. isolation or purification of human EPO from mammalian cells grown in culture before November 30, 1984.
- **12.** All communications with any third party (including specifically Genetics Institute and Wyeth) concerning the patentability, validity or invalidity of the subject matter(s) described and/or claimed in U.S. Patent Application Serial No. 06/675,298 or any related application or related patent.
- 13. All facts and circumstances known to Roche concerning whether recombinant human EPO products have been commercially successful.
- **14.** All facts and circumstances known to Roche concerning whether there was a long-felt need for recombinant human EPO products as of November 30, 1984.
- 15. All facts and circumstances known to Roche concerning whether one of ordinary skill as of November 30, 1984 could have conjugated polyethylene glycol to a protein.
- 16. All facts and circumstances known to Roche concerning whether one of ordinary skill as of November 30, 1984 could have followed the teachings of Amgen's Patents to obtain a cDNA encoding human EPO without undue experimentation.
- **17.** All facts and circumstances known to Roche concerning in vitro and in vivo assays for measuring human EPO (including standards for use therein) available as of November 30, 1984.

- 18. All facts and circumstances known to Roche concerning the development, availability, or use of any radioimmunoassay method for determining the amount of human EPO in a sample (including standards for use therein) as of November 30, 1984.
- 19. All facts and circumstances known to Roche concerning the conception, reduction to practice, development and use of any subject matter(s) described and/or claimed in U.S. Pat. No. 4,667,016 to Lai *et al*.
- 20. All facts and circumstances known to Roche concerning the meaning of the terms "erythropoietin," "human erythropoietin," "glycoprotein," "glycosylated," "glycosylated erythropoietin," "erythropoietin glycoprotein," "U of erythropoietin per 10⁶ cells in 48 hours as determined by radioimmunoassay," and "effective for erythropoietin therapy" to one of ordinary skill in the art as of November 30, 1984.
- 21. All facts and circumstances concerning Roche's alleged detrimental reliance on Amgen's public statements before November 8, 2005 concerning whether Amgen would assert Amgen's Patents against Roche's importation, offer for sale, sale and/or use of pegylated human EPO in the United States.
- 22. All facts and circumstances concerning the transfer, and subsequent maintenance, of documents from Boehringer Mannheim GmbH or Chugai Pharmaceutical Co. Ltd. to Roche concerning human EPO and litigations concerning Genetics Institute's European patents EP 411 678 ("the '678 patent") and EP 209 539 ("the '539 patent"), Amgen's European patent EP 148 605 ("the '605 patent"), and any related patents.
- 23. All facts and circumstances concerning Roche's preparation for litigation with Amgen relating to Amgen's Patents before November 8, 2005.
- **24.** All prior art (including the specific combinations thereof) on which Roche will rely to support its 35 U.S.C. §102 and 103 defenses

- 25. All prior art (including the specific combinations thereof) on which Roche will rely to support its obviousness-type double patenting defense(s).
- **26.** All facts and circumstances known to Roche on which it may rely to support any contention concerning the knowledge of one of ordinary skill regarding glycosylation of recombinantly expressed proteins as of November 30, 1984.
- 27. All facts and circumstances known to Roche on which it may rely to support any contention by Roche that Amgen's Patents are unenforceable by reason of inequitable conduct before the U.S. Patent & Trademark Office.
- 28. All facts and circumstances known to Roche on which it may rely to support any contention that Amgen's Patents are unenforceable by reason of prosecution laches.
- 29. All facts and circumstances known to Roche on which it may rely to support any contention that Amgen's Patents are unenforceable by reason of unclean hands.
- **30.** All facts and circumstances known to Roche on which it may rely to support any contention that Amgen's Patents are unenforceable by reason of patent misuse.

Respectfully Submitted, AMGEN INC., By its attorneys,

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March 7, 2007

CERTIFICATE OF SERVICE

I hereby certify that a copy of this document was served upon the attorneys of record for the plaintiff (as listed below) via overnight delivery service and electronic mail on the above date.

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