Document 320-2 Filed 03/15/2007

Page 1 of 19

EXHIBIT A

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
vs.	Plaintiff,) CIVIL ACTION No.: 05-cv-12237WGY
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, AND HOFFMANN-LA ROCHE INC.,)))
	Defendants.))

DEFENDANTS' FIRST NOTICE OF DEPOSITION TO AMGEN PURSUANT TO RULE 30(b)(6)

PLEASE TAKE NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche" or "Defendants"), will take the deposition of Plaintiff Amgen Inc. ("Amgen" or "Plaintiff"), by a person or persons with knowledge of the following subject areas, at the offices of Kaye Scholer LLP, 425 Park Ave, New York, New York 10022 or such other place as mutually agreed between the parties, commencing at 9:00 a.m. on February 27, 2007. This deposition shall be taken before a notary public or another official authorized by law to administer oaths, and will continue from day to day thereafter until completed, excluding weekdays and holidays. The deposition will be recorded by videotape and/or audiotape, or other similar means in addition to recording this testimony by the stenographic method.

PLEASE TAKE FURTHER NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure and the Local Rules of the issuing Court, Amgen is required to designate one or more of its officers, directors, partners, managing agents, employees or other representatives as are most qualified, knowledgeable, and competent to testify on behalf of

1

Amgen as to all matters known or reasonably available to it to testify accurately and completely with respect to each of the following subjects set forth in Schedule A attached hereto. For each person designated, Amgen is to set forth all matters on which the person will testify on behalf of Amgen in a written response to be served on or before February 20, 2007.

DATED: February 9, 2007

F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC.

By its attorneys,

/s/ Patricia A. Carson
Leora Ben-Ami (pro hac vice)
Patricia A. Carson (pro hac vice)
Thomas F. Fleming (pro hac vice)
Howard Suh (pro hac vice)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480) Julia Huston (BBO# 562160) Keith E. Toms (BBO# 663369) BROMBERG & SUNSTEIN LLP 125 Summer Street Boston, MA 02110 Tel. (617) 443-9292

2

SCHEDULE A

DEFINITIONS AND INSTRUCTIONS

- 1. The term "Amgen" includes plaintiff Amgen, Inc., any predecessor company or companies, present and past divisions, subsidiaries, joint ventures, parent companies or other legal entities which are or wholly or partially owned or controlled by Amgen, Inc., and each of their respective present or former directors, officers, Employees, agents, consultants, experts, representatives, and attorneys, as well as all other individuals or business entities in the employ of or otherwise acting or purporting to act on behalf of Amgen, Inc.
- 2. The term "Roche" includes defendants F. Hoffmann-La Roche Ltd, Roche
 Diagnostics GmbH, and Hoffmann-La Roche Inc., any predecessor company or companies,
 present and past divisions, subsidiaries, joint ventures, parent companies or other legal entities
 which are wholly or partially owned or controlled by F. Hoffmann-La Roche Ltd, Roche
 Diagnostics GmbH, or Hoffmann-La Roche Inc., and each of their respective present or former
 directors, officers, Employees, agents, consultants, experts, representatives, and attorneys, as
 well as all other individuals or business entities in the employ of or otherwise acting or
 purporting to act on behalf of F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, or
 Hoffmann-La Roche Inc.
- 3. The term "Affiliate" means a person or Entity that, directly or indirectly, through one or more intermediates, controls, is controlled by, or is under common control with the person or Entity specified.
- 4. The term "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.

- 5. The term "Amgen's EPO Patents" means the following patents and any foreign counterparts of any of them, considered individually, in groups of two or more, and collectively:
 - a. United States Patent No. 4,703,008 issued October 27, 1987, to Fu-Kuen Lin entitled "DNA Sequences Encoding Erythropoietin" ("the '008 patent"), the application from which it issued United States Patent Application No. 06/675,298, and all related United States Patent Applications Including United States Patent Application Nos. 06/655,841; 06/582,185; and 06/561,024;
 - b. United States Patent No. 5,441,868 issued August 15, 1995, to Fu-Kuen Lin entitled "Production of Recombinant Erythropoietin" ("the '868 patent"), the application from which it issued United States Patent Application No. 07/113,179, and all related United States Patent Applications Including United States Patent Application Nos. 06/675,298; 06/655,841; 06/582,185; and 06/561,024;
 - c. United States Patent No. 5,547,933 issued August 20, 1996, to Fu-Kuen Lin entitled "Production of Erythropoietin" ("the '933 patent"), the application from which it issued United States Patent Application No. 08/487,774, and all related United States Patent Applications Including United States Patent Application Nos. 07/202,874; 07/113,179; 06/675,298; 06/655,841; 06/582,185; and 06/561,024;
 - d. United States Patent No. 5,618,698 issued April 8, 1997, to Fu-Kuen Lin entitled "Production of Erythropoietin" ("the '698 patent"), the application from which it issued United States Patent Application No. 08/468,381, and all related United States Patent Applications Including United States Patent Application Nos. 07/113,179; 06/675,298; 06/655,841; 06/582,185; and 06/561,024;

- e. United States Patent No. 5,621,080 issued April 15, 1997, to Fu-Kuen Lin entitled "Production of Erythropoietin" ("the '080 patent"), the application from which it issued United States Patent Application No. 08/468,556, and all related United States Patent Applications Including United States Patent Application Nos. 07/202,874; 07/113,179; 06/675,298; 06/655,841; 06/582,185; and 06/561,024;
- f. United States Patent No. 5,756,349 issued May 26, 1998, to Fu-Kuen Lin entitled "Production of Erythropoietin" ("the '349 patent"), the application from which it issued United States Patent Application No. 08/468,369, and all related United States Patent Applications Including United States Patent Application Nos. 07/113,179; 06/675,298; 06/655,841; 06/582,185; and 06/561,024; and
- g. United States Patent No. 5,955,422 issued September 21, 1999, to Fu-Kuen Lin entitled "Production of Erythropoietin" ("the '422 patent"), the application from which it issued United States Patent Application No. 08/100,197, and all related United States Patent Applications Including United States Patent Application Nos. 07/957,073; 07/609,744; 07/113,179; 06/675,298; 06/655,841; 06/582,185; and 06/561,024.
- 6. The term "Patent Application" means all parent, continuation application, continuation-in-part application, divisional application, file-wrapper continuation, reexamination proceeding, reissue application, provisional application or abandoned application and other applications, including applications from which an issued patent claims priority in whole or in part, regardless of whether the patent application issued as a patent, was abandoned, or is currently pending, and regardless of whether the patent application was filed in the United States Patent and Trademark Office or any foreign patent office or both...

- 7. The term "Communication" is used in its broadest sense, and means any transmission of information from one person or Entity to another, by any means, Including oral conversations, telephone calls, written correspondence, memoranda or notes, email, facsimile transmissions, meetings, video conferences, or document transmittals.
 - 8. The term "Including" means "including but not limited to."
 - 9. The term "Thing" means each item, sample, specimen, concrete or tangible object.
- 10. The term "Person" shall include but is not limited to, any natural person, alive or deceased, business or corporation (whether for-profit or not-for-profit), firm, partnership, sole proprietorship, or other non-corporate business organization, or Employee, agent or representative of the foregoing.
- 11. The term "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.
- 12. The term "Concerning" or "Concern" means relating to, referring to, describing, evidencing, constituting, or mentioning in any way.
- 13. The term "Erythropoiesis Stimulating Agent" or "ESA" means any substance, drug or pharmaceutical composition that is capable of stimulating the production of red blood cells by bone marrow Including human erythropoietin or erythropoietin from any mammalian species, epoetin alfa, epoetin beta, darbepoetin alfa, and any fragment, mimetic or variant thereof, sold under any brand name, Including Epogen[®], Procrit[®], Eprex[®], NeoRecormon[®] and Aranesp[®].
- 14. The term "Pegylated Compounds" means any substance, drug or pharmaceutical incorporating into its chemical structure one or more polyethylene glycol polymers of any weight, size, shape, means of attachment, or degree of branching, and shall include without

limitation human erythropoietin or erythropoietin from any mammalian species, epoetin alfa, epoetin beta, darbepoetin alfa, and any fragment, mimetic or variant thereof chemically modified by pegylation.

- 15. As used herein MIRCERATM refers to the formulated product for which Biologic License Application (BLA) STN 125164/0 was submitted to the United States Food and Drug Administration on April 18, 2006 by Roche.
- 16. As used herein, "characterization" and "comparison" shall include a description of any experimental method used, identification of the persons involved, description of assumptions made and conclusions made.
- 17. The term "Health Care Provider" means any person or Entity involved in providing health services to the public, Including Large Dialysis Organizations (e.g., Fresenius Medical Care or Da Vita Inc.), small or medium chain dialysis centers, non-profit dialysis centers. independent dialysis centers, hospitals, distributors, purchasing groups, doctors or clinics, Including their affiliated Entities, parents, subsidiaries (for example, DaVita Clinical Research), related companies, and companies merged or acquired (for example, Renal Care Group, Inc. and Gambro Healthcare).
- 18. As used herein, the words "and" and "or" shall be construed either conjunctively and disjunctively as necessary to bring within the scope of the topic all responses that might otherwise be construed as being outside of its scope; the singular shall be deemed to refer to the plural and vice-versa; and any reference to the male gender shall include the female gender.

TOPICS

- 1. All efforts by Amgen through 1987, either planned and/or carried out, to characterize any human erythropoietin, but also including all efforts after 1987 where Amgen relied on, discussed, or referred to such characterization in connection with the prosecution of any of Amgen's EPO patents, 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"), including:
 - a. characterization of any human erythropoietin purified, isolated or otherwise
 derived from any mammalian cell or cell culture;
 - b. characterization of any erythropoietin purified, isolated or otherwise derived from human urine, plasma or blood, including any obtained through any collaboration with Eugene Goldwasser, or from any source material provided by Eugene Goldwasser;
 - c. characterization of any recombinant human erythropoietin purified, isolated or otherwise derived from any mammalian host cell;
 - d. characterization of any physical, chemical or biological property including structure, conformation, amino acid composition, carbohydrate composition, glycosylation, sialic acid content, number, and disposition, actual or apparent molecular weight, biological activity, interaction with the human erythropoietin receptor (including the equilibrium constant, disassociation constant, association rate constant, change in free energy), pharmacodynamics, internalization and recycling by cells, immunogenicity and/or antigenicity, manner of clearance:

8

Page 10 of 19

- any comparison of a recombinant human erythropoietin product produced through e. mammalian cell expression with any erythropoietin isolated from, or present in any human source, including plasma or urine, including any comparison or analysis of data from separate studies or experiments;
- f. all personnel involved in planning, conducting or supervising such efforts, including their titles, roles and activities;
- the experimental techniques, approaches and methods considered or used by g. Amgen in connection with such efforts;
- h. all memoranda, reports, summaries and/or other documentation of such efforts including any published articles and abstracts;
- i. any communication, at any time, of such efforts to any individual involved in prosecution of Amgen's EPO Patents.
- 2. The role of any Amgen Employee or Agent having any involvement in the prosecution of Amgen's EPO Patents in the United States, in (1) the prosecution of any of Amgen's EPO Patents in Europe or the United Kingdom (including but not limited to Amgen's EP 0 148,605) or (2) in connection with any opposition proceeding or litigation in Europe or the United Kingdom involving any of Amgen's EPO Patents (including but not limited to Amgen's EP 0 148,605), or (3) in connection with any opposition proceeding or litigation involving Genetics Institute's EP 0 411 678 and EP 0 209 539, including:
 - a. the identity of any such Employee or Agent;
 - b. the periods of time during which such Employee or Agent was involved in prosecution of Amgen's EPO Patents in the United States, and the matters for which that Employee or Agent was responsible:

- c. the periods of time during which such Employee or Agent was involved in the prosecution of, or in connection with any opposition proceeding or litigation in Europe or the United Kingdom involving any of Amgen's EPO Patents; and the matters for which that Employee or Agent was responsible;
- d. any representations, contentions or other statements by that Employee or Agent regarding the characterization of any recombinant human erythropoietin produced through mammalian cell expression, including any comparison of such a recombinant human erythropoietin with any erythropoietin isolated from, or present in any human source, including plasma or urine, including any comparison or analysis of data from different studies or experiments.
- 3. All efforts by Amgen, either planned and/or carried out, concerning any attempts to identify, and/or conduct any analysis of, any cell or tissue expressing, secreting and/or otherwise producing erythropoietin, (apart from any such characterization of cells used to make the active drug product in Epogen®) or of any erythropoietin purified, isolated or otherwise derived from human urine, plasma, blood or other body fluid, including (a) any characterization of erythropoietin produced by any such cell or tissue, (b) the source of any such cell, tissue or erythropoietin, (c) any comparison between any human erythropoietin purified, isolated or otherwise derived from any non-recombinant source (cell, tissue or body fluid) with any recombinant human erythropoietin produced through mammalian cell expression and (d) any communications by Amgen with any third party concerning such efforts.
- 4. All efforts by Amgen prior to 1985, either planned and/or carried out, to express any biologically active glycosylated protein or polypeptide in any mammalian cell, including:
 - a. all personnel involved in planning, conducting or supervising such efforts;

- all experimental techniques, approaches and methods considered or used by
 Amgen in connection with such efforts;
- the identity of each cell or cell line considered and/or used in connection with such efforts;
- d. all memoranda, reports, summaries and/or other documentation of such efforts;
- e. all communication, at any time, of such efforts to any individual involved in prosecution of Amgen's EPO Patents.
- 5. Research, development and evaluation of Pegylated Compounds by Amgen, including attempts by Amgen to modify EPO proteins or any ESA, including attempts successful or otherwise to create Pegylated Compounds using EPO or any ESA such that any chemical, physical, pharmacological and/or pharmacokinetic properties of the chemically modified compound differs from the EPO or ESA, and including attempts by Amgen to chemically modify the EPO protein such that its pharmacologic and/or pharmacokinetic profile is different from the active drug product in Epogen®, including increased half life and different erythropoiesis activity.
- 6. The contribution of any Amgen Employee or other Person of which Amgen is aware, including Dr. Fu-Kuen Lin, (a) to cloning of the human erythropoietin gene, (b) to developing any method for expressing DNA encoding human EPO in mammalian host cells, including without limitation identifying and developing any vectors, host cells, and/or protocols or procedures for transforming host cells, culturing host cells, glycosylating the EPO protein so expressed and/or isolating the resulting EPO protein to make a product having biological activity in vivo, (c) to developing the subject matter disclosed in the specification of Amgen's EPO Patents and (d) to the claimed subject matter of Amgen's EPO Patents, including without

limitation the date of any contribution, including the conception and/or reduction to practice of (a)-(d), and including the conception and reduction to practice of each claim element of the asserted claims of Amgen's EPO Patents.

- 7. The earliest effective filing date for each of the asserted claims of Amgen's EPO Patents including all facts and circumstances known to Amgen supporting such contention.
- 8. The relationship between Eugene Goldwasser and Amgen, including
 Communications between Dr. Goldwasser and Amgen, further including the transfer, exchange,
 provision or supply of information, know-how, or Things to Dr. Goldwasser from Amgen (or
 from Amgen to Dr. Goldwasser) concerning erythropoietin, crude or purified human urinary
 erythropoietin, erythropoietin radioimmunoassays, iodinated erythrypoietin, erythropoietin
 purification methods, and antibodies to erythropoietin.
- 9. Characterizations of the active drug product in Epogen® and of the active drug product in Aranesp®, including:
 - a. structure
 - b. composition
 - c. conformation
 - d. glycosylation
 - e. carbohydrate structure
 - f. sialic acid content, number, and disposition

12

- g. actual or apparent molecular weight
- h. positional isomers
- i. biological activity

- j. interaction with the human erythropoietin receptor (including the equilibrium constant, disassociation constant, association rate constant, change in free energy)
- k. pharmacodynamics
- 1. pharmacokinetics
- m. immunogenicity and/or antigenicity
- n. internalization and recycling by cells
- o. manner of clearance
- 10. Any comparisons, either experimental or otherwise (such as through the analysis of different studies) performed by Amgen, at the direction of, or for the benefit of Amgen of the active drug product in Aranesp[®] to recombinant human erythropoietin, including but not limited to comparisons to the active drug product in Epogen[®], Procrit[®], Eprex[®], NeoRecormon[®] or any other ESA, including MIRCERATM, including comparisons regarding:
 - a. structure
 - b. composition
 - c. conformation
 - d. glycosylation
 - e. carbohydrate structure
 - f. sialic acid content, number, and disposition
 - g. actual or apparent molecular weight
 - h. positional isomers
 - i. biological activity

- j. interaction with the human erythropoietin receptor (including the equilibrium constant, disassociation constant, association rate constant, change in free energy)
- k. pharmacodynamics
- 1. pharmacokinetics
- immunogenicity and/or antigenicity m.
- internalization and recycling by cells n.
- manner of clearance 0.
- 11. All facts and circumstances known to Amgen concerning the contention by Amgen that Aranesp® or the active drug product in Aranesp® is covered or falls within any claim of any of the patents in suit.
- 12. All facts and circumstances known to Amgen supporting any contention by Amgen that there has been any act of infringement of the patents in suit by Roche.
- 13. All facts and circumstances known to Amgen supporting any contention that Amgen is entitled to seek injunctive relief of any type against Roche in this action, and including that Amgen would be entitled to a permanent injunction should it succeed on the merits of the underlying action, based on the factors and relevant analysis under the decision of eBay v. MercExchange LLC, 126 S. Ct. 1837 (2006), or other applicable authorities, including all facts and circumstances known to Amgen supporting it position as to (1) any alleged irreparable harm it may suffer; (2) the alleged inadequacy of remedies at law including money damages; (3) how the balance of the hardships allegedly tip in its favor; and (4) how the public interest is affected.
- 14. All facts and circumstances known to Amgen supporting any contention that Amgen is or may be entitled to damages in this action, including all facts, circumstances and data which

Amgen has or knows supporting any claim for lost profits or reasonable royalty, or price erosion or any other form of damages.

- 15. The structure, parameters, and characteristics of any market(s) or submarket(s) in the United States for ESA products, including Amgen's share of total sales in such market(s) and submarket(s), and the extent of competition, if any, to Amgen's ESA products in such market(s) and submarket(s), the barriers to entry of new ESA products into such market(s) and submarket(s), and the terms and operation of the agreement between Amgen and Ortho Pharmaceuticals Corporation, dated September 30, 1985, and the effect of that agreement on such market(s) and submarket(s).
- 16. Actual or potential substitutes for ESA products for the treatment of anemia in patients with end-stage renal disease on dialysis ("ESRD") and in patients with chronic kidney disease not on dialysis ("CKD") in the United States.
- 17. The factors used by Amgen to determine the prices it charges for ESA products in the United States.
- 18. Government and private insurance reimbursement for ESA products in the United States, the effect of such reimbursement on Amgen's sales and marketing strategies for ESA products, and the potential consequences of entry of new ESA products on reimbursement.
- 19. Amgen's business plans, marketing plans, or sales strategies for ESA products in the United States, including Amgen's plans, strategies, or actions concerning, the entry of non-Amgen ESA products (including MIRCERATM), and Amgen's plans, strategies, or actions to compete against Procrit® in any market(s) or submarket(s) in the United States for ESA products.
- 20. Amgen's analyses of projected sales, market share, or other consequence of the entry of MIRCERATM into any market(s) for ESA products in the United States.

- 21. The structure, parameters, or characteristics of any market(s) or submarket(s) in the United States in which Neulasta® or Neupogen® is sold, including Amgen's share of total sales in such market(s) and submarket(s), the extent of competition, if any, to Neulasta[®] or Neupogen[®] in such market(s) and submarket(s), and the barriers to entry of new products into such market(s) and submarket(s).
- 22. Amgen's plans, strategies, or actions for contracting with Health Care Providers in any market(s) or submarket(s) in the United States for ESA products, including communications with Health Care Providers concerning the actual or potential purchase of MIRCERATM or any other potential entrant into such market(s).
- 23. Any actual or contemplated linkage in a contract or agreement by Amgen of discounts on a non-ESA Amgen product to a customer's purchase of an ESA product, including the reasons or justifications for any such linkage.
- 24. Amgen's basis for instituting and maintaining legal proceedings against Roche before the International Trade Commission in In re: Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, filed April 11, 2006 (the "ITC Investigation").
- 25. Any communications with any attorney or other Person on which Amgen relies to show that Amgen's intent in instituting and maintaining the ITC Investigation against Roche was not an attempt to interfere directly with Roche's business through the proceedings themselves as a competitive weapon against Roche.
- 26. Amgen's basis for asserting against Roche claims in the '080 Patent related to the mature erythropoietin amino acid sequence of figure 6 of the patent specification.
 - 27. Amgen's basis for asserting against Roche claims in the '933 Patent.

28. Amgen's gross revenue and variable or incremental costs associated with the sale in the United States of any Amgen ESA product, and the amount of and manner in which Amgen calculates its profit on the sale of any Amgen ESA product, including itemization of costs subtracted from the gross revenue of that Amgen ESA product in determining the profit.

29. Any written or oral communications with any attorney or other Person on which Amgen relies to show that it did not intend to mislead the United States Patent and Trademark Office in the prosecution or defense any of the EPO Patents during any prosecution or interference proceeding.

CERTIFICATE OF SERVICE

I hereby certify that a copy of DEFENDANTS' FIRST NOTICE OF DEPOSITION TO AMGEN PURSUANT TO RULE 30(b)(6) was served upon the attorneys of record for the plaintiff (as listed below) by facsimile on February 9, 2007.

Lloyd R. Day, Jr. (pro hac vice)
David A. Madrid (pro hac vice)
Linda A. Sasaki-Baxley (pro hac vice)
Deborah Fishman (pro hac vice)
DAY CASEBEER MADRID &
BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014

Telephone: (408) 873-0110 Facsimile: (408) 873-0220

William G. Gaede III (pro hac vice)
Michele E. Moreland (pro hac vice)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304

Telephone: (650) 813-5000 Facsimile: (650) 813-5100

D. Dennis Allegretti (BBO#545511) Michael R. Gottfried (BBO#542156) Patricia R. Rich (BBO# 640578) DUANE MORRIS LLP 470 Atlantic Avenue, Suite 500 Boston, MA 02210 Telephone: (617) 289-9200

Kevin M. Flowers (pro hac vice)
Thomas I. Ross (pro hac vice)
Mark Izraelewicz (pro hac vice)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474 6300

Telephone: (312) 474-6300 Facsimile: (312) 474-0448

Facsimile: (617) 289-9201

/s/Denise Lopez
Denise Lopez