EXHIBIT 11
PART 1 OF 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

AMGEN'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1 TO 224)

Pursuant to Fed. R. Civ. P. 26 and 34, Plaintiff Amgen Inc. ("Amgen"), hereby requests that Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann La Roche Inc., serve a written response and produce, in accordance with the Definitions and Instructions set forth below, all documents described below within thirty (30) days of service of this request at the offices of Day Casebeer Madrid & Batchelder LLP, 20300 Stevens Creek Blvd., Suite 400, Cupertino, CA 95014.

Amgen requests that documents withheld pursuant to a claim of attorney-client privilege or attorney work product be separately identified in a privileged document list.

DEFINITIONS

1. As used herein, "all" means "any and all"; "any" means "any and all."

2. As used herein, "Amgen's related patents and patent applications" means one or more of any United States or foreign patent which claims priority benefit in whole or in part based on the filing date(s) recited on the first page(s) of the patents-in-suit.

3. 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.

4. As used herein, "communication" means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise).

5. As used herein, "concerning" means referring to, describing, evidencing, or constituting.

6. As used herein, "document" shall have the same meaning as specified in Fed. R. Civ. P. 34(a), including any written, printed, typed, recorded, digital, magnetic, punched, copied, graphic or other tangible thing in, through, or from which information may be embodied, translated, conveyed, stored or obtained (including electronic mail, personal productivity software, databases, spreadsheets, group or collaboration servers and software, websites, electronic bulletin boards, electronic discussion boards, video recordings, audio recordings, digital recordings, computer tapes, computer disks, microfilm, microfiche and all other media from which information can be obtained. Pursuant to Local Rule 26.5(c)(2), drafts or non-identical copies are considered separate documents within the meaning of this term.

7. 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.

8. 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.

9. As used herein, "EPO" means any human erythropoietin or human erythropoietin analog produced from vertebrate cells, including (without limitation) the Chinese Hamster Ovary cell line designated "DN2-3α3."

10. As used herein, "ESP" means any erythropoiesis-stimulating protein or polypeptide, including EPO, peg-EPO and erythropoietin purified from urine or any other source.

11. As used herein, "including" means "including but not limited to."

12. As used herein, "infringement" and any variant thereof, means any form of infringement actionable under United States law, including direct infringement, contributory infringement, inducement to infringe, literal infringement, and infringement under the doctrine of equivalents.

13. As used herein, "non-peg component of peg-EPO" means every part or portion of peg-EPO other than polyethylene glycol.

14. As used herein, "patents-in-suit" means 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.

15. As used herein, "peg-EPO" means any erythropoietin having one or more molecules of polyethylene glycol attached or linked thereto, including but not limited to any form of the chemical entity/entities referred to as "CERA," "Continuous Erythropoiesis Receptor

Activator," "MIRCERA," "pegserepoetin alfa," "pegzerepoetin," "pegepoetin," "pegzyrepoetin," "Ro 50-3821," "R-744," "MIX," "Methoxy Polyethylene Glycol-Epoetin Beta," "pegylated epoetin beta," "peg-EPO," "PEG-epoetin beta," "pegylated erythropoietin," or "pegylated EPO," "peg-epoetin," "pegylated recombinant human erythropoietin," "polyethylene glycol conjugated recombinant human epoetin beta," any erythropoietic protein or polypeptide produced by the Chinese Hamster Ovary (CHO) cell line "DN2-3α3" having at least one attached moiety comprising polyethylene glycol and any other form of erythropoietin or erythropoietin analog having at least one attached moiety comprising polyethylene glycol.

16. 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).

17. As used herein, "related application" means any application, filed anywhere in the world, that: (a) is a parent, child or other ancestral application related in any way to a given patent; (b) is a continuation application, continuation-in-part application, divisional application, file-wrapper continuation, reexamination proceeding, reissue application, provisional application or abandoned application of such patent or the application that led to such patent; (c) claims priority in whole or in part from such patent or the application that led to such patent; (d) is the basis for a claim of priority in whole or in part (including claims of benefits under 35 U.S.C. §§ 119(e) or 120) for a given patent; or (e) shares subject matter with a given patent.

18. As used herein, "related patent" means any patent that issued from any related application.

19. 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.

20. As used herein, "ROCHE," "you" and "your" mean Defendant(s) Hoffmann-La 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 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.

21. As used herein, "thing" means each item, sample, specimen, concrete or tangible object.

INSTRUCTIONS

1. The documents requested hereby specifically include those documents in ROCHE's possession, custody, or control as well as those documents in the possession, custody, or control of ROCHE's present and former employees, directors, officers, affiliates, and any other person or entity acting or purporting to act on ROCHE's behalf.

2. If a request is silent as to the time period for which responsive documents and things are sought, you are to produce all documents originated in whole or in part and all things within your possession, custody, or control at any time during the period from January 1, 1995 through the date of your production.

3. For each copy of each document produced, identify the custodian from whose custody or control such copy was obtained.

4. Except as otherwise specifically requested or agreed, all documents produced in electronic form shall be produced in an electronic form that is readily usable with a cross-reference file in a fully documented XML format denoting for each such document its corresponding document production number(s) and file format.

5. All electronic data produced in response to these requests shall be produced on external hard drives with a corresponding text file that fully documents the data format(s) in which all such data are stored.

6. To the extent documents are maintained in both hard copy and magnetic or electronic form, you are to produce such data in all forms in which they are maintained.

7. You are to produce the original and each non-identical copy of each document or thing requested herein which is in your possession, custody or control.

8. All requested documents shall be produced in the same file or other organizational context in which they are kept by ROCHE. For example, a document that is part of a file, docket

or other grouping should be physically produced together with all other documents from said file, docket or grouping responsive to the Request, in the same order or manner of arrangement as the original.

9. If it is maintained that any requested document has been destroyed, identify such document, set forth the contents of the document, state the date of such destruction, and identify the person(s) who authorized or directed such destruction.

10. With respect to any claim of privilege by ROCHE relating to any information, document or communication sought by any of these discovery requests, ROCHE is hereby requested to identify each such communication, information, or document withheld on grounds of an alleged privilege, and specifically set forth the following:

(a) the nature and basis of the privilege claimed;

(b) the author(s);

(c) the addressee(s), including the recipients of copies;

(d) the date of the communication, document or information;

(e) the subject matter of the communication, document or information;

(f) if the privilege claimed is the attorney-client privilege, an indication of which author(s) or addressee(s) is/are attorneys;

(g) any other information necessary to support the claim of privilege; and

(h) page range including unique document identifier for pages being withheld.

11. ROCHE is required to supplement each response hereto to the full extent provided for in Federal Rules of Civil Procedure 26(e) and the local rules.

REQUESTS FOR PRODUCTION

1. All documents and things produced by ROCHE in discovery In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human

Erythropoietin, ITC Investigation No. 337-TA-568, including a transcript of each deposition and each declaration of each ROCHE witness therein.

2. A representative 10 mg purified bulk sample of the EPO from which MIRCERA is produced, and such documents and things as are sufficient to identify the origin, production lot, date of production, composition, characteristics, and all analytical test results of said purified bulk EPO sample.

3. A representative 10 mg purified bulk sample of the peg-EPO from which MIRCERA is produced, and such documents and things as are sufficient to identify the origin, production lot, date of production, composition, characteristics, and all analytical test results of said purified bulk peg-EPO sample.

4. The production batch records of the EPO and peg-EPO samples produced in response to Requests 2 and 3, above.

5. Documents and things sufficient to characterize accurately the amino acid sequence, molecular weight, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, and any other physical or functional characteristic of the EPO from which MIRCERA is produced.

6. Documents and things sufficient to characterize accurately the amino acid sequence, molecular weight, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, and any other physical or functional characteristic of MIRCERA.

7. All documents and things relating to any comparison of the amino acid sequence, molecular weight, structure, spectra, post-translational modification, glycosylation, sialylation,

acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, and any other physical or functional characteristic of the EPO from which MIRCERA is produced with the corresponding characteristic(s) of any other ESP, including MIRCERA or any ESP made or sold by Amgen or its licensee(s).

8. All documents and things relating to any comparison of the amino acid sequence, molecular weight, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, and any other physical or functional characteristic of MIRCERA with those of any other ESP, including any ESP made or sold by Amgen or its licensee(s).

9. All documents and things relating to any characterization, testing or analysis of the amino acid sequence, molecular weight, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, and any other physical or functional characteristic of any ESP other than MIRCERA, including any ESP made or sold by Amgen or its licensee(s).

10. All documents and things relating to any comparison of the amino acid sequence, glycosylation, biological activity and/or other physical, *in vitro* or *in vivo* attributes of MIRCERA or any EPO component thereof with any claim in any patent-in-suit.

11. A viable sample of each cell line used by ROCHE to produce the EPO component of MIRCERA (including the "DN2-3α3" cell line), and such documents and things as are sufficient to identify the origin, DNA composition, the growth characteristics and the quantity of EPO produced by each such cell line, including all results of all analytical tests performed on each such sell line.

12. The production record of each cell line produced in response to Request 11, above

13. For each cell line used by ROCHE to produce the EPO component of peg-EPO (including DN2-3α3 cells), documents and things sufficient to show how ROCHE stores and cultures each such cell line to produce the EPO component of MIRCERA, including all directions, materials and instructions needed to store, thaw, prepare culture media, and culture each such cell line.

14. For each cell line used by ROCHE to produce the EPO component of peg-EPO (including DN2-3α3 cells), all documents and things sufficient to show the amount of EPO produced in culture over 24 hours by each such cell line as measured by radioimmunoassay ("RIA") or comparable means, including documents sufficient to show the methods and materials by which such measurement or calculation is made.

15. All documents and things relating to the comparability or non-comparability of estimates of the amount of EPO in a sample based on RIA and enzyme-linked immunosorbent ("ELISA") assays.

16. Documents sufficient to show each cell line considered, evaluated and/or used by ROCHE to produce the EPO component of peg-EPO.

17. All documents and things relating to any comparison of each cell line used to produce the EPO component of MIRCERA with any claim in any patent-in-suit.

18. All documents and things relating to any comparison of each process used to produce the EPO component of MIRCERA with any claim in any patent-in-suit.

19. All documents and things relating to any analysis of the DNA sequence encoding EPO in each cell line (including the "DN2-3α3" cell line) used to produce the EPO component of MIRCERA, including documents sufficient to show the methods and materials by which each such determination is made.

20. All documents and things relating to any analysis of the DNA sequence that regulates or controls transcription and/or expression of EPO DNA in each cell line (including the "DN2-3α3" cell line) used to produce the EPO component of MIRCERA, including documents sufficient to show the methods and materials by which each such determination is made.

21. Documents sufficient to show all methods and materials considered, evaluated or used by ROCHE to express DNA encoding EPO in cells for use in producing peg-EPO.

22. Documents and things sufficient to show all methods and materials considered, evaluated or used by ROCHE to operatively link a regulatory DNA segment (*e.g.*, a promoter and/or enhancer) to DNA encoding EPO in a cell for use in producing peg-EPO.

23. All documents and things relating to any analysis of the copy number per cell of the DNA sequence encoding EPO in each cell line (including the "DN2-3α3" cell line) used to produce the EPO component of MIRCERA, including documents sufficient to show the methods and materials by which each such measurement or calculation is made.

24. Documents sufficient to show all methods and materials considered, evaluated or used by ROCHE to amplify DNA encoding EPO in a cell for use in producing peg-EPO.

25. All documents and things (including laboratory notebooks) of Pascal Bailon, each employee of ROCHE, and/or each third party working or collaborating with Pascal Bailon, relating to any work relating to any ESP, including peg-EPO.

26. All documents and things relating to the research and development of peg-EPO including research papers, experiments, and studies conducted to develop peg-EPO

27. All documents and things relating to each decision to approve or fund development of the RO0503821 drug substance, including process development, manufacturing, non-clinical pharmacology, toxicity, formulation, product characterization, formulation, and clinical development.

28. All documents and things relating to any comparison of peg-EPO to any non-pegylated ESP.

29. All documents and things relating to any difference between peg-EPO and any non-pegylated ESP.

30. All documents and things relating to any investigation or study by ROCHE or any third party of any interaction between peg-EPO and the erythropoietin receptor, including the *in vitro* or *in vivo* erythropoietin receptor binding activity of peg-EPO, the *in vitro* or *in vivo* affinity of peg-EPO for the erythropoietin receptor, the internalization of peg-EPO by cells, studies of Kd, Smax, or Bmax, on- and off-binding rates, structure-activity studies, modeling and analyses.

31. All documents and things relating to any comparison by ROCHE or any third party between (a) the interaction of peg-EPO with erythropoietin receptors, and (b) the interaction of any other ESP with erythropoietin receptors.

32. All documents and things relating to any communication between ROCHE or its attorneys and any third party regarding any study or investigation of any interaction of peg-EPO with erythropoietin receptors, the interaction of any other ESP with erythropoietin receptors, or any comparison between the interaction of peg-EPO with erythropoietin receptors and the interaction of any other ESP with erythropoietin receptors.

33. All documents and things relating to any comparison of the pharmacokinetics, pharmacodynamics, clearance, receptor binding activity, stimulation of intracellular responses, elevation or maintenance of hemoglobin levels, safety, antigenicity and/or immunogenicity of peg-EPO with the corresponding properties on any other ESP (including non-pegylated EPO).

34. All documents and things relating to any communication between ROCHE or its attorneys and any third party regarding any study or investigation to compare the

pharmacokinetics, pharmacodynamics, clearance, receptor binding activity, stimulation of intracellular responses, elevation or maintenance of hemoglobin levels, safety, antigenicity and/or immunogenicity of peg-EPO with the corresponding properties of any other ESP (including non-pegylated EPO).

35. All documents and things relating to any investigation or study of the mechanism of action and/or the pharmacodynamic and/or pharmacokinetic properties of peg-EPO upon administration to animals (including humans), including documents sufficient to describe the materials and methods by which each such study was made.

36. All documents and things relating to any comparison of the mechanism of action and/or the pharmacodynamic and/or pharmacokinetic properties of peg-EPO upon administration to animals (including humans) with the corresponding properties of any other ESP (including non-pegylated EPO), including documents sufficient to describe the materials and methods by which each such study was made.

37. A copy of each electronic submission of ROCHE to the FDA relating to or comprising its Biologics License Application and/or Investigational New Drug Applications (IND) for peg-EPO (in the electronic form and data format provided to FDA with all embedded links intact and operable), including all communications, updates, supplements and patient data related thereto.

38. All INDs filed with the FDA relating to peg-EPO, including the original IND filed by ROCHE with FDA in November 2001 and all communications with the FDA related thereto, including any amendment, supplement or update thereto.

39. All documents and things comprising or relating to any supplement or amendment to ROCHE's Biologics License Application for peg-EPO since April 19, 2006, including all communications, updates, analyses and patient data related thereto.

40. All documents and things comprising or relating to any communication, meeting or exchange of information between ROCHE and FDA regarding peg-EPO or EPO since April 19, 2006.

41. Documents and things sufficient to configure correctly and execute properly each electronic copy of submissions made to FDA produced in response to Requests 37-40, above.

42. All documents and things comprising or relating to any communication, meeting or exchange of information between ROCHE and any third party regarding ROCHE's Biologics License Application for peg-EPO and/or FDA's review or approval thereof.

43. All documents and things relating to any submission of information relating to peg-EPO to any governmental agency or body anywhere in the world.

44. All documents and things relating to any communication, meeting or exchange of information relating to peg-EPO between ROCHE and any governmental agency or body anywhere in the world.

45. Documents and things sufficient to show the respective role and responsibility of each ROCHE team, group and/or third party involved in proposing, reviewing or executing any preparation for or launch of ROCHE's commercial sale of MIRCERA in the United States, including the manufacture, importation, advertising, promotion, marketing, training, pricing, sale, offer to sell, distribution or reimbursement of MIRCERA.

46. All documents and things generated by or for ROCHE management or any ROCHE organization, group or team since January 1, 2003 that reference or relate to preparations for or the commercial launch, supply, commercialization, promotion, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, tasks lists, schedules and plans of action.

47. All documents and things related to any communication with current or prospective employees of ROCHE, members of any ROCHE advisory board, current or prospective customers of ROCHE, or any reimbursement authority or agency regarding the date(s) by which ROCHE expects or plans to obtain FDA approval to sell MIRCERA in the United States.

48. All documents and things related to any communication with current or prospective employees of ROCHE, members of any ROCHE advisory board, current or prospective customers of ROCHE, or any reimbursement authority or agency regarding the date(s) by which ROCHE expects or plans to commence the sale of MIRCERA in the United States.

49. All documents and things relating to any forecast, plan, study or estimate the date(s), package type(s) and amounts of MIRCERA to be imported into the United States for commercial sale at any time during 2006, 2007, 2008 and 2009.

50. All documents and things relating to any forecast, plan or study of the time required to commence distribution or sale of MIRCERA in the United States following FDA approval.

51. All documents and things that comprise or relate to ROCHE's marketing plan for MIRCERA in the United States.

52. All documents and things that comprise or relate to the 2006, 2007 and 2008 marketing budget and plan in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

53. All documents and things generated by or for ROCHE management, marketing or sales since January 1, 2005 that reference or relate to preparations for or the commercial launch,

supply, commercialization, clinical development, promotion, pricing, sale or reimbursement of MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

54. All documents and things generated by or for ROCHE management, marketing or sales since January 1, 2005 that reference or relate to current or future use of MIRCERA in the United States, including all goals, budgets, studies, clinical trials, protocols, forecasts, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

55. All documents and things generated by or for ROCHE management, marketing or sales since January 1, 2005 that reference or relate to the current or future cost or reimbursement of MIRCERA use in the United States, including all goals, budgets, studies, clinical trials, protocols, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

56. All documents and things generated by or for ROCHE management, marketing or sales regarding projected customers, sales, dosing, pricing, reimbursement, or use of MIRCERA in the United States at any time during 2006, 2007, 2008 and/or 2009, including all reports, analyses, presentations, spreadsheets, minutes, agendas, task lists, and plans of action of each team or group involved therein.

57. All documents and things relating to any analysis or evaluation of customers who may purchase or use MIRCERA in the United States at any time during 2006, 2007 and/or 2008.

58. All documents and things related to any form of DDD report ordered or obtained by ROCHE regarding MIRCERA or any other ESP (including EPOGEN®, ARANESP® and PROCRIT®).

59. All documents and things related to DDD reports ordered or purchased by ROCHE regarding the nephrology or chronic renal failure markets.

60. All documents and things that comprise any analysis, agreement, plan or draft of contract terms for sale, reimbursement or use of MIRCERA in the United States during 2006, 2007 and/or 2008 or any portion thereof, including each pro forma or draft contract for purchase or sale of MIRCERA by any category of prospective customer.

61. All documents and things relating to any analysis or evaluation of pricing of MIRCERA for sale or use in the United States, including any analysis or evaluation of discounts, rebates or other incentives for purchase or use of MIRCERA with patients.

62. All documents and things that comprise any forecast or projection of MIRCERA pricing in the United States during 2006, 2007 and/or 2008, including all documents forecasting pricing by any use, customer, or customer segment.

63. All documents and things relating to any analysis or evaluation of the dosing of MIRCERA for use in the United States, including any analysis or evaluation of the dose per patient, availability of overfill, use of overfill, and/or price per dose.

64. All documents and things that comprise any forecast or projection of MIRCERA dosing in the United States during 2006, 2007 and/or 2008, including all documents forecasting dosing by any use, customer, customer segment or patient category.

65. All documents and things relating to any analysis or evaluation of the intravenous and/or subcutaneous dose(s) and dosing regimen of MIRCERA that are equivalent or comparable to the doses and dosing regimen of any other ESP (including EPOGEN®, ARANESP® and PROCRIT®) for use in treatment of any patient category, including any analysis or evaluation of the dose conversion ratio between MIRCERA and EPOGEN®, ARANESP® and PROCRIT®.

66. All documents and things relating to any communication, presentation or meeting between ROCHE and any third party (including FDA, the Centers for Medicare & Medicaid Services (CMS), the Government Accounting Office ("GAO"), any purchaser or provider of ESP products) regarding any analysis or comparison of the intravenous and/or subcutaneous dose(s) and dosing regimen of MIRCERA and the dose(s) and dosing regimen of any other ESP (including EPOGEN®, ARANESP® and PROCRIT®) for use in treatment of any patient category, including any analysis or evaluation of the dose conversion ratio between MIRCERA and EPOGEN®, ARANESP® and PROCRIT®.

67. All documents and things relating to any analysis or evaluation of the ability of MIRCERA to regulate patient hemoglobin, including any analysis or evaluation of any relationship between dosing and hemoglobin.

68. All documents and things that comprise any forecast or projection of the hemoglobin levels of patients who receive MIRCERA in the United States during 2006, 2007 and/or 2008, including all documents forecasting hemoglobin by any dose level, use, customer, customer segment or patient category.

69. All documents and things relating to any current or projected effect of MIRCERA pricing on any large dialysis organization, small dialysis organization, hospital, nephrology clinic, physician, the Veterans Administration, pharmacies, wholesalers or retailers, including any effect on such entities' purchasing, consumption, use, reimbursement or profitability.

70. All documents and things relating to any current or projected effect of ROCHE's pricing of MIRCERA on the average wholesale price, the wholesale acquisition cost or the average selling price of any other ESP (including EPOGEN®, ARANESP® and PROCRIT®).

71. All documents and things relating to any current or projected effect of ROCHE's pricing of MIRCERA on the pricing, sales or use of any ESP for treatment of oncology patients.

72. All documents and things that comprise or relate to any budget or plan of ROCHE medical affairs relating to MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

73. All documents and things generated by or for ROCHE medical affairs since January 1, 2005 that reference or relate to preparations for or the commercial launch, supply, commercialization, clinical development, promotion, pricing, sale or reimbursement of MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

74. All documents and things generated by or for ROCHE medical affairs since January 1, 2005 that reference or relate to current or future use of MIRCERA in the United States, including all goals, budgets, studies, clinical trials, protocols, forecasts, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

75. All documents and things generated by or for ROCHE medical affairs since January 1, 2005 that reference or relate to the current or future cost or reimbursement of MIRCERA use in the United States, including all goals, budgets, studies, clinical trials, protocols, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

76. All documents and things that comprise or relate to any budget or plan of ROCHE governmental affairs relating to MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

77. All documents and things generated by or for ROCHE governmental affairs since January 1, 2005 that reference or relate to preparations for or the commercial launch, supply, commercialization, clinical development, promotion, pricing, sale or reimbursement of MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

78. All documents and things generated by or for ROCHE governmental affairs since January 1, 2005 that reference or relate to current or future use of MIRCERA in the United States, including all goals, budgets, studies, clinical trials, protocols, forecasts, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

79. All documents and things generated by or for ROCHE governmental affairs since January 1, 2005 that reference or relate to the current or future cost or reimbursement of MIRCERA use in the United States, including all goals, budgets, studies, clinical trials, protocols, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

80. All documents and things relating to any analysis or evaluation of any reimbursement rate, plan or policy for future MIRCERA use in the United States, including average selling price, discounts, rebates or other incentives for purchase or use of MIRCERA with patients.

81. All documents that comprise or relate to any plan, forecast or projection of Medicare, Medicaid and/or private reimbursement rates or policies for MIRCERA use in the United States at any time during 2006, 2007, 2008 and/or 2009.

82. All documents and things relating to any analysis, evaluation or presentation regarding the pharmaco-economics of MIRCERA use in anemic renal dialysis patients and/or anemic renal patients not on dialysis.

83. All documents and things relating to any comparison of the pharmaco-economics of MIRCERA use in anemic patients with the pharmaco-economics of the use of any other ESP in anemic patients, including EPOGEN®, ARANESP® and PROCRIT®.

84. All documents and things relating to any analysis, evaluation or presentation regarding the hemoglobin and/or dose response of anemic patients receiving MIRCERA therapy.

85. All documents and things relating to any communication, meeting, presentation or proposal between ROCHE and any representative of any public or private reimbursement authority or agency in the United States (including the CMS, GAO, any state Medicaid authority or any private reimbursement or health maintenance organization) relating to the current or future sale, use, efficacy, safety, cost-effectiveness, reimbursement or pricing of any ESP, including MIRCERA.

86. All documents and things relating to any communication, meeting, presentation or proposal between ROCHE and any representative of any public or private reimbursement authority or agency in the United States (including the CMS, GAO, any state Medicaid authority or any private reimbursement or health maintenance organization) relating to any analysis, evaluation or presentation regarding the hemoglobin and/or dose response of anemic patients receiving ESP therapy.

87. All documents and things relating to the "White Paper" attached hereto as Exhibit A, including communications within ROCHE or between ROCHE and any third party regarding the White Paper, any draft of the White Paper or communications referenced in the White Paper.

88. All documents and things relating to any current or projected effect of the sale of MIRCERA in the United States on government reimbursement of ESP use in the United States, including the effect on reimbursement of EPOGEN®, ARANESP® and PROCRIT®.

89. All documents and things that comprise or relate to ROCHE's 2006, 2007 and 2008 sales budget and plan for MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

90. All documents and things that comprise or relate to any forecast or projection of MIRCERA sales in the United States during 2006, 2007 and/or 2008 or any portion thereof, including all documents forecasting sales by territory, patient use or customer segment.

91. All documents and things relating to any solicitation, recruitment or hiring of sales personnel, medical liaisons or reimbursement specialists whose duties include promotion or support of MIRCERA, including any budget, plan, or forecast of hiring positions and levels.

92. All documents and things relating to any training or instruction of sales personnel, medical liaisons or reimbursement specialists regarding the forecasting, budget, marketing, promotion, contracting, use, pricing, dosing, and/or reimbursement of MIRCERA, including all such instructional materials provided to or used with such individuals.

93. All manuals, sales forms, sales contact forms, forecasts, quotas, and tracking documents used by ROCHE to train its personnel to market, sell and/or obtain reimbursement of MIRCERA in the United States.

94. All documents and things relating to any training or instruction of physicians, nurses, patients, clinic administrators, reimbursement authorities or other customers regarding the promotion, contracting, training, use, pricing, dosing, and/or reimbursement of MIRCERA use, including all such instructional materials provided to or used with such individuals.

95. All documents and things relating to any communication, meeting, presentation or solicitation between ROCHE and any purchaser or consumer of ESP products (including any dialysis care organizations, hospitals, nephrology clinics, nephrologists, dialysis nurses, group purchasing organizations, the Veterans Administration, the Department of Defense and other governmental organizations) relating to the current or future purchase, pricing, use or reimbursement of peg-EPO or MIRCERA in the United States.

96. All documents and things relating to any monthly or other report or summary of activities relating to MIRCERA during any period since October 1, 2005 of any ROCHE sales director, sales manager, sales representative, medical liaison, or member of any marketing, sales, brand, medical affairs or governmental affairs team or group.

97. Documents and things sufficient to show the most current quota or forecast of MIRCERA sales by month, quarter and year for each sales territory and region in the United States and its possessions during 2006, 2007 and 2008.

98. Documents and things sufficient to show the most current quota or forecast of MIRCERA sales by month, quarter and year for each customer in the United States and its possessions during 2006, 2007 and 2008.

99. Documents and things sufficient to show the policy and method by which sales of MIRCERA in the United States will affect the compensation of members of ROCHE's sales force, medical liaison, and medical affairs personnel.

100. All documents and things relating to any customer or potential customer for peg-EPO, including large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government pharmacies, individual clinics, and/or individual physicians, but excluding patient specific information, relating to the importation, use, offer for sale, sale or reimbursement of peg-EPO in the United States .

101. All documents and things relating to any communication between ROCHE and any customer or potential customer for peg-EPO, including large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government pharmacies, individual clinics, and/or individual physicians, but excluding patient specific information, relating to the importation, use, offer to sell, sale or reimbursement of peg-EPO in the United States.

102. All documents and thing relating to any negotiation between ROCHE and any customer or potential customer for peg-EPO, including large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government pharmacies, individual clinics, and/or individual physicians relating to the importation, use, offer to sell, sale or reimbursement of peg-EPO in the United States.

103. All documents and things relating to any agreement or contract between ROCHE and any customer or potential customer for peg-EPO in the United States, including but not limited to large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government pharmacies, individual clinics, and/or individual physicians, relating to the importation, use, offer to sell, sale, or reimbursement of peg-EPO in the United States.

104. Documents and things sufficient to show all communications between ROCHE and DaVita Inc. or its affiliates relating to peg-EPO or any other ESP.

105. Documents and things sufficient to show all communications between ROCHE and Dialysis Clinic Inc. (DCI) or its affiliates relating to peg-EPO or any other ESP.

106. Documents and things sufficient to show all communications between ROCHE and Fresenius Medical Care North America or Fresenius Medical Care AG & Co. KGaA or their affiliates relating to peg-EPO or any other ESP.

107. Documents and things sufficient to show all communications between ROCHE and Gambro AG or its affiliates relating to peg-EPO or any other ESP.

108. Documents and things sufficient to show all communications between ROCHE and Renal Care Group, Inc. (RCG) or its affiliates relating to peg-EPO or any other ESP.

109. Documents and things sufficient to show all communications between ROCHE and any agency or procurement office of the United States Department of Defense, Veterans Administration or other governmental procurement office relating to peg-EPO or any other ESP.

110. All documents and things relating to any agreement, assignment, license, or transfer between ROCHE and a third party in the United States regarding any ESP potentially useful in the treatment of anemia.

111. All documents and things relating to any executed or proposed understanding or agreement between ROCHE and any third party relating to any past, current or future use of peg-EPO or EPO in the United States.

112. All documents and things relating to any executed or proposed understanding or agreement between any of the ROCHE entities relating to any past, current or future use of peg-EPO or EPO in the United States.

113. All documents and things relating to any offer to provide peg-EPO or EPO for use in the United States to any person or entity for any purpose or use that is not related to the development and submission of information to FDA under a federal law regulates the manufacture, use, or sale of erythropoietin products.

114. All documents and things relating to any offer to sell peg-EPO or EPO to any person or entity for any use in the United States not related to the development and submission of information to FDA under a federal law that regulates the manufacture, use, or sale of peg-EPO or EPO products.

115. All documents and things relating to any agreement or understanding to sell, supply or provide peg-EPO or EPO for use in the United States at any time after FDA approval of ROCHE's pending BLA.

116. All documents and things related to the recruitment, solicitation or hiring of any Amgen employee by ROCHE since January 1, 2004.

117. All documents and things related to any plan or budget of ROCHE to recruit, solicit or hire Amgen sales personnel, medical liaisons, reimbursement specialists or marketing personnel.

118. All documents and things related to any communication between ROCHE and any third party regarding recruitment, solicitation or hiring of any Amgen employee for employment by ROCHE since January 1, 2004.

119. All documents and things related to any listing, directory or other information of Amgen regarding its employees, business dealings, customers or internal organization.

120. All documents and things related to any listing, directory or other information of Amgen regarding its employees, business dealings, customers or internal organization.

121. All documents and things relating to information of Amgen regarding its instruction, training, organization, supervision or compensation of its employees, including manuals, directories, forms, reports and spreadsheets.

122. All documents and things relating to information of Amgen regarding its instruction, training or support of customers or reimbursement personnel.

123. Documents and things sufficient to identify and describe all activities sponsored by ROCHE since January 1, 2005 to enhance the competitive profile of peg-EPO.

124. Documents and things sufficient to identify and describe each clinical use or study of peg-EPO in the United States (excluding patient-specific information) after April 19, 2006,

including the identity and location of each facility, the sponsor administering drug and the clinical protocol pursuant to which such administration was, is or will be made.

125. All documents and things related to any plan, study protocol, draft protocol, concept, schedule, budget or supply forecast for use of peg-EPO in humans in the United States for any study not included in ROCHE's April 19, 2006 Biologics License Application, including any "Phase IIIb/IV" study.

126. All documents and things comprising or related to any communication or presentation after January 1, 2006 between ROCHE and any third party (including all communications with clinicians and investigational review boards) regarding any plan, study protocol, draft protocol, concept, schedule or budget to study the use of peg-EPO in anemic renal patients in the United States, including any "Phase IIIb/IV" study.

127. All documents and things related to the conception, development, budget, cost, funding for, work performed, results, or presentation of the information contained in Abstract Nos. TH-PO072, TH,-PO230, TH-PO359, TH-PO361, TH-PO1001, TH-PO1002, TH-PO1007, PUB376, PUB377, F-PO375, F-PO408, F-PO671, F-PO685, SA-PO019, SA-PO034, SA-PO035, SA-PO192, SA-PO197, SA-PO198, SA-PO205, SA-PO207, SA-PO208, SA-PO209, SA-PO210, SA-PO212, and SA-PO225 (attached hereto as Exhibit B), as submitted for publication in 2006 to the American Society of Nephrology.

128. All documents and things comprising or related to any communication or presentation between ROCHE and any third party (including all communications with clinicians and investigational review boards) regarding Abstract No. SA-PO205 (Exhibit C), including all drafts of the study protocol.

129. All documents and things relating to the use of control variables in the development of a case-mix adjusted payment system for dialysis systems, as described in ASN Abstract TH-PO1007 (attached hereto as Exhibit D).

130. All documents and things relating to any communication between ROCHE and J. Wheeler, M. Turenne, R. Hirth, J. Messana, or A. Pozniak regarding any study or investigation of the use of control variables in the development of a case-mix adjusted payment system for dialysis systems, as described in the previous request for production.

131. All documents and things relating to any association between missed dialysis sessions and hemoglobin variability, as described in ASN Abstract F-PO375 (attached hereto as Exhibit E).

132. All documents and things relating to any communication between ROCHE and Robert N. Foley, Qi Li, David T. Gilbertson, Allan J. Collins, or Stephan C. Dunning regarding any study or investigation of any association between missed dialysis sessions and hemoglobin variability, as described in the previous request for production.

133. All documents and things relating to any association of persistently low hemoglobin levels with medical expenditures in dialysis patients, as described in ASN Abstract F-PO408 (attached hereto as Exhibit F).

134. All documents and things relating to any communication between ROCHE and Jiannong Liu, Haifeng Guo, David T. Gilbertson, or Allan J. Collins, regarding any study or investigation of any association of persistently low hemoglobin levels with medical expenditures in dialysis patients, as described in the previous request for production.

135. All documents and things relating to any association between hemoglobin variability and mortality among dialysis patients, as described in ASN Abstract SA-PO034 or SA-PO035 (attached hereto as Exhibits G and H).

136. All documents and things relating to any communication between ROCHE and H.I. Feldman, R.K. Israni, W. Yang, S. Fishbane, or M. Joffe regarding any study or investigation of any association between hemoglobin variability and mortality among dialysis patients, as described in the previous request for production.

137. For each clinical trial involving peg-EPO, a copy of the study protocol, investigator brochure and material transfer agreement.

138. For each clinical trial involving peg-EPO, documents and things sufficient to show the peg-EPO used, the principal investigators conducting each such trial, and the clinical and safety results of each such clinical trial.

139. For each clinical trial involving peg-EPO, all documents and things comprising or relating to any analysis or assessment of the safety of peg-EPO use in humans.

140. Documents and things sufficient to show the respective role and responsibility of each ROCHE employee, team, group and/or third party involved in any preclinical study or characterization of peg-EPO, including any comparison of any property or characteristic of peg-EPO with any other ESP(s).

141. All documents and things relating to any study involving the administration of peg-EPO or EPO to any non-human animal in the United States after 1995.

142. All documents and things that comprise or relate to the goals, budgets and tasks (including all milestones, minutes, agendas, presentations, tasks lists, plans of action, schedules and priorities) of each team or group within ROCHE involved in any preclinical study or characterization of peg-EPO at any time since January 1, 2002, including any investigation or study of peg-EPO's mechanism of action, its pharmacokinetic or pharmacodynamic properties, or any comparison of any characteristic or property of peg-EPO with those of any other ESP(s).

143. All documents and things relating to any study or investigation sponsored or funded by ROCHE or its attorneys relating to the mechanism of action of peg-EPO in relation to erythropoietin receptors.

144. All documents and things relating to any study or investigation sponsored or funded by ROCHE or its attorneys relating to any comparison of any activity, property or characteristic of peg-EPO with the corresponding activity, properties or characteristics of any other ESP.

145. All documents and things (including all communications, plans, grants, grant applications, and research contracts or related drafts) relating to any work or study of any third party regarding peg-EPO or EPO, including documents relating to comparative studies or analysis of the mechanism of action and pharmacodynamic and/or pharmacokinetic properties of peg-EPO.

146. All documents and things comprising or relating to any communication, presentation or proposal between ROCHE or its attorneys and any third party regarding any non-clinical study or investigation of peg-EPO, EPO, or any other ESP.

147. Documents and things sufficient to show the relationship between and among the ROCHE Defendants and their subsidiaries, affiliates, divisions, parent(s), and/or other related companies.

148. Documents and things sufficient to show the role of each ROCHE-affiliated entity in any current or future importation, distribution, sale or use of peg-EPO in the United States, including the manufacture, supply, distribution, use, marketing, sale or reimbursement of MIRCERA.

149. Documents and things sufficient to show the role of F. Hoffmann-La Roche Ltd. in any current or future importation, distribution, sale or use of peg-EPO in the United States,

including the manufacture, supply, distribution, use, marketing, sale or reimbursement of MIRCERA.

150. Documents and things sufficient to show the role of Roche Diagnostics GmbH in any current or future importation, distribution, sale or use of peg-EPO in the United States, including the manufacture, supply, distribution, use, marketing, sale or reimbursement of MIRCERA.

151. Documents and things sufficient to show the internal business organization and employee hierarchy of ROCHE from 2000 to the present with respect to the development and commercialization of peg-EPO, including the reporting relationships of officers, managing agents, and employees within ROCHE whose duties and/or responsibilities relate in any way to peg-EPO.

152. Documents and things sufficient to identify each person employed by or affiliated with ROCHE who has or had responsibility relating to peg-EPO, by name, title, employment duties, and area of responsibility, including organizational charts showing the titles, employment duties, and relationships between and among such persons, and any analysis or evaluation relating to the performance of such persons while employed by or affiliated with ROCHE.

153. An electronic copy of any software tool or database that identifies the name, title, responsibility and/or location of each ROCHE employee, contractor and/or consultant whose duties relate in any way to the clinical development, manufacture, supply, inventory, pricing, marketing, advertising, reimbursement, sale or medical support of peg-EPO (including MIRCERA).

154. Documents and things sufficient to identify and describe the goals, milestones, budgets and tasks, for each quarterly and annual period from 2001 through 2008, of each team or

group within ROCHE involved in the preclinical, clinical, regulatory or technical development, manufacture and supply of MIRCERA for sale in the United States.

155. Documents and things sufficient to identify and describe the goals, milestones, budgets and tasks, for each quarterly and annual period from 2001 through 2008, of each team or group within ROCHE involved in the marketing, commercial launch, brand strategy, reimbursement, promotion, or medical education of MIRCERA use in the United States.

156. Documents and things sufficient to show every URL, directory, website structure and home page view of each internal ROCHE website containing any information relating to the clinical development, manufacture, inventory, transfer, marketing, sale, pricing, reimbursement or distribution of peg-EPO (including MIRCERA).

157. Documents and things sufficient to show all directories and menus of MIRCERA-related documents, files and electronic links accessible via ROCHE's internal computer network to each of Phillippe Van der Auwera, Frank C. Dougherty, Michael Jarsch, George Abercrombie, Ute Dugan, Lars Birgerson, Dick Hinson, Barbara Senich, Chrys Kokino, Ken Miller, John Keefe, and George Esgro.

158. Documents and things sufficient to identify, describe and explain ROCHE'S use of enterprise resource planning (ERP) and product lifecycle management (PLM) software and databases in connection with its manufacture, packaging, labeling, inventory, transfer, importation, distribution and sale of peg-EPO in the United States (including MIRCERA).

159. Documents and things sufficient to identify and explain all material master numbers assigned or used by ROCHE to track or record the manufacture, packaging, labeling, inventory, transfer, importation, distribution and sale of peg-EPO (including MIRCERA) in the United States.

160. Documents and things sufficient to show all locations throughout the world at which ROCHE maintains any inventory of peg-EPO and the most current stock levels of peg-EPO (including MIRCERA) at each location by vial or syringe size and quantity.

161. Documents and things sufficient to identify, describe and explain ROCHE'S use of software database systems, including any SAP or PMX system used to track transfers and shipments of peg-EPO to and within the United States.

162. Documents and things sufficient to identify, describe and explain every tabulation of EPO and peg-EPO imported into the United States.

163. Documents and things sufficient to account for the transfer or shipment into the United States and ultimate disposition of all EPO and peg-EPO imported into the United States.

164. For each instance of importation into the United States of any EPO product, including (without limitation) peg-EPO, EPO, or any non-PEG component of peg-EPO, documents and things sufficient to separately describe and account for each importation of such product, including (without limitation):

(a) The location(s) where the EPO or peg-EPO is manufactured;

(b) The date(s) of each importation;

(c) The ROCHE entity that contracted to ship the product to the United States;

(d) The commercial carrier for each importation;

(e) The ROCHE entity that delivered the product to such carrier;

(f) The unit(s) and volume(s) of product(s) imported;

(g) Any customs agent or broker for such importation;

(h) The ROCHE entity receiving the imported product(s);

(i) The port of entry for the imported product(s);

(j) The disposition of all imported product(s) after importation, including (without limitation) identifying each recipient of such product(s), the unit(s) and volume(s) of such product(s) provided to each recipient, the date(s) such product(s) was provided to each recipient, and all purposes for which such product was provided to each recipient;

(k) All uses of such product(s) including the date(s) of use and the unit(s) and volume(s) used; and

(l) All documents recording or reflecting any purpose(s) and use(s) for which any product was consumed or used by ROCHE or any recipient.

165. All documents and things relating to the location(s) and amount(s) of all EPO and peg-EPO in the United States.

166. Documents and things sufficient to show the quarterly and monthly volume of peg-EPO, EPO or any non-peg component of peg-EPO ROCHE plans to import into the United States at any time through December 31, 2008, including United States sales forecasts, manufacturing requirement forecasts (either worldwide or for the United States), and manufacturing schedules and plans.

167. Documents and things sufficient to show how ROCHE plans to use the EPO, peg-EPO, or any non-peg component of peg-EPO to be imported into the United States from January 1, 1995 through December 31, 2008.

168. All documents and things relating to the manufacture and use by Nektar Therapeutics and/or its subsidiary Shearwater of polyethylene glycol that has been or will be used to make peg-EPO including any contract(s), agreement(s), proposal(s), and/or plan(s) relating thereto.

169. All documents and things relating to polyethylene glycol ordered or supplied to ROCHE in the United States (including but not limited to ROCHE's facilities in Nutley, New Jersey) that has been or will be used to manufacture peg-EPO.

170. All documents and things relating to EPO ordered or supplied to ROCHE in the United States (including but not limited to ROCHE's facilities in Nutley, New Jersey) after 1995.

171. All documents and things relating to the manufacture or attempted manufacture of peg-EPO or EPO by or on behalf of ROCHE in the United States after 1995.

172. Documents and things sufficient to show the volume and units of peg-EPO or EPO manufactured in the United States by or for ROCHE after 1995, including the volume and units of peg-EPO or EPO manufactured at ROCHE's facilities in Nutley, New Jersey.

173. All documents and things relating to the peg-EPO or EPO manufacturing, production or purification process developed or refined by or for ROCHE in the United States.

174. All documents and things relating to the transfer of Roche's peg-EPO manufacturing, production or purification process, including transfer of EPO products, from any facility in the United States (including but not limited to ROCHE's facilities in Nutley, New Jersey) to any ROCHE facility outside the United States.

175. All documents and things relating to any contract or agreement between any of the ROCHE defendants or between any of the ROCHE defendants and any third party regarding the importation or transfer of peg-EPO or any non-peg component of peg-EPO in the U.S.

176. All documents and things relating to any existing or proposed understanding or agreement relating to peg-EPO between ROCHE and any person that is not a party to this lawsuit regarding the importation or transfer of peg-EPO or any non-peg component of peg-EPO in the U.S.

177. All documents and things relating to any existing or proposed understanding or agreement relating to peg-EPO between or among any of the ROCHE Defendants, including by or between any of the Roche subsidiaries, affiliates, divisions, parents, and/or otherwise related persons, including any existing or proposed understanding or agreement regarding the transfer of peg-EPO between or among such entities.

178. All documents and things relating to any agreement or contract between or among any of the ROCHE defendants or any of their affiliates regarding the manufacture, use, sale, offer for sale, reimbursement, or transfer of peg-EPO or any component of peg-EPO intended for use in the United States.

179. All documents and things relating to the transfer price of peg-EPO between or amongst the ROCHE Defendants or their subsidiaries, affiliates, parents, agents, and/or otherwise related persons.

180. Documents and things sufficient to identify and describe each transfer of peg-EPO between or among the ROCHE Defendants or their subsidiaries, affiliates, parents, agents, and/or otherwise related persons.

181. All documents and things concerning any document, product, composition, method or event considered by ROCHE to be, to have been, or to relate to prior art to any claim in Amgen's patents-in-suit under 35 U.S.C. §§ 102 or 103.

182. All documents and things comprising or relating to any communication made at any time since 1978 involving Shin Ashida, Joseph Baron, Shyozo Chiba, Harald Conradt, Dale Cumming, R.E. Gaines Das, Margaret Smith Dordal, Dimitrios Emmanouel, Allan Erslev, Joaquin Espada, James Fisher, Edward Fritsch, Minoru Fukuda, Eugene Goldwasser, Masaki Goto, Masamichi Hagiwara, Ken Hayashibara, Yasushi Hayashibara, Rodney Hewick, Hajime Hiratani, Nobuo Imai, Akira Kobata, Charles Kung, Por Lai, Takaji Miyake, Manfred Nimtz,

Ryuzo Sasaki, Judith Sherwood, Daniel Shouval, P.L. Storring, Kaname Sugimoto, Makoto Takeuchi, Kenji Takezawa, Keisuke Toyama or Shin-Ichi Yanagawa relating to erythropoietin.

183. All documents and things comprising or relating to any communication made at any time since 1983 involving any current or former employee of Genetics Institute or any of its successors-in-interest regarding erythropoietin.

184. All documents and things comprising or relating to any communication made at any time since 1983 involving any current or former employee of Chugai Pharmaceutical Co., Ltd., or any of its successors-in-interest regarding erythropoietin.

185. All documents and things comprising or relating to any communication made at any time since 1983 involving any current or former employee of Amgen or Kirin-Amgen regarding erythropoietin.

186. All documents and things comprising or relating to any communication made at any time since 1983 involving any current or former employee of Johnson & Johnson or any of its affiliates regarding erythropoietin.

187. All documents and things concerning any attempt to reproduce, test, or characterize any product, composition, and/or method that ROCHE contends constitutes or relates to prior art to any claim in Amgen's patents-in-suit under 35 U.S.C. §§ 102 or 103.

188. All documents and things relating to any proposal, plan or attempt to obtain or purify erythropoietin from human urine.

189. A representative 10 mg purified bulk sample of any ESP obtained from human urine, and such documents and things as are sufficient to identify the origin, production lot, date of production, composition, characteristics, and all analytical test results of said purified bulk ESP sample.

190. All documents and things relating to testing, analysis, characterization or evaluation of any ESP product or composition derived from human urine, including any characterization or evaluation of its molecular weight, amino acid sequence, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, sulfation, phosphorylation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, or any other physical or functional characteristic.

191. All documents and things relating to any comparison between the molecular weight, amino acid sequence, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, or any other physical or functional characteristic of any ESP product or composition derived from human urine, and the corresponding characteristic(s) of any other ESP, including MIRCERA, NeoRecormon, or any ESP made or sold by Amgen or its licensee(s).

192. All documents and things concerning any activity by or for ROCHE relating to whether any claim in Amgen's patents-in-suit is or is not enabled under 35 U.S.C. § 112.

193. All documents and things concerning any activity by or for ROCHE relating to whether any claim in Amgen's patents-in-suit is or is not adequately described under 35 U.S.C. § 112.

194. All documents and things relating to any contention that Amgen did or did not engage in inequitable conduct while prosecuting the patents-in-suit.

195. All documents and things relating to any contention that Amgen has misused or is misusing any of Amgen's patents-in-suit.

196. All documents and things relating to any contention that Amgen has acted in an anticompetitive manner in regard to its patents-in-suit.

197. All documents and things relating to any investigation, opinion, testing, evaluation, or analysis as to whether any claim of Amgen's patents-in-suit was or is or will be infringed by the manufacture, importation, use, offer for sale, or sale of peg-EPO, including but not limited to oral or written opinions of an attorney (other than investigation(s), opinion(s), testing, evaluation(s), or analysis by counsel of record in this action after ROCHE received notice that the Complaint had been filed in this action), or any other person.

198. All documents and things relating to any investigation, opinion, testing, evaluation, or analysis as to whether any claim in Amgen's patents-in-suit was or is patentable, valid, and/or enforceable, including oral or written opinions of an attorney (other than investigation(s), opinion(s), testing, evaluation(s), or analysis by counsel of record in this action after ROCHE received notice that the Complaint had been filed in this action), or any other person.

199. All documents and things relating to any discussion, analysis, or decision by ROCHE to seek or not to seek a license under any Amgen patent, including the patents-in-suit.

200. All documents and things relating to any effort of ROCHE to avoid infringement of any claim of any Amgen patent, including the patents-in-suit.

201. All documents and things relating to any proposal or plan of ROCHE to modify or alter its manufacture, importation, sale, offer to sell, or use of any ESP, including MIRCERA, to avoid infringement of any claim of any Amgen patent, including the patents-in-suit.

202. All documents and things relating to any ESP studied or evaluated by ROCHE as a potential treatment for anemia which has not been the subject of an IND or BLA filing.

203. All documents and things relating to any use at any time by Genetics Institute, ROCHE, any predecessor-in-interest of ROCHE, or any other person or entity of host cells (other than Chinese hamster ovary cells) to produce erythropoietin, including the selection or creation

of such cells and the production, isolation, testing, analysis, or evaluation of any erythropoietin obtained from such cells.

204. All documents and things relating to testing, analysis, characterization or evaluation of any EPO product or composition derived from cells other than CHO cells, including any characterization or evaluation of its molecular weight, amino acid sequence, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, or any other physical or functional characteristic.

205. All documents and things relating to any comparison between the molecular weight, amino acid sequence, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, or any other physical or functional characteristic of any EPO product or composition derived from cells other than CHO cells, and the corresponding characteristic(s) of any other ESP, including MIRCERA, NeoRecormon, or any ESP made or sold by Amgen or its licensee(s).

206. All documents and things relating to any license or agreement to which ROCHE is a party or successor-in-interest that relates to the manufacture, importation or sale of EPO or peg-EPO in the United States, including all licenses granted by Genetics Institute, Inc. and its successors-in-interest.

207. Documents and things sufficient to show by quarter and by year all payments (including royalties) made by or on behalf of ROCHE to any third party pursuant to any license or agreement that relates to the manufacture, importation or sale of EPO or peg-EPO in the United States, including all payments relating to licenses granted by Genetics Institute, Inc. and its successors-in-interest.

208. All documents and things relating to the prosecution, in any jurisdiction, of Fritsch U.S. patent applications Serial Nos. 06/688,622 and 06/693,258, and any related application or related patent.

209. All documents and things relating to the prosecution, in any jurisdiction, of Hewick U.S. patent application Serial No. 06/690,853 and any related application or related patent.

210. All documents and things relating to the prosecution, in any jurisdiction, of patent applications of Franze et al., U.S. Serial No. 09/555,533, and PCT No. PCT/EP98/07819, and any related application or related patent.

211. All documents and things relating to any litigation, interference, opposition, hearing, re-examination or other proceeding in any jurisdiction relating to Lin U.S. patent application Serial No. 06/675,298 or any related application or related patent, including pleadings, motions, briefs, declarations, exhibits, reports, transcripts, and produced documents.

212. All documents and things relating to any litigation, interference, opposition, hearing, re-examination or other proceeding in any jurisdiction relating to Fritsch U.S. patent application Serial No. 06/688,622 or 06/693,258 or any related application or related patent, including pleadings, motions, briefs, declarations, exhibits, reports, transcripts, and produced documents.

213. All documents and things relating to any patent or patent application relating to peg-EPO that has been or will be filed by or on behalf of ROCHE and/or issued anywhere in the world.

214. All documents and things relating to any patent or patent application relating to peg-EPO that is or is expected to be licensed or assigned to ROCHE.

215. All documents and things relating to the prosecution, in any jurisdiction, of U.S. patent applications of Bailon, Serial Nos. 09/604,938, 60/142,254, 60/150,225, 60/151,548, 60/166,151, and any related application or related patent.

216. All documents and things relating to the prosecution, in any jurisdiction, of U.S. patent applications of Burg et al., Serial Nos. 09/604,871, 60/142,243, 60/147,452, and 60/151,454, and any related application or related patent.

217. All documents and things relating to the prosecution, in any jurisdiction, of patent applications of Franze et al., U.S. Serial No. 09/555,533, and PCT No. PCT/EP98/07819, and any related application or related patent.

218. All documents and things relating to the origin and meaning of each name by which ROCHE refers to peg-EPO, including "CERA," "MIRCERA," "Continuous Erythropoiesis Receptor Activator" and any established name or USAN.

219. All documents and things relating to every proprietary and non-proprietary name Roche considered for peg-EPO.

220. All documents and things relating to any communication between ROCHE and any third party (including FDA) regarding any name for peg-EPO.

221. All documents and things identified, mentioned, otherwise referred to in, or reviewed or consulted during the process of considering or responding to, any interrogatory served on ROCHE by Amgen, heretofore and in the future.

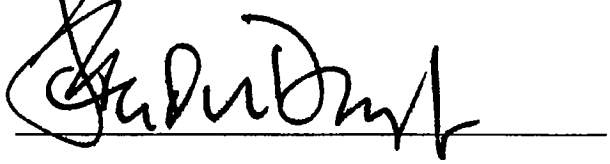
222. All documents and things identified, mentioned, otherwise referred to in, or reviewed or consulted during the process of considering or responding to, a request for admission served on ROCHE by Amgen, heretofore and in the future.

223. All documents and things relating to any communication between ROCHE and Ortho Biotech, Inc., Ortho Pharmaceutical Corporation, Ortho-McNeil Pharmaceutical Inc.,

and/or any other person affiliated with the Johnson & Johnson Company regarding EPO, peg-EPO and/or Amgen's patents-in-suit.

224. Documents sufficient to show each document retention and/or destruction policy and/or practice of ROCHE in effect at any time from 1995 to the present, including the date(s) such policies or practices were in effect.

AMGEN INC.,
By its attorneys,



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October 30, 2006

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 federal express overnight delivery and electronic mail on the above date.

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Sandya Rajagopalan

EXHIBIT A

Role of Competition in the Pharmaceutical Market and its Potential Impact in the ESRD Program

April 25, 2006

Role of Competition in the Pharmaceutical Market and its Potential Impact in the ESRD Program

I. Introduction

Research shows that competition plays an important role in stimulating innovation in pharmaceutical product development and can have a significant impact on overall healthcare spending. Innovation also helps to expand access to new patients as a result of research that targets clinical indications representing an unmet healthcare need. In the area of erythropoietin stimulating agents (ESAs), a new, innovative product being developed offers the potential to lower costs and potentially expand access to new patient groups by stimulating price competition in a therapeutic area that has been dominated by one company since 1989.[1] While the company developed a new ESA in 2001, the competitive effects typically seen with the introduction of a new product have been limited, possibly as a result of the monopoly status of the product manufacturer.[2]

This paper was developed to show the important role that the introduction of a new manufacturer and a new product can have in stimulating price competition in a therapeutic class that has been dominated by one manufacturer. Given the structure of the ESRD marketplace and the segmentation of the ESA market by type of use, it is critical that the current approach of distinguishing Healthcare Common Procedure Coding System (HCPCS) product codes by type of use be continued and that an average sales price (ASP) be calculated for each product and type of use. While this approach may seem counterintuitive, it is understandable in the context of the unique situation where Medicare is the predominant single payer for ESRD services and the dialysis market is concentrated among two provider organizations who account for 70 percent of the market. The lack of ESA price competition in the ESRD market can be contrasted with the competition that was stimulated in the non-ESRD market where Procrit® and Aranesp® compete based on several factors, including price. Amgen's introduction of Aranesp® into the non-ESRD market stimulated a competitive response from Ortho Biotech indicating the value of having more than one manufacturer operating in a therapeutic segment. While Aranesp® was approved for use initially for dialysis patients, it has not stimulated the same competitive response in the ESRD market, indicating the monopoly power of one company with a two-product advantage.

II. Current Status of ESA Payment and Potential for Competition

ESAs play a critical role in treating anemia, which is a frequent complication of chronic kidney disease (CKD) and end-stage renal disease (ESRD), particularly for patients who receive hemodialysis. Recombinant human erythropoietin (EPO) is the principal treatment for anemia.[3] In fact, between 80 and 90 percent of Medicare beneficiaries

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[1] Greer, et al. Trends in Use, Cost, and Outcomes of Human Recombinant Erythropoietin, 1989-98, *Health Care Financing Review*. Spring 1999. 20:55.
[2] Commercial Perspectives: Drug Treatment in End-Stage Renal Disease The Price of Failure, *Data Monitor*, January 18, 2006.
[3] Lenz, et al, Barriers to successful care for chronic kidney disease, *BMC Nephrology* 2005, October 27 2005.