Document 172-6

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UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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

AMGEN INC.'S OBJECTIONS AND RESPONSES TO DEFENDANTS' FIRST SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-123)

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiff/Counterdefendant Amgen Inc. ("Amgen") hereby responds to "Defendants' First Set of Requests for the Production of Documents and Things to Amgen, Inc. (Nos. 1-123)."

PRELIMINARY STATEMENT

Amgen has not completed its discovery, investigation, research, or trial preparation. The following responses are based solely on the information that is presently available and specifically known to Amgen. Amgen provides the following responses without prejudice to its right to produce evidence of any subsequently-discovered documents or facts. Amgen reserves the right to supplement the following responses and to change any and all responses therein as additional documents are discovered or facts are ascertained. Finally, Amgen's objections as set forth herein are made without prejudice to Amgen's right to assert any additional or supplemental objections should additional grounds for such objections become apparent.

Amgen makes the objections and responses set forth below without in any manner waiving: (1) the right to object to the use of any response, document or thing for any purpose in this action or any other actions on grounds of privilege, relevancy, materiality or any other appropriate basis; (2) the right to object to any other interrogatories or Requests involving or relating to the subject matter of the responses herein and any documents or things produced by Amgen; and (3) the right to revise, correct, supplement, or clarify any of the responses provided below at any time. Amgen expressly reserves the right to supplement its responses and production of documents and things.

GENERAL OBJECTIONS

1. These General Objections are hereby incorporated by reference into the responses made with respect to each separate request. Neither the inclusion of any Specific Objection in response to a request, nor the failure to include any General Objection or Specific Objection in response to a request shall in any way be deemed as a waiver of any general objection made herein or that may be asserted at another date.

- 2. Amgen objects to each Request to the extent that Defendants seek production of information protected from disclosure by the attorney-client privilege, the work product immunity, or any other lawfully recognized privilege or immunity, including statements made under the protection of a joint defense agreement. Amgen will not produce such information in response to Defendants' First Set of Document Requests, and any inadvertent production thereof shall not be deemed a waiver of any privilege or work product rights with respect to such documents or things. Moreover, in every Response in which Amgen has agreed to provide non-privileged documents, Amgen defines "non-privileged documents" to exclude any documents (and electronic data) concerning information protected by the attorney-client privilege, work product immunity, or other privilege or immunity.
- 3. Amgen objects to each Definition, Instruction, and Request to the extent that Defendants seek to impose upon Amgen any requirement or discovery obligation greater than or different from those under the Federal Rules of Civil Procedure, the Local Rules for the United States District Court for the District of Massachusetts, or any Order of the Court in this action. In every response in which Amgen has agreed to provide documents, subject to its General Objections and any Specific Objections, Amgen will conduct a reasonable search for and produce relevant, responsive, non-privileged documents to the extent that any exist, are in Amgen's possession, custody, or control, and have not been previously produced in this action (pursuant to the Court's November 6, 2006, Order, at 6, Court Docket No. 142, discovery produced by the parties in the ITC action is deemed to have been produced in this action).
- 4. Amgen objects to each Definition, Instruction, and Request to the extent that Defendants might give meaning to a word different from its ordinary English meaning or definitions set forth in applicable statutes or rules.

- 5. Amgen objects to each Definition, Instruction, or Request to the extent that Defendants request Amgen to produce information that is publicly available or is as equally accessible to Defendants as it is to Amgen as being unduly burdensome.
- 6. Amgen objects to each Request, specifically Requests Nos. 27-31, to the extent that those requests seek information relating to U.S. and foreign patents and/or applications, that are neither asserted in this action nor related to any patent asserted in this action. Accordingly, Amgen objects to those Requests as overly broad, unduly burdensome, calling for production of documents irrelevant to any claim or defense in this action, and not reasonably calculated to lead to the discovery of admissible information.
- Amgen objects to each Request to the extent that it is directed to allegations which are the subject matter of one or more of Defendants' non-patent counterclaims on the grounds that such Requests are premature. See, e.g., Request Nos. 2, 3, 43, 60-66, 70-74, 76, 79, 80, 104, 114, 116-118, 120, and 121. Whether or not such allegations are at issue in this action remains to be decided on the basis of Amgen's pending motion to dismiss Defendants' counterclaims. The Court's ruling on Amgen's motion to dismiss may render such Requests irrelevant, moot, and/or unrelated to any pending claim in this action. However, in the interest of expediency, Amgen is setting forth its responses to such Requests should the Defendants' corresponding counterclaim(s) or a legally sufficient version thereof be maintained in the action. If Amgen's motion to dismiss a challenged counterclaim is denied, and/or Defendants serve and file an amended, legally sufficient counterclaim that is no longer subject to an Amgen motion to dismiss, Amgen will produce responsive documents, if any, in accordance with its responses to such Requests.

- 8. Amgen objects to Definition No. 1 of Defendants' First Set of Document Requests and each Request that incorporates that definition to the extent Defendants' definition of "Amgen" requests production of documents and electronic data that are not within Amgen's possession, custody, or control.
- 9. Amgen objects to Definition Nos. 8 and 10 of the terms "Documents" and "Electronic Data," respectively, and each Request that recites those terms to the extent that Defendants seek to impose upon Amgen any requirement or discovery obligation greater than or different from those under the Federal Rules of Civil Procedure (e.g., Fed. R. Civ. P. 34), the Local Rules for the United States District Court for the District of Massachusetts, or any Order of the Court in this action. Amgen is currently negotiating with the Defendants a mutually-agreeable format for the production of documents and electronic data. See, for example, letter from Deborah E. Fishman (Amgen's counsel) to Thomas F. Fleming (Defendants' counsel) dated November 30, 2006, proposing a format for the parties' production of documents and electronic data.
- 10. Amgen objects to Definition No. 16 of Defendants' First Set of Document Requests defining "Erythropoiesis Stimulating Agent" or "ESA" as "any substance, drug or pharmaceutical composition that is capable of stimulating the production of red blood cells by bone marrow," and to each Request reciting those terms or adopting that definition. To the extent that definition and those Requests seek to encompass information concerning substances, drugs or pharmaceutical compositions that are not within the subject matter claimed in the patents which Amgen asserts in this action, the prior art, or Defendants' definition of any market, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Insofar as Roche seeks to rely on its definition of "ESA" to request production of documents relevant to the enforcement of Amgen's asserted patent claims against

infringing products, it is irrelevant, overbroad, burdensome and unlikely to lead to the discovery of admissible evidence because Roche's definition would include an unlimited universe of undefined substances other than erythropoietin or compositions comprising erythropoietin.

Insofar as Roche seeks to rely on the definition of "ESA" to seek production of documents relevant to product(s) that may be clinically substituted for erythropoietin to treat anemia,

Amgen objects that Roche's definition is overbroad and ambiguous.

- 11. Amgen objects to Definition No. 17 of Defendants' First Set of Document Requests and each Request that incorporates that definition to the extent Defendants' definition of "Pegylated Compounds" encompasses "any substance, drug or pharmaceutical incorporating into its chemical structure one or more polyethylene glycol polymers," and is not limited to pegylated substances, drugs or pharmaceuticals that are the subject matter described in the patents which Amgen asserts in this action or encompassed by some other defense or claim in this action, on the grounds that the Definition and corresponding Requests are overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.
- 12. Amgen objects to Definition No. 21 of Defendants' First Set of Document Requests and each Request that incorporates that definition to the extent Defendants' definition of "Health Care Provider" on the grounds that it is overly broad in that it encompasses "any person or Entity providing health care services" without restriction and is not limited to subject matter described in the patents which Amgen asserts in this action or encompassed by some other defense or claim in this action.
- 13. Amgen objects to Instruction No. 3 of Defendants' First Set of Document Requests and each Request that incorporates that instruction to the extent that Defendants request Amgen to state "[w]henever a Request calls for information which is not available to Amgen in the form

requested, but is available in another form or can be obtained, at least in part, from other data in Amgen's possession," on the grounds that Defendants seek to impose upon Amgen a requirement or discovery obligation greater than or different from those under the Federal Rules of Civil Procedure, the Local Rules for the United States District Court for the District of Massachusetts, or any Order of the Court in this action. To the extent that Defendants request information that "is not available to Amgen in the form requested, but is available in another form or can be obtained, at least in part, from other data in Amgen's possession," and Amgen agrees to produce relevant, responsive, non-privileged documents in response to Defendants' Requests, Amgen does not thereby agree or undertake to identify each corresponding occurrence, and will simply produce to Defendants relevant, responsive, non-privileged documents.

- 14. Amgen objects to Instruction No. 5 and each Request incorporating that definition as overbroad, unduly burdensome and harassing to the extent Defendants seek production of over twenty-five years' worth of documents and electronic data "originated in whole or in part . . . at any time during the period of 1980 through the date of your production."
- 15. Amgen objects to Instruction No. 7 of Defendants' First Set of Document Requests and each Request that incorporates that instruction to the extent that Defendants seek to impose upon Amgen a requirement or discovery obligation greater than or different from those under the Federal Rules of Civil Procedure (e.g., Fed. R. Civ. P. 26), the Local Rules for the United States District Court for the District of Massachusetts, or any Order of the Court in this action.

Subject to the foregoing General Objections, and without waiver of these objections, Amgen responds as follows:

OBJECTIONS AND RESPONSES TO DEFENDANTS' REQUESTS

REQUEST FOR PRODUCTION NO. 1:

All Documents and Electronic Data that support the allegations that form the basis of the complaint filed by Amgen in <u>Amgen, Inc. v. F. Hoffmann-La Roche Ltd, Roche Diagnostics</u> <u>GmbH, and Hoffmann-La Roche, Inc.</u>, C.A. No. 05-cv-12237WGY, D. Mass (Nov. 8, 2005).

RESPONSE:

Subject to and without waiver of its General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 2:

All Documents and Electronic Data that support the allegations that form the basis of the Verified Complaint of Amgen Inc. under Section 337 of the Tariff Act of 1930, as Amended, filed with the International Trade Commission on April 11, 2006, In the Matter of: Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin.

RESPONSE:

Subject to and without waiver of its General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 3:

All Documents sufficient to identify all requests for an investigation by the International Trade Commission in <u>In the Matter of: Certain Products and Pharmaceutical Compositions</u>
<u>Containing Recombinant Human Erythropoietin</u>, filed April 11, 2006.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data already in Defendants' possession. For example, Defendants' already possess copies of Amgen's complaint filed in the ITC in connection with the ITC action

on April 11, 2006, and Amgen's amended complaint filed in the ITC in connection with the ITC action on April 27, 2006.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 4:

All Documents and Electronic Data which Amgen relied upon and intends to rely upon in the proceeding before the International Trade Commission and the appeal therefrom, <u>In the Matter of: Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin</u>, first filed April 11, 2006.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 5:

All Documents and Electronic Data Concerning the preparation and/or prosecution of all Patent Applications for Amgen's EPO Patents and any related Patent Applications, Including any internal invention disclosures related to Amgen's EPO Patents, any communications to and from the PTO related to the prosecution of Amgen's EPO Patents, all documents related to any communications to and from the PTO related to the prosecution of Amgen's EPO Patents, and all documents provided to outside counsel in connection with Amgen's EPO Patents.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 6:

All Documents and Electronic Data relating to any Information Disclosure Statement Concerning the prosecution of any of the Patent Applications for Amgen's EPO Patents,

Including any prior art reviewed and/or considered in connection with said Information Disclosure Statement, and any documents related in any way to such prior art.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 7:

All Documents and Electronic Data Concerning any prior art reviewed, known to, or considered by any patent agent, attorney, inventor, or declarant involved in any way with the prosecution of the Patent Applications for Amgen's EPO Patents. Including any document related in any way to such prior art.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 8:

All Documents and Electronic Data Concerning any communication, investigation, study, evaluation, and/or opinion Concerning any declaration prepared and/or filed in connection with the prosecution of Amgen's EPO patents, including any documents Concerning the drafting of such declaration, including any draft of such declaration.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 9:

All Documents and Electronic Data, Including laboratory notebooks, data, internal memoranda, meeting minutes, and correspondence Concerning the subject matter claimed in Amgen's EPO Patents Including without limitation the specific examples disclosed in Amgen's EPO Patents and any product made by Amgen utilizing the methods and/or processes described in Amgen's EPO Patents.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of "All Documents and Electronic Data . . . Concerning the subject matter claimed in Amgen's EPO patents," it encompasses every document relating to erythropoietin ever created at Amgen. Amgen, therefore, objects to this Request on grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents. Amgen is willing to negotiate with Defendants regarding narrowing this Request to a reasonable scope.

REQUEST FOR PRODUCTION NO. 10:

All Documents and Electronic Data Concerning any work of Fu-Kuen Lin and/or his researchers or assistants, that refers to or relates to the subject matter disclosed or claimed in any of Amgen's EPO Patents.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 11:

All Documents and Electronic Data Concerning the preparation and/or prosecution of any non-U.S. patents or Patent Applications for Amgen's EPO Patents, and any related Patent Applications.

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 12:

All prior art to the subject matter claimed in Amgen's EPO Patents or any U.S. or non-U.S. patents or Patent Applications corresponding in whole or in part to such patents and any related Patent Applications, Including prior art cited or referred to during the preparation or prosecution of such patents or Patent Applications.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 13:

All Documents and Electronic Data Concerning the alleged conception of each invention claimed or described in Amgen's EPO Patents.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 14:

All Documents and Electronic Data Concerning the alleged reduction to practice of each invention claimed or described in Amgen's EPO Patents.

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 15:

All Documents and Electronic Data Concerning the patentability of the subject matter of the inventions claimed in Amgen's EPO Patents, Including without limitation: any search for U.S. or foreign patents, patent applications or literature regarding expression or production of erythropoietin; and any search, study or investigation of the patentability of an erythropoietin coding sequence or cells expressing erythropoietin.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 16:

All Documents and Electronic Data Concerning any investigation, study, evaluation or opinion Concerning prior art to Amgen's EPO Patents.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 17:

All Documents and Electronic Data Concerning any investigation, study, evaluation or opinion Concerning the infringement, validity, or enforceability of Amgen's EPO Patents.

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 18:

All Documents and Electronic Data Concerning any communications with Fu-Kuen Lin and/or his researchers or assistants, that Concern the subject matter disclosed or claimed in Amgen's EPO Patents.

RESPONSE:

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 19:

All Documents and Electronic Data Concerning any communications with Lawrence Souza and/or his researchers or assistants, that Concern the subject matter disclosed or claimed in Amgen's EPO Patents, or to the design, development and manufacture of pegylated erythropoietin or pegylated G-CSF.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data concerning "the design, development and manufacture of . . . pegylated G-CSF" on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen will produce relevant, responsive, non-privileged documents regarding erythropoietin.

REQUEST FOR PRODUCTION NO. 20:

All Documents and Electronic Data Concerning any communications with Joan C. Egrie and/or her researchers or assistants, that Concern the subject matter disclosed or claimed in Amgen's EPO Patents, or to the design development and manufacture of any erythropoiesis stimulating agent other than human erythropoietin, or to the design, development and manufacture of any Pegylated Compound.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data concerning "the design development and manufacture of any erythropoiesis stimulating agent" or "any Pegylated Compound" other than erythropoietin, on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 21:

All Documents and Electronic Data Concerning any communications with Stephen Elliott and/or his researchers or assistants, that Concern the subject matter disclosed or claimed in Amgen's EPO Patents.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request, to the extent that it seeks all communications with Stephen Elliott regarding the subject matter claimed in Amgen's EPO patents (e.g, <u>all</u> communications relating to Epogen®), on grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents. Amgen is willing to negotiate with Defendants regarding narrowing this Request to a reasonable scope of documents relevant to a claim or defense in this action.

REQUEST FOR PRODUCTION NO. 22:

All Documents and Electronic Data, Including meeting minutes and project reports Concerning Amgen's EPO Patents, and/or any of the subject matter disclosed or claimed therein.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of "All Documents" and Electronic Data . . . Concerning Amgen's EPO Patents, and/or any of the subject matter disclosed or claimed therein," it encompasses every document relating to erythropoietin ever created at Amgen. Amgen, therefore, objects to this Request on grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 23:

All Documents and Electronic Data Concerning any scientific publications, posters, conferences, meetings, symposiums or gatherings prepared or attended by Fu-Kuen Lin and/or his researchers or assistants that Concern, in any way, the subject matter claimed or disclosed in any of the asserted claims of Amgen's EPO Patents, Including all papers, slides, abstracts, speeches, outlines, or notes made or submitted by or on behalf of such individuals.

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 24:

All Documents and Electronic Data Concerning any submissions to or communications with the United States Food and Drug Administration (FDA) by or on behalf of Amgen, with respect to any ESA, Including epoetin alfa, marketed and sold under the brand names Epogen®. Procrit®, Eprex®, and Erypo®, and darbepoetin alfa, marketed and sold under the brand name Aranesp®.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any submissions to or communications with the ... FDA ... with respect to any ESA" other than "epoetin alfa, marketed and sold under the brand names Epogen®, Procrit®, Eprex®, and Erypo®," it is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. To the extent that this Request also seeks production of "all" documents and electronic data concerning "any submissions to or communications with" the FDA with respect to epoetin alfa, it is overly broad and unduly burdensome. Amgen does not understand how the requested scope of documents is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference. Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REOUEST FOR PRODUCTION NO. 25:

All Documents and Electronic Data Concerning any submissions to or communications with any government agency or department which regulates drugs or biologics outside the United States by or on behalf of Amgen, with respect to any ESA, Including epoetin alfa, marketed and sold under the brand names Epogen®, Procrit®, Eprex®, and Erypo®, and darbepoetin alfa, marketed and sold under the brand name Aranesp®.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any submissions to or communications with any government agency or department which regulates drugs or biologics outside the United States ... with respect to any ESA" other than "epoetin alfa, marketed and sold under the brand names Epogen®, Procrit®, Eprex®, and Erypo®," it is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. To the extent that this Request also seeks production of "all" documents and electronic data concerning "any submissions to or communications with any government agency or department which regulates drugs or biologics outside of the United States" with respect to "epoetin alfa," it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Amgen does not understand how the requested scope of documents is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference. Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 26:

All Documents and Electronic Data Concerning communications between Amgen or any of its employees, agents, designees, directors or consultants, and any regulatory agency responsible for approval of drugs for use in humans, Including the FDA and the EMEA, wherein said communications mention CERA or any compound having erythropoiesis stimulating activity sponsored by Roche.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request on grounds that "sponsored by Roche" is vague and ambiguous. Amgen also objects to this Request, to the extent it seeks documents concerning "any compound having erythropoiesis stimulating activity" other than CERA as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, and to the extent that the Request refers to compounds for which Roche has sought approval as a "sponsor," Amgen responds as follows: Amgen will produce relevant, responsive, non-privileged documents found after a reasonable search.

REQUEST FOR PRODUCTION NO. 27:

All Documents and Electronic Data Concerning the preparation and/or prosecution of any Patent Application Concerning the following patents, and all Documents and Electronic Data Concerning the preparation and/or prosecution of any non-U.S. patents or Patent Applications corresponding in whole or in part to such patents:

1. U.S. Patent No. 5,264,209, titled "Modified HIL-6";

- 2. U.S. Patent No. 5,747,639, titled "Use of Hydrophobic Interaction" Chromatography to Purify Polyethylene Glycols";
- 3. U.S. Patent No. 5,766,581, titled "Method for Treating Mammals with Monopegylated Proteins that Stimulates Megakaryocyte Stimulation and Differentiation";
- 4. U.S. Patent No. 5,770,577, titled "BDNF and NT-3 Polypeptides Selectively Linked to Polyethylene Glycol";
- 5. U.S. Patent No. 5,795,569, titled "Mono-Pegylated Proteins that Stimulate Megakaryocyte Growth and Differentiation";
- 6. U.S. Patent No. 5,824,778, titled "Chemically-Modified G-CSF":
- 7. U.S. Patent No. 5,824,784, titled "N-Terminally Modified Protein Compositions and Methods";
- 8. U.S. Patent No. 5,856,298, titled "Erythropoietin Isoforms";
- 9. U.S. Patent No. 5,935,964, titled "Use of Hydrophobic Interaction Chromatography to Purify Polyethylene Glycols";
- 10. U.S. Patent No. 5,985,265, titled "N-Terminally Modified Protein Compositions" and Methods";
- 11. U.S. Patent No. 6,166,183, titled "Chemically Modified G-CSF";
- 12. U.S. Patent No. 6,420,339, titled "Site-Directed Dual Pegylation of Proteins for Improved Bioactivity and Biocompatibility";
- 13. U.S. Patent No. 6,420,340, titled "Chemical Modification of Proteins to Improve Biocompatibility and Bioactivity";
- 14. U.S. Patent No. 6,433,158, titled "Site Specific Protein Modification":
- 15. U.S. Patent No. 6,441,136, titled "Site Specific Protein Modification";
- U.S. Patent No. 6,451,986, titled "Site Specific Protein Modification"; 16.
- 17. U.S. Patent No. 6,548,644, titled "Site Specific Protein Modification";
- 18. U.S. Patent No. 6,552,170, titled "Pegylation Reagents and Compounds Formed Therewith";
- 19. U.S. Patent No. 6,565,841, titled "Pulmonary Administration of Granulocyte Colony Stimulating Factor";

- 20. U.S. Patent No. 6,586,398, titled "Chemically Modified Novel Erythropoietin Stimulating Protein Compositions and Methods";
- 21. U.S. Patent No. 7,090,835, titled "N-Terminally Chemically Modified Protein Compositions and Methods."

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents concerning patents which Amgen has not asserted in this action, and are unrelated to the patents which Amgen has asserted in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding the prosecution of U.S. Patent Nos. 5,856,298 and 7,090,835.

REQUEST FOR PRODUCTION NO. 28:

All Documents and Electronic Data Concerning the preparation and/or prosecution of any Patent Application Concerning the following patents, and all Documents and Electronic Data Concerning the preparation and/or prosecution of any U.S. patents or Patent Applications corresponding in whole or in part to such patents:

- 1. European Patent No. EP 0726778 B1, titled, "Oral Delivery System of Chemically Modified Proteins G-CSF":
- 2. European Patent No. EP 0428267, titled "Erythropoietin Isoforms";
- European Patent No. EP 0640619, titled "Erythropoietin Analogs with Additional 3. Glycosylation Sites":
- 4. European Patent No. EP 0822199, titled "N-Terminally Monopegylated" Polypeptides and Process for Their Preparation."

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks documents concerning patents which Amgen has not asserted in this action, and are unrelated to the patents which Amgen has asserted in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding the prosecution of European Patent No. EP 0428267.

REQUEST FOR PRODUCTION NO. 29:

All Documents and Electronic Data Concerning the alleged conception and reduction to practice of each invention claimed or described in the United States patents listed in Request for Production No. 27.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks documents concerning patents and "invention claimed or described" in those patents which Amgen has not asserted in this action, and are unrelated to the patents which Amgen has asserted in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

REQUEST FOR PRODUCTION NO. 30:

All Documents and Electronic Data Concerning the alleged conception and reduction to practice of each invention claimed or described in the foreign patents listed in Request for Production No. 28.

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks documents concerning patents and "invention claimed or described" in those patents which Amgen has not asserted in this action, and are unrelated to the patents which Amgen has asserted in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

REQUEST FOR PRODUCTION NO. 31:

All Documents and Electronic Data Concerning any pending United States or foreign Patent Application relating to any ESA and/or any Pegylated Compounds or related methods.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA" and/or "any Pegylated Compounds" other than erythropoietin, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 32:

All Documents and Electronic Data Concerning the preparation and publication of the following articles, Including all drafts, underlying data and lab notebooks, and all communications referring or relating thereto:

1. Ankeny, et al., PEGYLATED BRAIN-DERIVED NEUROTROPHIC FACTOR SHOWS IMPROVED DISTRIBUTION INTO THE SPINAL CORD AND

- STIMULATES LOCOMOTOR ACTIVITY AND MORPHOLOGICAL CHANGES AFTER INJURY, Exp. Neurol. 170, 85 - 100 (2001)
- 2. Archimbaud, et al., A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY WITH PEGYLATED RECOMBINANT HUMAN MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR (PEG-RHUMGDF) AS AN ADJUNCT TO CHEMOTHERAPY FOR ADULTS WITH DE NOVO ACUTE MYELOID LEUKEMIA, Blood 94, 3694-3701 (1999)
- 3 Basser, et al., RANDOMIZED, BLINDED, PLACEBO-CONTROLLED PHASE I TRIAL OF PEGYLATED RECOMBINANT HUMAN MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR WITH FILGRASTIM AFTER DOSE-INTENSIVE CHEMOTHERAPY IN PATIENTS WITH ADVANCED CANCER, Blood 89, pp 3118 -28 (1997)
- 4. Beveridge, et al., IMPACT OF LONG-ACTING GROWTH FACTORS ON PRACTICE DYNAMICS AND PATIENT SATISFACTION, Pharmacotherapy 23, 101S - 109S (2003)
- 5. Bukowski, et al., POLYETHYLENE GLYCOL CONJUGATED INTERLEUKIN-2: CLINICAL AND IMMUNOLOGIC EFFECTS IN PATIENTS WITH ADVANCED RENAL CELL CARCINOMA, Investigational New Drugs 11, pp 211 - 17 (1993)
- 6. Callahan, et al., SODIUM CHLORIDE ENHANCES THE STORAGE AND CONFORMATIONAL STABILITY OF BDNF AND PEG-BDNF, Pharm, Res. 18, pp 261 - 266 (2001)
- 7. Crawford, ONCE-PER-CYCLE PEGFILGRASTIM (NEULASTA) FOR THE MANAGEMENT OF CHEMOTHERAPY-INDUCED NEUTROPENIA, Seminars in Oncology 30 (Suppl. 13), 24 - 30 (2003)
- 8. Crawford, CLINICAL USES OF PEGYLATED PHARMACEUTICALS IN ONCOLOGY, Cancer Treatment Rev. 28 (Suppl. A.), 7 - 11 (2002)
- 9. De Boer, et al., PHARMACOKINETIC ANALYSIS OF PEGYLATED MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR IN HUMANS, Growth Factors 18, pp 215 - 226 (2000)
- 10. Fanucchi, et al., EFFECTS OF POLYETHYLENE GLYCOL-CONJUGATED RECOMBINANT HUMAN MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR ON PLATELET COUNTS AFTER CHEMOTHERAPY FOR LUNG CANCER, N.E.J.M. 336, pp 404 - 409 (1997)
- 11. Farese, et al., HEMATOPOIETIC RECOVERY FOLLOWING AUTOLOGOUS BONE MARROW TRANSPLANTATION IN A NONHUMAN PRIMATE: EFFECT OF VARIATION IN TREATMENT SCHEDULE WITH PEG-RHUMGDF, Stem Cells 21, pp 79 - 89 (2003)

- 12. Green, et al., A RANDOMIZED DOUBLE-BLIND MULTICENTER PHASE III STUDY OF FIXED-DOSE SINGLE-ADMINISTRATION PEGFILGRASTIM VERSUS DAILY FILGRASTIM IN PATIENTS RECEIVING MYELOSUPPRESSIVE CHEMOTHERAPY, Annals of Oncology 14, 29 - 35 (2003)
- 13. Guerra, et al., PEGYLATION PREVENTS THE N-TERMINAL DEGRADATION OF MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR, Pharm. Res. 15, pp 1822 - 1827 (1998)
- 14. Harker, et al., EFFECTS OF MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR ON PLATELET PRODUCTION, PLATELET LIFE SPAN, AND PLATELET FUNCTION IN HEALTHY HUMAN VOLUNTEERS, Blood 95, pp 2514 - 22 (2000)
- 15. Harker, et al., PREVENTION OF THROMBOCYTOPENIA AND NEUTROPENIA IN A NONHUMAN PRIMATE MODEL OF MARROW SUPPRESSIVE CHEMOTHERAPY BY COMBINING PEGYLATED RECOMBINANT HUMAN MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR AND RECOMBINANT HUMAN GRANULOCYTE COLONY-STIMULATING FACTOR, Blood 89, pp 155 -165 (1997)
- 16. Harker, et al., DOSE-RESPONSE EFFECTS OF PEGYLATED HUMAN MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR ON PLATELET PRODUCTION AND FUNCTION IN NONHUMAN PRIMATES. Blood 88, pp 511 - 21 (1996)
- 17. Jensen-Pippo, et al., ENTERAL BIOAVAILABILITY OF HUMAN GRANULOCYTE COLONY STIMULATING FACTOR CONJUGATED WITH POLY(ETHYLENE GLYCOL), Pharm. Res. 13, pp 102 - 107 (1996)
- 18. Kendrick, et al., ONLINE SIZE-EXCLUSION HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY LIGHT SCATTERING AND DIFFERENTIAL REFRACTOMETRY METHODS TO DETERMINE DEGREE OF POLYMER CONJUGATION TO PROTEINS AND PROTEIN-PROTEIN OR PROTEIN-LIGAND ASSOCIATION STATES, Analytical Biochemistry 299, pp 136 - 146 (2001)
- 19. Kerwin, et al., INTERACTIONS BETWEEN PEG AND TYPE I SOLUBLE TUMOR NECROSIS FACTOR RECEPTOR: MODULATION BY pH AND BY PEGYLATION AT THE N TERMINUS, Protein Science 11, pp 1825 - 1833 (2002)
- 20. Kerwin, et al., INTERACTIONS BETWEEN PEG AND TYPE I SOLUBLE TUMOR NECROSIS FACTOR RECEPTOR: MODULATION BY pH AND BY PEGYLATION AT THE N TERMINUS, Protein Science 11, pp 1825 - 1833 (2002)

- 21. Kinstler, et al., MONO-N-TERMINAL POLY(ETHYLENE GLYCOL)-PROTEIN CONJUGATES, Adv. Drug Deliv. Rev. 54, pp 477 485 (2002)
- 22. Kinstler, et al., CHARACTERIZATION AND STABILITY OF N-TERMINALLY PEGYLATED rhG-CSF, Pharm. Res. 13, pp 996 1002 (1996)
- 23. Long, et al., DESIGN OF HOMOGENEOUS, MONOPEGYLATED ERYTHROPOIETIN ANALOGS WITH PRESERVED IN VITRO BIOACTIVITY, Exp. Hematol. 34, pp 697 704 (2006)
- 24. Lord, et al., KINETICS OF NEUTROPHIL PRODUCTION IN NORMAL AND NEUTROPENIC ANIMALS DURING THE RESPONSE TO FILGRASTIM (r-metHu G-CSF) OR FILGRASTIM SD/01 (PEG-r-metHu G-CSF), Clinical Cancer Res. 7, 2085 90 (2001)
- 25. Molineux, PEGFILGRASTIM: USING PEGYLATION TECHNOLOGY TO IMPROVE NEUTROPENIA SUPPORT IN CANCER PATIENTS, Anti-Cancer Drugs 14, 259 264 (2003)
- 26. Molineux, PEGYLATION: ENGINEERING IMPROVED
 BIOPHARMACEUTICALS FOR ONCOLOGY, Pharmacotherapy 23, 3S 8S
 (2003)
- 27. Molineux, et al., A NEW FORM OF FILGRASTIM WITH SUSTAINED DURATION IN VIVO AND ENHANCED ABILITY TO MOBILIZE PBPC IN BOTH MICE AND HUMANS, Experimental Hematology 27, pp 1724 34 (1999)
- 28. Molineux, et al., AN ANALYSIS OF THE EFFECTS OF COMBINED TREATMENT WITH RMGM-CSF AND PEG-RHUMGDF IN MURINE BONE MARROW TRANSPLANT RECIPIENTS, Stem Cells 15, pp 43 49 (1997)
- 29. Molineux, et al., MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR ACCELERATES PLATELET RECOVERY IN PERIPHERAL BLOOD PROGENITOR CELL TRANSPLANT RECIPIENTS, Blood 88, pp 366 376 (1996)
- 30. Molineux, et al., MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR STIMULATES ENHANCED PLATELET RECOVERY IN MICE AFTER BONE MARROW TRANSPLANTATION, Blood 88, pp 1509 1514 (1996)
- 31. Morstyn, et al., FILGRASTIM (r-met Hu G-CSF) IN THE 21ST CENTURY: SD/01, Acta Haematol. 105, 151 55 (2001)
- 32. Nichol et al., MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR ANALYSES OF IN VITRO EFFECTS ON HUMAN MEGAKARYOPOIESIS AND ENDOGENOUS SERUM LEVELS DURING

- CHEMOTHERAPY-INDUCED THROMBOCYTOPENIA. J. Clin. Invest. 95. pp 2973 - 2978 (1995)
- 33. Niven, et al., THE PULMONARY ABSORPTION OF AEROSOLIZED AND INTRATRACHEALLY INSTILLED rhG-CSF AND MONOPEGYLATED rhG-CSF, Pharm. Res. 12, pp 1343 - 1349 (1995)
- 34. O'Malley et al., ADMINISTRATION OF PEGYLATED RECOMBINANT HUMAN MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR TO HUMANS STIMULATES THE PRODUCTION OF FUNCTIONAL PLATELETS THAT SHOW NO EVIDENCE OF IN VIVO ACTIVATION, Blood 88, pp 3288 - 3298 (1996)
- Pettit, et al., STRUCTURE-FUNCTION STUDIES OF INTERLEUKIN 15 35. USING SITESPECIFIC MUTAGENESIS, POLYETHYLENE GLYCOL CONJUGATION, AND HOMOLOGY MODELING, J. Biol. Chem. 272, 2312 -2318 (1997)
- 36. Rajan, et al., MODULATION OF PROTEIN AGGREGATION BY POLYETHYLENE GLYCOL CONJUGATION: GCSF AS A CASE STUDY, Protein Sci. 15, pp 1063 -1075 (2006)
- 37. Sarkar, et al., CELL-LEVEL PHARMACOKINETIC MODEL OF GRANULOCYTE COLONY-STIMULATING FACTOR: IMPLICATIONS FOR LIGAND LIFETIME AND POTENCY IN VIVO, Molecular Pharmacology 63, 147 - 158 (2003)
- 38. Schiffer et al., A DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF PEGYLATED RECOMBINANT HUMAN MEGAKARYOCYTE GROWTH AND DEVELOPMENT FACTOR AS AN ADJUNCT TO INDUCTION AND CONSOLIDATION THERAPY FOR PATIENTS WITH ACUTE MYELOID LEUKEMIA, Blood 95, pp 2530 - 2535 (2000)
- 39. Ulich, et al., THE PROLONGED HEMATOLOGIC EFFECTS OF A SINGLE INJECTION OF PEG-rHuMGDF IN NORMAL AND THROMBOCYTOPENIC MICE, Exp. Hematol. 27, pp 117 - 130 (1999)
- 40. Ulich et al., SYSTEMIC HEMATOLOGIC EFFECTS OF PEG-RHUMGDF-INDUCED MEGAKARYOCYTE HYPERPLASIA IN MICE, Blood 87, pp 5006 - 5015 (1996)
- 41. Verdijk & Kuter et al., THROMBOPOIETIN IN HEALTHY DONORS / THROMBOPOIETIN THERAPY INCREASES PLATELET YIELDS IN HEALTHY PLATELET DONORS, Blood 99, pp 3867 - 3868 (2002)
- 42. Zimmerman, et al., SCHEDULE DEPENDENCY OF THE ANTITUMOR ACTIVITY AND TOXICITY OF POLYETHYLENE GLYCOL-MODIFIED

INTERLEUKIN 2 IN MURINE TUMOR MODELS, Can. Res. 49, pp 6521 -6528 (1989)

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents unrelated to erythropoietin, Defendants' accused product, the patents-in-suit, or any claim or defense in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

REOUEST FOR PRODUCTION NO. 33:

All Documents and Electronic Data Concerning the preparation and publication of any articles not listed in Request for Production No. 32 that refer or relate to any ESA, any Pegylated Compounds, pegylation or any related methods. Including all drafts, underlying data and lab notebooks, and all Communications referring or relating thereto.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents unrelated to erythropoietin, Defendants' accused product, the patents-in-suit, or any claim or defense in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

REQUEST FOR PRODUCTION NO. 34:

All Documents and Electronic Data Concerning any ESA, any Pegylated Compounds, pegylation or any related methods maintained by Graham Molineux, Olaf Kinstler and/or Stephen Elliot and/or their researchers or assistants.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA, any Pegylated Compounds, pegylation or any related

methods" not directed to erythropoietin, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding erythropoietin. Amgen is willing to negotiate with Defendants regarding narrowing this Request to a reasonable scope of documents relevant to a claim or defense in this action.

REQUEST FOR PRODUCTION NO. 35:

All Documents and Electronic Data Concerning any ESA, any Pegylated Compounds, pegylation or any related methods currently or previously maintained by the following people:

- 1. **Thomas Boone**
- 2. David N. Brems
- 3. Robert Briddell
- William J. Callahan 4.
- 5. Byeong S. Chang
- Art Cohen 6.
- Randolph B. DePrince 7.
- Stephen P. Eisenberg 8.
- Gary S. Elliott 9.
- Christine E. Farrar 10.
- 11. Frederick A. Fletcher
- MarvAnn Foote 12.
- Nancy E. Gabriel 13.
- 14. Sheila Gardner
- Colin V. Gegg 15.
- V. Goldshtevn 16.
- 17. Alan D. Habberfield
- James B. Hamburger 18.
- 19. Cynthia Hartley
- R. Wayne Hendren 20.
- 21. Jerry M. Housman
- Anna Y. Ip 22.
- 23. Kathleen E. Jensen-Pippo
- Brent S. Kendrick 24.
- Brent Kern 25.
- Bruce A. Kerwin 26.
- Patrick Kerzic 27.

- 28. Elliot Korach
- 29. Andrew A. Kosky
- 30. David Ladd
- 31. Scott L. Lauren
- Tiansheng Li 32:
- 33. B. C. Liang
- Pamela Lockbaum 34.
- 35. Alexis M.K. Lueras
- 36. Patricia McElroy
- 37. Eugene S. Medlock
- Mary Ann Miller-Messana 38.
- 39. Russell T. Migita
- George Morstyn 40.
- Linda O. Narhi 41.
- 42. Ralph W. Niven
- 43. Amiee G. Paige
- Rahul S. Rajan 44.
- Lloyd Ralph 45.
- J. Renwick 46.
- Gisela Schwab 47.
- 48. Linda Shaner
- Christopher Sloey 49.
- Greg Stoney 50.
- Weston Sutherland 51.
- Lisa D. Trebasky 52.
- T. Tressel 53.
- 54. Michael Treuheit
- Tom Ulich 55.
- 56. Tim Walker
- 57. K. Lane Whitcomb
- 58. J. Wilson
- 59. D. Winters
- 60. Qiao Yan
- Heather Yeghnazar 61.
- John D. Young 62.
- 63. V. Zani
- Yu Zhang 64.

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA, any Pegylated Compounds, pegylation or any related

methods" not limited to erythropoietin, Defendants' accused product, the patents-in-suit, or any claim or defense in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding erythropoietin.

REQUEST FOR PRODUCTION NO. 36:

All Documents and Electronic Data Concerning any Reexamination Proceedings, Interference Proceedings and/or Opposition Proceedings, for any and all of Amgen's EPO Patents, related patents, Patent Applications or related Patent Applications, Including Fritsch et al. v. Lin, Interference No. 102,096; Fritsch et al. v. Lin, Interference No. 102,097; and Fritsch et al. v. Lin, Interference No. 102,334; Including transcripts from depositions and interviews, expert reports, and all external references relied upon, and further Including all draft and final versions of pleadings and submissions involved in the aforementioned actions.

RESPONSE:

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 37:

All Documents and Electronic Data Concerning any Protests by the Public Against Pending Applications pursuant to 37 C.F.R. 1.291 for any and all of Amgen's EPO Patents, or Patent Applications, Including the Protest filed on or about July 23, 1993 by Por-Hsiung Lai Regarding Inventorship of United States Patent Application No. 07/113,179, Including transcripts from depositions and interviews, expert reports, and all external references relied upon, and further Including all draft and final versions of pleadings and submissions involved in the aforementioned actions.

Subject to and without waiver of the General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 38:

All Documents and Electronic Data Concerning Amgen, Inc. v. Chugai Pharm. Co., Ltd. and Genetics Institute, Inc., Civ. A. No. 87-2617-Y, D. Mass, Including all draft and final versions of pleadings, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence at trial; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned civil action.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by a court in another judicial proceeding and to which Amgen is still bound.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 39:

All Documents and Electronic Data Concerning Amgen, Inc., et al. v. Genetics Institute, Inc., Civ. A. No. 94-11818-WGY, D. Mass, Including all draft and final versions of pleadings, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests for answers and responses and

objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence at trial; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned civil action.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by a court in another judicial proceeding and to which Amgen is still bound.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference. Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 40:

All Documents and Electronic Data Concerning Amgen, Inc., v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc., Civ. A. No. 97-10814-WGY, D. Mass, Including all draft and final versions of pleadings, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence at trial; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned civil action.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by a court in another judicial proceeding and to which Amgen is still bound.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 41:

All Documents and Electronic Data Concerning Amgen, Inc., v. Thomas Scully and Tommy Thompson, Civ. A. No. 1:02CV02259, D.D.C., Including all draft and final versions of pleadings, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence at trial; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned civil action.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Because the above-identified action does not relate to any claim regarding enforcement of the patents-in-suit, this Request is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Amgen further objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by a court in another judicial proceeding and to which Amgen is still bound. Amgen does not understand how the referenced action is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

REQUEST FOR PRODUCTION NO. 42:

All Documents and Electronic Data Concerning the arbitration before the America Arbitration Association, No. 51 13300242 97, between Ortho-Biotech, Inc. and Ortho-McNeil Pharmaceutical Corp. as claimants and Amgen and Kirin-Amgen, Inc. as respondents, Including all draft and final versions of forms submitted to the arbitrators, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, all discovery Including interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence in the arbitration; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned arbitration.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Because the above-identified arbitration does not relate to any claim regarding enforcement of the patents-in-suit, this Request is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Amgen further objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by an arbitrator or tribunal (the American Arbitration Association) in another judicial proceeding and to which Amgen is still bound. Amgen does not understand how the referenced arbitration concerning the interpretation of contracts is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

REQUEST FOR PRODUCTION NO. 43:

All Documents and Electronic Data Concerning Ortho Biotech Products, L.P. v. Amgen, Inc., Civ. A. No. 3:05-cv-04850-SRC-JJH, D.N.J., Including all draft and final versions of pleadings, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence at trial; all external references relied upon; and any other

Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned civil action.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Because the above-identified action does not relate to any claim regarding enforcement of the patents-in-suit, this Request is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Amgen further objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by a court in another judicial proceeding and to which Amgen is still bound. Amgen does not understand how the referenced action is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

REQUEST FOR PRODUCTION NO. 44:

All Documents and Electronic Data Concerning proceedings Concerning recombinant human erythropoietin in the United Kingdom Including Kirin-Amgen, Inc. v. Hoechst Marion Roussel Ltd, EWCA Civ 1096 (2002), Kirin-Amgen, Inc. v. Hoechst Marion Roussel Ltd, IP & T 694 Civ 1096 (2003), and Kirin-Amgen, Inc. v. Hoechst Marion Roussel Ltd, UKHL 46 (2004), Including all draft and final versions of pleadings, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence at trial; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned civil action.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that the disclosure of

documents responsive to this request would cause Amgen to violate a protective order entered into by a court in another judicial proceeding and to which Amgen is still bound.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 45:

All Documents and Electronic Data Concerning any communications between or Concerning Amgen and Leroy Hood and/or his pre-doctoral, postdoctoral and professional researchers, or his colleagues, collaborators or assistants, that generally refer or relate to protein or nucleic acids and related technologies, or more specifically refer or relate to the subject matter disclosed or claimed in Amgen's EPO Patents.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data concerning "any communications ... that generally refer or relate to protein or nucleic acids and related technologies" in so far as it is not limited to erythropoietin as being overly broad, vague and ambiguous, unduly burdensome, and calling for the production of documents not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 46:

All Documents and Electronic Data Concerning any communications between or Concerning Amgen and Eugene Goldwasser and/or his pre-doctoral, postdoctoral and professional researchers, or his colleagues, collaborators or assistants, that generally refer or relate to mammalian proteins, Including human proteins, or more specifically refer or relate to the subject matter disclosed or claimed in Amgen's EPO Patents.

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data concerning "any communications ... that generally refer or relate to mammalian proteins, Including human proteins" in so far as it is not limited to erythropoietin as being overly broad, vague and ambiguous, unduly burdensome, and calling for the production of documents not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 47:

All Documents and Electronic Data Concerning any communications with The University of Chicago, Including any affiliated researchers, clinicians, technicians or assistants, that refer to or relate to funding or administration of any research projects in which Amgen either commissioned, sponsored, sanctioned, participated or supported in any way, Including financial and material support, said projects related to any discipline Concerning the subject matter disclosed or claimed in Amgen's EPO Patents.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data concerning "any communications with The University of Chicago ... that refer to or relate to funding or administration of any research projects in which Amgen ... participated or supported in any way . . . related to any discipline" in so far as it is not limited to erythropoietin as being overly broad, vague and ambiguous, unduly burdensome, and calling for the production of documents not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 48:

All Documents and Electronic Data Concerning Amgen and Leroy Hood and/or his predoctoral, postdoctoral and professional researchers, or his colleagues, collaborators or assistants, that generally refer or relate to protein or nucleic acids and related technologies, or more specifically refer or relate to the subject matter disclosed or claimed in Amgen's EPO Patents.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data "that generally refer or relate to protein or nucleic acids and related technologies" in so far as it is not limited to erythropoietin as being overly broad, vague and ambiguous, unduly burdensome, and calling for the production of documents, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 49:

All Documents and Electronic Data Concerning Amgen and Eugene Goldwasser and/or his pre-doctoral, postdoctoral and professional researchers, or his colleagues, collaborators or assistants, that generally refer or relate to mammalian proteins, Including human proteins, or more specifically refer or relate to the subject matter disclosed or claimed in Amgen's EPO Patents.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen also objects to this Request to the extent that it seeks

production of documents and electronic data "that generally refer or relate to mammalian proteins, Including human proteins" in so far as it is not limited to erythropoietin as being overly broad, vague and ambiguous, unduly burdensome, and calling for the production of documents not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

REQUEST FOR PRODUCTION NO. 50:

All Documents and Electronic Data Concerning The University of Chicago, Including any affiliated researchers, clinicians, technicians or assistants, that refer to or relate to funding or administration of any research projects in which Amgen either commissioned, sponsored, sanctioned, participated or supported in any way, Including financial and material support, said projects related to any discipline Concerning the subject matter disclosed or claimed in Amgen's EPO Patents.

RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to the Request to the extent it seeks production of documents and electronic data concerning "funding or administration of any research projects" and "any discipline" in so far as it is not limited to erythropoietin as being overly broad, vague and ambiguous, unduly burdensome, and calling for the production of documents not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.