EXHIBIT A

CONTAINS RESTRICTED ACCESS CONFIDENTIAL BLA/IND MATERIAL
PURSUANT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' SUPPLEMENTAL RESPONSES AND OBJECTIONS TO PLAINTIFF AMGEN INC.'S FIRST SET OF INTERROGATORIES TO DEFENDANTS (NOS. 1-15)

Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") make the following objections and responses to Plaintiff Amgen Inc.'s ("Amgen") First Set of Interrogatories (Nos. 1-15).

GENERAL OBJECTIONS

The following general objections apply to all of Defendants' responses and shall be incorporated in each response as if fully set forth therein. To the extent specific General Objections are cited in response to a specific interrogatory, those specific General Objections are provided because they are believed to be particularly applicable to the specific interrogatory and are not to be construed as waiver of any other General Objections applicable to the interrogatory.

Defendants object to each and every interrogatory to the extent it seeks information protected by the attorney-client privilege, the attorney work product doctrine and/or any other applicable privilege. All answers herein shall be subject to this objection, and no provision of information herein may act as a waiver of these objections.

INTERROGATORY NO. 8

Identify each individual (other than patients) and each entity (other than Roche) that has ever used PEG-EPO (including MIRCERA) within the United States for any purpose at any time, stating separately for each such individual or entity:

(a) the date(s) and all locations of each such use;

(b) the purpose(s) of each such use; and

(c) each document (excluding only patient-specific information) recording or reflecting any communication, agreement, or understanding between each such individual or entity and Roche or its agents or attorneys regarding such use; and

(d) each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory including the nature and substance of each such person's knowledge or information; and

(e) the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory, stating the nature and substance of each such person's knowledge or information.

RESPONSE:

See Objections and Response To Interrogatory No. 7 above.

INTERROGATORY NO. 9

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend in your Fifth and Sixth Affirmative Defenses or Tenth Counterclaim is invalid, identify:

(a) on a limitation-by-limitation basis, the legal and factual grounds on which you contend that such claim is invalid;

(b) the level of skill of a person having ordinary skill in the art to which the subject matter of the patents-in-suit pertains at the time of the claimed inventions;

(c) all evidence on which you rely in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support your contention(s), every test, experiment, and/or data upon which you rely in support of each contention that a claim is invalid;

(d) each person, other than counsel, who furnished information or was consulted regarding Roche's response to this interrogatory including the nature and substance of each such person's knowledge or information; and

(e) the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory, stating the nature and substance of each such person's knowledge or information.

RESPONSE:

Defendants object to this interrogatory as unduly vague, ambiguous and overly broad. Moreover, Defendants object to this interrogatory to the extent that it calls for information protected by the attorney-client privilege or work-product immunity. Defendants also object to this interrogatory because it constitutes multiple interrogatories and should be counted against Amgen as such for purposes of the 40 interrogatory limit imposed by the Court.

Defendants also object to this interrogatory because it is premature and calls for expert testimony. The asserted claims of the patents-in-suit have not been construed and the Court does not expect a *Markman* hearing on these claims until April 2, 2007.

Defendants reserve the right to modify or supplement this response at any time upon receipt of relevant materials from any source during discovery.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Defendants respond as follows.

A. Obviousness-Type Double Patenting and Same Invention Double Patenting under Section 101

All of the asserted claims of the patents-in-suit are invalid for obviousness-type double patenting over Amgen's now expired U.S. Patent No. 4,703,008 ("the '008 patent"). The '008 patent claims, among other things, the isolated DNA sequence encoding EPO as well as mammalian host cells transformed with this DNA sequence in a manner allowing these cells to express biologically active and glycosylated EPO protein. The '008 patent and the patents-in-suit all share the same specification and single inventor, and demonstrate that Amgen possessed

the microheterogeneity of glycoproteins and therefore Amgen has failed to set out with the requisite degree of precision and particularity the bounds of the invention which it has claimed and has failed to provide the necessary clear warning to others as to what constitutes infringement of the patent.

J. Lack of Definiteness Under Section 112 – "capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay"

Asserted claim 7 of the '349 patent depends from claims 1-6, each directed to vertebrate cells capable of producing erythropoietin in the medium of their growth. The claims require that claimed cells produce a specified number of "U of erythropoietin," either 100, 500, or 1000, per 100,000 cells in 48 hours. Claims 1-6 further require that "U of erythropoietin" be determined by radioimmunoassay. It is Roche's contention that the phrase as used in the claims is indefinite, cannot be properly defined in view of the patent specification and is otherwise scientifically inaccurate, as radioimmunoassay alone cannot measure erythropoietin units ("U") as required by the claim phrase. The specification does not define "U of erythropoietin" nor does it disclose any method for measuring "U of erythropoietin." Without further guidance that the specification fails to provide, the proper metes and bounds of this limitation cannot be determined. Because claim 7 depends from claims 1-6, each of which contains this limitation, claim 7 itself is indefinite under § 112 for failing to distinctly claim the subject matter in a manner that enables one skilled in the art to understand its true scope.

SUPPLEMENTAL RESPONSE

Roche supplements this response with the following chart showing which of the asserted claims of the patents-in-suit are invalid by certain defenses.

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Claims Asserted by Roche to Be Invalid

'080 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C. § 101
3. A non-naturally occurring erythropoietin glycoprotein having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6.	✓	✓	✓	✓
4. A pharmaceutical composition comprising a therapeutically effective amount an erythropoietin glycoprotein product according to claim 1, 2 or 3	✓	✓	✓	✓
6. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 4 in an amount effective to increase the hematocrit level of said patient.		✓	✓	✓

'868 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
1. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of: (a) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin; and (b) isolating said glycosylated erythropoietin polypeptide therefrom..		✓	✓	✓
2. The process according to claim 1 wherein said host cells are CHO cells.		✓	✓	✓

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'698 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
4. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of: a) growing, under suitable nutrient conditions, vertebrate cells comprising promoter DNA, other than human erythropoietin promoter DNA, operatively linked to DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; and b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.		✓	✓	✓
5. The process of claim 4 wherein said promoter DNA is viral promoter DNA.		✓	✓	✓
6. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of: a) growing, under suitable nutrient conditions, vertebrate cells comprising amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; and b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.		✓	✓	✓
7. The process of claim 6 wherein said vertebrate cells further comprise amplified marker gene DNA.		✓	✓	✓
8. The process of claim 7 wherein said amplified marker gene DNA is Dihydrofolate reductase (DHFR) gene DNA.		✓	✓	✓
9. The process according to claims 2, 4 and 6 wherein said cells are mammalian cells		✓	✓	✓

'349 Patent				
Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting/ 35 U.S.C §101
7. A process for producing erythropoietin comprising the step of culturing, under suitable nutrient conditions, vertebrate cells according to claim 1, 2, 3, 4, 5 or 6.		✓	✓	✓

'422 Patent				
Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
1. A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.	✓	✓	✓	✓

'933 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
3. A non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin said product possessing the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells.	✓	✓	✓	✓
7. The glycoprotein product according to claim 3, 4, 5 or 6 wherein the host cell is a non-human mammalian cell.	✓	✓	✓	✓
8. The glycoprotein product according to claim 7 wherein the non-human mammalian cell is a CHO cell.	✓	✓	✓	✓
9. A pharmaceutical composition comprising an effective amount [sic. of] a gylcoprotein product effective for erythropoietin therapy according to claim 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier.	✓	✓	✓	✓
11. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 9 in an amount effective to increase the hematocrit level of said patient.		✓	✓	✓
12. A pharmaceutical composition comprising an effective amount of a glycoprotein product effective for erythropoietin therapy according to claim 7 and a pharmaceutically acceptable diluent, adjuvant or carrier.	✓	✓	✓	✓
14. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 12 in an amount effective to increase the hematocrit level of said product [sic. patient?].		✓	✓	✓

With respect to double patenting, Roche contends that at least claims 1, 2, 4, 5, 6, 7, 8, 23, 24, 25, 26, and 27 of U.S. Patent No. 4,703,008 render the asserted claims of the patents-in-suit invalid as identified above.

INTERROGATORY NO. 10

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend is invalid under 35 U.S.C. § 102, identify and describe on a limitation-by-limitation basis for each claim:

(a) where, on a limitation-by-limitation basis, you contend each claim limitation is disclosed in the prior art;

(b) how each such limitation is disclosed in the prior art, including specific references to pages, claims, columns and/or line numbers (if applicable) in each document supporting such contention;

(c) all evidence on which you rely in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support your contention(s), and every test, experiment, and/or data upon which you rely in support of each contention that a claim is invalid;

(d) each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory including the nature and substance of each such person's knowledge or information; and

(e) the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory, stating the nature and substance of each such person's knowledge or information.

RESPONSE:

See Objections and Response To Interrogatory No. 9 above.

INTERROGATORY NO. 11

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend is invalid under 35 U.S.C. § 103 or for double patenting, identify and describe for each claim and for each asserted defense:

(a) where, on a limitation-by-limitation basis, you contend each claim limitation is found or disclosed in the prior art or earlier Lin patent claims;