UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. Defendants.	) CIVIL ACTION No.: 05-CV-12237WGY

APPENDIX D, EXHIBIT 3 TO DEFENDANTS' MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DOCUMENTS IMPROPERLY WITHHELD ON GROUNDS OF PRIVILEGE

Dated: March 27, 2007
Boston, Massachusetts

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

By their attorneys,
/s/ Robert L. Kann

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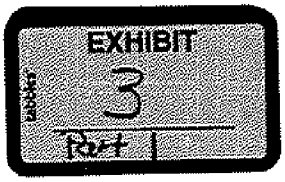

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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, Defendants.	Civil Action No.: 05-12237 WGY

DEFENDANTS' SECOND 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 Second Supplemental 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

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SUPPLEMENTAL OBJECTION

These supplemental interrogatory responses are continuing in nature and Defendants reserve the right to supplement and modify these responses through the course of discovery as more information becomes available.

RESPONSES TO INTERROGATORIES

INTERROGATORY NO. 1

Separately, in claim chart form for each asserted claim of Amgen's patents-in-suit that you contend in your Third Affirmative Defense or Eleventh Counterclaim will not be infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval, state in complete detail what construction you contend the Court should apply to each limitation of each claim and identify all evidence on which you rely in support of your proposed construction of each claim limitation, including all documents, prior court rulings and/or testimony upon which you rely in support of each construction.

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 shall be counted against Amgen as such for purposes of the 40 interrogatory limit imposed by the Court.

Defendants answer this interrogatory based solely on their current understanding of the case, prior to any meaningful fact or expert discovery on any of these topics.

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 will provide Markman briefing detailing their proposed construction of limitations of the claims, with support from both intrinsic and extrinsic evidence, in accordance with the Court's schedule. Although

certain terms or limitations of claims of the patents-in-suit have been construed by this Court before, Defendants do not concede that prior constructions necessarily apply based on their incorporation in this response. While these constructions are binding on Amgen, Defendants do not necessarily accept or adopt these constructions as binding on Defendants.

In light of the fact that Amgen only notified Defendants two days ago that it would be asserting additional claims (claims 7 and 8 of the '933 patent) to the claims asserted in the ITC action, Defendants have not addressed these claims in their response to this interrogatory.

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:

'868 Patent	Construction	Reference
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.	Mammalian host cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
2. The process according to claim 1 wherein said host cells are CHO cells.	Mammalian host cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).

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'933 Patent		
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.	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	Mammalian host cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
9. A pharmaceutical composition comprising an effective amount a glycoprotein product effective for erythropoietin therapy according to claim 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier.	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	Mammalian host cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
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.	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).

	Mammalian host cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
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.	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	Mammalian host cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
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.	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	Mammalian host cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).

'698 Patent		
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.	Vertebrate cells are "cells from an animal having a backbone."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 85 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).
5. The process of claim 4 wherein said promoter DNA is viral promoter DNA.	Vertebrate cells are "cells from an animal having a backbone."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 85 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).

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.	Vertebrate cells are "cells from an animal having a backbone."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 85 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).
7. The process of claim 6 wherein said vertebrate cells further comprise amplified marker gene DNA.	Vertebrate cells are "cells from an animal having a backbone."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 85 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).
8. The process of claim 7 wherein said amplified marker gene DNA is Dihydrofolate reductase (DHFR) gene DNA.	Vertebrate cells are "cells from an animal having a backbone."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 85 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).

	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).
9. The process according to claims 2, 4 and 6 wherein said cells are mammalian cells.	Mammalian cells are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 86 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).
'080 Patent		
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	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).

FIG. 6.	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).
4. A pharmaceutical composition comprising a therapeutically effective amount an erythropoietin glycoprotein product according to claim 1, 2 or 3.	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).
	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
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.	The phrase "the mature amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." This phrase is limited to 166 amino acids without equivalent because Amgen cannot rebut the presumption that prosecution history estoppel applies.	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).

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	"Non-naturally occurring" means "not occurring in nature."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 91 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
'349 Patent		
[1. Vertebrate cells which can be propagated in vitro and which are 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, said cells comprising non-human DNA sequences which control transcription of DNA encoding human erythropoietin.]	The term vertebrate cells means "cells from an animal having a backbone."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 85 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	"Non-human DNA sequences which control transcription of DNA encoding human erythropoietin" are "DNA sequences that initiate and may regulate the processes of transcription" wherein said DNA sequences are "not part of the human genome."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87-88 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
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.	The term vertebrate cells means "cells from an animal having a backbone."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 85 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).
	"Non-human DNA sequences which control transcription of DNA encoding human erythropoietin" are "DNA sequences that initiate and may regulate the processes of transcription" wherein said DNA sequences are "not part of the human genome."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 87-88 (D.Mass. 2001); *aff'd Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003).

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'422 Patent		
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.	"[A] therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the ['422 patent] specification, column 33, lines 16 through 22: stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals."	*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1303 (Fed. Cir. 2006).

SUPPLEMENTAL RESPONSE

In addition to the above claims terms, Roche has determined that the following limitations will require construction by the Court. Roche's proposed construction of these terms will be forthcoming in Roche's *Markman* brief.

PROPOSED TERMS FOR CLAIM CONSTRUCTION

ITEM	TERMS AND PHRASES REQUIRING CONSTRUCTION[1]	RECITED IN AT LEAST THE FOLLOWING CLAIMS
1.	genomic DNA; cDNA	868: 4, 5

[1] Terms and phrases have been grouped together for presentation purposes and convenience. Defendants do not represent that the terms and phrases within an itemized group or in a separate groups have the same or different meaning from each other.

ITEM	TERMS AND PHRASES REQUIRING CONSTRUCTION	RECITED IN CLAIM(S) THE FOLLOWING CLAIMS
2.	administering a pharmaceutical composition . . . in an amount effective to increase the hematocrit level of said patient	933: 11, 14 080: 6
3.	fragment thereof	933:4
4.	amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; amplified marker gene DNA is Dihydrofolate reductase (DHFR) gene DNA; amplified marker gene DNA	698: 6, 7, 8
5.	can be propagated in vitro	349: 1
6.	capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 106 cells in 48 hours as determined by radioimmunoassay	349: 1
7.	CHO cell	868: 2 933: 8
8.	DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; DNA encoding human erythropoietin; DNA sequence encoding	868: 1 933: 3 349: 1 698: 4, 6
9.	effective amount of a glycoprotein product	933: 9, 12

ITEM	TERMS AND PHRASES REQUIRING CONSTRUCTION	PROPOSED RELEASE IN THE FOLLOWING CLAIMS
	effective for erythropoietin therapy	
10.	erythropoietin; erythropoietin glycoprotein product; erythropoietin polypeptide; glycosylated erythropoietin polypeptide; human erythropoietin	868: 1 933: 3 080: 3,4 349: 1, 7 422: 1 698: 4, 6 349: 7
11.	culturing, under suitable nutrient conditions, vertebrate cells; growing, under suitable nutrient conditions, mammalian host cells; growing, under suitable nutrient conditions, vertebrate cells	868: 1 698: 4, 6 349: 7
12.	having an average carbohydrate composition which differs from that of naturally occurring erythropoietin	933:6
13.	having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells; possessing the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells	868: 1 933: 3 698: 4, 6 080: 3

ITEM	TERMS AND PHRASES REQUIRING CONSTRUCTION	RECITED IN AT LEAST THE FOLLOWING CLAIMS
14.	isolating said glycosylated erythropoietin polypeptide expressed by said cells; isolating said glycosylated erythropoietin polypeptide therefrom	868: 1 698: 4, 6
15.	non-human DNA sequences which control transcription of DNA encoding human erythropoietin; promoter DNA, other than human erythropoietin promoter DNA. transcription control DNA sequences, other than human erythropoietin transcription control sequences, for production of human erythropoietin	698: 4 349: 1, 4
16.	non-naturally occurring erythropoietin glycoprotein; non-naturally occurring glycoprotein; non-naturally occurring human erythropoietin glycoprotein;	933: 3, 4 080: 3
17.	not isolated from human urine	080:2
18.	pharmaceutical composition; pharmaceutically acceptable diluent, adjuvant or carrier.	933: 9, 12 080: 4 422: 1
19.	process for producing erythropoietin; process for the production of a glycosylated erythropoietin polypeptide	868: 1 698: 4, 6 349:7

[illegible]	[illegible]	[illegible]
20.	product of the expression in a mammalian host cell of an exogenous DNA sequence	933: 3
21.	purified from mammalian cells grown in culture	422: 1
22.	transformed or transfected with an isolated DNA sequence encoding human erythropoietin transforming or transfecting a host cell with an isolated DNA sequence encoding the mature erythropoietin amino acid sequence of Fig. 6	868: 1 698: 2

SECOND SUPPLEMENTAL RESPONSE

Roche incorporates the substance of the letter dated February 27, 2007 from Thomas F. Fleming to Deborah Fishman as its supplemental response to this Interrogatory No. 1, and incorporates its statements and positions set for in the *Markman* submissions to be filed with the Court on March 5, 2007.

INTERROGATORY NO. 2

Separately, in claim chart form for each asserted claim of Amgen's patents-in-suit that you contend in your Third Affirmative Defense or Eleventh Counterclaim will not be infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval:

(a) state, on a claim-by-claim basis, whether you contend that you do not infringe each claim literally or under the doctrine of equivalents, and whether you do not infringe each such claim directly or indirectly and for each claim that you contend you do not infringe, identify by claim limitation each and every limitation on which you base such contention;

(b) state, on a limitation-by-limitation basis, the factual basis for each contention that MIRCERA does not embody each such claim limitation;

(c) identify all evidence on which you rely in support of each contention in 2(a) and (b) above, including all documents, tests, experiments, and/or data upon which you rely in support of each contention; and

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

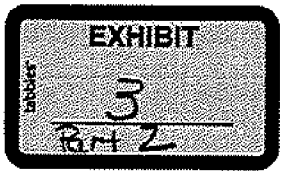
(e) identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory, stating the nature and substance of each such person's knowledge or information.

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 shall 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 answer this interrogatory based solely on their current understanding of the case, prior to any meaningful fact or expert discovery on any of these topics. In particular, in light of the fact that Amgen only notified Defendants two days ago that it would be asserting additional claims (claims 7 and 8 of the '933 patent) to the claims asserted in the ITC action, Defendants have not addressed these claims in their response to this interrogatory.

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



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

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. Defendants generally maintain that the asserted claims of the patents-in-suit are each invalid for reasons outlined in Defendants' response to Interrogatory No. 9, *infra*, and invalid claims cannot be infringed. Specifically for each asserted claim, Defendants respond as follows:

'868 Patent	Contention	Factual Support and Reference
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.	Claim 1 of the '868 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval, for at least the following reasons: Neither MIRCERA nor the drug substance RO0503821 is a "glycosylated erythropoietin polypeptide" as properly construed that Amgen is entitled to claim according to the '868 patent specification. Neither MIRCERA nor the drug substance RO0503821 is an equivalent of a "glycosylated erythropoietin polypeptide" as properly construed that Amgen is entitled to claim according to the '868 patent specification. Defendants do not practice the claimed process or its equivalent for several reasons, including the fact that mammalian cells are not used according to this Court's claim construction, and Amgen is estopped from arguing a different claim construction in this litigation. Defendants do not practice the claimed process or its equivalent in the United States. Neither MIRCERA nor the drug substance RO0503821 is the product of	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,441,868, col. 5, ll. 67-68.

	the process described in this claim. MIRCERA and the drug substance RO0503821 have been materially changed by subsequent processes according to 35 U.S.C. § 271(g)(1).	
2. The process according to claim 1 wherein said host cells are CHO cells.	Roche does not infringe independent claim 1, from which claim 2 depends. Therefore, for at least the reasons set forth in response to claim 1, claim 2 of the '868 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval.	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,441,868, col. 5, ll. 67-68.
'933 Patent	**Contention**	**Reference**
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.	Claim 3 of the '933 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval, for at least the following reasons: Defendants do not use mammalian cells as that claim limitation has been construed by this Court. Amgen is estopped from arguing a different claim construction in this litigation. Neither MIRCERA nor the drug substance RO0503821 is a "glycoprotein product of the expression in a mammalian host cell" that Amgen is entitled to claim according to the '933 patent specification Neither MIRCERA nor the drug substance RO0503821 is an equivalent of a "glycoprotein product of the expression in a mammalian host cell" that Amgen is entitled to claim according to the '933 patent specification.	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,547,933, col. 10, ll. 15-20.
9. A pharmaceutical composition comprising an effective amount a glycoprotein product effective for erythropoietin therapy according to	Roche does not infringe independent claim 3 from which claim 9 depends. Therefore, for at least the reasons set forth with respect to those claims, claim	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,547,933,

claim 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier.	9 of the '933 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval.	col. 5, ll. 48-49; col. 10, ll. 15-20.
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.	Roche does not infringe independent claim 3 nor dependent claim 9 from which claim 11 depends. Therefore, for at least the reasons set forth with respect to those claims, claim 11 of the '933 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval.	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,547,933, col. 5, ll. 48-49; col. 10, ll. 15-20.
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.	Roche does not infringe independent claim 3 nor dependent claim 7 from which claim 12 depends. Therefore, for at least the reasons set forth with respect to those claims, claim 12 of the '933 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval.	ITC-R-BLA-00004027; ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,547,933, col. 5, ll. 48-49; col. 10, ll. 15-20.
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.	Roche does not infringe independent claim 3 nor dependent claim 12 from which claim 14 depends. Therefore, for at least the reasons set forth with respect to those claims, claim 14 of the '933 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval.	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,547,933, col. 5, ll. 48-49; col. 10, ll. 15-20.