EXHIBIT 13

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.

Defendants object to each and every interrogatory to the extent it seeks information that is confidential and proprietary to Roche. All answers herein shall be subject to this objection, and no provision of information herein may act as a waiver of this objection. Information subject to this objection shall be or has been provided only in accordance with the Protective Order entered by the Court on December 21, 2006, which governs the disclosure and use of confidential and proprietary business information produced during discovery in this action.

Defendants incorporate their Supplemental Objections and Responses to Amgen's First Set of Requests for Admission, dated January 8, 2007 as if fully set forth herein. Defendants incorporate their Objections and Responses from the following submissions from the ITC proceeding as if fully set forth herein: Respondents' Response to Amgen Inc.'s First Set of Interrogatories (Nos. 1-23), dated May 30, 2006; Respondents' Response to Amgen Inc.'s Second Set of Interrogatories (Nos. 24-29), dated May 31, 2006; Respondents' Supplemental Response to Amgen Inc.'s Interrogatory No. 28, dated June 23, 2006; Respondents' Response to Amgen Inc.'s Third Set of Interrogatories (Nos. 30-31), dated June 23, 2006; Respondent's Supplemental Response to Amgen Inc.'s Interrogatories Nos. 11, 24, 25, 26 and 29, dated June 23, 2006; and Respondents' Supplemental Response to Amgen Inc.'s Interrogatories Nos. 5 and 6, dated June 22, 2006.

Defendants incorporate their Objections to Amgen's Definitions in Defendants' Responses and Objections to Amgen's First Set of Requests for Production of Documents and Things, dated December 4, 2006 as if fully set forth herein.

Defendants object on the basis of Fed. R. Civ. P. 33(d) where the information requested by Amgen may be derived from documents previously produced by Defendants and the burden of deriving such information is substantially the same for Amgen as it is for Defendants.

Defendants objects to each interrogatory to the extent it is overbroad and unduly burdensome. Defendants object to Amgen's First Set of Interrogatories to the extent that Amgen seeks to impose an obligation on Defendants greater than those imposed by relevant Federal Rules of Civil Procedure and all applicable Local Rules. Fed. R. Civ. P. 26(b)(1) precludes discovery beyond matters relevant to the claims or defenses of the parties. Accordingly, Defendants object to these interrogatories to the extent that they seek information that is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence. Defendants further object to these interrogatories to the extent that they are unreasonably cumulative or duplicative of previous discovery requests made by Amgen in this litigation.

Defendants object to the interrogatories as overly broad and unduly burdensome in seeking the identification of "each" person, "all" persons, "all" documents or the description of "all" facts. Moreover, Defendants object to these interrogatories to the extent that they seek the identity of 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" to the extent that such a request relates to Amgen requests regarding Defendants' legal contentions of non-infringement, invalidity, and unenforceability. It is unduly prejudicial and unfairly burdensome to expect Defendants to identify persons other than counsel in relation to such contentions. For those interrogatories that do not seek legal contentions, knowledgeable individuals can be determined based upon the disclosed document in accordance with Fed. R. Civ. P. 33(d).

Defendants object to each interrogatory and instruction to the extent that they seek to require Defendants to "describe the factual basis" for or to identify each document that supports any given factual assertion, or which include the phrases "all evidence," "all documents," "all

testimony," "all prior knowledge," "all legal and factual grounds," or "all specific statements." These terms are overly broad, vague and ambiguous. Defendants object to any such interrogatory to the extent the terms require the subjective judgment on part of Defendants' attorneys and require a legal conclusion or opinion of counsel in violation of attorney work product doctrine. Without waiving this and all other applicable privileges and objections, when appropriate, Defendants will identify in response to any such interrogatory, documents that expressly reflect on their face information relevant to the specified subject.

Defendants also object to these interrogatories as seeking expert information pursuant to Fed. R. Civ. P. 26(b)(4)(A). Such discovery is premature and impermissibly seeks discovery of expert opinion. Such information shall be disclosed during expert discovery in accordance with the Court's Amended Scheduling Order, dated November 7, 2007.

Moreover, Defendants object that discovery regarding claims construction is premature as the parties have not yet provided their respective constructions of relevant claim terms nor completed fact or expert discovery, and the Court has not yet conducted a *Markman* hearing nor issued a *Markman* order. Such information shall be disclosed during *Markman* discovery in accordance with the Court's Amended Scheduling Order. Defendants object to these interrogatories as premature to the extent that Amgen has not yet provided Roche with substantial document discovery.

Defendants further object to these interrogatories to the extent that they seek information about "each asserted claim" of the patents-in-suit. As of the time of making these interrogatories, Amgen had never identified which particular claims it was asserting. Defendants have therefore been unduly prejudiced by having to speculate as to Amgen's contentions. As a

result, Defendants reserve the right to supplement and modify their responses upon Amgen's disclosure of this information.

To the extent that these interrogatories are premature and discovery is ongoing, Defendants reserve the right to amend, modify, supplement, or change these objections and responses, or to make any use of, or to introduce at any hearing or trial, information and/or documents responsive to these interrogatories.

With respect to Amgen Instruction No. 5, in all instances Roche intends to preserve its claim of attorney-client privilege and/or work product immunity in responding to Amgen's Interrogatories. If any such information is disclosed, except pursuant to a specific written agreement covering such information, the disclosure is inadvertent and shall not be construed as an intention to waive any applicable privilege. Defendants will identify information excluded from discovery on grounds of attorney-client privilege and/or work product immunity and will expressly identify the basis for the privilege or immunity asserted in manner consistent with the Federal Rules of Civil Procedure. Defendants also reserves the right to assert other privileges under Fed. R. Evid. 501.

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).
'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	"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).

production of reticulocytes and red blood 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).
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 FIG. 6.	"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).
	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).
	"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).
'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
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

[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 AT LEAST THE FOLLOWING CLAIMS
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 effective for erythropoietin therapy	933: 9, 12
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

ITEM*	TERMS AND PHRASES REQUIRING CONSTRUCTION	RECITED IN AT LEAST THE FOLLOWING CLAIMS
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
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

ITEM	TERMS AND PHRASES REQUIRING CONSTRUCTION	RECITED IN AT LEAST THE FOLLOWING CLAIMS
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
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

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.

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.

'698 Patent	Contention	Reference
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.	Claim 4 of the '698 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 '698 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 '698 patent specification. Defendants do not practice the claimed process or its equivalent for several reasons, including the fact that vertebrate 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 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).	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,618,698, col. 5, ll. 51-52.
5. The process of claim 4 wherein said promoter DNA is viral promoter DNA.	Roche does not infringe independent claim 4 from which claim 5 depends. Therefore, for at least the reasons set forth with respect to claim 4, claim 5 of the '698 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,618,698, col. 5, ll. 51-52.

	manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval.	
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.	Claim 6 of the '698 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" that Amgen is entitled to claim according to the '698 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 '698 patent specification. Defendants do not practice the claimed process or its equivalent for several reasons, including the fact that vertebrate 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 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).	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,618,698, col. 5, ll. 51-52.
7. The process of claim 6 wherein said vertebrate cells further comprise amplified marker gene DNA.	Roche does not infringe independent claim 6 from which claim 7 depends. Therefore, for at least the reasons set forth with respect to claim 6 claim 7 of the '698 patent will neither be literally infringed, nor infringed under the doctrine of equivalents, nor directly infringed, nor indirectly infringed by the	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,618,698, col. 5, ll. 51-52.

	manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval.	
8. The process of claim 7 wherein said amplified marker gene DNA is Dihydrofolate reductase (DHFR) gene DNA.	Roche does not infringe independent claim 6 nor dependent claim 7 from which claim 8 depends. Therefore, for at least the reasons set forth with respect to those claims claim 8 of the '698 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. 5,618,698, col. 5, ll. 51-52.
9. The process according to claims 2, 4 and 6 wherein said cells are mammalian cells.	Roche does not infringe independent claim 6 from which claim 9 depends. Therefore, for at least the reasons set forth with respect to claim 6, claim 9 of the '698 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. 5,618,698, col. 5, ll. 51-52.
'080 Patent	**Contention**	**Reference**
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.	Claim 3 of the '080 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 "non-naturally occurring erythropoietin glycoprotein" as properly construed that Amgen is entitled to claim according to the '080 patent specification. Neither MIRCERA nor the drug substance RO0503821 is an equivalent of a "non-naturally occurring erythropoietin glycoprotein" as properly construed that Amgen is entitled to claim according to the '080 patent specification.	ITC-R-BLA-00004024-6253; *see* U.S. Patent No. 5,621,080, col. 5, ll. 54-55.

	Roche does not practice the claimed process or its equivalent. Roche does not practice the claimed process or its equivalent in the United States. Neither MIRCERA nor the drug substance RO0503821 is the product of 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). The Federal Circuit has held that 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. Thus, this element is not meant literally or under the doctrine of equivalents.	
4. A pharmaceutical composition comprising a therapeutically effective amount an erythropoietin glycoprotein product according to claim 1, 2 or 3.	Roche does not infringe independent claims 1, 2, or 3 from which claim 4 depends. Therefore for at least the reasons set forth with respect to those claims, claim 4 of the '080 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. 5,621,080, col. 5, ll. 54-55.
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.	Roche does not infringe independent claims 1, 2, or 3, nor dependent claim 4 from which claim 6 depends. Therefore for at least the reasons set forth with respect to those claims, claim 6 of the '080 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. 5,621,080, col. 5, ll. 54-55.

'349 Patent	Contention	Reference
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.	Claim 7 of the '349 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 "erythropoietin" as properly construed that Amgen is entitled to claim according to the '349 patent specification. Neither MIRCERA nor the drug substance RO0503821 is an equivalent of a "erythropoietin" as properly construed that Amgen is entitled to claim according to the '349 patent specification. Defendants do not practice the claimed process or its equivalent for several reasons, including the fact that vertebrate 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 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).	ITC-R-BLA-00004027; *see* U.S. Patent No. 5,756,349, col. 5, ll. 47-48.
'422 Patent	**Contention**	**Reference**
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.	Claim 1 of the '422 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:	ITC-R-BLA-00004027; *see* U.S. Patent No. 5,955,422, col. 5, ll. 51-52.

	MIRCERA is not a "pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin" that Amgen is entitled to claim according to the '422 patent specification, nor is MIRCERA an equivalent of a "pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin" that Amgen is entitled to claim. Defendants do not use mammalian cells according to this Court's claim construction, and Amgen is estopped from arguing a different claim construction in this litigation.	

SUPPLEMENTAL RESPONSE

Roche identifies Anton Haselbeck, Michael Jarsch and Philippe Van der Auwera as knowledgeable individuals regarding the subject matter of this interrogatory due to their knowledge of the characteristics of MIRCERA™.

INTERROGATORY NO. 3

Separately, in claim chart form for each asserted claim of Amgen's patents-in-suit that you contend will not be infringed under 35 U.S.C. § 271(g) by the manufacture, importation, offer for sale, sale, or use of MIRCERA in the U.S. after FDA approval, and to the extent not stated in response to Interrogatory No. 2, describe the factual basis for each such contention, including:

(a) the factual basis for any contention that MIRCERA is "materially changed" from the product described in such claim;

(b) the factual basis for any contention that EPO is a "trivial and nonessential component" of MIRCERA;

(c) each document and the relevant page(s) and statements therein that tend to support or refute your contention(s) as well as all documents relating to, mentioning, or concerning the bases for such contention(s);

(d) every test, experiment, and/or data upon which you rely in support of your contention that a product of a process claimed in Amgen's patents-in-suit is "materially changed" or is "a trivial and nonessential component" of MIRCERA; and