

Exhibit 4

Part 1 of 3

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

**ROCHE’S RESPONSES AND OBJECTIONS TO AMGEN’S FIRST SET OF
REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1 TO 224)**

Pursuant to Fed. R. Civ. P. 26 and 34, Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively “Roche”) respond as follows to Amgen’s First Set of Requests for the Production of Documents and Things.

GENERAL RESPONSES AND OBJECTIONS

The following general responses and objections apply to each individual response to Amgen’s Requests as if fully set forth therein.

1. The following responses are based on Roche’s current knowledge, understanding and belief and the information and documents available to it. These responses thus only constitute a preliminary position. Discovery in this action has only just begun. Roche anticipates that as this action proceeds, Roche may discover further facts and documents. Pursuant to Federal Rule of Civil Procedure 26(e), Roche reserves the right to supplement, modify, alter or otherwise change any of their responses to these Requests as this matter

continues, whether as a result of subsequent investigation, later acquired information or otherwise.

2. Roche objects to Amgen's First Set of Requests for the Production of Documents and Things to the extent Amgen seeks to impose any obligation on Roche 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.

3. Roche objects to Amgen's First Set of Requests for the Production of Documents and Things to the extent they seek documents and things protected by the attorney-client privilege, attorney work product immunity, the investigative privilege, the witness statement privilege, the party-communication privilege or any other protective doctrine. Such documents or things shall not be produced in response to Amgen's Requests, and any inadvertent production thereof shall not be deemed a waiver of any privilege with respect to such documents or information or of any work product immunity or other protective doctrine which may attach thereto, and Amgen shall return such inadvertently produced documents immediately upon request.

4. Roche objects to Amgen's First Set of Requests for the Production of Documents and Things as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant information, including, without limitation, by seeking "all" documents relating to a given subject or documents identifying "each" person or "all" persons involved in any given activity.

5. Roche objects to Amgen's First Set of Requests for the Production of Documents and Things and the instructions and definitions therein to the extent they seek documents and things that are protected from disclosure by third party confidentiality agreements or obligations.

6. Roche objects to Amgen's First Set of Requests for the Production of Documents and Things to the extent they seek documents that are not in the possession, custody or control of Roche, or documents from individuals or entities over which Roche has no control.

7. Roche objects to Amgen's First Set of Requests for the Production of Documents and Things to the extent they seek the production of documents that have previously been disclosed and identified in Roche's Rule 26(a)(1) Initial Disclosures as available for inspection and/or copying by Amgen's counsel subject to entry of an appropriate protective order. Roche also objects to these Requests to the extent they seek information and documents duplicative of or cumulative to information and documents already provided by Roche in discovery, including, without limitation, information and documents already produced In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, ITC Investigation No. 337-TA-568.

8. To the extent Roche responds to any Request, such response does not constitute a concession that information produced pursuant to such Request is relevant to this action. Roche reserves all objections or other questions as to the competency, relevance, materiality, privilege or admissibility as evidence, in any subsequent proceeding in or trial of this or any other action for any purpose whatsoever, of any document or thing identified or provided in response to these Requests for Production of Documents and Things. A partial response to any Request to which Roche has objected, in whole or in part, does not constitute a waiver of any objection. The mere recital of an objection or response does not constitute a concession that Roche possesses any

information or documents responsive to such Request or that any documents or information provided is relevant to this litigation.

9. Roche's representation that it will produce responsive, non-privileged, non-protected, non-cumulative documents is not to be construed as an admission that any such documents exist, but rather that Roche will undertake a good faith effort to search for and identify such documents.

10. Roche objects to these Requests to the extent they are unreasonably cumulative or duplicative. Any response to an overbroad or generalized Request shall be deemed limited by a more particularized response to a further Request.

11. Roche objects to these Requests to the extent they require legal conclusions, expert opinion or construction of any of the terms of the patents-in-suit.

12. Roche objects to each and every Request 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 that is confidential shall be or has been provided only in accordance with any protective order that governs the disclosure and use of confidential and proprietary business information produced during discovery in this action.

13. Roche objects to these Requests' use of the undefined terms "EPO component", "DNA sequence encoding EPO" or "DNA encoding EPO" or any other terms used synonymously therewith as vague, ambiguous, indeterminate, misleading and inaccurate.

RESPONSES AND OBJECTIONS TO AMGEN'S DEFINITIONS AND INSTRUCTIONS

The following responses and objections to Amgen's definitions and instructions apply to each individual response to Amgen's Requests as if fully set forth therein.

1. Roche objects to Amgen's Definition No. 6 to the extent it attempts to broaden the definition of the term "document" as set forth in Rule 34 of the Federal Rules of Civil Procedure.

2. Roche objects to Amgen's Definition No. 9 regarding "EPO" as overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of relevant information. Amgen's definition of the term "EPO" as including any "human erythropoietin analog" encompasses indeterminate and unlimited subject matter outside the scope of any claim or defense in this action.

3. Roche objects to Amgen's Definition No. 10 regarding "ESP" as overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of relevant information. Amgen's use of the term "ESP" as meaning "any erythropoiesis-stimulating protein or polypeptide, including EPO, peg-EPO and erythropoietin purified from urine or any other source" encompasses indeterminate and unlimited subject matter outside the scope of any claim or defense in this action.

4. Roche objects to Amgen's Definition No. 13 regarding "non-peg component of peg-EPO" as overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of relevant information. Roche objects to this definition as misleading and inaccurate to the extent it uses "peg-EPO" to mean Roche's MIRCERA™, whether referred to as CERA or any other internal Roche designation. Roche further objects to this definition as misleading and inaccurate to the extent it refers to a "non-peg component" as a part of the MIRCERA™ molecule. MIRCERA™ is a unique, new molecule created using a complex series of specific chemical reactions to integrate polyethylene glycol polymers into the final molecule, and differs considerably from erythropoietin in both its chemical and biological properties.

Roche further objects to this definition to the extent Amgen's definition erroneously characterizes this final molecule as a combination of discrete entities or parts that are separable into "non-peg" or other components.

5. Roche objects to Amgen's Definition No. 15 regarding "peg-EPO" for the same reasons noted above with respect to Amgen's Definition No. 13. Moreover, the term "peg-EPO" is also misleading as applied to MIRCERA™ to the extent it equates MIRCERA™ with any other molecule engineered through use of pegylation. MIRCERA™ is a distinct chemical entity with distinct properties as compared to other such molecules. Roche further objects to Definition No. 15 to the extent it erroneously implies that MIRCERA™ is an "erythropoietin" or "erythropoietin analog." MIRCERA™ is not an "erythropoietin" or "erythropoietin analog" within the meaning of Amgen's patents-in-suit. Unless otherwise noted, Roche's responses to these Requests are limited to MIRCERA™ -- whether referred to as CERA or any other internal Roche designation -- rather than "peg-EPO" and products containing "peg-EPO."

6. Roche objects to Amgen's Definition No. 17 regarding "related application" as overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of relevant information to the extent it defines an application as related to another application or patent in the absence of any familial link. Roche objects to the definition of an application as related merely because it "shares subject matter with a given patent." Moreover, Roche objects to Amgen's Definition No. 17 as overly broad, unduly burdensome and seeking privileged and confidential information to the extent it encompasses documents relating to any application that is still pending before the U.S. Patent and Trademark Office.

7. Roche objects to Amgen's Definition No. 20 regarding the terms "ROCHE," "you" and "your" as overly broad, unduly burdensome, vague, ambiguous, harassing, misleading

and not reasonably calculated to lead to the discovery of relevant information to the extent they purport to include persons or entities other than the named defendants to this lawsuit, F.

Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. Roche objects to Amgen's Definition No. 20 as including persons and entities that do not control the corporate decisions or policy-making of the named parties and possess no information bearing any relevance to any claim or defense in this action. Moreover, Roche objects to Amgen's Definition No. 20 as it seeks to place an obligation on Roche to provide documents and information from persons and entities which Roche has no control over nor access to. Roche's responses to Amgen's Requests for the Production of Documents and Things are limited to the named defendants to this lawsuit.

8. Roche objects to Amgen's Instruction No. 2 as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant information to the extent it seeks documents and things that post-date Roche's filing of its Biologics License Application ("BLA") No. STN 125164/0 filed with the U.S. Food and Drug Administration ("FDA") on April 18, 2006. Amgen bases its claims of infringement solely on the proposed product described in Roche's BLA No. STN 125164/0 and currently Amgen seeks only injunctive relief and no damages. Therefore, Roche will not provide documents and things that originate after April 18, 2006, except documents and things that relate to a relevant update, supplement, amendment or continuation of its BLA No. STN 125164/0 upon completion of any ongoing studies.

9. That Roche has not lodged a particular objection to one of Amgen's definitions or instructions does not constitute a concession that any of Amgen's definitions or instructions are proper or reasonably calculated to lead to the discovery of relevant information. Roche's

individualized responses and objections to Amgen's Requests below may also reject, amend or narrow any of Amgen's definitions and instructions. Roche further reserves its right to object to the scope of any of Amgen's definitions and instructions in this and any subsequent litigation.

RESPONSES AND OBJECTIONS TO AMGEN'S REQUESTS FOR PRODUCTION

REQUEST NO. 1:

All documents and things produced by ROCHE in discovery In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, ITC Investigation No. 337-TA-568, including a transcript of each deposition and each declaration of each ROCHE witness therein.

RESPONSE TO REQUEST NO. 1:

Roche objects to this Request as overly broad, unduly burdensome, duplicative and harassing to the extent it seeks documents and things already in Amgen's possession. For instance, Amgen is already in possession of the declarations of each Roche witness from the ITC investigation and all the transcripts of the depositions from the ITC investigation as Amgen itself requested the depositions and hired the court reporters that transcribed them and therefore Roche will not reproduce these documents. Moreover, Roche already expended great effort and expense during the ITC investigation to produce its extremely voluminous BLA No. STN 125164/0 and IND Nos. BB-IND 10158 and BB-IND 10964 related to MIRCERA™ in both hard copy and the searchable electronic format requested by Amgen and therefore Roche will not reproduce these documents.

Subject to these objections and the General Responses and Objections above, the documents produced by Roche during ITC Investigation No. 337-TA-568, excluding the depositions and declarations from that matter and Roche's BLA and INDs relating to MIRCERA™, will be produced or made available for inspection and copying in this action.

REQUEST NO. 2:

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

RESPONSE TO REQUEST NO. 2:

Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request to the extent it seeks the production of material that could constitute a non-exempt use under 35 U.S.C. § 271(e)(1) and subject Roche to potential liability. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™. Roche will not produce any samples of EPO to Amgen as such samples are unnecessary and irrelevant.

REQUEST NO. 3:

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

RESPONSE TO REQUEST NO. 3:

Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request to the extent it seeks the production of material that could constitute a non-exempt use under 35 U.S.C. § 271(e)(1) and subject Roche to potential liability.

Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™. Roche will not produce any samples of any substance Amgen defines as "peg-EPO" as such samples are unnecessary and irrelevant.

REQUEST NO. 4:

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

RESPONSE TO REQUEST NO. 4:

Roche incorporates herein by reference its Responses to Request Nos. 2 and 3 above.

REQUEST NO. 5:

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

RESPONSE TO REQUEST NO. 5:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Moreover, Roche objects to this Request to the extent it uses terms that may require construction by the Court. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™.

REQUEST NO. 6:

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

RESPONSE TO REQUEST NO. 6:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

Moreover, Roche objects to this Request to the extent it uses terms that may require construction by the Court. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 7:

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

RESPONSE TO REQUEST NO. 7:

Roche incorporates herein by reference its Response to Request No. 5 above.

REQUEST NO. 8:

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

RESPONSE TO REQUEST NO. 8:

Roche incorporates herein by reference its Response to Request No. 6 above.

REQUEST NO. 9:

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

RESPONSE TO REQUEST NO. 9:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as relating only to products and substances other than the accused product in this case and therefore seeking documents and information bearing no relevance to any claim or defense in this action. Moreover, Roche objects to this Request to the extent it uses terms that may require construction by the Court. Roche further objects to this Request to the extent it calls for a legal conclusion.

REQUEST NO. 10:

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

RESPONSE TO REQUEST NO. 10:

Roche objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Moreover, Roche objects to this Request to the extent it uses terms that may require construction by the Court. Roche further objects to this Request to the extent it calls for a legal conclusion.

REQUEST NO. 11:

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

RESPONSE TO REQUEST NO. 11:

Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Roche also objects to this Request to the extent it seeks production of material that could constitute a non-exempt use under 35 U.S.C. § 271(e)(1) and subject Roche to potential liability. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™. Roche will not produce any samples of cell lines to Amgen as such samples are unnecessary and irrelevant.

REQUEST NO. 12:

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

RESPONSE TO REQUEST NO. 12:

Roche incorporates herein by reference its Response to Request No. 11 above.

REQUEST NO. 13:

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

RESPONSE TO REQUEST NO. 13:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Roche also objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request to the extent it seeks information regarding cell lines other than those used to create Roche's MIRCERA™ product for which commercial approval is sought in Roche's BLA No. STN 125164/0. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the cell lines used to produce MIRCERA™.

REQUEST NO. 14:

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

RESPONSE TO REQUEST NO. 14:

Roche objects to this Request to the extent it calls for Roche to perform experiments or analysis for the benefit of Amgen and to the extent it may call for expert opinion. Roche incorporates herein by reference its Response to Request No. 13 above.

REQUEST NO. 15:

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

RESPONSE TO REQUEST NO. 15:

Roche objects to this Request as vague, ambiguous and indeterminate with respect to its use of the terms “comparability or non-comparability” and “the amount of EPO in a sample.” This Request does not identify a particular sample nor does it identify what that sample should be compared to. See Responses to Request Nos. 13 and 14 above.

REQUEST NO. 16:

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

RESPONSE TO REQUEST NO. 16:

Roche incorporates herein by reference its Response to Request No. 13 above.

REQUEST NO. 17:

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

RESPONSE TO REQUEST NO. 17:

Roche objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Roche further objects to this Request to the extent it calls for a legal conclusion. Roche incorporates herein by reference its Response to Request No. 13 above.

REQUEST NO. 18:

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

RESPONSE TO REQUEST NO. 18:

Roche incorporates herein by reference its Responses to Request Nos. 13 and 17 above.

REQUEST NO. 19:

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

RESPONSE TO REQUEST NO. 19:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Moreover, Roche objects to the phrase "DNA sequence encoding EPO" as vague, ambiguous, misleading, inaccurate, and requiring claim construction and/or expert opinion. Roche further objects to this Request to the extent it seeks information regarding cell lines and DNA sequences other than those used to create Roche's CERA or MIRCERA™ product for which commercial approval is sought in Roche's BLA No. STN 125164/0.

Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the DNA sequence used to produce MIRCERA™.

REQUEST NO. 20:

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

RESPONSE TO REQUEST NO. 20:

Roche incorporates herein by reference its Response to Request No. 19 above.

REQUEST NO. 21:

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

RESPONSE TO REQUEST NO. 21:

Roche incorporates herein by reference its Response to Request No. 19 above.

REQUEST NO. 22:

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

RESPONSE TO REQUEST NO. 22:

Roche incorporates herein by reference its Response to Request No. 19 above.

REQUEST NO. 23:

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

RESPONSE TO REQUEST NO. 23:

Roche incorporates herein by reference its Response to Request No. 19 above.

REQUEST NO. 24:

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

RESPONSE TO REQUEST NO. 24:

Roche incorporates herein by reference its Response to Request No. 19 above.

REQUEST NO. 25:

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

RESPONSE TO REQUEST NO. 25:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 26:

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

RESPONSE TO REQUEST NO. 26:

Roche incorporates herein by reference its Response to Request No. 25 above.

REQUEST NO. 27:

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

RESPONSE TO REQUEST NO. 27:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "each decision" as overly broad, unduly burdensome and harassing.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 28:

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

RESPONSE TO REQUEST NO. 28:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request as cumulative and duplicative of other Requests herein. Moreover, Roche objects to this Request to the extent it seeks information regarding products or molecules other than Roche's CERA or MIRCERA™ product for which commercial approval is sought in Roche's BLA No. STN 125164/0.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or

otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 29:

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

RESPONSE TO REQUEST NO. 29:

Roche incorporates herein by reference its Response to Request No. 28 above.

REQUEST NO. 30:

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

RESPONSE TO REQUEST NO. 30:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request to the extent it seeks information regarding products or molecules other than Roche's CERA or MIRCERA™ product for which commercial approval is sought in Roche's BLA No. STN 125164/0. Moreover, Roche objects to this Request to the extent it calls for expert opinion.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 31:

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

RESPONSE TO REQUEST NO. 31:

Roche incorporates herein by reference its Response to Request No. 30 above.

REQUEST NO. 32:

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

RESPONSE TO REQUEST NO. 32:

Roche objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Roche incorporates herein by reference its Response to Request No. 30 above.

REQUEST NO. 33:

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

RESPONSE TO REQUEST NO. 33:

Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information responsive to this Request. Roche incorporates herein by reference its Response to Request No. 30 above.

REQUEST NO. 34:

All documents and things relating to any communication between ROCHE or its attorneys and any third party regarding any study or investigation to compare the pharmacokinetics, pharmacodynamics, clearance, receptor binding activity, stimulation of intracellular responses, elevation or maintenance of hemoglobin levels, safety, antigenicity

and/or immunogenicity of peg-EPO with the corresponding properties of any other ESP (including non-pegylated EPO).

RESPONSE TO REQUEST NO. 34:

Roche objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Roche incorporates herein by reference its Responses to Request Nos. 30 and 33 above.

REQUEST NO. 35:

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

RESPONSE TO REQUEST NO. 35:

Roche incorporates herein by reference its Responses to Request Nos. 30 and 33 above.

REQUEST NO. 36:

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

RESPONSE TO REQUEST NO. 36:

Roche incorporates herein by reference its Responses to Request Nos. 30 and 33 above.

REQUEST NO. 37:

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

RESPONSE TO REQUEST NO. 37:

Roche objects to this Request as overly broad, unduly burdensome, duplicative and harassing to the extent it seeks documents and things already in Amgen's possession. Roche also objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading.

Roche refers Amgen to Roche's BLA No. STN 125164/0, IND No. BB-IND 10158 and IND No. BB-IND 10964 and documents related thereto previously produced In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, ITC Investigation No. 337-TA-568, which are to be treated as duly produced in this case, for documents responsive to this Request. During the ITC investigation, Roche went to great lengths to produce its extremely voluminous BLA and INDs in both hard copy and the OCR'ed searchable electronic format then specifically requested by Amgen. This electronic format is not compatible with the embedded hyperlink format Amgen now requests. The information contained in the BLA and INDs in both these formats is the same and Roche will not reproduce these documents solely based on Amgen's changing whims. Moreover, in light of the Court's recent decision denying Amgen's motion for reconsideration of the restrictions placed on the use of the BLA and INDs, Roche will not change the format of these documents. See D.I. 159.

Subject to these objections and the General Responses and Objections above, relevant, non-duplicative, non-cumulative documents relating to any completed communications, updates, amendments or supplements to Roche's BLA No. STN 125164/0 and INDs Nos. BB-IND 10158 and BB-IND 10964 and the final results of any completed studies or protocols underlying these submissions, which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 38:

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

RESPONSE TO REQUEST NO. 38:

Roche incorporates herein by reference its Response to Request No. 37 above.

REQUEST NO. 39:

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

RESPONSE TO REQUEST NO. 39:

Roche incorporates herein by reference its Response to Request No. 37 above.

REQUEST NO. 40:

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

RESPONSE TO REQUEST NO. 40:

Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case.

Roche incorporates herein by reference its Response to Request No. 37 above.

REQUEST NO. 41:

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

RESPONSE TO REQUEST NO. 41:

Roche incorporates herein by reference its Responses to Request Nos. 37 and 40 above.

REQUEST NO. 42:

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

RESPONSE TO REQUEST NO. 42:

Roche incorporates herein by reference its Response to Request No. 37 above.

REQUEST NO. 43:

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

RESPONSE TO REQUEST NO. 43:

Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche objects to this Request as oppressive and of unreasonable scope as it seeks documents and things concerning foreign governmental agencies and bodies that have no relevance to any claim or defense in this action.

REQUEST NO. 44:

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

RESPONSE TO REQUEST NO. 44:

Roche incorporates herein by reference its Response to Request No. 43 above.

REQUEST NO. 45:

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

RESPONSE TO REQUEST NO. 45:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to importation, distribution and related areas. To the extent any of these areas are still relevant to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, pricing, marketing and reimbursement, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 46:

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

RESPONSE TO REQUEST NO. 46:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to supply and related areas. To the extent any

of these areas are still relevant to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, pricing, marketing and reimbursement, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 47:

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

RESPONSE TO REQUEST NO. 47:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) and imminence of FDA approval and commercial launch that were the subject of ITC Investigation No. 337-TA-568. To the extent any of these areas are still relevant

to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales and reimbursement, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 48:

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

RESPONSE TO REQUEST NO. 48:

Roche incorporates herein by reference its Response to Request No. 47 above.

REQUEST NO. 49:

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

RESPONSE TO REQUEST NO. 49:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 50:

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

RESPONSE TO REQUEST NO. 50:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) and imminence of FDA approval and commercial launch that were the subject of ITC Investigation No. 337-TA-568. To the extent any of these areas are still relevant

to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 51:

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

RESPONSE TO REQUEST NO. 51:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to marketing, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary

or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 52:

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

RESPONSE TO REQUEST NO. 52:

Roche incorporates herein by reference its Response to Request No. 51 above.

REQUEST NO. 53:

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

RESPONSE TO REQUEST NO. 53:

Roche objects that this Request is duplicative of Request No. 46. Roche incorporates herein by reference its Response to Request No. 46 above.

REQUEST NO. 54:

All documents and things generated by or for ROCHE management, marketing or sales since January 1, 2005 that reference or relate to current or future use of MIRCERA in the United

States, including all goals, budgets, studies, clinical trials, protocols, forecasts, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

RESPONSE TO REQUEST NO. 54:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche also objects to this Request as duplicative and cumulative over other Requests herein.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to marketing and sales, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 55:

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

RESPONSE TO REQUEST NO. 55:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to cost and reimbursement, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 56:

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

RESPONSE TO REQUEST NO. 56:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche also objects to this Request as duplicative and cumulative over other Requests herein.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to projected customers, marketing, pricing, reimbursement and sales, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 57:

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

RESPONSE TO REQUEST NO. 57:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to projected customers, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent

Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 58:

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

RESPONSE TO REQUEST NO. 58:

Roche objects to this Request to the extent it is overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as vague and ambiguous with respect to the undefined term "DDD report."

REQUEST NO. 59:

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

RESPONSE TO REQUEST NO. 59:

Roche incorporates herein by reference its Response to Request No. 58 above.

REQUEST NO. 60:

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

RESPONSE TO REQUEST NO. 60:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to projected customers, sales, reimbursement or marketing, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 61:

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

RESPONSE TO REQUEST NO. 61:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to projected customers, sales and pricing, that bear no relevance to any claim or defense in this

action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 62:

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

RESPONSE TO REQUEST NO. 62:

Roche incorporates herein by reference its Response to Request No. 61 above.

REQUEST NO. 63:

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

RESPONSE TO REQUEST NO. 63:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, and not reasonably calculated to lead to the discovery of admissible evidence.

Roche objects to this Request to the extent the use or availability of "overfill" lacks relevance to any claim or defense in this action.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to

pricing, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 64:

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

RESPONSE TO REQUEST NO. 64:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to projected customers, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 65:

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

RESPONSE TO REQUEST NO. 65:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "dosing regimen" to the extent it is vague, ambiguous and undefined.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 66:

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

category, including any analysis or evaluation of the dose conversion ratio between MIRCERA and EPOGEN[®], ARANESP[®] and PROCRT[®].

RESPONSE TO REQUEST NO. 66:

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to reimbursement and pricing, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request. Roche incorporates herein by reference its Response to Request No. 65 above.

REQUEST NO. 67:

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

RESPONSE TO REQUEST NO. 67:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

REQUEST NO. 68:

All documents and things that comprise any forecast or projection of the hemoglobin levels of patients who receive MIRCERA in the United States during 2006, 2007 and/or 2008,