Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 283 Att. 12

Exhibit 12

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

ROCHE'S RESPONSES AND OBJECTIONS TO AMGEN'S SECOND SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 225-371)

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 Second 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. 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 its 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 Second 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 Second 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 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 Second Set 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 Second 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 Second 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 Second Set of Requests for the Production of Documents and Things 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 this case and in 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 the 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 are relevant to this litigation.

9. Roche objects to Amgen's Second Set of Requests for the Production of Documents and Things and the instructions and definitions therein to the extent they seek documents and things which exceed the limits of discovery ordered by the Court in this case and otherwise limited by the discussions and negotiations of the parties.

10. 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.

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

12. 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.

13. 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.

14. Roche objects to these Requests' use of the undefined terms "EPO component", "DNA sequence encoding EPO" and "DNA encoding EPO" and 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. 7 from its Second Set of Requests to the extent it attempts to broaden the definition of "document" as set forth in Rule 34 of the Federal Rules of Civil Procedure.

2. Roche objects to Amgen's Definition No. 9 from its Second Set of Requests 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. 11 from its Second Set of Requests 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" 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. 17 from its Second Set of Requests regarding "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. 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. MIRCERA™ is 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 Definition No. 17 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".

5. Roche objects to Amgen's Definition No. 19 in its Second Set of Requests 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.

6. Roche objects to Amgen's Definition No. 22 from its Second Set of Requests 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. 22 as including persons and entities that do not control the corporate decisions or policy-making of the named parties and that possess no information bearing any relevance to any claim or defense in this action. Moreover, Roche objects to Amgen's Definition No. 22 as it seeks to place an obligation on Roche to provide documents and information from persons and entities which Roche has neither 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.

7. Roche objects to Amgen's Instruction No. 2 from its Second Set of Requests with respect to the time period for which responsive documents and things are sought as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant information.

8. Roche objects to Amgen's Instruction No. 2 from its Second Set of Requests as overly broad, unduly burdensome and harassing to the extent it seeks documents and things relating to clinical trials or studies for MIRCERA™ 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 or documents and things relating to any ongoing or future clinical study for MIRCERA™. 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. Moreover, in its December 29, 2006 order and again in its January 22, 2007 order, the Court denied Amgen's requests for documents relating to ongoing trials and ongoing communications with the FDA. Instead, the Court has adopted Roche's compromise position of producing documents reflecting data from ongoing clinical trials once completed and submitted to the FDA. Therefore, Roche will not otherwise provide documents and things that originate after April 18, 2006 relating to communications and interactions with the FDA for MIRCERA™, except documents showing data from such completed and submitted clinical trials with MIRCERA™.

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. 225:

Documents and things sufficient to show the Life Cycle management review and decision-making process for MIRCERA, including the Full Decision Point, Decision to File, Strategic Positioning Statement, Strategic Launch Concept Plan and/or Launch Plan for each indication under development by ROCHE, including each renal and oncology indication.

RESPONSE TO REQUEST NO. 225:

10. 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 terms "Full Decision Point, Decision to File, Strategic Positioning Statement, Strategic Launch Concept Plan and/or Launch Plan" are undefined, vague and indeterminate and Amgen's conception of these terms does not necessarily comport with Roche's conception of these terms, if any, or of similar terms. Roche also objects to this Request to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006 which denied numerous Amgen requests seeking such documents. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce its corresponding marketing, financial, pricing, sales, reimbursement and production documents from its own files. To date, Amgen has failed to do so. Roche objects to Amgen's Second Set of Requests for the Production of Documents and Things and the instructions and definitions therein to the extent they seek documents and things which exceed the limits of discovery ordered by the Court in this case and otherwise limited by the discussions and negotiations of the parties.

Roche further objects to this Request to the extent that it is duplicative of other requests in scope and content and therefore unduly oppressive and burdensome at this late stage of litigation. Roche also objects to this Request to the extent it seeks documents and information relating to ongoing or future clinical studies for MIRCERA™ as such requests were denied by the Court's December 29, 2006 and January 22, 2007 orders. Roche also objects to this Request to the extent it seeks documents and information relevant only to issues relating to imminence of FDA

approval and commercial launch that were the subject of ITC Investigation No. 337-TA-568. To the extent these issues are still at all relevant to this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

Subject to these objections and the General Responses and Objections above, Roche will provide, further responsive, non-privileged, non-cumulative documents sufficient to show the projected sales, market share, potential customers and pricing and reimbursement plans to the extent that they cover the same period as provided by Amgen, and to the extent that they have not already been produced or made available for inspection and copying, if any.

REQUEST NO. 226:

Documents generated by or for the NAOC since January 1, 2005 sufficient to show preparations of ROCHE for the commercial launch, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action.

RESPONSE TO REQUEST NO. 226:

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 overly broad and unduly burdensome to the extent it seeks "each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action." Roche also objects to this Request to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006. Roche also objects to this Request

to the extent it seeks documents and information relating to topics of requests which were denied by the Court's December 29, 2006 and January 22, 2007 orders. Otherwise, Roche refers Amgen to its response to Request No. 225.

REQUEST NO. 227:

Each Marketing Plan reviewed by the NAOC since January 1, 2005 for clinical development, commercialization, sale, and/or reimbursement of MIRCERA in the United States.

RESPONSE TO REQUEST NO. 227:

Roche incorporates herein by reference its response to Request No. 225.

REQUEST NO. 228:

Each Business Plan reviewed by the NAOC since January 1, 2005 for clinical development, commercialization, sale, and/or reimbursement of MIRCERA in the United States.

RESPONSE TO REQUEST NO. 228:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 229:

Each Plan of Action reviewed by the NAOC since January 1, 2005 for clinical development, commercialization, sale, and/or reimbursement of MIRCERA in the United States.

RESPONSE TO REQUEST NO. 229:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 230:

Each annual Medical Plan for MIRCERA reviewed by the NAOC since January 1, 2005.

RESPONSE TO REQUEST NO. 230:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 231:

Each Forecast reviewed by the NAOC of U.S. MIRCERA sales, prices or doses during any period after January 1, 2007.

RESPONSE TO REQUEST NO. 231:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 232:

Documents and things generated by or for the MIRCERA Launch Team (including any predecessor or successor body) since January 1, 2005 sufficient to show the preparations of ROCHE for the commercial launch, commercialization, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action.

RESPONSE TO REQUEST NO. 232:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 233:

Documents and things generated by or for the MIRCERA Steering Committee including any predecessor or successor body) since January 1, 2005 sufficient to show the preparations for the commercial launch, commercialization, clinical development, and current or future pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action.

RESPONSE TO REQUEST NO. 233:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 234:

Documents and things generated by or for the MIRCERA Brand Team (including any predecessor or successor body) since January 1, 2005 sufficient to show the preparations for the commercial launch, commercialization, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action.**RESPONSE TO REQUEST NO. 234:**

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 235:

Documents and things generated by or for the Medical Affairs Team since January 1, 2005 sufficient to show all preparations for the commercial launch, commercialization, clinical development, pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, task list, schedule and plan of action.

RESPONSE TO REQUEST NO. 235:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 236:

Documents and things generated by or for Roche's Market Analytics (including any predecessor or successor body) since January 1, 2005 sufficient to show its projection or analysis of ESA markets or market segments, MIRCERA customers, MIRCERA prices, MIRCERA doses or dosing, MIRCERA reimbursement, MIRCERA sales, and/or MIRCERA revenues or profits in the United States for any time period after January 1, 2007.

RESPONSE TO REQUEST NO. 236:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 237:

Documents and things generated by or for Roche's Market Analytics (including any predecessor or successor body) since January 1, 2005 sufficient to show its projection or analysis of the ESA competitive environment, ESA market dynamics, ESA customers, ESA prices, ESA doses or dosing, ESA reimbursement, ESA sales, and/or ESA revenues or profits in the United States for any time period after January 1, 2000.

RESPONSE TO REQUEST NO. 237:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 238:

Documents and things generated by or for Roche's Strategic Pricing (including any predecessor or successor body) since January 1, 2005 sufficient to show its projection or analysis of ESA markets or market segments, MIRCERA customers, MIRCERA prices, MIRCERA doses or dosing, MIRCERA reimbursement, customer costs, profits or incentives, MIRCERA sales, and/or MIRCERA revenues or profits in the United States for any time period after January 1, 2007.

RESPONSE TO REQUEST NO. 238:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 239:

Documents and things generated by or for Roche's Strategic Pricing (including any predecessor or successor body) since January 1, 2005 sufficient to show its projection or analysis of the ESA competitive environment, ESA market dynamics, ESA customers, ESA prices, ESA doses or dosing, ESA reimbursement, customer costs, profits or incentives, ESA sales, and/or ESA revenues or profits in the United States for any time period after January 1, 2000.

RESPONSE TO REQUEST NO. 239:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 240:

Documents generated by or for any ROCHE consultant since January 1, 2005 sufficient to show all preparations proposed by each consultant regarding the commercial launch, clinical development, current or future pricing, promotion, branding, sale or reimbursement of MIRCERA in the United States.

RESPONSE TO REQUEST NO. 240:

Roche objects to this Request to the extent it calls for "preparations proposed by each consultant" as vague and ambiguous, and further objects to this Request to the extent it seeks any information or documents protected by any applicable third party confidentiality obligation. Roche also incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 241:

Documents and things generated by or for the MIRCERA Life Cycle Team for Renal Anemia (including any predecessor or successor body) and each sub-team thereof (including the Preclinical, Technical Development, Supply, Regulatory, Business and Study Management subteams) since January 1, 2005 that reference or relate to preparations for the commercial launch, commercialization, clinical development, and current or future 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.

RESPONSE TO REQUEST NO. 241:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 242:

Documents and things generated by or for the International Business Team (including any sub-team or sub-group thereof and any predecessor or successor body) since January 1, 2005 sufficient to show the preparations for the commercial launch, commercialization, clinical development, and current or future pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action.

RESPONSE TO REQUEST NO. 242:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 243:

Documents and things generated by or for the Pharma Business Management Team (PBMT), the Life Cycle Committee (LCC) or the Development Leader Team (DLT) (including any predecessor or successor bodies) since January 1, 2005 sufficient to show the preparations for the commercial launch, commercialization, clinical development, and current or future pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action.

RESPONSE TO REQUEST NO. 243:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 244:

Documents and things generated by or for any committee, team, or group within ROCHE (other than those specified in Requests 225-243) since January 1, 2005 sufficient to show the preparations for the commercial launch, commercialization, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, tasks list, schedule and plan of action.

RESPONSE TO REQUEST NO. 244:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 245:

Documents and things sufficient to identify and describe the goals, milestones, budgets and tasks of the MIRCERA Life Cycle Team for Renal Anemia and each subteam thereof (including the Preclinical, Clinical, Technical Development, Supply, Regulatory, Business and Study Management subteams) for each quarterly and annual period from 2001 through 2007.

RESPONSE TO REQUEST NO. 245:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 246:

Documents and things sufficient to identify the officers and employees of ROCHE who have responsibilities for clinical development, regulatory approval, marketing, brand strategy, commercial supply, commercial sale, pricing, contracting, and reimbursement of peg-EPO in the United States, including their names, job titles and departments.

RESPONSE TO REQUEST NO. 246:

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, Roche will provide, further responsive, non-privileged, non-cumulative documents sufficient to identify Roche employees involved in projected sales, market share, potential customers and pricing and reimbursement plans to the extent that they cover the same period as provided by Amgen, and to the extent that they have not already been produced or made available for inspection and copying, if any.

REQUEST NO. 247:

All documents and things regarding peg-EPO or EPO from the files of each member of the MIRCERA Preclinical Project Team, including Anton Haselbeck, Michael

Jarsch, Martin Lanzendörfer, Olaf Mundigl, Michael Brandt, Thomas Schindler, Manfred Kubbies, Wolfgang Hösel, Fran Herting, and Sabina Bauer.

RESPONSE TO REQUEST NO. 247:

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 objects to this Request as overly broad and unduly burdensome to the extent it seeks "all documents and things regarding peg-EPO or EPO." Moreover, 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. In addition, Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 248:

Documents and things created by or for the MIRCERA Preclinical Project Team since January 1, 2001, sufficient to show each goal, budget, forecast, milestone, meeting minutes, agenda, presentation, task list, plan of action, schedule and priority regarding MIRCERA.

RESPONSE TO REQUEST NO. 248:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 249:

Documents and things relating to each communication or presentation between (a) Anton Haselbeck, Michael Jarsch, any other member of the MIRCERA Preclinical Project Team or any attorney representing ROCHE, and (b) any other ROCHE employee or third party regarding the mechanism of action of peg-EPO in relation to the erythropoietin receptor.

RESPONSE TO REQUEST NO. 249:

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. Additionally, Roche objects to this Request to the extent it is duplicative of its Request for Production No. 143. Roche also objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. 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. In addition, Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 250:

Documents and things sufficient to show each comparative study or analysis of the mechanism of action, pharmacodynamic and/or pharmacokinetic properties of peg-EPO and EPO.

RESPONSE TO REQUEST NO. 250:

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 it is duplicative of Amgen's Request for Production No. 145. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and undefined. Roche also objects to this Request's use of the terms "comparative study" "analysis of the mechanism of action" and "pharmacodynamic" as vague, ambiguous and undefined. 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 further objects to this Request since Amgen has refused to produce equivalent materials, including but not limited to its BLA for Aranesp, studies and data relating to the structure, composition and function of "Super-Nesp" and other molecules. 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. Moreover, Roche objects to this Request to the extent it seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third party confidentiality agreements.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 251:

All meeting minutes of each MIRCERA Life Cycle "Technical Sub-team" meeting.

RESPONSE TO REQUEST NO. 251:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 252:

All meeting minutes of each "MIRCERA–Preclinical Project Team" meeting.

RESPONSE TO REQUEST NO. 252:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 253:

Documents and things relating to Dr. Peter Veng-Pedersen's work regarding peg-EPO or EPO, including each draft and final communication with Dr. Veng-Pedersen, each work plan, grant application, grant, research contract, and all experimental results of Dr. Veng-Pedersen.

RESPONSE TO REQUEST NO. 253:

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 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 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, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 254:

Documents and things sufficient to show each communication between ROCHE and Dr. Veng-Pedersen or any person employed by Dr. Veng-Pedersen or the University of Iowa regarding peg-EPO, EPO, or any other ESP.

RESPONSE TO REQUEST NO. 254:

Roche incorporates by reference its Response to Request No. 253.

REQUEST NO. 255:

Documents and things sufficient to show each communication between Dr. Veng-Pedersen and ROCHE's attorneys regarding peg-EPO, EPO, or any other ESP.

RESPONSE TO REQUEST NO. 255:

Roche objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine; otherwise refers Amgen to Roche's response to Request No. 253..

REQUEST NO. 256:

Documents and things sufficient to identify and account for each shipment of EPO and peg-EPO exported from Europe or imported by or on behalf of ROCHE into the United States, including a complete tabulation thereof, prior to trial of this matter.

RESPONSE TO REQUEST NO. 256:

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. Moreover, 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 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 and are duplicative of other of Amgen's Requests for Production, including Nos. 162-167, which were denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed the unreasonable breadth of those Requests.

REQUEST NO. 257:

Documents and things sufficient to identify and describe each accounting or tabulation of EPO or peg-EPO imported into the United States prepared by or for Dr. Michael Jarsch, Dr. John-Paul Pfeffen, Dr. Jean-Pierre Buch, Mr. Peter Schuepbach, Dr. Adrienne Favid, Dr. Robert Joseph, Mr. Mathew Engelsbe, Dr. Hing Char, Ms. Joanne Franzino, and Ms. Lisa Marcopolus.

RESPONSE TO REQUEST NO. 257:

Roche incorporates by reference its Response to Request No. 255.

REQUEST NO. 258:

Documents and things sufficient to show ROCHE's projection(s) or plan(s) for importation of MIRCERA for Commercial Sale in the United States, including the quantities, put-ups, and date(s) of all such imports.

RESPONSE TO REQUEST NO. 258:

Roche incorporates by reference its Response to Request No. 255.

REQUEST NO. 259:

Documents and things sufficient to show all current or future use of MIRCERA in the United States.

RESPONSE TO REQUEST NO. 259:

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 also 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 an issue in this action to the extent it refers to importation 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. Roche also objects to this Request to the extent it seeks documents and information relating to future clinical

studies for MIRCERA™ as such requests were denied by the Court's December 29, 2006 and January 22, 2007 orders. Roche will not provide information or documents as to "future" activities, but will provide relevant data from ongoing trials only upon their completion and submitted to the FDA.

Roche also objects to this Request inasmuch as it is duplicative of Amgen's Requests for Production Nos. 54, 74, 78, and 111 which were denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed the unreasonable breadth of those Requests.

REQUEST NO. 260:

All documents and things relating to any work or communication by an employee or agent of Roche including Pascal Bailon, Josef Burg, Anton Haselbeck, Michael Jarsch, Martin Lanzendörfer, Olaf Mundigl, Michael Brandt, Thomas Schindler, Manfred Kubbies, Wolfgang Hösel, Fran Herting, and Sabina Bauer, that refers or relates to EPO or peg-EPO.

RESPONSE TO REQUEST NO. 260:

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 duplicative of other Requests, overly broad and unduly burdensome in its reference to "[a]ll documents and things relating to any work or communication" at this late stage of discovery. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. 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.

Rocher incorporates herein its response to Request No. 247, and further states that subject to these objections and the General Responses and Objections above, further

responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 261:

All documents and things relating to the alleged conception, reduction of practice, or inventorship of each invention claimed or described in the patents-in-suit.

RESPONSE TO REQUEST NO. 261:

Roche objects to this Request as 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 it calls for claim construction and no Markman hearing has been conducted yet in this case. Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 262:

All documents and things relating to any investigation, study, evaluation, opinion, meeting minutes, or project reports concerning any alleged lack of patentability, invalidity, or unenforceability of the patents-in-suit.

RESPONSE TO REQUEST NO. 262:

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, particularly as Amgen has not asserted any claim of willful infringement. Additionally, Roche objects to this Request to the extent it is duplicative of Amgen's

Request for Production No. 198. Moreover, Roche objects to this Request to the extent it calls for claim construction and no Markman hearing has been conducted yet in this case. Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion. Roche also objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine and therefore will not produce any such documents.

REQUEST NO. 263:

All documents and things relating to any scientific publications, posters, conferences, meetings, symposia, or gatherings prepared or attended by any employee or agent of Roche including Pascal Bailon, Josef Burg, Anton Haselbeck, Michael Jarsch, Martin Lanzendörfer, Olaf Mundigl, Michael Brandt, Thomas Schindler, Manfred Kubbies, Wolfgang Hösel, Fran Herting, and Sabina Bauer related to EPO or the subject matter claimed or disclosed in any of the asserted claims of the patents-in-suit, including all papers, slides, abstracts, speeches, outlines, or notes made or submitted by or on behalf of such individuals.

RESPONSE TO REQUEST NO. 263:

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 encompassing 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.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control

REQUEST NO. 264:

All documents and things relating to Leroy Hood and/or his pre-doctoral, postdoctoral and professional researchers, his colleagues, collaborators or assistants, that refer or relate to the subject matter disclosed or claimed in the patents-in-suit.

RESPONSE TO REQUEST NO. 264:

Roche objects to this Request as 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 it seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third party confidentiality agreements.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 265:

All documents and things referring or relating to research and/or work performed by any person at the University of Chicago, including Dr. Eugene Goldwasser and/or his pre-doctoral, postdoctoral and professional researchers, his colleagues, collaborators or assistants, referring or relating to the isolation, purification and/or characterization of any mammalian EPO, including human urinary erythropoietin, or the subject matter disclosed or claimed in the patents-in-suit.

RESPONSE TO REQUEST NO. 265:

Roche objects to this Request as 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 it seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third party confidentiality agreements.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 266:

All documents, things, and communications relating to any animal model considered or used by Roche for testing peg-EPO for anemia, chronic kidney disease, or end-stage renal disease.

RESPONSE TO REQUEST NO. 266:

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.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 267:

All documents and things relating to any notice or communication by or on behalf of Amgen to ROCHE of the claims, substance, content, or the issuance of Amgen's patents-in-suit.

RESPONSE TO REQUEST NO. 267:

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 and better known to Amgen.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 268:

All documents and things referring or relating to any communications by ROCHE evaluating the attributes, merits, properties, characteristics, deficiencies, or shortcomings of various host cells to express human EPO.

RESPONSE TO REQUEST NO. 268

Roche objects to this Request to the extent it is 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 overly broad, harassing, oppressive and seeking documents and things that have no relevance to any claim or defense in this action as EPO is not the accused product in this case and the Request is not limited to MIRCERA™. Moreover, this Request is duplicative of Amgen's Requests for Production Nos. 16 and 203.

REQUEST NO. 269:

All documents and things referring or relating to any studies conducted by or on behalf of ROCHE referring or relating to the glycosylation of urinary or recombinant human EPO.

RESPONSE TO REQUEST NO. 269:

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 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 further 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, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 270:

All documents and things that tend to show that the subject matter disclosed and/or claimed in the Fritsch EPO patents (U.S. patent applications Serial Nos. 06/688,622 and 06/693,258, and any related application or related patent) constitute pioneering inventions, to the extent that ROCHE, Chugai, or Boehringer Mannheim has so claimed.

RESPONSE TO REQUEST NO. 270:

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 it calls for a legal conclusion or expert opinion.

Roche objects that this Request is ambiguous and incomprehensible and Roche cannot determine its relevance. Roche is willing to negotiate a Response if Amgen can explain this request and its relevance to this case.

REQUEST NO. 271:

All documents and things that support, refute, or relate to ROCHE's contention that subject matter disclosed and or claimed in the patents-in-suit and related patents do not constitute "distinct" inventions.

RESPONSE TO REQUEST NO. 271:

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 also objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine.

REQUEST NO. 272:

All documents and things referring or relating to the commercial success or lack thereof of Amgen's recombinant human erythropoietin.

RESPONSE TO REQUEST NO. 272

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 unduly burdensome, duplicative and harassing to the extent it seeks documents and things already in Amgen's possession and that relate to issues for which Amgen bears the burden of production. Roche also objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Moreover, Roche objects to this Request to the extent it calls for a legal conclusion.

REQUEST NO. 273:

All documents and things that support, refute, or relate to ROCHE's Fifth Affirmative Defense and Counterclaim Count X (Invalidity) as set forth in its Answer and Counterclaims or Proposed First Amended Answer and Counterclaims.

RESPONSE TO REQUEST NO. 273:

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. Discovery is still ongoing, and not all such information has been identified, and Roche refers Amgen to the materials identified in Roche's interrogatory responses. Roche also objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Moreover, Roche objects to this Request to the extent it calls for a legal conclusion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 274:

All documents and things that support, refute, or relate to ROCHE's Sixth Affirmative Defense (Double Patenting) as set forth in its Answer and Counterclaims or Proposed First Amended Answer and Counterclaims.

RESPONSE TO REQUEST NO. 274:

Roche incorporates by reference its Response to Request No. 273.

REQUEST NO. 275:

All documents and things that support, refute, or relate to ROCHE's Seventh Affirmative Defense and Counterclaim Count XII (Inequitable Conduct/Unenforceability) as set forth in its Answer and Counterclaims or Proposed First Amended Answer and Counterclaims, specifically including "Inequitable Conduct

Relating to Double Patenting," "Inequitable Conduct Relating to the Failure to Disclose the Basis for an Examiner's Rejections of Substantially Similar Claims in Co-pending Applications," and "Inequitable Conduct Relating to Misrepresentations Regarding Alleged Differences Between r-EPO and u-EPO."

RESPONSE TO REQUEST NO. 275:

Roche incorporates by reference its Response to Request No. 273.

REQUEST NO. 276:

All documents and things that support, refute, or relate to ROCHE's Eighth Affirmative Defense (Unclean Hands) as set forth in its Answer and Counterclaims or Proposed First Amended Answer and Counterclaims.

RESPONSE TO REQUEST NO. 276:

Roche incorporates by reference its Response to Request No. 273.

REQUEST NO. 277:

All documents and things that support, refute, or relate to ROCHE's Tenth Affirmative Defense (Damages Estoppel) as set forth in its Answer and Counterclaims or Proposed First Amended Answer and Counterclaims.

RESPONSE TO REQUEST NO. 277:

Roche incorporates by reference its Response to Request No. 273.

REQUEST NO. 278:

All documents and things that support, refute, or relate to ROCHE's Eleventh Affirmative Defense (File Wrapper Estoppel) as set forth in its Answer and Counterclaims or Proposed First Amended Answer and Counterclaims.

RESPONSE TO REQUEST NO. 278:

Roche incorporates by reference its Response to Request No. 273.

REQUEST NO. 279:

All documents and things that support, refute, or relate to Roche's alleged equitable estoppel affirmative defense or counterclaim, including any notice or communication by or on behalf of Amgen to ROCHE of the claims, substance, content, or the issuance of the patents-in-suit.

RESPONSE TO REQUEST NO. 279:

Roche incorporates by reference its Response to Request No. 273.

REQUEST NO. 280:

All documents and things that support, refute, or relate to ROCHE's Thirteenth Affirmative Defense (Prosecution Laches Estoppel) as set forth in its Answer and Counterclaims or Proposed First Amended Answer and Counterclaims.

RESPONSE TO REQUEST NO. 280:

Roche incorporates by reference its Response to Request No. 273.

REQUEST NO. 281:

Documents and things sufficient to show the comparability or non-comparability of estimates in the amount of EPO in a sample based on RIA and enzyme-linked immunosorbent ("ELISA") assays.

RESPONSE TO REQUEST NO. 281:

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 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. Roche also objects to this Request insofar as it is duplicative of Amgen's Request for Production No. 15 which was denied by the Court's December 29, 2006 order. This Request has not appreciably explained, narrowed or focused the overbreadth and ambiguity of Amgen's Request No. 15.

REQUEST NO. 282:

Documents and things sufficient to show each comparison of each cell line used to produce the EPO component of MIRCERA with any claim of the patents-in-suit.

RESPONSE TO REQUEST NO. 282:

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 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 duplicative of Amgen's Request for Production No. 17 which was denied by the Court's December 29, 2006 order. Moreover, Roche 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 the ITC investigation and other documents produced in this case .

REQUEST NO. 283:

Documents and things sufficient to show any comparison of each process used to produce the EPO component of MIRCERA with any claim of the patents-in-suit.

RESPONSE TO REQUEST NO. 283:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 18 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 18. Roche incorporates by reference its Response to Request No. 282.

REQUEST NO. 284:

Documents and things sufficient to show any analysis of the DNA sequence encoding EPO in each cell line (including the "DN2-3*a*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. 284:

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 objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 19 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 19.

REQUEST NO. 285:

Documents and things sufficient to show 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*a*3" cell line) used to produce the EPO component of MIRCERA, including documents sufficient to show the methods and materials used by which each such determination is made.

RESPONSE TO REQUEST NO. 285:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 20 which was denied by the Court's December 29, 2006 order. This

Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 20.

Roche incorporates herein by reference its Response to Request No. 284.

REQUEST NO. 286:

Documents and things sufficient to show any analysis of the copy number of DNAs encoding EPO per cell in each cell line (including the "DN2-3*a*3" cell line) used to produce the EPO component of MIRCERA, including documents sufficient to show the methods and materials by which such measurement or calculation was made.

RESPONSE TO REQUEST NO. 286:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 23 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 23.

Roche incorporates herein by reference its Response to Request No. 284.

REQUEST NO. 287:

Documents and things sufficient to show any communication between ROCHE and H.I. Feldman, R.K. Israni, W. Yang, S. Fishbane, or M. Joffe regarding any study or investigation of any association between hemoglobin variability and mortality among dialysis patients, as described in ASN Abstract SA-PO034 and SA-PO035 (attached hereto as exhibits 1 and 2).

RESPONSE TO REQUEST NO. 287:

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 it is duplicative of Amgen's Requests for Production Nos. 135-136 .

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic

responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 288:

Documents and things sufficient to show each communication or proposal between ROCHE or its attorneys and any third party regarding each non-clinical study or investigation of peg-EPO, EPO, or any other ESP.

RESPONSE TO REQUEST NO. 288:

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 information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Roche also objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also 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 seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third party confidentiality agreements. Additionally, Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 146 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 146.

REQUEST NO. 289:

Documents and things sufficient to show each effort of ROCHE to avoid infringement of any claim of any Amgen patent, including the patents-in-suit.

RESPONSE TO REQUEST NO. 289:

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 information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Roche also objects to this Request to the extent it calls for a legal conclusion. Moreover, Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 200 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 200.

REQUEST NO. 290:

Documents and things sufficient to show each proposal or plan of ROCHE to modify or alter its manufacture, importation, sale, offer to sell, or use of peg-EPO to avoid infringement of any claim of any Amgen patent, including the patents-in-suit.

RESPONSE TO REQUEST NO. 290:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 201 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 201.

Roche incorporates herein by reference its Response to Request No. 289 above.

REQUEST NO. 291:

Documents and things sufficient to show each ESP studied or evaluated by ROCHE as a potential treatment for anemia that has not been the subject of an IND or BLA filing.

RESPONSE TO REQUEST NO. 291:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 202 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 202.

REQUEST NO. 292:

Documents and things sufficient to show each use at any time by Genetics Institute, ROCHE, and any predecessor-in-interest of ROCHE of host cells (other than Chinese hamster ovary cells) to produce EPO, including the selection or creation of such cells and the production, isolation, testing, analysis, or evaluation of any EPO obtained from such cells.

RESPONSE TO REQUEST NO. 292:

Roche objects to this Request as overly broad, harassing, oppressive and seeking documents and things that have no relevance to any claim or defense in this action as EPO is not the accused product in this case and the Request is not limited to MIRCERA™. Moreover, Roche objects to this Request to the extent it seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third party confidentiality agreements. Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 203 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 203.

REQUEST NO. 293:

Documents and things sufficient to show each test, analysis, characterization or evaluation of any EPO product or composition derived from cells other than CHO cells, including characterization of molecular weight, amino acid sequence, structure, spectra, post-translational modification, glycosylation, sialylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, or any other physical or functional characteristic.

RESPONSE TO REQUEST NO. 293:

Roche objects to this Request as overly broad, harassing, oppressive and seeking documents and things that have no relevance to any claim or defense in this action as EPO is not the accused product in this case and the Request is not limited to MIRCERA™. Moreover, Roche objects to this Request to the extent it seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third party confidentiality agreements. Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 204 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 204.

REQUEST NO. 294:

Documents and things sufficient to show each comparison between the molecular weight, amino acid sequence, structure, spectra, post-translational modification, glycosylation, sialylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, or any other physical or functional characteristic of any EPO product or composition derived from cells other than CHO cells, and the corresponding characteristic(s) of any other ESP, including MIRCERA, NeoRecormon, or any ESP made or sold by Amgen or its licensee(s).

RESPONSE TO REQUEST NO. 294:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 205 which was denied by the Court's December 29, 2006 order. This Request has not appreciably narrowed or focused the overbreadth of Amgen's Request No. 205.

Roche incorporates herein by reference its Response to Request No. 293 above.

REQUEST NO. 295:

Documents and things sufficient to show the origin and meaning of each name by which ROCHE refers to peg-EPO, including "MIRCERA" and "Continuous Erythropoiesis Receptor Activator" and any other established name or USAN.

RESPONSE TO REQUEST NO. 295:

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. Moreover, Roche objects to this Request as the naming of MIRCERA™ bears no relevance to any claim or defense in this action. Roche further objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 218 which was denied by the Court's December 29, 2006 order.

REQUEST NO. 296:

Documents and things sufficient to show each proprietary and non-proprietary name ROCHE considered for peg-EPO.

RESPONSE TO REQUEST NO. 296:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 219 which was denied by the Court's December 29, 2006 order.

Roche incorporates herein by reference its Response to Request No. 295 above.

REQUEST NO. 297:

Documents and things sufficient to show each communication between ROCHE and any third party (including FDA) regarding any name for peg-EPO.

RESPONSE TO REQUEST NO. 297:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 220 which was denied by the Court's December 29, 2006 order.

Roche incorporates herein by reference its Response to Request No. 295 above.

REQUEST NO. 298:

A copy of each electronic submission of ROCHE to FDA comprising its Biologics License Application (BLA) 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 each communication, update, supplement and patient data related thereto.

RESPONSE TO REQUEST NO. 298:

Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. 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. In a spirit of compromise, Roche has already produced to Amgen Roche's BLA No. STN 125164/0, IND No. BB-IND 10158 and IND No. BB-IND 10964 in both TIFF format and native format containing operable embedded links.

Roche further objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 37 which was denied by the Court's December 29, 2006 order.

REQUEST NO. 299:

Each IND filed by ROCHE with FDA for peg-EPO, including the original IND filed by ROCHE with FDA in November 2001, and each communication with the FDA related thereto, including each amendment, supplement or update thereto.

RESPONSE TO REQUEST NO. 299:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 38 which was denied by the Court's December 29, 2006 order.

Roche incorporates herein by reference its Response to Request No. 298 above.

REQUEST NO. 300:

Each supplement or amendment to ROCHE's BLA, including draft supplements and amendments of each, for peg-EPO since April 16, 2006, including each communication, update, analysis and patient data related thereto.

RESPONSE TO REQUEST NO. 300:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 39 which was denied by the Court's December 29, 2006 order.

Roche incorporates herein by reference its Response to Request No. 298 above.

REQUEST NO. 301:

Documents sufficient to show each communication, meeting or exchange of information between ROCHE and FDA regarding peg-EPO or EPO since April 19, 2006.

RESPONSE TO REQUEST NO. 301:

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 further objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 40 which was denied by the Court's December 29, 2006 order.

Roche incorporates herein by reference its Response to Request No. 298 above.

REQUEST NO. 302:

Documents sufficient to show each communication, meeting or exchange of information between ROCHE and any third party regarding ROCHE's BLA for peg-EPO and/or FDA's review or approval.

RESPONSE TO REQUEST NO. 302:

Roche further objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 42 which was denied by the Court's December 29, 2006 order.

Roche incorporates herein by reference its Response to Request No. 298 above.

REQUEST NO. 303:

Documents and things sufficient to show each analysis or testing done by or on behalf of ROCHE of any product or material produced by Amgen that contains or is derived from EPO.

RESPONSE TO REQUEST NO. 303:

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 as "each analysis or testing" done by Roche of any Amgen product or material is not related to any issue in this case and may implicate privileged information.

REQUEST NO. 304:

Documents and things sufficient to show each effort to compare (i) the DNA sequence of any gene used by ROCHE which codes for EPO with (ii) any DNA sequence claimed in the patents-in-suit.

RESPONSE TO REQUEST NO. 304:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and duplicative of other of Amgen's Requests herein, the responses to which are incorporated herein by reference by Roche.

REQUEST NO. 305:

Documents and things relating to the possible infringement by ROCHE of the patents-in-suit.

RESPONSE TO REQUEST NO. 305:

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

from disclosure by the attorney-client privilege and the attorney work product doctrine. Moreover, Roche objects to this Request to the extent it calls for a legal conclusion.

REQUEST NO. 306:

Documents and things relating to each notice to ROCHE's that it may be infringing the patents-in-suit.

RESPONSE TO REQUEST NO. 306:

Roche incorporates herein by reference its Response to Amgen Request No. 267.

REQUEST NO. 307:

Documents and things sufficient to show each communication by ROCHE with health care providers regarding clinical trials involving patients with anemia, including clinical trials conducted by Amgen or ROCHE.

RESPONSE TO REQUEST NO. 307:

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 further 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. Roche also objects to this Request to the extent it seeks documents and information relating to ongoing or future clinical studies for MIRCERA™ as such requests were denied by the Court's December 29, 2006 and January 22, 2007 orders.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 308:

Documents and things relating to ROCHE's resources for conducting clinical trials related to ESA drugs between 2000 and the present, including the availability of clinical investigators, investigation sites, and the number of patients needed or desired for such clinical trials.

RESPONSE TO REQUEST NO. 308:

To the extent this Request seeks production of documents and things concerning information unrelated to activities in the United States, it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. To the extent this Request seeks production of documents and things concerning information without limitation to any field of customers, it is overly broad and not reasonably calculated to lead to the discovery of admissible evidence.

Roche incorporates herein by reference its Response to Request No. 307 above.

REQUEST NO. 309:

Documents and things sufficient to show ROCHE's efforts to obtain FDA approval of MIRCERA, including ROCHE's communications with third parties regarding that effort.

RESPONSE TO REQUEST NO. 309:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche incorporates herein by reference its response to Requests 304 above.

REQUEST NO. 310:

All documents and things identified by ROCHE in response to any interrogatory served on ROCHE in this action.

RESPONSE TO REQUEST NO. 310:

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 objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 221.

REQUEST NO. 311:

All documents and things which ROCHE intends to rely upon at trial in this action.

RESPONSE TO REQUEST NO. 311:

Roche objects to this Request as overly broad, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche further objects to this Request as premature and unduly burdensome to the extent that fact discovery in this case is ongoing, expert discovery has not yet begun, no Markman hearing has taken place and trial is over 6 months away. Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control at the appropriate time as directed by the Court.

REQUEST NO. 312:

Documents and things sufficient to show each presentation, analysis, and communication made by or on behalf or ROCHE regarding its current reimbursement plans or assumptions for MIRCERA.

RESPONSE TO REQUEST NO. 312:

Roche incorporates herein by reference its response to Request No. 225.

REQUEST NO. 313:

Documents sufficient to show each analysis of the effect of government or private insurance reimbursement of health care providers for the use of an ESP on the price, sale, or market share of EPOGEN, MIRCERA, and any other ESP.

RESPONSE TO REQUEST NO. 313:

Roche objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 88.

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 314:

Documents sufficient to show ROCHE's anticipated profits and/or losses from MIRCERA for 2007-2010.

RESPONSE TO REQUEST NO. 314:

Roche objects to this Request as overly broad and unduly burdensome to the extent it seeks documents relating to projections up through 2010, especially in the absence of any claim for damages by Amgen.

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 315:

Documents sufficient to show all pricing analyses for any ESP (as ROCHE has defined that term in its Answer and Counterclaims) including, but not limited, to any analysis tending to prove or disprove that Amgen offers a "supracompetitive" price for any ESP.

RESPONSE TO REQUEST NO. 315:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 316:

All business plans, marketing plans, sales or market projections, market analyses, market share projections, pricing plans, pricing analyses, sales plans or projections for the sale or license of MIRCERA in the United States.

RESPONSE TO REQUEST NO. 316:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 317:

All documents that relate to the consideration of tying or bundling the sale or discounting of MIRCERA with other ROCHE products.

RESPONSE TO REQUEST NO. 317:

Roche objects to this Request to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce all such marketing, financial, pricing, sales, reimbursement and production documents from its own files. Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

No documents will be produced in response unless this Request is redrafted.

REQUEST NO. 318:

All documents concerning communications with government entities regarding possible prices for, utilization or dosing of, or reimbursement for MIRCERA that ROCHE has discussed with government entities, including the average sale price, best price, average wholesale price, and average acquisition cost.

RESPONSE TO REQUEST NO. 318:

Roche objects to this Request to the extent the terms "average sale price", "best price", "average wholesale price" and "average acquisition cost" are vague, ambiguous and undefined. Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 319:

All documents that concern ROCHE's consideration of splitting MIRCERA into two brands, or securing separate pricing for MIRCERA based upon the type of provider, patient, payer or other characteristics.

RESPONSE TO REQUEST NO. 319:

Roche objects to this Request as vague and ambiguous in its use of the phrase "splitting MIRCERA into two brands."

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 320:

Documents sufficient to show all pharmaco-economic arguments that relate to MIRCERA.

RESPONSE TO REQUEST NO. 320:

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 because the term "pharmaco-economic" is not defined. Roche further objects to this Request to the extent it is duplicative of Amgen's Request for Production No. 82.

Roche incorporates herein by reference its Response to Request No. 304 above

REQUEST NO. 321:

All documents that relate to pricing, discounting, or reimbursement for EPOGEN, Aranesp, and Procrit.

RESPONSE TO REQUEST NO. 321:

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 further objects to this Request as duplicative and harassing to the extent it seeks documents and things already in Amgen's possession.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 322:

All documents that show ROCHE's consideration of a multi-brand approach that relates to MIRCERA (R000234779).

RESPONSE TO REQUEST NO. 322:

Roche incorporates herein by reference its Responses to Request Nos. 225 and 304 above.

REQUEST NO. 323:

Documents sufficient to show ROCHE's anticipated sales of MIRCERA for 2007-2010, including the number of units to be sold, the unit size, and total sales in U.S. Dollars.

RESPONSE TO REQUEST NO. 323:

Roche incorporates herein by reference its Responses to Request Nos. 225 and 304 above.

REQUEST NO. 324:

Documents sufficient to show ROCHE's actual costs to date associated with MIRCERA, including, but not limited to, the following: research, development, clinical trials, manufacturing costs, marketing costs, material costs, sales costs, general overhead costs, administration costs, packaging costs, leased costs, reserve costs, and rebates.

RESPONSE TO REQUEST NO. 324:

Roche incorporates herein by reference its Responses to Request Nos. 225 and 304 above.

REQUEST NO. 325:

All documents that constitute or discuss pricing models for MIRCERA.

RESPONSE TO REQUEST NO. 325:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 326:

All documents that show how Amgen's conduct has affected pricing considerations for MIRCERA.

RESPONSE TO REQUEST NO. 326:

Roche incorporates herein by reference its Response to Request No. 225 and 304 above.

REQUEST NO. 327:

All documents you intend to use in this case to support claims that ROCHE has suffered or will suffer monetary damages as a result of Amgen's alleged anticompetitive conduct.

RESPONSE TO REQUEST NO. 327:

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 premature and unduly burdensome to the extent that fact discovery in this case is ongoing, expert discovery has not yet begun, no Markman hearing has taken place and trial is over 6 months away. Roche objects to this Request as seeking information protected from disclosure by the attorney-client privilege

and the attorney work product doctrine. Moreover, Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 328:

All documents that relate to the Bundling Project and MIRCERA. (R000234779).

RESPONSE TO REQUEST NO. 328:

Roche incorporates herein by reference its Response to Request No. 225 and 304 above.

REQUEST NO. 329:

Documents and things comprising each of ROCHE's SEC filings and equivalent or corresponding European filings that refer or relate to MIRCERA since 2001.

RESPONSE TO REQUEST NO. 329:

To the extent that this Request seeks production of documents and things concerning information unrelated to activities in the United States, it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. To the extent that this Request seeks production of documents and things concerning information without limitation to any field of customers, it is overly broad, and not reasonably calculated to lead to the discovery of admissible evidence.

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 330:

Each document that shows any financial incentives, medical advisory boards, honoraria or other incentives or items of value ROCHE has given to health care providers, related to the marketing of MIRCERA.

RESPONSE TO REQUEST NO. 330:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 331:

All documents that show that ROCHE had reason to believe that customers or potential customers chose not to enter into commercial relationships with ROCHE for MIRCERA because of Amgen's conduct.

RESPONSE TO REQUEST NO. 331:

Roche incorporates herein by reference its Response to Request No. 225.

REQUEST NO. 332:

All documents that show all threats, boycotts, or refusals to deal (including threats for suits for contributory infringement) by Amgen.

RESPONSE TO REQUEST NO. 332:

Roche objects to this Request to the extent the terms "all threats, boycotts, or refusals to deal" render the Request overly broad, unduly burdensome, vague and ambiguous.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 333:

All documents that show that Amgen's contracts and business relationships with Fresenius Medical Care, Inc. has or has not had an impact on ROCHE's plans or strategy

related to MIRCERA, including documents indicating how any alleged sole source or exclusive contract has impacted ROCHE.

RESPONSE TO REQUEST NO. 333:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 334:

All documents that show that Amgen's contracts and business relationships with DaVita, Inc. has or has not had an impact on ROCHE's plans or strategy related to MIRCERA, including documents indicating how any alleged sole source or exclusive contract has impacted ROCHE.

RESPONSE TO REQUEST NO. 334:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 335:

All documents relating to communications with Fresenius Medical Care, Inc. or DaVita relating to the potential purchase or use of MIRCERA upon FDA approval.

RESPONSE TO REQUEST NO. 335:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 336:

All documents that show any alleged anticompetitive acts by Amgen or other third parties that you contend are relevant to any of ROCHE's Counterclaims or Affirmative Defenses, including Amgen's alleged customer contracts, pricing structures, financial relationships, or threats.

RESPONSE TO REQUEST NO. 336:

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 seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 337:

All documents that support your contention that Amgen has engaged in "sham litigation," and all documents that show Amgen has not engaged in "sham litigation."

RESPONSE TO REQUEST NO. 337:

Roche incorporates its response to Request No. 336 above.

REQUEST NO. 338:

All documents that tend to support or refute your contention that Amgen engaged in inequitable conduct before the PTO or fraud on the PTO.

RESPONSE TO REQUEST NO. 338:

Roche incorporates herein by reference its Response to Request No. 336 above.

REQUEST NO. 339:

Documents sufficient to identify each ROCHE employee allegedly distracted as a result of the ITC discovery process.

RESPONSE TO REQUEST NO. 339:

Roche objects to this Request because it is overly broad and fails to provide any meaningful direction to Roche as to the actual subject matter sought by Amgen.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 340:

All documents that show whether and how the ITC litigation intimidated investigators, distracted ROCHE employees, delayed or otherwise impacted ROCHE's clinical trials or the timing of the FDA approval for MIRCERA.

RESPONSE TO REQUEST NO. 340:

Roche incorporates herein by reference its Response to Request No. 339 above.

REQUEST NO. 341:

All documents that show each of the anticompetitive financial incentives you contend Amgen has given to customers or others, including documents each such incentive, to whom they were provided, and how they have impacted ROCHE.

RESPONSE TO REQUEST NO. 341:

Roche incorporates herein by reference its response to Request No. 304 above.

REQUEST NO. 342:

All documents that show whether and how Amgen has intimidated customers, including documents identifying each purported act of intimidation, the customers implicated, the individuals who participated in the alleged intimidation, and how it impacted those customers and ROCHE.

RESPONSE TO REQUEST NO. 342:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 343:

All documents that show how Amgen's actions have affected ROCHE's ability or plans to sell MIRCERA, including documents showing the identity of the affected customers, the volume, price, and timing of the affected sales, changes in manufacturing, changes in market share, and how this has to date or will in the future impact your ability to market and sell MIRCERA.

RESPONSE TO REQUEST NO. 343:

Roche incorporates herein by reference its response to Request Nos. 304.

REQUEST NO. 344:

All documents that show the amount ROCHE contends its entry costs have been increased by Amgen's alleged conduct.

RESPONSE TO REQUEST NO. 344:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 345:

All documents that support the contention in your Counterclaims that Amgen's conduct has or may in the future affect ROCHE's scale economies, including documents sufficient to show the impact of Amgen's alleged conduct on ROCHE's entry prospects or market strategies.

RESPONSE TO REQUEST NO. 345:

Roche objects to this Request to the extent it seeks documents and information protected from disclosure by the attorney client privilege or work product doctrine. Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 346:

All documents that support the contention in your Counterclaims that Amgen's conduct has increased barriers to entry for ROCHE.

RESPONSE TO REQUEST NO. 346:

Roche incorporates herein by reference its Response to Request No. 345 above.

REQUEST NO. 347:

All documents that support the contention in paragraph 63 of the Counterclaim that higher entry costs for ROCHE will result in higher prices for consumers of ESP products. Include documents showing (a) what the price would have been but for the alleged higher entry costs, and (b) what the price will be as a result of such alleged higher entry costs.

RESPONSE TO REQUEST NO. 347:

Roche incorporates herein by reference its Response to Request No. 345 above.

REQUEST NO. 348:

All documents that tend to prove or disprove your contention that Amgen has engaged in patent misuse, and all documents that show Amgen has not engaged in patent misuse.

RESPONSE TO REQUEST NO. 348:

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 also 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 calls for a legal conclusion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 349:

All documents that tend to prove or disprove Amgen's current knowledge or belief regarding the validity or invalidity of the patents-in-suit.

RESPONSE TO REQUEST NO. 349:

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 to the extent Roche cannot determine what Amgen subjectively "knows" or "believes" nor can it make a determination as to what Amgen represents it "knows" or "believes" due to Amgen's incomplete fact and contention discovery. Roche also 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 calls for a legal conclusion. Roche is unable to respond to this Request as phrased.

REQUEST NO. 350:

All documents that tend to prove or disprove Amgen's belief and knowledge regarding whether or not MIRCERA infringes the patents-in-suit.

RESPONSE TO REQUEST NO. 350:

Roche incorporates herein by reference its Response to Request No. 349 above.

REQUEST NO. 351:

Documents that show the action ROCHE expects FDA to take on ROCHE's submission to obtain approval for MIRCERA, and when it expects FDA to act.

RESPONSE TO REQUEST NO. 351:

Roche incorporates by reference herein its response to Request No. 304 above.

REQUEST NO. 352:

All documents that show the types and amount of damages ROCHE has already suffered as a result of Amgen's alleged anticompetitive conduct prior to any FDA approval for MIRCERA.

RESPONSE TO REQUEST NO. 352:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 353:

All documents that show the types and amount of damages ROCHE contends it will suffer as a result of Amgen's alleged anticompetitive conduct after ROCHE obtains FDA approval, if any, to market and sell MIRCERA.

RESPONSE TO REQUEST NO. 353:

Roche incorporates herein by reference its Response to Request No. 304 above.

REQUEST NO. 354:

All documents that show that ROCHE has the intent, preparedness, and capability to enter the ESP market, including without limitation, documents concerning actions to engage in the business of selling MIRCERA, consummation of any contracts regarding MIRCERA, and ROCHE's capability to market and sell MIRCERA.

RESPONSE TO REQUEST NO. 354:

Roche incorporates by reference herein its response to Request No. 304 above.

REQUEST NO. 355:

All documents that relate to the decision in December 2006 to extend for three months FDA's response to ROCHE's application for approval to market MIRCERA.

RESPONSE TO REQUEST NO. 355:

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 it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce all such marketing, financial, pricing, sales, reimbursement and production documents from its own files. To date, Amgen has failed to do so. Roche also objects to this Request to the extent it seeks documents and information relevant only to issues relating to imminence of FDA approval and commercial launch that were the subject of ITC Investigation No. 337-TA-568 and are no longer at issue in this case as the Court has accepted jurisdiction.

Roche also objects to this Request to the extent it seeks documents and information relating to ongoing or future clinical studies for MIRCERA™ as such

requests were denied by the Court's December 29, 2006 and January 22, 2007 orders. Roche will provide relevant documents relating to such trials only upon their completion. The Court has adopted Roche's compromise position regarding ongoing communications with the FDA and Roche has complied by notifying the Court and Amgen of the December, 2006 extension to which this Request refers.

REQUEST NO. 356:

All documents that show ROCHE's analysis of the current status, timing and potential impact of entry on commercial sales in the United States of any ESPs produced or developed by non-parties to this lawsuit, including but not limited to Affymax, Fibrogen, and/or Johnson & Johnson, and their affiliates or subsidiaries.

RESPONSE TO REQUEST NO. 356:

Roche objects to this Request as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce all such marketing, financial, pricing, sales, reimbursement and production documents from its own files. To date, Amgen has failed to do so.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 357:

Documents sufficient to show how ROCHE defines all markets and submarkets for MIRCERA.

RESPONSE TO REQUEST NO. 357:

Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

Roche incorporates herein by reference its Response to Request No. 356 above.

REQUEST NO. 358:

Documents sufficient to show how ROCHE defines all markets and submarkets for EPOGEN, Aranesp, and other ESPs sold in the United States.

RESPONSE TO REQUEST NO. 358:

Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

Roche incorporates herein by reference its Response to Request No. 356 above.

REQUEST NO. 359:

Documents sufficient to show all barriers to entry to all markets or submarkets for ESPs in the United States.

RESPONSE TO REQUEST NO. 359:

Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

Roche incorporates herein by reference its Response to Request No. 356 above.

REQUEST NO. 360:

Each document that shows each comparison of MIRCERA to any product made by Amgen, including comparisons of safety, efficacy, cost, reimbursement, or dosage.

RESPONSE TO REQUEST NO. 360:

Roche objects to this Request to the extent it is vague, ambiguous, overly broad and unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as overly broad and unduly burdensome to the extent it refers to "each comparison." Roche objects to this Request to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce all such marketing, financial, pricing, sales, reimbursement and production documents from its own files. To date, Amgen has failed to do so. Roche also objects to this Request to the extent it seeks documents and information relating to ongoing or future clinical studies for MIRCERA™ as such requests were denied by the Court's December 29, 2006 and January 22, 2007 orders. Roche will provide relevant documents relating to such trials only upon their completion.

Roche further objects to this Request to the extent it encompasses comparison data that the Court denied in its December 29, 2006 order. Instead, the Court adopted Roche's compromise position to produce documents showing comparison data between MIRCERA™ and EPO. Roche has produced such documents in this case and refers Amgen to such documents.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic

responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 361:

Documents and things which refer or relate to the amino acid sequence and length of the EPO component in peg-EPO or the EPO used during the manufacturing process for peg-EPO, including documents sufficient to show the C-terminus sequencing results for all manufacturing batches of peg-EPO or the EPO component of peg-EPO, the length of the EPO polypeptide produced by ROCHE, and/or the presence or absence of an Arginine residue at position 166 in any fraction of peg-EPO or any other EPO manufactured by ROCHE.

RESPONSE TO REQUEST NO. 361:

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 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 further 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 a legal conclusion or expert opinion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 362:

All documents and things relating to all pharmacokinetic or pharmacodynamic analyses relating to or conducted for Phase I, II, and/or III studies for all patients by indication regarding peg-EPO.

RESPONSE TO REQUEST NO. 362:

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 overly broad, unduly burdensome and harassing to the extent it refers to "all patients." 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. Roche also objects to this Request to the extent it seeks documents and information relating to ongoing or future clinical studies for MIRCERA™ as such requests were denied by the Court's December 29, 2006 and January 22, 2007 orders. Roche will provide relevant documents relating to such trials only upon their completion. Roche also objects to this Request to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006 which denied numerous Amgen requests seeking such documents. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce all such marketing, financial, pricing, sales, reimbursement and production documents from its own files. To date, Amgen has failed to do so.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 363:

All documents and things relating to all pharmacokinetic or pharmacodynamic analyses relating to, conducted by, reviewed by, or commented on by R. Giescheke, K.P. Zuideveld, A. Haselbeck, or M. Jarsch regarding peg-EPO.

RESPONSE TO REQUEST NO. 363:

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. Roche also objects to this Request to the extent it seeks documents and information relating to ongoing or future clinical studies for MIRCERA™ as such requests were denied by the Court's December 29, 2006 and January 22, 2007 orders. Roche will provide relevant documents relating to such trials only upon their completion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 364:

All documents that tend to prove or disprove the claim in paragraph 40 of your Counterclaims that MIRCERA offers an alternative that is "more appropriate either medically or as a matter of convenience and compliance."

RESPONSE TO REQUEST NO. 364:

Roche objects to this Request as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Roche also objects to this Request as seeking information protected from disclosure by the attorney-client privilege and the attorney work product doctrine. Moreover, Roche objects to this Request to the extent it calls for a legal conclusion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 365:

All documents and things relating to any public benefit or harm offered by MIRCERA.

RESPONSE TO REQUEST NO. 365:

Roche objects to this Request as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 366:

Copies of all training, sales and marketing materials for MIRCERA's launch.

RESPONSE TO REQUEST NO. 366:

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 to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce all such marketing, financial, pricing, sales, reimbursement and production documents from its own files. To date, Amgen has failed to do so.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 367:

All documents that relate to ROCHE's surveys of patients, health care providers or buyers about unmet needs, reimbursement, Amgen, EPOGEN, Aranesp, Procrit, or other issues relevant to anemia management.

RESPONSE TO REQUEST NO. 367:

To the extent this Request seeks production of documents and things concerning information unrelated to activities in the United States, it is overly broad, vague and ambiguous, unduly burdensome and not reasonably calculated to lead to the discovery of

admissible evidence. To the extent this Request seeks production of documents and things concerning information without limitation to any field of customers, it is overly broad and not reasonably calculated to lead to the discovery of admissible evidence.

Roche incorporates herein by reference its Response to Request No. 366 above.

REQUEST NO. 368:

All documents that relate to public policy initiatives involving MIRCERA, (R000234779).

RESPONSE TO REQUEST NO. 368:

Roche incorporates herein by reference its Response to Request No. 366 above.

REQUEST NO. 369:

All declarations, affidavits, letters, or other documents provided by persons and/or entities other than ROCHE that you intend to use in support of your Counterclaims against Amgen.

RESPONSE TO REQUEST NO. 369:

Roche objects to this Request as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence in its reference to "all declarations, affidavits, letters, or other documents". Roche further objects to this Request as premature and unduly burdensome to the extent that fact discovery in this case is ongoing, expert discovery has not yet begun, no Markman hearing has taken place and trial is over 6 months away.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 370:

All declarations, affidavits, letters, or other documents provided by persons and/or entities other than ROCHE that are not consistent with the allegations in your Counterclaims.

RESPONSE TO REQUEST NO. 370:

Roche objects to this Request as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence in its reference to "all declarations, affidavits, letters, or other documents." Roche objects to this Request to the extent it calls for a legal conclusion or expert opinion.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

REQUEST NO. 371:

Documents sufficient to show the design and results of any customer or market surveys related to the introduction of MIRCERA or customer knowledge of MIRCERA.

RESPONSE TO REQUEST NO. 371:

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 to the extent it encompasses marketing, financial, pricing, sales, reimbursement or production documents that would be relevant to a claim for damages by Amgen and are covered by the Court's order of December 29, 2006. As per that order, should Amgen seek further production of such documents for its injunction presentation, it must first produce all such marketing, financial, pricing, sales,

reimbursement and production documents from its own files. To date, Amgen has failed to do so.

Subject to these objections and the General Responses and Objections above, further responsive, non-cumulative, non-privileged documents sufficient to show a topic responsive to this Request may be produced if identified and to the extent they exist and are in Roche's possession, custody or control.

Respectfully submitted,

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February 9, 2007

CERTIFICATE OF SERVICE

I hereby certify that a copy of this document was served upon the attorneys of record for the plaintiff (as listed below) via federal express overnight delivery and electronic mail on February 9, 2007.

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