

Amgen Inc. v. Hoffmann LaRoche, Ltd., et. al.
Case No. 05-CV-12237WGY

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- I. INTRODUCTION (no requests and responses cited in Memorandum).**
- II. ROCHE SHOULD PRODUCE DOCUMENTS RELATING TO AMGEN'S REQUESTED RELIEF AND ROCHE'S CURRENT AND IMMINENT ACTS OF INFRINGEMENT.**

Amgen's Request for Production No. 45:

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

Roche's Response to Amgen's Request for Production No. 45:

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

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

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

Amgen's Request for Production No. 46:

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

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Roche's Responses to Amgen's Request No. 46:

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

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

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

Amgen's Request for Production No. 47:

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

Roche's Response to Amgen's Request for Production No. 47:

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

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

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

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

Amgen's Request for Production No. 48:

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

Roche's Response to Amgen's Request for Production No. 48:

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

Amgen's Request for Production No. 49:

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

Roche's Response to Amgen's Request for Production No. 49:

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

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

Amgen's Request for Production No. 50:

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

Roche's Response to Amgen's Request for Production No. 50:

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

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

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

Amgen's Request for Production No. 51:

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

Roche's Response to Amgen's Request for Production No. 51:

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

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

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

Amgen's Request for Production No. 52:

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

Roche's Response to Amgen's Request for Production No. 52:

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

Amgen's Request for Production No. 53:

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

Roche's Response to Amgen's Request for Production No. 53:

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

Amgen's Request for Production No. 54:

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

Roche's Response to Amgen's Request for Production No. 54:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche also objects to this Request as duplicative and cumulative over other Requests herein. In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to marketing and sales, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

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

Amgen's Request for Production No. 55:

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

Roche's Response to Amgen's Request for Production No. 55:

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

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

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

Amgen's Request for Production No. 56:

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

Roche's Response to Amgen's Request for Production No. 56:

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

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

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

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

Amgen's Request for Production No. 57:

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

Roche's Response to Amgen's Request for Production No. 57:

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

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

Amgen's Request for Production No. 58:

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

Roche's Response to Amgen's Request for Production No. 58:

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

Amgen's Request for Production No. 59:

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

Roche's Response to Amgen's Request for Production No. 59:

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

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Amgen's Request for Production No. 60:

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

Roche's Response to Amgen's Request for Production No. 60:

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

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

Amgen's Request for Production No. 61:

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

Roche's Response to Amgen's Request for Production No. 61:

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

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

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

Amgen's Request for Production No. 62:

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

Roche's Response to Amgen's Request for Production No. 62:

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

Amgen's Request for Production No. 63:

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

Roche's Response to Amgen's Request for Production No. 63:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request to the extent the use or availability of "overfill" lacks relevance to any claim or defense in this action.

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

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

Amgen's Request for Production No. 64:

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

Roche's Response to Amgen's Request for Production No. 64:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. In light of Amgen's current position that it does not seek relief in the form of damages,

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

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

Amgen's Request for Production No. 65:

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

Roche's Response to Amgen's Request for Production No. 65:

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

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

Amgen's Request for Production No. 66:

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

Roche's Response to Amgen's Request for Production No. 66:

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

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particularly to reimbursement and pricing, that bear no relevance to any claim or defense in this action. Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request. Roche incorporates herein by reference its Response to Request No. 65 above.

Amgen’s Request for Production No. 69:

All documents and things relating to any current or projected effect of MIRCERA pricing on any large dialysis organization, small dialysis organization, hospital, nephrology clinic, physician, the Veterans Administration, pharmacies, wholesalers or retailers, including any effect on such entities’ purchasing, consumption, use, reimbursement or profitability.

Roche’s Responses to Amgen’s Request for Production No. 69:

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

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

Amgen’s Request for Production No. 70:

All documents and things relating to any current or projected effect of ROCHE’s pricing of MIRCERA on the average wholesale price, the wholesale acquisition cost or the average selling price of any other ESP (including EPOGEN®, ARANESP® and PROCRIIT®).

Roche’s Response to Amgen’s Request for Production No. 70:

Roche objects to this Request’s use of the terms “wholesale price,” “wholesale acquisition cost” and “average selling price” to the extent they are vague, ambiguous and undefined. Roche incorporates herein by reference its Response to Request No. 69 above.

Amgen’s Request for Production No. 71:

All documents and things relating to any current or projected effect of ROCHE’s pricing of MIRCERA on the pricing, sales or use of any ESP for treatment of oncology patients.

Roche’s Response to Amgen’s Request for Production No. 71:

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Roche incorporates herein by reference its Response to Request No. 69 above.

Amgen's Request for Production No. 72:

All documents and things that comprise or relate to any budget or plan of ROCHE medical affairs relating to MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

Roche's Response to Amgen's Request for Production No. 72:

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

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

Amgen's Request for Production No. 73:

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

Roche's Response to Amgen's Request for Production No. 73:

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 seeks documents and things relating to ongoing clinical trials post-dating Roche's filing of its BLA No. STN 125164/0. In order to avoid unnecessarily delaying or disrupting these trials, Roche will provide relevant documents relating to these trials only upon their completion, if any.

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

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

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

Amgen's Request for Production No. 74:

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

Roche's Response to Amgen's Request for Production No. 74:

Roche incorporates herein by reference its Response to Request No. 73 above.

Amgen's Request for Production No. 75:

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

Roche's Response to Amgen's Request for Production No. 75:

Roche incorporates herein by reference its Response to Request No. 73 above.

Amgen's Request for Production No. 76:

All documents and things that comprise or relate to any budget or plan of ROCHE governmental affairs relating to MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, task lists, schedules and plans of action of each team or group involved therein.

Roche's Response to Amgen's Request for Production No.76:

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

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

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

Amgen's Request for Production No. 77:

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

Roche's Response to Amgen's Request for Production No.77:

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 seeks documents and things relating to ongoing clinical trials post-dating Roche's filing of its BLA No. STN 125164/0. In order to avoid unnecessarily delaying or disrupting these trials, Roche will provide relevant documents relating to these trials only upon their completion, if any.

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

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

Amgen's Request for Production No. 78:

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

Roche's Response to Amgen's Request for Production No. 78:

Roche incorporates herein by reference its Response to Request No. 77 above.

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Amgen's Request for Production No. 79:

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

Roche's Response to Amgen's Request for Production No. 79:

Roche incorporates herein by reference its Response to Request No. 77 above.

Amgen's Request for Production No. 80:

All documents and things relating to any analysis or evaluation of any reimbursement rate, plan or policy for future MIRCERA use in the United States, including average selling price, discounts, rebates or other incentives for purchase or use of MIRCERA with patients.

Roche's Response to Amgen's Request for Production No. 80:

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 "average selling price" to the extent it is vague, ambiguous and undefined.

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

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

Amgen's Request for Production No. 81:

All documents that comprise or relate to any plan, forecast or projection of Medicare, Medicaid and/or private reimbursement rates or policies for MIRCERA use in the United States at any time during 2006, 2007, 2008 and/or 2009.

Roche's Response to Amgen's Request for Production No. 81:

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.

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

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

Amgen's Request for Production No. 82:

All documents and things relating to any analysis, evaluation or presentation regarding the pharmaco-economics of MIRCERA use in anemic renal dialysis patients and/or anemic renal patients not on dialysis.

Roche's Response to Amgen's Request for Production No. 82:

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-economics" is vague, ambiguous and undefined.

Amgen's Request for Production No. 83:

All documents and things relating to any comparison of the pharmaco-economics of MIRCERA use in anemic patients with the pharmaco-economics of the use of any other ESP in anemic patients, including EPOGEN®, ARANESP® and PROCRI®.

Roche's Response to Amgen's Request for Production No. 83:

Roche incorporates herein by reference its Response to Request No. 82 above.

Amgen's Request for Production No. 85:

All documents and things relating to any communication, meeting, presentation or proposal between ROCHE and any representative of any public or private reimbursement authority or agency in the United States (including the CMS, GAO, any state Medicaid authority or any private reimbursement or health maintenance organization) relating to the current or future sale, use, efficacy, safety, cost-effectiveness, reimbursement or pricing of any ESP, including MIRCERA.

Roche's Response to Amgen's Request for Production No. 85:

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.

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Roche objects to this Request as overly broad and seeking information not relevant to any claim or defense in this action to the extent it refers to “any ESP” other than MIRCERA.

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

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

Amgen’s Request for Production No. 86:

All documents and things relating to any communication, meeting, presentation or proposal between ROCHE and any representative of any public or private reimbursement authority or agency in the United States (including the CMS, GAO, any state Medicaid authority or any private reimbursement or health maintenance organization) relating to any analysis, evaluation or presentation regarding the hemoglobin and/or dose response of anemic patients receiving ESP therapy.

Roche’s Response to Amgen’s Request for Production No. 86:

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 seeking information not relevant to any claim or defense in this action to the extent it is not limited to anemic patients receiving MIRCERA TM Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

Amgen’s Request for Production No. 87:

All documents and things relating to the “White Paper” attached hereto as Exhibit A, including communications within ROCHE or between ROCHE and any third party regarding the White Paper, any draft of the White Paper or communications referenced in the White Paper.

Roche’s Response to Amgen’s Request for Production No. 87:

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.

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

Amgen's Request for Production No. 88:

All documents and things relating to any current or projected effect of the sale of MIRCERA in the United States on government reimbursement of ESP use in the United States, including the effect on reimbursement of EPOGEN®, ARANESP® and PROCRTIT®.

Roche's Response to Amgen's Request for Production No. 88:

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

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

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

Amgen's Request for Production No. 89:

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

Roche's Response to Amgen's Request for Production No. 89:

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

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

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

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

Amgen's Request for Production No. 90:

All documents and things that comprise or relate to any forecast or projection of MIRCERA sales in the United States during 2006, 2007 and/or 2008 or any portion thereof, including all documents forecasting sales by territory, patient use or customer segment.

Roche's Response to Amgen's Request for Production No. 90:

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

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

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

Amgen's Request for Production No. 91:

All documents and things relating to any solicitation, recruitment or hiring of sales personnel, medical liaisons or reimbursement specialists whose duties include promotion or support of MIRCERA, including any budget, plan, or forecast of hiring positions and levels.

Roche's Response to Amgen's Request for Production No. 91:

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.

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales and reimbursement, that bear no relevance to any claim or defense in this action. Moreover, Roche objects to this Request as any solicitation, recruitment and

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hiring of sales personnel, medical liaisons and reimbursement specialists bears no relevance to any claim or defense in this action.

Amgen's Request for Production No. 92:

All documents and things relating to any training or instruction of sales personnel, medical liaisons or reimbursement specialists regarding the forecasting, budget, marketing, promotion, contracting, use, pricing, dosing, and/or reimbursement of MIRCERA, including all such instructional materials provided to or used with such individuals.

Response to Amgen's Request for Production No. 92:

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. In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, forecasting, budgeting, marketing, pricing and reimbursement, that bear no relevance to any claim or defense in this action. Moreover, Roche objects to this Request as any training and instruction of sales personnel, medical liaisons and reimbursement specialists bears no relevance to any claim or defense in this action.

Amgen's Request for Production No. 93:

All manuals, sales forms, sales contact forms, forecasts, quotas, and tracking documents used by ROCHE to train its personnel to market, sell and/or obtain reimbursement of MIRCERA in the United States.

Roche's Response to Amgen's Request for Production No. 93:

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. In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, forecasts and quotas, that bear no relevance to any claim or defense in this action. Moreover, Roche objects to this Request as any training and instruction of sales, marketing and reimbursement personnel bears no relevance to any claim or defense in this action.

Amgen's Request for Production No. 94:

All documents and things relating to any training or instruction of physicians, nurses, patients, clinic administrators, reimbursement authorities or other customers regarding the promotion, contracting, training, use, pricing, dosing, and/or reimbursement of MIRCERA use, including all such instructional materials provided to or used with such individuals.

Roche's Response to Amgen's Request for Production No. 94:

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

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particularly to pricing, promotion and reimbursement, that bear no relevance to any claim or defense in this action. Moreover, Roche objects to this Request as any training and instruction of physicians, nurses, patients, clinic administrators, reimbursement authorities and other customers bears no relevance to any claim or defense in this action.

Amgen's Request for Production No. 95:

All documents and things relating to any communication, meeting, presentation or solicitation between ROCHE and any purchaser or consumer of ESP products (including any dialysis care organizations, hospitals, nephrology clinics, nephrologists, dialysis nurses, group purchasing organizations, the Veterans Administration, the Department of Defense and other governmental organizations) relating to the current or future purchase, pricing, use or reimbursement of peg-EPO or MIRCERA in the United States.

Roche's Response to Amgen's Request for Production No. 95:

Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing, duplicative, cumulative and not reasonably calculated to lead to the discovery of admissible evidence. Roche also objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche objects to this Request to the extent it seeks documents, things and information protected from disclosure by third party confidentiality agreements. In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to pricing and reimbursement, that bear no relevance to any claim or defense in this action.

Amgen's Request for Production No. 96:

All documents and things relating to any monthly or other report or summary of activities relating to MIRCERA during any period since October 1, 2005 of any ROCHE sales director, sales manager, sales representative, medical liaison, or member of any marketing, sales, brand, medical affairs or governmental affairs team or group.

Roche's Response to Amgen's Request for Production No. 96:

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

Amgen's Request for Production No. 97:

Documents and things sufficient to show the most current quota or forecast of MIRCERA sales by month, quarter and year for each sales territory and region in the United States and its possessions during 2006, 2007 and 2008.

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Roche's Response to Amgen's Request for Production No. 97:

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

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

Amgen's Request for Production No. 98:

Documents and things sufficient to show the most current quota or forecast of MIRCERA sales by month, quarter and year for each customer in the United States and its possessions during 2006, 2007 and 2008.

Roche's Response to Amgen's Request for Production No. 98:

Roche incorporates herein by reference its Response to Request No. 97 above.

Amgen's Request for Production No. 99:

Documents and things sufficient to show the policy and method by which sales of MIRCERA in the United States will affect the compensation of members of ROCHE's sales force, medical liaison, and medical affairs personnel.

Roche's Response to Amgen's Request for Production No. 99:

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. In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, that bear no relevance to any claim or defense in this action. Moreover, Roche objects to this Request as the compensation of members of ROCHE's sales force, medical liaison and medical affairs personnel bears no relevance to any claim or defense in this action.

Amgen's Request for Production No. 100:

All documents and things relating to any customer or potential customer for peg-EPO, including large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government pharmacies, individual clinics, and/or individual

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physicians, but excluding patient specific information, relating to the importation, use, offer for sale, sale or reimbursement of peg-EPO in the United States.

Roche's Response to Amgen's Request for Production No. 100:

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 documents, things and information protected from disclosure by third party confidentiality agreements. Moreover, Roche objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to importation and related areas. To the extent any of these areas are relevant to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

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

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

Amgen's Request for Production No. 101:

All documents and things relating to any communication between ROCHE and any customer or potential customer for peg-EPO, including large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government pharmacies, individual clinics, and/or individual physicians, but excluding patient specific information, relating to the importation, use, offer to sell, sale or reimbursement of peg-EPO in the United States.

Roche's Response to Amgen's Request for Production No. 101:

Roche incorporates herein by reference its Response to Request No. 100 above.

Amgen's Request for Production No. 102:

All documents and thing relating to any negotiation between ROCHE and any customer or potential customer for peg-EPO, including large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government

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pharmacies, individual clinics, and/or individual physicians relating to the importation, use, offer to sell, sale or reimbursement of peg-EPO in the United States.

Roche's Response to Amgen's Request for Production No. 102:

Roche objects to this Request's use of the term "negotiation" as vague and ambiguous. Roche incorporates herein by reference its Response to Request No. 100 above.

Amgen's Request for Production No. 103:

All documents and things relating to any agreement or contract between ROCHE and any customer or potential customer for peg-EPO in the United States, including but not limited to large dialysis organizations, small dialysis organizations, group purchasing organizations, hospital-based dialysis centers, government pharmacies, individual clinics, and/or individual physicians, relating to the importation, use, offer to sell, sale, or reimbursement of peg-EPO in the United States.

Roche's Response to Amgen's Request for Production No. 103:

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 documents, things and information protected from disclosure by third party confidentiality agreements. Moreover, Roche objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to importation and related areas. In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales and reimbursement, that bear no relevance to any claim or defense in this action. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request.

To Roche's current knowledge, no documents or things responsive to this Request exist.

Amgens' Request for Production No. 104:

Documents and things sufficient to show all communications between ROCHE and DaVita Inc. or its affiliates relating to peg-EPO or any other ESP.

Roche's Response to Amgens' Request for Production No. 104:

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 to the extent it seeks documents, things and information protected from disclosure by third party confidentiality agreements. Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege

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

Amgen's Request for Production No. 105:

Documents and things sufficient to show all communications between ROCHE and Dialysis Clinic Inc. (DCI) or its affiliates relating to peg-EPO or any other ESP.

Roche's Response to Amgen's Request for Production No. 105:

Roche incorporates herein by reference its Response to Request No. 104 above.

Amgen's Request for Production No. 106:

Documents and things sufficient to show all communications between ROCHE and Fresenius Medical Care North America or Fresenius Medical Care AG & Co . KGaA or their affiliates relating to peg-EPO or any other ESP.

Roche's Response to Amgen's Request for Production No. 106:

Roche incorporates herein by reference its Response to Request No. 104 above.

Amgen's Request for Production of Documents No. 107:

Documents and things sufficient to show all communications between ROCHE and Gambro AG or its affiliates relating to peg-EPO or any other ESP.

Roche's Response to Amgen's Request for Production No. 107:

Roche incorporates herein by reference its Response to Request No. 104 above.

Amgen's Request for Production No. 108:

Documents and things sufficient to show all communications between ROCHE and Renal Care Group, Inc . (RCG) or its affiliates relating to peg-EPO or any other ESP.

Roche's Response to Amgen's Request for Production No. 108:

Roche incorporates herein by reference its Response to Request No. 104 above.

Amgen's Request for Production No. 109:

Documents and things sufficient to show all communications between ROCHE and any agency or procurement office of the United States Department of Defense, Veterans Administration or other governmental procurement office relating to peg-EPO or any other ESP.

Roche's Response to Amgen's Request for Production No. 109:

Roche incorporates herein by reference its Response to Request No. 104 above.

Amgen's Request for Production No. 111:

All documents and things relating to any executed or proposed understanding or agreement between ROCHE and any third party relating to any past, current or future use of peg-EPO or EPO in the United States.

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Roche's Response to Amgen's Request for Production No. 111:

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 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. Moreover, Roche objects to this Request to the extent it seeks documents, things and information protected from disclosure by third party confidentiality agreements.

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

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

Amgen's Request for Production No. 113:

All documents and things relating to any offer to provide peg-EPO or EPO for use in the United States to any person or entity for any purpose or use that is not related to the development and submission of information to FDA under a federal law regulates the manufacture, use, or sale of erythropoietin products.

Roche's Response to Amgen's Request for Production No. 113:

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 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. Moreover, to Roche's current knowledge, no documents or things responsive to this Request exist.

Amgen's Request for Production No. 114:

All documents and things relating to any offer to sell peg-EPO or EPO to any person or entity for any use in the United States not related to the development and submission of information to FDA under a federal law that regulates the manufacture, use, or sale of peg-EPO or EPO products.

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Roche's Response to Amgen's Request for Production No. 114:

Roche incorporates herein by reference its Response to Request No. 113 above.

Amgen's Request for Production No. 115:

All documents and things relating to any agreement or understanding to sell, supply or provide peg-EPO or EPO for use in the United States at any time after FDA approval of ROCHE's pending BLA.

Roche's Response to Amgen's Request for Production No. 115:

Roche incorporates herein by reference its Response to Request No. 113 above.

Amgen's Request for Production No. 116:

All documents and things related to the recruitment, solicitation or hiring of any Amgen employee by ROCHE since January 1, 2004.

Roche's Response to Amgen's Request for Production No. 116:

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 relating to the recruitment, solicitation and hiring of Amgen employees by Roche and therefore seeking documents and things bearing no relevance to any claim or defense in this action.

Amgen's Request for Production No. 117:

All documents and things related to any plan or budget of ROCHE to recruit, solicit or hire Amgen sales personnel, medical liaisons, reimbursement specialists or marketing personnel.

Roche's Response to Amgen's Request for Production No.117:

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. In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to sales, marketing and reimbursement, that bear no relevance to any claim or defense in this action. Moreover, Roche objects to this Request as relating to the recruitment, solicitation and hiring of Amgen employees by Roche and therefore seeking documents and things bearing no relevance to any claim or defense in this action.

Amgen's Request for Production No. 118:

All documents and things related to any communication between ROCHE and any third party regarding recruitment, solicitation or hiring of any Amgen employee for employment by ROCHE since January 1, 2004.

Roche's Response to Amgen's Request for Production No. 118:

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 to the extent it seeks documents, things and information

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protected from disclosure by third party confidentiality agreements. Moreover, Roche objects to this Request as relating to the recruitment, solicitation and hiring of Amgen employees by Roche and therefore seeking documents and things bearing no relevance to any claim or defense in this action.

Amgen's Request for Production No. 119:

All documents and things related to any listing, directory or other information of Amgen regarding its employees, business dealings, customers or internal organization.

Roche's Response to Amgen's Request for Production No. 119:

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 relating to the employees, customers and internal organization of Amgen and therefore seeking documents and things bearing no relevance to any claim or defense in this action.

Amgen's Request for Production No. 120:

All documents and things related to any listing, directory or other information of Amgen regarding its employees, business dealings, customers or internal organization.

Roche's Response to Amgen's Request for Production No. 120:

Roche incorporates herein by reference its Response to Request No. 119 above.

Amgen's Request for Production No. 121:

All documents and things relating to information of Amgen regarding its instruction, training, organization, supervision or compensation of its employees, including manuals, directories, forms, reports and spreadsheets.

Roche's Response to Amgen's Request for Production No. 121:

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 relating to the instruction, training, organization, supervision and compensation of Amgen employees and therefore seeking documents and things bearing no relevance to any claim or defense in this action.

Amgen's Request for Production No. 122:

All documents and things relating to information of Amgen regarding its instruction, training or support of customers or reimbursement personnel.

Roche's Response to Amgen's Request for Production No. 122:

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

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bear no relevance to any claim or defense in this action. Moreover, Roche objects to this Request as relating to the instruction, training or support of Amgen customers and reimbursement personnel and therefore seeking documents and things bearing no relevance to any claim or defense in this action.

Amgen's Request for Production No. 123:

Documents and things sufficient to identify and describe all activities sponsored by ROCHE since January 1, 2005 to enhance the competitive profile of peg-EPO.

Roche's Response to Amgen's Request for Production No. 123:

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's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche objects to this Request's use of the term "enhance the competitive profile" as it is vague, ambiguous and undefined.

Amgen's Request for Production No. 124:

Documents and things sufficient to identify and describe each clinical use or study of peg-EPO in the United States (excluding patient-specific information) after April 19, 2006, including the identity and location of each facility, the sponsor administering drug and the clinical protocol pursuant to which such administration was, is or will be made.

Roche's Response to Amgen's Request for Production No. 124:

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 refers Amgen to Roche's No. STN 125164/0 and IND Nos. BB-IND 10158 and BB-IND 10964, already produced to Amgen in ITC Investigation No. 337-TA-568, for information concerning the clinical use and study of MIRCERA TM.

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

Amgen's Request for Production No. 125:

All documents and things related to any plan, study protocol, draft protocol, concept, schedule, budget or supply forecast for use of peg-EPO in humans in the United States for any study not included in ROCHE's April 19, 2006 Biologics License Application, including any "Phase IIIb/IV" study.

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Roche's Response to Amgen's Request for Production No. 125:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Subject to these objections and the General Responses and Objections above, relevant, non-duplicative, non-cumulative documents relating to any completed communications, updates, amendments or supplements to Roche's BLA No. STN 125164/0 and INDs Nos. BB-IND 10158 and BB-IND 10964, and the final results of any completed studies or protocols underlying these submissions, which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

Amgen's Request for Production No. 126:

All documents and things comprising or related to any communication or presentation after January 1, 2006 between ROCHE and any third party (including all communications with clinicians and investigational review boards) regarding any plan, study protocol, draft protocol, concept, schedule or budget to study the use of peg-EPO in anemic renal patients in the United States, including any "Phase IIIb/IV" study.

Roche's Response to Amgen's Request for Production No. 126:

Roche incorporates herein by reference its Response to Request No. 125 above.

Amgen's Request for Production No. 137:

For each clinical trial involving peg-EPO, a copy of the study protocol, investigator brochure and material transfer agreement.

Roche's Response to Amgen's Request for Production No. 137:

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 refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information responsive to this Request. Roche also objects to this Request to the extent it seeks documents and things relating to ongoing clinical trials postdating Roche's filing of its BLA No. STN 125164/0. In order to avoid unnecessarily delaying or disrupting these trials, Roche will provide relevant documents relating to these trials only upon their completion, if any.

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

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Amgen's Request for Production No. 138:

For each clinical trial involving peg-EPO, documents and things sufficient to show the peg-EPO used, the principal investigators conducting each such trial, and the clinical and safety results of each such clinical trial.

Roche's Response to Amgen's Request for Production No. 138:

Roche incorporates herein by reference its Response to Request No. 137 above.

Amgen's Request for Production No. 139:

For each clinical trial involving peg-EPO, all documents and things comprising or relating to any analysis or assessment of the safety of peg-EPO use in humans.

Roche's Response to Amgen's Request for Production No. 139:

Roche incorporates herein by reference its Response to Request No. 137 above. Roche Should be Ordered to Produce Documents Regarding its Recruitment and Training of a Sales Force To Sell peg-EPO in the United States.

Amgen's Request for Production No. 146:

All documents and things comprising or relating to any communication, presentation or proposal between ROCHE or its attorneys and any third party regarding any non-clinical study or investigation of peg-EPO, EPO, or any other ESP.

Roche's Response to Amgen's Request for Production No. 146:

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. Roche further objects to this Request to the extent it seeks information regarding products or molecules other than Roche's CERA or MIRCERATM product for which commercial approval is sought in Roche's BLA No. STN 125164/0.

Amgen's Request for Production No. 148:

Documents and things sufficient to show the role of each ROCHE-affiliated entity in any current or future importation, distribution, sale or use of peg-EPO in the United States, including the manufacture, supply, distribution, use, marketing, sale or reimbursement of MIRCERA.

Roche's Response to Amgen's Request for Production No. 148:

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.

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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 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 no longer in issue in this action to the extent it refers to importation, distribution and related areas. To the extent any of these areas are still relevant to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

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

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

Amgen's Request for Production No. 149:

Documents and things sufficient to show the role of F. Hoffmann-La Roche Ltd. in any current or future importation, distribution, sale or use of peg-EPO in the United States, including the manufacture, supply, distribution, use, marketing, sale or reimbursement of MIRCERA.

Roche's Response to Amgen's Request for Production No. 149:

Roche incorporates herein by reference its Response to Request No. 148 above.

Amgen's Request for Production No. 150:

Documents and things sufficient to show the role of Roche Diagnostics GmbH in any current or future importation, distribution, sale or use of peg-EPO in the United States, including the manufacture, supply, distribution, use, marketing, sale or reimbursement of MIRCERA.

Roche's Response to Amgen's Request for Production No. 150:

Roche incorporates herein by reference its Response to Request No. 148 above.

Amgen's Request for Production No. 154:

Documents and things sufficient to identify and describe the goals, milestones, budgets and tasks, for each quarterly and annual period from 2001 through 2008, of each team or group within ROCHE involved in the preclinical, clinical, regulatory or technical development, manufacture and supply of MIRCERA for sale in the United States.

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Roche's Response to Amgen's Request for Production No. 154:

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 seeks documents and things relating to ongoing clinical trials post-dating Roche's filing of its BLA No. STN 125164/0. In order to avoid unnecessarily delaying or disrupting these trials, Roche will provide relevant documents relating to these trials only upon their completion, if any.

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

Amgen's Request for Production No. 155:

Documents and things sufficient to identify and describe the goals, milestones, budgets and tasks, for each quarterly and annual period from 2001 through 2008, of each team or group within ROCHE involved in the marketing, commercial launch, brand strategy, reimbursement, promotion, or medical education of MIRCERA use in the United States.

Roche's Response to Amgen's Request for Production No. 155:

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

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

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

Amgen's Request for Production No. 158:

Documents and things sufficient to identify, describe and explain ROCHE'S use of enterprise resource planning (ERP) and product lifecycle management (PLM) software and databases in connection with its manufacture, packaging, labeling, inventory, transfer, importation, distribution and sale of peg-EPO in the United States (including MIRCERA).

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Roche's Response to Amgen's Request for Production No. 158:

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 documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to inventory, importation, distribution and related areas. To the extent any of these areas are still relevant to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

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

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

Amgen's Request for Production No. 159:

Documents and things sufficient to identify and explain all material master numbers assigned or used by ROCHE to track or record the manufacture, packaging, labeling, inventory, transfer, importation, distribution and sale of peg-EPO (including MIRCERA) in the United States.

Roche's Response to Amgen's Request for Production No. 159:

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 the use of the term "material master numbers" as it is vague, ambiguous and undefined. Roche also objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Moreover, Roche objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to inventory, transfer, importation, distribution and related areas. To the extent any of these areas are still relevant to any issue in this action, Roche refers Amgen to Roche's production from the ITC investigation for documents responsive to this Request.

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Amgen's Request for Production No. 160:

Documents and things sufficient to show all locations throughout the world at which ROCHE maintains any inventory of peg-EPO and the most current stock levels of peg-EPO (including MIRCERA) at each location by vial or syringe size and quantity.

Roche's Response to Amgen's Request for Production No. 160:

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 overly broad and harassing as it relates to inventory and stock levels "throughout the world" and therefore seeks documents and things bearing no relevance to any claim or defense in this action. 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 in issue in this action to the extent it refers to stock levels and inventory 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.

Amgen's Request for Production No. 161:

Documents and things sufficient to identify, describe and explain ROCHE'S use of software database systems, including any SAP or PMX system used to track transfers and shipments of peg-EPO to and within the United States.

Roche's Response to Amgen's Request for Production No. 161:

Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to transfers and shipments 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.

Moreover, Roche objects to this Request as relating to the use of software database systems and therefore seeking documents and things bearing no relevance to any claim or defense in this action.

Amgen's Request for Production No. 162:

Documents and things sufficient to identify, describe and explain every tabulation of EPO and peg-EPO imported into the United States.

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Roche's Response to Amgen's Request for Production No. 162:

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 that are no longer in 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.

Amgen's Request for Production No. 163:

Documents and things sufficient to account for the transfer or shipment into the United States and ultimate disposition of all EPO and peg-EPO imported into the United States.

Roche's Response to Amgen's Request for Production No. 163:

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 that are no longer in issue in this action to the extent it refers to transfer[s], shipment[s], 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.

Amgen's Request for Production No. 164:

For each instance of importation into the United States of any EPO product, including (without limitation) peg-EPO, EPO, or any non-PEG component of peg-EPO, documents and things sufficient to separately describe and account for each importation of such product, including (without limitation):

- (a) The location(s) where the EPO or peg-EPO is manufactured;
- (b) The date(s) of each importation;
- (c) The ROCHE entity that contracted to ship the product to the United States;
- (d) The commercial carrier for each importation;
- (e) The ROCHE entity that delivered the product to such carrier;
- (f) The unit(s) and volume(s) of product(s) imported;
- (g) Any customs agent or broker for such importation;

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- (h) The ROCHE entity receiving the imported product(s);
- (i) The port of entry for the imported product(s);
- (j) The disposition of all imported product(s) after importation, including (without limitation) identifying each recipient of such product(s), the unit(s) and volume(s) of such product(s) provided to each recipient, the date(s) such product(s) was provided to each recipient, and all purposes for which such product was provided to each recipient;
- (k) All uses of such product(s) including the date(s) of use and the unit(s) and volume(s) used; and
- (l) All documents recording or reflecting any purpose(s) and use(s) for which any product was consumed or used by ROCHE or any recipient.

Roche's Response to Amgen's Request for Production No. 164:

Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request 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 as compound and duplicative. Roche further objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to importation, shipments 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.

Amgen's Request for Production No. 165:

All documents and things relating to the location(s) and amount(s) of all EPO and peg-EPO in the United States.

Roche's Response to Amgen's Request for Production No. 165:

Roche objects to this Request as overly broad, duplicative, 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 further objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to "the location(s) and amount(s) of all EPO and peg-EPO in the United States" 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.

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Amgen's Request for Production No. 166:

Documents and things sufficient to show the quarterly and monthly volume of peg-EPO, EPO or any non-peg component of peg-EPO ROCHE plans to import into the United States at any time through December 31, 2008, including United States sales forecasts, manufacturing requirement forecasts (either worldwide or for the United States), and manufacturing schedules and plans.

Roche's Response to Amgen's Request for Production No. 166:

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'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 as overly broad and harassing as it relates to sales and manufacturing forecasts "worldwide" and "at any time through December 31, 2008" and therefore seeks documents and things bearing no relevance to any claim or defense in this action.

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

Roche further 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-TH-568 that are no longer in 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.

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

Amgen's Request for Production No. 167:

Documents and things sufficient to show how ROCHE plans to use the EPO, peg-EPO, or any non-peg component of peg-EPO to be imported into the United States from January 1, 1995 through December 31, 2008.

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Roche's Response to Amgen's Request for Production No. 167:

Roche objects to this Request as overly broad, duplicative, 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. Moreover, Roche objects to this Request as overly broad and harassing as it relates to importation and use "through December 31, 2008" and therefore seeks documents and things bearing no relevance to any claim or defense in this action. Roche further objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to importation 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.

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

Amgen's Request for Production No. 176:

All documents and things relating to any existing or proposed understanding or agreement relating to peg-EPO between ROCHE and any person that is not a party to this lawsuit regarding the importation or transfer of peg-EPO or any non-peg component of peg-EPO in the U.S.

Roche's Response to Amgen's Request for Production No. 176:

Roche incorporates herein by reference its Response to Request No. 175 above [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 to the extent it seeks documents, things and information protected from disclosure by third party confidentiality agreements. Roche further objects to this Request as seeking documents and information relevant only to issues relating to 35 U.S.C. § 271(e)(1) that were the subject of ITC Investigation No. 337-TA-568 that are no longer in issue in this action to the extent it refers to importation, transfer 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].

III. ROCHE SHOULD PRODUCE DOCUMENTS AND THINGS REGARDING THE STRUCTURE AND ACTIVITY OF THE EPO CONTAINED IN ITS ACCUSED PRODUCT.

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Amgen's Request for Production No. 5:

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

Roche's Response to Amgen's Request for Production No. 5:

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

Amgen's Request for Production No. 14:

For each cell line used by ROCHE to produce the EPO component of peg-EPO (including DN2-3a3 cells), all documents and things sufficient to show the amount of EPO produced in culture over 24 hours by each such cell line as measured by radioimmunoassay ("RIA") or comparable means, including documents sufficient to show the methods and materials by which such measurement or calculation is made.

Roche's Response to Amgen's Request for Production No. 14:

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

Amgen's Request for Production No. 15:

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

Roche's Response to Amgen's Request for Production No. 15:

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

Amgen's Request for Production No. 16:

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

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Roche's Response to Amgen's Request for Production No. 16:

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

Amgen's Request for Production No. 17:

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

Roche's Response to Amgen's Request for Production No. 17:

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

Request to the extent it calls for a legal conclusion. Roche incorporates herein by reference its Response to Request No. 13 above.

Amgen's Request for Production No. 18:

Roche incorporates herein by reference its Responses to Request Nos. 13 [Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Roche also objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request to the extent it seeks information regarding cell lines other than those used to create Roche's MIRCERATM product for which commercial approval is sought in Roche's BLA No. STN 125164/0. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the cell lines used to produce MIRCERATM.] and 17 above.

Roche's Response to Amgen's Request for Production No. 18:

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

Amgen's Request for Production No. 19:

All documents and things relating to any analysis of the DNA sequence encoding EPO in each cell line (including the "DN2-30" 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.

Roche's Response to Amgen's Request for Production No. 19:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined.

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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 MIRCERATM product for which commercial approval is sought in Roche's BLA No. STN 125164/0.

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

Amgen's Request for Production No. 20:

All documents and things relating to any analysis of the DNA sequence that regulates or controls transcription and/or expression of EPO DNA in each cell line (including the “DN2-30” 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.

Roche's Response to Amgen's Request for Production No. 20:

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

Amgen's Request for Production No. 21:

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

Roche's Response to Amgen's Request for Production No. 21:

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

Amgen's Request for Production No. 22:

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

Roche's Response to Amgen's Request for Production No. 22:

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

Amgen's Request for Production No. 23:

All documents and things relating to any analysis of the copy number per cell of the DNA sequence encoding EPO in each cell line (including the “DN2-30” cell line) used to produce the EPO component of MIRCERA, including documents sufficient to show the methods and materials by which each such measurement or calculation is made.

Roche's Response to Amgen's Request for Production No. 23:

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

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Amgen's Request for Production No. 24:

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

Roche's Response to Amgen's Request for Production No. 24:

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

Amgen's Request for Production No. 218:

All documents and things relating to the origin and meaning of each name by which ROCHE refers to peg-EPO, including "CERA," "MIRCERA," "Continuous Erythropoiesis Receptor Activator" and any established name or USAN.

Roche's Response to Amgen's Request for Production No. 218:

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 TM bears no relevance to any claim or defense in this action.

Amgen's Request for Production No. 219:

All documents and things relating to every proprietary and non-proprietary name Roche considered for peg-EPO.

Roche's Response to Amgen's Request for Production No. 219:

Roche incorporates herein by reference its Response to Request No. 218 above.

Amgen's Request for Production No. 220:

All documents and things relating to any communication between ROCHE and any third party (including FDA) regarding any name for peg-EPO.

Roche's Response to Amgen's Request for Production No. 220:

Roche incorporates herein by reference its Response to Request No. 218 above.

IV. ROCHE SHOULD BE ORDERED TO PRODUCE A COMPLETE COPY OF ITS BLA AND IND DOCUMENTS.

Amgen's Request for Production No. 1:

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

Roche's Response to Amgen's Request for Production No. 1:

Roche objects to this Request as overly broad, unduly burdensome, duplicative and harassing to the extent it seeks documents and things already in Amgen's possession. For

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instance, Amgen is already in possession of the declarations of each Roche witness from the ITC investigation and all the transcripts of the depositions from the ITC investigation as Amgen itself requested the depositions and hired the court reporters that transcribed them and therefore Roche will not reproduce these documents. Moreover, Roche already expended great effort and expense during the ITC investigation to produce its extremely voluminous BLA No. STN125164/0 and IND Nos. BB-IND 10158 and BB-IND 10964 related to MIRCERA™ in both hard copy and the searchable electronic format requested by Amgen and therefore Roche will not reproduce these documents.

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

Amgen's Request for Production No. 37:

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

Roche's Response to Amgen's Request for Production No. 37:

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

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

Subject to these objections and the General Responses and Objections above, relevant, non-duplicative, non-cumulative documents relating to any completed communications, updates, amendments or supplements to Roche's BLA No. STN 125164/0 and INDs Nos. BB-IND 10158 and BB-IND 10964 and the final results of any completed studies or

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protocols underlying these submissions, which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

Amgen's Request for Production No. 38:

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

Roche's Response to Amgen's Request for Production No. 38:

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

Amgen's Request for Production No. 39:

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

Roche's Response to Amgen's Request for Production No. 39:

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

Amgen's Request for Production No. 40:

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

Roche's Response to Amgen's Request for Production No. 40:

Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche incorporates herein by reference its Response to Request No. 37 above.

Amgen's Request for Production No. 41:

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

Roche's Response to Amgen's Request for Production No. 41:

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

Amgen's Request for Production No. 42:

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

Roche's Response to Amgen's Request for Production No. 42:

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

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V. ROCHE SHOULD BE ORDERED TO PRODUCE DOCUMENTS REGARDING ITS FAILED ATTEMPTS TO DESIGN-AROUND AMGEN'S PATENTS.

Amgen's Request for Production No. 16:

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

Roche's Response to Amgen's Request for Production No. 16:

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

Amgen's Request for Production No. 17:

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

Roche's Response to Amgen's Request for Production No. 17:

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

Amgen's Request for Production No. 18:

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

Roche's Response to Amgen's Request for Production No. 18:

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

Amgen's Request for Production No. 19:

All documents and things relating to any analysis of the DNA sequence encoding EPO in each cell line (including the "DN2-30" 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.

Roche's Response to Amgen's Request for Production No. 19:

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined.

Moreover, Roche objects to the phrase "DNA sequence encoding EPO" as vague, ambiguous, misleading, inaccurate, and requiring claim construction and/or expert opinion. Roche further objects to this Request to the extent it seeks information regarding

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cell lines and DNA sequences other than those used to create Roche's CERA or MIRCERATM product for which commercial approval is sought in Roche's BLA No. STN 125164/0.

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

Amgen's Request for Production No. 20:

All documents and things relating to any analysis of the DNA sequence that regulates or controls transcription and/or expression of EPO DNA in each cell line (including the "DN2-30" 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.

Roche's Response to Amgen's Request for Production No. 20:

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

Amgen's Request for Production No. 21:

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

Roche's Response to Amgen's Request for Production No. 21:

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

Amgen's Request for Production No. 22:

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

Roche's Response to Amgen's Request for Production No. 22:

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

Amgen's Request for Production No. 23:

All documents and things relating to any analysis of the copy number per cell of the DNA sequence encoding EPO in each cell line (including the "DN2-30" cell line) used to produce the EPO component of MIRCERA, including documents sufficient to show the methods and materials by which each such measurement or calculation is made.

Roche's Response to Amgen's Request for Production No. 23:

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

Amgen's Request for Production No. 24:

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

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Roche's Response to Amgen's Request for Production No. 24:

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

Amgen's Request for Production No. 200:

All documents and things relating to any effort of ROCHE to avoid infringement of any claim of any Amgen patent, including the patents-in-suit.

Roche's Response to Amgen's Request for Production No. 200:

In light of Amgen's current position that it does not seek relief in the form of damages, this Request is of unreasonable scope and seeks documents and things, relating particularly to design-around, that bear no relevance to any claim or defense in this action. Roche incorporates herein by reference its Response to Request No. 198 above.

Amgen's Request for Production No. 201:

All documents and things relating to any proposal or plan of ROCHE to modify or alter its manufacture, importation, sale, offer to sell, or use of any ESP, including MIRCERA, to avoid infringement of any claim of any Amgen patent, including the patents-in-suit.

Roche's Response to Amgen's Request for Production No. 201:

Roche incorporates herein by reference its Responses to Request Nos. 198 and 200 above.

Amgen's Request for Production No. 202:

All documents and things relating to any ESP studied or evaluated by ROCHE as a potential treatment for anemia which has not been the subject of an IND or BLA filing.

Roche's Response to Amgen's Request for Production No. 202:

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 bearing no relevance to any claim or defense in this action because it is not limited to MIRCERA™.

Amgen's Request for Production No. 203:

All documents and things relating to any use at any time by Genetics Institute, ROCHE, any predecessor-in-interest of ROCHE, or any other person or entity of host cells (other than Chinese hamster ovary cells) to produce erythropoietin, including the selection or creation of such cells and the production, isolation, testing, analysis, or evaluation of any erythropoietin obtained from such cells.

Roche's Response to Amgen's Request for Production No. 203:

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

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action as erythropoietin is not the accused product in this case and the Request is not limited to MIRCERATM. 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.

Amgen's Request for Production No. 204:

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

Roche's Response to Amgen's Request for Production No. 204:

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 MIRCERATM. 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.

Amgen's Request for Production No. 205:

All documents and things relating to any comparison between the molecular weight, amino acid sequence, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, 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).

Roche's Response to Amgen's Request for Production No. 205:

Roche incorporates herein by reference its Response to Request No. 204 above.