# Exhibit 4 Part 2 of 3

including all documents forecasting hemoglobin by any dose level, use, customer, customer segment or patient category.

#### **RESPONSE TO REQUEST NO. 68:**

Roche incorporates herein by reference its Response to Request No. 67 above.

#### **REQUEST 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.

#### **RESPONSE TO REQUEST 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.

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# REQUEST 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<sup>®</sup>, ARANESP<sup>®</sup> and PROCRIT<sup>®</sup>).

# **RESPONSE TO REQUEST 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.

# REQUEST 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.

# **RESPONSE TO REQUEST NO. 71**:

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

# REQUEST 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.

# **RESPONSE TO REQUEST 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.

#### REQUEST 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.

## **RESPONSE TO REQUEST 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 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.

# REQUEST 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.

# **RESPONSE TO REQUEST NO. 74:**

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

# REQUEST 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.

# **RESPONSE TO REQUEST NO. 75:**

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

# REQUEST 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.

# **RESPONSE TO REQUEST 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.

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

# **REQUEST NO. 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.

# **RESPONSE TO REQUEST 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.

# **REQUEST 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.

# **RESPONSE TO REQUEST NO. 78:**

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

# **REQUEST 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.

# **RESPONSE TO REQUEST NO. 79:**

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

## REQUEST 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.

# **RESPONSE TO REQUEST 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.

#### **REQUEST 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.

## **RESPONSE TO REQUEST 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.

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.

# **REQUEST 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.

# **RESPONSE TO REQUEST 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.

# REQUEST 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<sup>®</sup>, ARANESP<sup>®</sup> and PROCRIT<sup>®</sup>.

# **RESPONSE TO REQUEST NO. 83:**

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

# **REQUEST NO. 84:**

All documents and things relating to any analysis, evaluation or presentation regarding the hemoglobin and/or dose response of anemic patients receiving MIRCERA therapy.

# **RESPONSE TO REQUEST NO. 84:**

Roche objects to this Request as cumulative of Request No. 67. Roche incorporates

herein by reference its Response to Request No. 67 above.

# REQUEST 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.

# **RESPONSE TO REQUEST 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. 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.

# **REQUEST 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.

# **RESPONSE TO REQUEST 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<sup>TM</sup>.

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

## REQUEST NO. 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.

# **RESPONSE TO REQUEST 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.

Subject to these objections and the General Responses and Objections above, relevant,

non-cumulative documents responsive to this Request which are in Roche's possession, custody

or control and which are not subject to a claim of privilege or work product immunity or

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

copying.

## REQUEST NO. 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<sup>®</sup>, ARANESP<sup>®</sup> and PROCRIT<sup>®</sup>.

# **RESPONSE TO REQUEST 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.

#### **REQUEST 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.

#### **RESPONSE TO REQUEST 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 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.

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### REQUEST 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.

## **RESPONSE TO REQUEST 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.

#### **REQUEST 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.

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

## **REQUEST 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 REQUEST 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.

#### REQUEST 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.

## **RESPONSE TO REQUEST 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.

## **REQUEST 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.

## **RESPONSE TO REQUEST 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 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.

# **REQUEST 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.

# **RESPONSE TO REQUEST 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.

# **REQUEST 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.

# **RESPONSE TO REQUEST 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.

# REQUEST 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.

# **RESPONSE TO REQUEST 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.

# **REQUEST 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.

#### **RESPONSE TO REQUEST NO. 98:**

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

# REQUEST 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.

#### **RESPONSE TO REQUEST 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.

## **<u>REQUEST NO. 100</u>**:

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

#### **RESPONSE TO REQUEST 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.

# REQUEST 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.

## **RESPONSE TO REQUEST NO. 101**:

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

# REQUEST 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 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.

## **RESPONSE TO REQUEST 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.

#### **REQUEST 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.

## **RESPONSE TO REQUEST 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.

# REQUEST 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.

# **RESPONSE TO REQUEST 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 or work product immunity or

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

copying.

# **REQUEST 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.

# **RESPONSE TO REQUEST NO. 105:**

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

# REQUEST 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.

# **RESPONSE TO REQUEST NO. 106:**

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

# **REQUEST 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.

# **RESPONSE TO REQUEST NO. 107:**

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

# REQUEST 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.

# **RESPONSE TO REQUEST NO. 108:**

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

# REQUEST 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.

# **RESPONSE TO REQUEST NO. 109:**

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

# **REQUEST NO. 110:**

All documents and things relating to any agreement, assignment, license, or transfer between ROCHE and a third party in the United States regarding any ESP potentially useful in the treatment of anemia.

# **RESPONSE TO REQUEST NO. 110:**

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, things and information protected from

disclosure by third party confidentiality agreements. Roche also 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, relating particularly 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.

# REQUEST 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.

## **RESPONSE TO REQUEST 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.

## **REQUEST NO. 112:**

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

## **RESPONSE TO REQUEST NO. 112:**

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 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. 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 relates to internal transfer of MIRCERATM

and related areas.

# **<u>REQUEST NO. 113</u>**:

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.

# **RESPONSE TO REQUEST 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.

# REQUEST 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.

# **RESPONSE TO REQUEST NO. 114:**

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

# **REQUEST 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.

# **RESPONSE TO REQUEST NO. 115:**

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

## REQUEST NO. 116:

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

## **RESPONSE TO REQUEST 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.

## REQUEST 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.

## **RESPONSE TO REQUEST 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.

# **REQUEST 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.

# **RESPONSE TO REQUEST 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 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.

#### REQUEST 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.

# **RESPONSE TO REQUEST 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.

# **REQUEST 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.

# **RESPONSE TO REQUEST NO. 120:**

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

# REQUEST 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.

## **RESPONSE TO REQUEST 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.

## REQUEST NO. 122:

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

# **RESPONSE TO REQUEST 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 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.

#### REQUEST 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.

# **RESPONSE TO REQUEST 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.

# **REQUEST 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.

# **RESPONSE TO REQUEST 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<sup>TM</sup>.

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

# REQUEST NO. 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.

## **RESPONSE TO REQUEST 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.

# **REQUEST 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.

### **RESPONSE TO REQUEST NO. 126:**

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

# **REQUEST NO. 127:**

All documents and things related to the conception, development, budget, cost, funding for, work performed, results, or presentation of the information contained in Abstract Nos. TH-PO072, TH,-PO230, TH-PO359, TH-PO361, TH-PO1001, TH-PO1002, TH-PO1007, PUB376, PUB377, F-PO375, F-PO408, F-PO671, F-PO685, SA-PO019, SA-PO034, SA-PO035, SA-PO192, SA-PO197, SA-PO198, SA-PO205, SA-PO207, SA-PO208, SA-PO209, SA-PO210, SA-PO212, and SA-PO225 (attached hereto as Exhibit B), as submitted for publication in 2006 to the American Society of Nephrology.

## **RESPONSE TO REQUEST NO. 127:**

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

Subject to these objections and the General Responses and Objections above, relevant,

non-cumulative documents responsive to this Request which are in Roche's possession, custody

or control and which are not subject to a claim of privilege or work product immunity or

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

copying.

## **REQUEST NO. 128:**

All documents and things comprising or related to any communication or presentation between ROCHE and any third party (including all communications with clinicians and investigational review boards) regarding Abstract No. SA-PO205 (Exhibit C), including all drafts of the study protocol.

## **RESPONSE TO REQUEST NO. 128:**

Roche incorporates herein by reference its Response to Request No. 127 above.

# REQUEST NO. 129:

All documents and things relating to the use of control variables in the development of a case-mix adjusted payment system for dialysis systems, as described in ASN Abstract TH-PO1007 (attached hereto as Exhibit D).

#### **RESPONSE TO REQUEST NO. 129:**

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 things unrelated to MIRCERA<sup>™</sup> and having

no relevance to any claim or defense in this action. Moreover, Roche objects to this Request's

use of the term "case-mix adjusted payment system for dialysis systems" as vague, ambiguous,

indeterminate and seeking information irrelevant in light of Amgen's absence of any damages

claim.

# **REQUEST NO. 130:**

All documents and things relating to any communication between ROCHE and J. Wheeler, M. Turenne, R. Hirth, J. Messana, or A. Pozniak regarding any study or investigation of the use of control variables in the development of a case-mix adjusted payment system for dialysis systems, as described in the previous request for production.

## **RESPONSE TO REQUEST NO. 130:**

Roche incorporates herein by reference its Response to Request No. 129 above.

## **REQUEST NO. 131**:

All documents and things relating to any association between missed dialysis sessions and hemoglobin variability, as described in ASN Abstract F-PO375 (attached hereto as Exhibit E).

## **RESPONSE TO REQUEST NO. 131:**

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague,

ambiguous and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections and the General Responses and Objections above, relevant,

non-cumulative documents responsive to this Request which are in Roche's possession, custody

or control and which are not subject to a claim of privilege or work product immunity or

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

copying.

# REQUEST NO. 132:

All documents and things relating to any communication between ROCHE and Robert N. Foley, Qi Li, David T. Gilbertson, Allan J. Collins, or Stephan C. Dunning regarding any study or investigation of any association between missed dialysis sessions and hemoglobin variability, as described in the previous request for production.

# **RESPONSE TO REQUEST NO. 132:**

Roche incorporates herein by reference its Response to Request No. 131 above.

# REQUEST NO. 133:

All documents and things relating to any association of persistently low hemoglobin levels with medical expenditures in dialysis patients, as described in ASN Abstract F-PO408 (attached hereto as Exhibit F).

# **RESPONSE TO REQUEST NO. 133**:

See Response to Request No. 131 above.

# REQUEST NO. 134:

All documents and things relating to any communication between ROCHE and Jiannong Liu, Haifeng Guo, David T. Gilbertson, or Allan J. Collins, regarding any study or investigation of any association of persistently low hemoglobin levels with medical expenditures in dialysis patients, as described in the previous request for production.

# **RESPONSE TO REQUEST NO. 134:**

Roche incorporates herein by reference its Response to Request No. 131 above.

## REQUEST NO. 135:

All documents and things relating to any association between hemoglobin variability and mortality among dialysis patients, as described in ASN Abstract SA-PO034 or SA-PO035 (attached hereto as Exhibits G and H).

# **RESPONSE TO REQUEST NO. 135:**

Roche incorporates herein by reference its Response to Request No. 131 above.

# REQUEST NO. 136:

All documents and things relating to any communication between ROCHE and H.I. Feldman, R.K. Israni, W. Yang, S. Fishbane, or M. Joffe regarding any study or investigation of any association between hemoglobin variability and mortality among dialysis patients, as described in the previous request for production.

# **RESPONSE TO REQUEST NO. 136:**

Roche incorporates herein by reference its Response to Request No. 131 above.

# <u>**REQUEST NO. 137:</u>**</u>

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

## **RESPONSE TO REQUEST 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 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.

#### **REQUEST 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.

#### **RESPONSE TO REQUEST NO. 138:**

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

# **REQUEST 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.

#### **RESPONSE TO REQUEST NO. 139**:

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

## REQUEST NO. 140

Documents and things sufficient to show the respective role and responsibility of each ROCHE employee, team, group and/or third party involved in any preclinical study or characterization of peg-EPO, including any comparison of any property or characteristic of peg-EPO with any other ESP(s).

## **RESPONSE TO REQUEST NO. 140:**

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.

Subject to these objections and the General Responses and Objections above, relevant,

non-cumulative documents responsive to this Request which are in Roche's possession, custody

or control and which are not subject to a claim of privilege or work product immunity or

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

copying.

# REQUEST NO. 141:

All documents and things relating to any study involving the administration of peg-EPO or EPO to any non-human animal in the United States after 1995.

#### **RESPONSE TO REQUEST NO. 141:**

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. 140 above.

# **REQUEST NO. 142:**

All documents and things that comprise or relate to the goals, budgets and tasks (including all milestones, minutes, agendas, presentations, tasks lists, plans of action, schedules and priorities) of each team or group within ROCHE involved in any preclinical study or characterization of peg-EPO at any time since January 1, 2002, including any investigation or study of peg-EPO's mechanism of action, its pharmacokinetic or pharmacodynamic properties, or any comparison of any characteristic or property of peg-EPO with those of any other ESP(s).

# **RESPONSE TO REQUEST NO. 142:**

Roche incorporates herein by reference its Response to Request No. 140 above.

# **REQUEST NO. 143:**

All documents and things relating to any study or investigation sponsored or funded by ROCHE or its attorneys relating to the mechanism of action of peg-EPO in relation to erythropoietin receptors.

# **RESPONSE TO REQUEST NO. 143:**

Roche objects to this Request as seeking information protected from disclosure by the

attorney-client privilege and the attorney work product doctrine. Roche objects to this Request

as duplicative of other Requests herein. Roche incorporates herein by reference its Response to

Request No. 140 above.

# **REQUEST NO. 144:**

All documents and things relating to any study or investigation sponsored or funded by ROCHE or its attorneys relating to any comparison of any activity, property or characteristic of peg-EPO with the corresponding activity, properties or characteristics of any other ESP.

# **RESPONSE TO REQUEST NO. 144:**

Roche incorporates herein by reference its Responses to Request Nos. 140 and 143

above.

# **REQUEST NO. 145:**

All documents and things (including all communications, plans, grants, grant applications, and research contracts or related drafts) relating to any work or study of any third party regarding peg-EPO or EPO, including documents relating to comparative studies or analysis of the mechanism of action and pharmacodynamic and/or pharmacokinetic properties of peg-EPO.

## **RESPONSE TO REQUEST NO. 145:**

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Moreover, Roche further 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 MIRCERA<sup>TM</sup> product for which commercial approval is sought in Roche's BLA No. STN 125164/0.

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

#### **REQUEST NO. 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.

#### **RESPONSE TO REQUEST 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 MIRCERA<sup>™</sup> product for which commercial approval is sought in Roche's BLA No. STN 125164/0.

#### REQUEST NO. 147:

Documents and things sufficient to show the relationship between and among the ROCHE Defendants and their subsidiaries, affiliates, divisions, parent(s), and/or other related companies.

#### **RESPONSE TO REQUEST NO. 147:**

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 indeterminate, harassing, oppressive and of unreasonable scope in its reference to "related companies" which potentially encompasses entities possessing no documents, things or information of any relevance to any claim or defense in this action.

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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#### <u>**REQUEST NO. 148:</u>**</u>

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.

## **RESPONSE TO REQUEST 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. 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

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

copying.

## REQUEST 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.

## **RESPONSE TO REQUEST NO. 149:**

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

## REQUEST 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.

## **RESPONSE TO REQUEST NO. 150:**

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

## **REQUEST NO. 151:**

Documents and things sufficient to show the internal business organization and employee hierarchy of ROCHE from 2000 to the present with respect to the development and commercialization of peg-EPO, including the reporting relationships of officers, managing agents, and employees within ROCHE whose duties and/or responsibilities relate in any way to peg-EPO.

# **RESPONSE TO REQUEST NO. 151:**

Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague,

ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche

objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading.

Subject to these objections and the General Responses and Objections above, relevant,

non-cumulative documents responsive to this Request which are in Roche's possession, custody

or control and which are not subject to a claim of privilege or work product immunity or