UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DOCUMENTS

511157_4

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I. INTRODUCTION

Roche has objected to and refused to produce documents in response to more than half of Amgen's pending Requests for Production—refusing to produce documents responsive to 132 of Amgen's Requests and agreeing to produce documents in response to only 92 such requests. Even where Roche has agreed to produce certain documents, it seeks to circumscribe the documents it will produce by excluding:

- Any document (other than FDA filings) created on or after April 18, 2006;
- Documents regarding its past and current marketing, sales, pricing and reimbursement plans and activities for the commercial sale of peg-EPO in the United States;
- Documents regarding its on-going and impending uses of peg-EPO in the United States;
- Documents regarding its recruitment, hiring and training of a U.S. sales force for peg-EPO;
- Documents regarding the EPO component of peg-EPO unless contained in Roche's BLA;
- A complete and fully text-searchable copy of its BLA and IND; and
- Documents regarding Roche's failed attempts to design-around Amgen's patents.

Amgen first raised its concerns with Roche's refusals on December 5, 2006. Since that date, Amgen has written, met and conferred with Roche in a good faith effort to narrow the issues in dispute.[1] While the parties have been able to agree on a few issues, Roche refuses to produce documents regarding its most recent and relevant acts of infringement, as well as evidence regarding its asserted defenses.

The Court's November 7, 2006 Scheduling Order requires the completion of document production by February 16, 2007 and the close of fact discovery by April 6, 2007. In light of this

[1] *See* Exh. 1 (12/6/06 Fishman letter to Suh); Exh. 2 (12/8/06 Fishman letter to Suh); and Exh. 3 (12/11/06 Fishman letter to Suh) to the Declaration of Krista M. Carter filed in Support of Amgen's Motion to Compel the Production of Documents (hereafter "Carter Decl.).

extremely tight schedule, the Court admonished the parties during the October 23, 2006 Scheduling Conference to provide full, prompt discovery to ensure complete preparation of the case for trial in September 2007. For just that reason, Amgen's counsel served its first production requests on Roche on October 30, 2006, and wrote to Roche's counsel on November 21, 2006 to identify the priority discovery Amgen asked Roche to produce at the outset of its production in early December.[2] Notably, it is precisely that discovery that Roche refuses to produce in its December 4, 2006 Responses to Amgen's Requests for Production.

For all of these reasons, Amgen respectfully requests the Court to overrule Roche's stated objections and to order Roche to immediately produce non-privileged documents responsive to Amgen's requests as further detailed below.

II. ROCHE SHOULD PRODUCE DOCUMENTS RELATING TO AMGEN'S REQUESTED RELIEF AND ROCHE'S CURRENT AND IMMINENT ACTS OF INFRINGEMENT.

Amgen's Amended Complaint alleges that Roche currently infringes or will imminently infringe the patents-in-suit, and seeks both declaratory and injunctive relief by this action.[3] In its Answer, Roche has denied that it imports peg-EPO into the United States, denied that it uses peg-EPO in the United States, denied that it expects to obtain regulatory approval to market and sell peg-EPO in the United States within 12-14 months, and denied that it is making meaningful preparations to market and sell peg-EPO in the United States.[4] In addition, Roche alleges that its past and current activities do not constitute infringement under the "safe harbor" provisions of 35 U.S.C. § 271(e)(1).[5]

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[2] 11/21/06 D. Fishman letter H. Suh (Docket No. 157, Exh. 12).

[3] Amgen's Amended Complaint (Docket No. 52) at ¶¶ 25-32.

[4] Roche's Answer (Docket 140) to Amended Complaint and proposed Amended Answer (Docket 161, Exh. A) at ¶¶ 18, 22, 28, 29, and corresponding allegations in Amgen's Amended Complaint (Docket No. 52).

[5] Roche's Answer to Amgen's Amended Complaint and Counterclaims (hereafter "Roche's

To secure evidence relevant to Amgen's claims and requested relief as well as Roche's defenses, Amgen served a number of requests for production relating to Roche's on-going preparations for commercial launch of peg-EPO in the United States, including its marketing and sales plans and efforts, its pricing and reimbursement plans and efforts, and its contacts with potential or actual customers and purchasers. *See* Amgen Requests for Production Nos. 46-71, 76-109. The following Amgen Requests for Production are illustrative:

> **Request No. 46:** All documents and things generated by or for ROCHE management or any ROCHE organization, group or team since January 1, 2003 that reference or relate to preparations for or the commercial launch, supply, commercialization, promotion, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, tasks lists, schedules and plans of action.
>
> **Request No. 51:** All documents and things that comprise or relate to ROCHE's marketing plan for MIRCERA in the United States.
>
> **Request No. 56:** All documents and things generated by or for ROCHE management, marketing or sales regarding projected customers, sales, dosing, pricing, reimbursement, or use of MIRCERA in the United States at any time during 2006, 2007, 2008 and/or 2009, including all reports, analyses, presentations, spreadsheets, minutes, agendas, task lists, and plans of action of each team or group involved therein.
>
> **Request No. 61:** All documents and things relating to any analysis or evaluation of pricing of MIRCERA for sale or use in the United States, including any analysis or evaluation of discounts, rebates or other incentives for purchase or use of MIRCERA with patients.
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> **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.
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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.

Answer and Counterclaims") (Docket No. 140) at ¶ 35.

Roche's response to these requests is two-fold. First, in Roche's general objections, it objects to all of Amgen's requests and refuses to produce any documents (other than FDA filings) created after April 18, 2006, the date on which Roche filed its BLA for peg-EPO with FDA.[6] The only excuse Roche offers to justify its refusal to produce documents generated after April 18, 2006 is stated in Roche's General Objection No. 8:

> Roche objects to Amgen's Instruction No. 2 as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant information to the extent it seeks documents and things that post-date Roche's filing of its Biologics License Application ("BLA") No. STN 125164/0 filed with the U.S. Food and Drug Administration ("FDA") on April 18, 2006. Amgen bases its claims of infringement solely on the proposed product described in Roche's BLA No. STN 125164/0 and currently Amgen seeks only injunctive relief and no damages. Therefore, Roche will not provide documents and things that originate after April 18, 2006, except documents and things that relate to a relevant update, supplement, amendment or continuation of its BLA No. STN 125164/0 upon completion of any ongoing studies.[7]

Roche's refusal to produce documents generated after April 18, 2006 would preclude discovery of the evidence most relevant to Amgen's requested relief, including the likely impact and effect of Roche's market entry on Amgen and the public interest, as well as Roche's current and imminent infringement.[8]

Second, in addition to its general objection regarding documents generated after April 18, 2006, Roche further objects to Amgen's specific requests regarding its past and current marketing, sales, pricing and reimbursement activities by contending that the requested documents are not relevant to any issue in this action, and offering to produce only such

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[6] *See* Carter Decl., Exh. 4. (Roche's Responses and Objections to Amgen's First Set of Requests for Production of Documents and Things (hereafter "Roche's Responses and Objections") at 7, ¶8.) Absent a specific time period in a request, Amgen's Instruction No. 2 requested production of documents and things generated during the period January 1, 1995 through the date of production.

[7] *See* Carter Decl., Exh. 4. (Roche's Responses and Objections at 7 (¶ 8)).

[8] Roche's suggestion that it will produce the supplemental filings to its BLA once those studies are completed is an empty offer since Roche's own internal projections do not estimate

documents as it—Roche—unilaterally considers relevant to factors relevant to a preliminary or permanent injunction determination. But even then, Roche does not specify what it believes those factors are or what scope of documents will be produced. Roche's response to Amgen's RFP 46 is exemplary of Roche's position:

> **Request No. 46:** All documents and things generated by or for ROCHE management or any ROCHE organization, group or team since January 1, 2003 that reference or relate to preparations for or the commercial launch, supply, commercialization, promotion, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, tasks lists, schedules and plans of action.
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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.

During the parties' December 11 meet and confer, Roche clarified that it will ***not*** produce any responsive documents to Amgen's requests unless Roche—not Amgen—files for an injunction

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completion for those studies until after a trial in this matter, as discussed in Section B below.

(in which case it would produce such documents as it deems relevant), or unless and until Amgen specifically alleges a claim for damages.[9] In short, notwithstanding Roche's stated objection, it has informed Amgen that it will not produce any of the requested documents until it seeks an injunction or Amgen files a claim for damages.

Roche's position is without merit. Amgen has requested a permanent injunction in this action. Under *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006), Amgen must satisfy the following four-factor test before such relief can be granted:

> "(1) that [Amgen] has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between [Amgen] and [Roche], a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction."[10]

Drawing from the list of documents requested that Roche refuses to produce, the following types of documents are relevant to these factors:[11]

- Documents relating to pricing of MIRCERA (Req. Nos. 46, 61, 80) – required to calculate the effect of Roche's market entry on Amgen's business and resultant irreparable harm to Amgen.

- Documents relating to projected customers (Req. No. 56) and projected sales (Req. 90) – required to calculate the impact of Roche's market entry on additional irreparable harm factors such as loss of customer goodwill.

- Documents relating to promotion of MIRCERA (Req. No. 46) and marketing of MIRCERA (Req. Nos. 51, 56) – serve to demonstrate the potential public benefits (or lack thereof) of MIRCERA.

- Documents relating to clinical development (Req. No. 46) or dosing (Req. No. 56) – serve to demonstrate potential public benefits (or lack thereof) of MIRCERA.

- Documents relating to government reimbursement (Req. Nos. 46, 56, 61, 80) – serve to demonstrate potential public benefits (or lack thereof) in terms of overall

[9] *See* Carter Decl., Exh. 3 (12/11/06 Fishman letter to Suh); Exh. 30 (12/13/06 H. Suh letter to D. Fishman).

[10] *eBay*, 126 S. Ct. at 1839.

[11] The following list is merely exemplary and not exhaustive.

government spending.

- In addition, the documents noted above further serve to demonstrate Roche's efforts and financial outlays for MIRCERA, which may relate to a balance of the hardships should an injunction issue.

In addition to the relevance of these requested documents to Amgen's requested relief, Amgen's Complaint alleges that Roche is currently infringing and will imminently infringe Amgen's patents. In response, Roche contends that § 271(e)(1) insulates its past and current activities from liability from infringement. How can Roche assert an affirmative defense, then foreclose Amgen from the discovery needed to test that defense? Roche's assertion of a § 271(e)(1) defense does not free Roche from the obligation to produce the discovery Amgen requires to test the merits of Roche's defense. Indeed, it is precisely Roche's post-filing activities since April 2006 that are most probative of the claim Amgen asserts, and the defense Roche interposes.

For all of these reasons, Roche's General Objection No. 8 should be overruled and Roche should be ordered to produce documents and things created on and after April 18, 2006 responsive to Amgen's requests. In addition, because Roche's preparations for market launch are relevant to Amgen's claim and its requested relief, as well as Roche's affirmative defense, Roche's relevance and other objections to Amgen's Requests for Production Nos. 45-66, 69-83, 85, 88-103, 111, 113-126, 137-139, 146, 148-150, 154-155, 158-167, 176 should be overruled, and Roche should be ordered to produce its responsive documents to each of these requests.[12]

[12] For ease of reference and to comply with L.R. 37.1, Amgen refers the Court to Appendix A attached hereto that sets forth each of Amgen's Requests for Production and Roche's corresponding Responses and Objections that is the subject of Section I of this motion. *See* Appendix A, Section I for Amgen's Requests for Production Nos. 45-66, 69-83, 85, 88-103, 111, 113-126, 137-139, 146, 148-150, 154-155, 158-167 and 176 and Roche's corresponding Responses and Objections.

A. ROCHE SHOULD BE ORDERED TO PRODUCE DOCUMENTS REGARDING ITS ON-GOING AND FUTURE OFFERS FOR SALE AND SALES OF ITS ACCUSED PRODUCT TO THIRD PARTIES.

Amgen's Requests for Production Nos. 47-48, 94-95, 100-109, 111, and 113-115 seek documents concerning Roche's communications with customers or potential customers regarding the purchase, pricing, use or reimbursement of MIRCERA in the United States.[13] In addition to General Objection No. 8, Roche objects on the grounds of relevance and refuses to produce any documents responsive to Amgen's requests. Roche's response to Request No. 95 is illustrative:

> **Request No. 95:** All documents and things related to any communication, meeting, presentation or solicitation between ROCHE and any purchaser or consumer of ESP products . . . relating to the current or future purchase, pricing, use or reimbursement of peg-EPO or MIRCERA in the United States.
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> **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.

The discovery Amgen requests is directly relevant to the allegations in Amgen's Amended Complaint—which Roche denied—that "Roche has been and is making meaningful preparations to market and sell peg-EPO in the United States, including: . . .contacting potential customers, including large dialysis organizations ("LDOs"), to solicit interest in purchasing peg-EPO from Roche upon regulatory approval in the United States."[14] The substance of Roche's relationships with customers and potential customers also directly relates to Amgen's allegations of current

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[13] See Appendix A, Section I.A.. for Amgen's Requests for Production Nos. 47-48, 94-95, 100-109, 111, and 113-115 and Roche's corresponding Responses and Objections.

[14] *See* Amgen's Amended Complaint (Docket No. 52) at ¶ 29; "Roche's Answer and Counterclaims" (Docket No. 140) at ¶ 29.

infringement,[15] as well as Roche's tortuous interference counterclaim[16] and § 271(e)(1) defense.[17]

None of Roche's objections justify its refusal to produce documents responsive to these Requests. Roche's relevance objection depends entirely on the false premise that that the discovery Amgen seeks is relevant only to damages and that Amgen is estopped from recovering damages. Neither is true. And even if Amgen were limited to declaratory and injunctive relief (which it is not), the substance of Roche's communications with customers and potential customers would remain relevant to Amgen's declaratory judgment claim, Amgen's entitlement to an injunction, Roche's defenses, and the basis for Roche's counterclaims (*i.e.*, whether Roche has had any existing or prospective business relationships with which Amgen tortiously interfered).

Roche's objections to Amgen's Requests for Production Nos. 47-48, 94-95, 100-109, 111, and 113-115 should be overruled, and Roche should be ordered to produce the requested documents.

B. ROCHE SHOULD BE ORDERED TO PRODUCE DOCUMENTS REGARDING ITS ON-GOING AND PLANNED USES OF PEG-EPO IN THE UNITED STATES.

Amgen's Requests for Production Nos. 72-75, 123-126, and 137-139 are directed to Roche's ongoing and planned uses of peg-EPO in the United States, including studies designed by Roche's Medical Affairs group to support the impending market launch of peg-EPO and enhance its competitive profile.[18] Roche has categorically refused to produce documents in

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[15] *See* Amgen's Amended Complaint (Docket No. 52) at ¶¶ 26, 32.

[16] *See* "Roche's Answer and Counterclaims" (Docket No. 140) at ¶¶ 94, 50.

[17] *See* Roche's Answer and Counterclaims at ¶ 35 (Docket No. 140).

[18] Documents regarding ongoing and planned clinical uses were also the subject of two motions to compel in the ITC action.

response to each of these requests.[19] Roche's response to Amgen's Request for Production No. 74 is illustrative:

> **Request for Production 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 Request for Production 74**: 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.
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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, 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.

First, Roche refuses to produce any documents generated after April 18, 2006 based on General Objection No. 8 discussed above. Next, Roche refuses to produce documents responsive to Amgen's Requests unless and until such trials are completed and submitted to FDA.[20] By this objection, Roche seeks to avoid discovery of studies that are not completed and submitted to

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[19] See Appendix A, Section I.B. for Amgen's Request Nos. 72-75, 123-126, and 137-139 and Roche's corresponding Responses and objections.

[20] *See* Carter Decl., Exh. 4 (Roche's Responses and Objections to Nos. 73-75, 77-79, 124-126, 137-139, and 154). In the parties' December 11 meet and confer, Roche elaborated its position that it would not produce responsive documents until it had filed such documents with FDA. *See* Carter Decl., Exh. 3 (12/11/06 Fishman letter to Suh); Exh. 30 (12/13/06 H. Suh letter to D. Fishman).

FDA prior to trial, even if such uses are not exempt pursuant to § 271(e)(1). Finally, Roche objects to and refuses to produce all documents regarding its current and future activities as not relevant to any claim or defense in this case.

During the parties' December 11 meet and confer, Roche further stated that it will not produce documents responsive to these requests (or any other request that it has stated is potentially relevant to a preliminary or permanent injunction) unless and until Roche moves for an injunction or Amgen specifically alleges a claim for damages.[21]

Roche's refusal is unfounded. Roche's current and future uses of its imported and accused peg-EPO product are directly relevant to Amgen's First Cause of Action ("Roche's importation and/or use of peg-EPO in the United States currently infringes or will imminently infringe the claims of Amgen's patents-in-suit),"[22] as well as Roche's alleged 35 U.S.C. § 271(e)(1) affirmative defense to infringement.

Roche's own documents indicate that

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[23] Roche's refusal to produce this discovery on the pretext of avoiding "unnecessarily delaying or disrupting these trials," ignores the fact that under the two-tier Protective Order endorsed by the Court, only outside counsel will have access to Highly Confidential Material, expressly including "on-going and future clinical trials and

[21] Carter Decl., Exh. 3 (12/11/06 Fishman letter to Suh); Exh. 30 (12/13/06 H. Suh letter to D. Fishman).

[22] Amgen's Amended Complaint for Declaratory Judgment of Infringement (hereafter "Amgen's Amended Complaint") (Docket No. 52) at 7.

[23] *See, e.g.*, Carter Decl., Exh. 6 (ITC-R-00024046-93).

communications with regulatory authorities regarding such trials."[24]

Roche's offer to produce the requested documents and "final results of any completed studies or protocols," but "only upon their completion," begs the question of whether Roche's activities are exempt in the first place. Roche's self-help remedy is to deny Amgen discovery of any use or study that Roche ***does not submit to FDA***—precisely the uses and studies most likely to fall outside any exemption under § 271(e)(1).

Given the heightened protection already afforded such documents in the parties' Protective Order, Roche's objections should be seen for what they are—an attempt to avoid highly relevant and probative discovery.

C. 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 Requests for Production Nos. 91-94 and 116-122 seek documents concerning Roche's solicitation, recruitment, hiring and training of U.S. sales and marketing personnel for peg-EPO, including Amgen employees, as well as its training programs for physicians and nurses.[25] In addition to General Objection No. 8, Roche objects to Amgen's requests on the basis or relevance and refuses to produce any of the requested documents.

For example, in response to Amgen's Request No. 94, seeking discovery of the customer training and instructional materials developed and used by Roche to promote the sale and reimbursement of MIRCERA in the United States, Roche simply refuses to produce any document on the grounds of relevance:

Request No. 94: All documents and things relating to any training or instruction

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[24] *See* November 30, 2006 Order (Docket No. 159) ("Highly Confidential Material"); Plaintiff Amgen Inc.'s Memorandum in Support of Its Motion for Reconsideration or Clarification of the November 6, 2006 Order (Docket No. 156) at 12.

[25] See Appendix A, Section I.C. for Amgen's Requests for Production Nos. 91 and 116-122 and Roche's corresponding Responses and Objections.

> of physicians, nurses, 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 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.

Amgen's request is relevant to Roche's inducement of third parties to directly infringe Amgen's patents through use of its infringing product as well as the timing, nature and extent of the infringing uses Roche seeks to promote. It is calculated to lead to the discovery of evidence relevant to imminence and extent of Roche's infringing activities, as well as the nature and extent of the harm that Roche's promotion and sale of MIRCERA will inflict on Amgen.

Similarly, in response to Amgen's Request No. 116, seeking discovery of Roche's attempts to recruit and hire Amgen employees since January 2004, Roche again refuses to produce any documents on the grounds of relevance:

> **Request 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 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.

Roche's on-going efforts to recruit, hire and train a sales force are relevant to the imminence with which Roche will commence commercial sales of peg-EPO in the United States as well as the nature and extent of the harm Roche's infringing activities will inflict on Amgen. Discovery

of Roche's solicitation and recruitment of Amgen employees is directly relevant to the allegations in Amgen's Amended Complaint—which Roche denied—that "Roche has been and is making meaningful preparations to market and sell peg-EPO in the United States, including: Hiring key management, support, and sales personnel, including actively recruiting Amgen marketing and medical personnel involved in the sale and use of recombinant human EPO, to market and sell peg-EPO upon receipt of regulatory approval to market and sell peg-EPO in the United States...."[26] Such evidence not only demonstrates the imminence and extent of Roche's preparations to market and sell peg-EPO in the United States—an element of Amgen's declaratory judgment claim which Roche has refused to concede—but also the nature and extent of the harm Roche's infringing activities have and will inflict on Amgen.

Roche's objections to Amgen's Requests for Production Nos. 91-94 and 116-122 should be overruled and Roche should be ordered to produce the requested documents and things.

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

A. ROCHE'S OBJECTION TO AND REFUSAL TO PRODUCE DOCUMENTS REGARDING "EPO" SHOULD BE OVERRULED.

Roche objects—incredibly—to Amgen's requests for production of documents relating to "EPO" based on its argument that "EPO" is "not the accused product in this case."[27] Amgen's Request No. 5 and Roche's Response to that Request are illustrative:

> **Request No. 5:** Documents and things sufficient to characterize accurately the amino acid sequence, molecular weight, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, in vitro or in vivo

[26] *See* Amgen's Amended Complaint (Docket No. 52) at ¶ 29; Roche's Answer and Counterclaims (Docket No. 140) at ¶ 29.

[27] *See* Carter Decl., Exh. 4. (Roche's Responses and Objections for Production No. 5, set forth *infra)*; *see also* Carter Decl., Exh. 30 (12/13/06 H. Suh letter to D. Fishman).

biological activity, and any other physical or functional characteristic of the EPO from which MIRCERA is produced.

Roche's Response to Request No. 5: Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. ***Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case.*** Moreover, Roche objects to this Request to the extent it uses terms that may require construction by the Court. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™. (emphasis supplied)

Likewise, in its General Objections, Roche objects to every Amgen Request to the extent it uses the terms "EPO" or "peg-EPO" and expressly limits its production to MIRCERA: "Unless otherwise noted, Roche's responses to these Requests are limited to MIRCERA™—whether referred to as CERA or any other internal Roche designation—rather than "peg-EPO" and products containing "peg-EPO."[28] Based on its objections, Roche refuses to produce documents regarding the structural and functional characterization of the EPO from which MIRCERA is produced in response to Amgen's Requests for Production Nos. 14-24.[29] In short, Roche seeks

[28] *See* Carter Decl., Exh. 4 (Roche's Responses and Objections at 6, ¶ 5).

[29] **Amgen's Request for Production No. 14:** For each cell line used by ROCHE to produce the EPO component of peg-EPO (including DN2-3α3 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

to elevate its principal non-infringement argument—that MIRCERA is not comprised of human recombinant EPO—to a refusal to produce the discovery that Amgen requires to test Roche's contention.

REDACTED

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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.

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. Amgen's Request Nos. 19-24 and Roche's Responses to those requests are set forth in full in Section I.B. below.

[30] *See* Carter Decl., Exh. 8 (ITC-R-00050548).

[31] *See* Carter Decl., Exh. 9 (ITC-R-00517745); Exh. 10 (ITC-R-IND-00114978).

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Roche has also objected to and foreclosed discovery into the names it has given MIRCERA including its litigation-inspired efforts to convince third parties to refer to peg-EPO by some name other than erythropoietin. Roche's objection to Amgen's Request No. 218 is representative of Roche's refusal[35]:

Amgen's Request for Production No. 218: All documents and things relating to

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[32] *See* Carter Decl.,Exh. 11(6/8/06 Franzino Dep. Tr. 10-12, emphasis supplied).

[33] *See, e.g.,* See Carter Decl., Exh. 12 (ITC-R-00038885-887), Exh. 13(ITC-R-00004056), Exh. 14 (ITC-R-00089133-139 at 133); Exh. 15 (ITC-R-00503039-045); Exh. 16 (ITC-R-00000805).

[34] *See* Carter Decl., Exh. 17 (http://www.dana-farber.org/can/dictionary/?index=r).

[35] **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.

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

It is Roche, not Amgen, that has put Roche's naming efforts at issue by alleging that MIRCERA is a different chemical entity than peg-EPO, and that it is not comprised of EPO. Roche's objection to Amgen's requests for documents relating to "EPO" should be overruled and Roche should be ordered to produce documents responsive to Amgen's Requests No. 5, 14-24 and 218-220.

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

Roche has failed to produce—and refuses to produce—a complete paper copy and 10 text-searchable electronic CD copies of its BLA and IND documents, despite the Court's Order and Roche's agreement to do so. In addition, Roche refuses to produce any documents regarding communications with FDA and third parties, updates and supplemental filings, including updates on its on-going and future clinical trials until such time as it makes a formal filing with FDA.

A. ROCHE'S PREVIOUSLY PRODUCED BLA AND IND ARE DEMONSTRABLY INCOMPLETE.

Because Roche's prior production of its BLA and IND filings with FDA are incomplete, unintelligible and functionally inoperable,[36] Amgen's Requests for Production Nos. 1 and 37-42 seek a complete production of Roche's MIRCERA regulatory filings with the FDA in the electronic form provided to FDA. In response to each of Amgen's requests, Roche has taken the

[36] *See* Carter Decl., at ¶¶ 4-14.

position that it has completed production of its BLA and IND submissions and that it will produce supplemental filings only at such time as Roche submits those filings to FDA. Roche's Response to Amgen's Request for Production No. 37 illustrates Roche's position:

> **Request for Production 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 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 0158 and IND No. BB-IND 10964 and documents related thereto previously produced In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, ITC Investigation No. 337-TA-568, which are to be treated as duly produced in this case, for documents responsive to this Request. ***During the ITC investigation, Roche went to great lengths to produce its extremely voluminous BLA and INDs in both hard copy and the OCR'ed searchable electronic format then specifically requested by Amgen. This electronic format is not compatible with the embedded hyperlink format Amgen now requests. The information contained in the BLA and INDs in both these formats is the same and Roche will not reproduce these documents solely based on Amgen's changing whims. Moreover, in light of the Court's recent decision denying Amgen's motion for reconsideration of the restrictions placed on the use of the BLA and INDs, Roche will not change the format of these documents***. See D.I. 159. Subject to these objections and the General Responses and Objections above, relevant, non-duplicative, non-cumulative documents relating to any completed communications, updates, amendments or supplements to Roche's BLA No . STN 125164/0 and INDs Nos. BB-IND 10158 and BB-IND 10964 and the final results of any completed studies or protocols underlying these submissions, which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying. (emphasis supplied)

In fact, in response to 16 of Amgen's Requests for Production, Roche asserts that it made a

complete production of its BLA in the ITC proceeding, in both paper and electronic form.[37] In 12 of those responses, Roche refuses to produce responsive materials beyond its previously produced version of its BLA.

Contrary to Roche's assertion, the previously produced paper copy and the previously produced electronic copies of Roche's BLA and IND omit extensive, highly relevant sections of its BLA and IND submissions to FDA.[38] Roche's paper copy production of its BLA and IND documents are incomplete and scrambled in page order, rendering the produced copies virtually unusable.[39] The electronic copies that Roche produced of its BLA and IND duplicate all of the same deficiencies as the paper copy. The electronic copies produced by Roche are likewise incomplete and scrambled in page order. They fail to provide the patient data submitted to FDA in the same electronically useful format as provided to FDA, and all of the hypertext links contained in the submission made to FDA are inoperable in the copies produced to Amgen, thus rendering the thousands of linked references and associated text incomprehensible and unsearchable.[40] Moreover, the electronic form in which portions of the BLA were produced to Amgen—CDs containing OCR images of a hyper-linked document—are fundamentally different from, less complete and far less usable than the electronic copy that Roche submitted to FDA in April 2006 and has in its possession.[41]

Roche is aware of all of these deficiencies. Beginning in June of this year, just ***one day*** after Roche produced the electronic copy of its BLA and IND documents, and continuing through the present day, Amgen has informed Roche of several significant deficiencies in the

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[37] Amgen's Request Nos. 2-4, 19-24, 33-36, and 189-191 (Docket No. 156) and *See* Carter Decl., Exh. 11 and Exh. 4 (Roche's Responses and Objections).

[38] *See* Carter Decl. at ¶¶ 4, 9, and 11.

[39] *See* Carter Decl. at ¶¶ 4,6-8.

[40] *See* Carter Decl. at ¶¶ 9, 12, and 13.

produced BLA that have gone unanswered.[42] While Amgen is unable to identify ***all*** missing BLA documents due to the format of Roche's production, Amgen has identified significant portions of the BLA, including datasets and data definition files for the Phase I, Phase II, and Phase III studies, the Integrated Safety Dataset, and several of the datasets that provide the data support for the BLA included in the submission to the FDA that are missing from the versions of the BLA and IND documents produced by Roche.

Notably, in response to Amgen's Requests Nos. 1 and 37-42, Roche doesn't claim that the previously produced BLA is satisfactory, but instead seeks to blame Amgen for the deficiencies on the pretext that Amgen received what Amgen requested. Roche fails to mention that it kept silent and never informed Amgen, contrary to Fed. R. Civ. P. 26(a)(1)(B),[43] that it has in its possession a complete, fully searchable electronic version of the BLA that it submitted to FDA.[44] Had Roche candidly informed Amgen that a complete, fully searchable copy of its BLA already existed in electronic form, with operable hyperlinks and underlying data intact, Amgen would obviously have requested an electronic copy in that complete and useful format.

As detailed in the accompanying Declaration of Krista M. Carter, the only way for Roche

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[41] *See* Carter Decl. at ¶¶ 24 and 26.

[42] *See* Carter Decl., Exh. 18 (6/4/06 V. Smith letter to H. Suh); (Docket No. 157) Exh. 12 (11/21/06 D. Fishman letter to T. Fleming); (Docket No. 156) Exh. 9 (11/08/06 K. Carter letter to P. Fratangelo); Exh. 24 (6/30/06 D. Fishman letter to H. Suh); *see* Carter Decl., Exh. 25 (7/07/06 P. Fratangelo to D. Fishman); Exh. 30 (12/13/06 H. Suh letter to D. Fishman).

[43] *See* Fed. R. Civ. P. 26(a)(1)(B) committee note. Also in the context of a discovery dispute, the Court in *In re Bristol-Myers Squibb Securities Litigation*, 205 F.R.D. 437 (D. N.J. 2002) found that the defendants acted improperly by failing to advise the plaintiffs that they had an electronic copy of its New Drug Application, as they were mandated by Rule 26(a)(1)(B) to do. "[W]here a party already possesses relevant information in electronic format, ***it is obligated, by way of mandatory disclosure, to so advise the adversary***. Once advised of the existence of electronic data, a party may then make an informed decision as to the manner by which discovery could be produced." *In re Bristol-Myers*, at 441 (emphasis added).

[44] *See* Carter Decl., at ¶¶ 22-23.

to fulfill its discovery obligation to provide a complete and fully text-searchable copy of its BLA and IND documents is to require Roche to produce its BLA and IND in the native electronic format that Roche has in its possession and that was submitted to FDA. Amgen, therefore, respectfully requests the Court to overrule Roche's objections and order Roche to produce documents and things responsive to Amgen's Requests Nos. 1 and 37- 42.

B. ROCHE SHOULD PRODUCE ITS EXISTING COMMUNICATIONS, UPDATES, AND SUPPLEMENTS REGARDING ITS BLA AND IND FILINGS.

In addition to seeking a complete production of all of Roche's past BLA and IND filings on MIRCERA with FDA, Amgen's Requests 38-42 also seek discovery of Roche's on-going and future filings, amendments and supplements, as well as communications with either the FDA or third parties about such filings and supplements. In response to each of these requests, Roche Roche refuses to produce any responsive documents unless and until it has completed any on-going studies. Amgen's Requests 38-42 and Roche's corresponding Responses are set forth below:

> **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 No. 42: Roche incorporates herein by reference its Response to Request No. 37 above.

Roche further refined its response in the parties December 11 meet and confer to refuse to produce responsive documents unless and until Roche submits supplemental filings (including filings on its on-going and planned studies to FDA).[45]

As discussed in Section I.B. above, Roche's position is at odds with the two-tier Protective Order endorsed by the Court that expressly provides for the production of on-going and future clinical trials—"the on-going and future clinical trials and communications with regulatory authorities regarding such trials"—not just completed trials, as Roche would have it.[46] Moreover, Roche's offer to produce "final results of any completed studies or protocols" rings hollow since,

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[45] *See* Carter Decl., Exh. 3 (12/11/06 Fishman letter to Suh).

[46] *See* November 30, 2006 Order (Docket No. 159); *see also* Plaintiff Amgen Inc.'s Memorandum in Support of Its Motion for Reconsideration or Clarification of the November 6,

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Because Roche's on-going and future filings, amendments and supplements, as well as communications with both the FDA and third parties about such filings and supplements is directly relevant to Amgen's claims for declaratory judgment as well as Roche's defenses, Roche should be ordered to produce non-privileged documents responsive to Amgen's Requests for Production Nos. 38-42.

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

Roche also objects to producing documents and things regarding its attempts—including its failures—to design around Amgen's patents and make its MIRCERA product without appropriating Dr. Lin's inventions. Amgen's Requests for Production Nos. 16-24 seek discovery regarding the cell lines, processes and DNA sequences considered or evaluated by Roche to make the EPO component of MIRCERA. Roche has objected to each such request and refused to produce documents beyond the cell line, DNA sequence, and process ***actually used*** to make its MIRCERA product.[48] Roche's Response to Amgen's Request for Production No. 19 is

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2006 Order (Docket No. 156) at 12.

[47] *See* Carter Decl., Exh. 7 (ITC-R-00085385-93).

[48] **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 "DN2-3α3" 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

exemplary of its position:

> **Request 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 Request No. 19:** Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Moreover, Roche objects to the phrase "DNA sequence encoding EPO" as vague, ambiguous, misleading, inaccurate, and requiring claim construction and/or expert opinion. ***Roche further objects to this Request to the extent it seeks information regarding cell lines and DNA sequences other than those used to create Roche's CERA or MIRCERA™ product for which commercial approval is sought in Roche's***

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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 "DN2-3α3" 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 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.

Roche's Response to Amgen's Request for Production No. 24: Roche incorporates herein by reference its Response to Request No. 19 above.

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

Likewise, Roche has foreclosed discovery into its efforts (if any) to avoid infringement of Amgen's patents-in-suit. *See* Amgen's Requests 200-205.[49] Roche's Response to Amgen's

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[49] **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 action as erythropoietin is not the accused product in this case and the Request is not limited to MIRCERA™. Moreover, Roche objects to this Request to the extent it seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third party confidentiality agreements.

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,

Request No. 200 is exemplary of Roche's refusal to provide the discovery Amgen has requested:

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

But Roche's efforts – including its failed attempts – to make the accused product, processes, and

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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 MIRCERA™.

Moreover, Roche objects to this Request to the extent it seeks documents and things in the possession, custody or control of parties other than Roche or protected from disclosure by third parry 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.

cells without infringing Amgen's patents are relevant to Roche's invalidity defenses as well as to Amgen's claim of infringement. Roche has pled invalidity based on obviousness and, in so doing, put squarely at issue its own attempts and failures to design-around Amgen's patents in creating the accused product, process, and cells.[50] Likewise, evidence of Roche's failed attempts to design-around and its copying are highly relevant to Amgen's infringement case, particularly in the context of doctrine of equivalents infringement.

The Federal Circuit has weighed in on this subject. In *Advanced Display Systems*, the Federal Circuit vacated the lower court's ruling and remanded for a new trial on the issues of obviousness, anticipation and infringement because the defendant concealed evidence of its failed attempts to design-around—and its ultimate copying of—the claimed invention, which did not come to light until the plaintiff uncovered the evidence during a trial on the merits. The Federal Circuit found that the new evidence of failed attempts to design-around and copying was potentially outcome determinative on those topics and ordered a new trial because "to do otherwise would be to prejudice the party who acts diligently and complies with the Federal Rules of Civil Procedure and to benefit the party who contravenes those rules and uses dilatory discovery tactics."[51]

Because Roche's failed attempts to make DNA sequences, cells, and processes to produce the EPO component of MIRCERA without infringing Amgen's patents-in-suit are highly relevant to infringement and validity issues in this case, Roche should be compelled to produce documents responsive to Amgen's Request Nos. 16-24 and 200-205.

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[50] 11/6/06 Roche's Answer and Counterclaims (Docket No. 140), p.4; *see Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 1285-86 (Fed. Cir. 2000); *see also Dow Chem. Co. v. American Cyanamid Co.*, 816 F. 2d617, 622 (Fed. Cir. 1987).

[51] *Advanced Display Systems, Inc. v. Kent State University*, 212 F. 3d 1272, 1287 (Fed. Cir. 2000).

VI. CONCLUSION.

For each of the foregoing reasons, Amgen respectfully requests that the Court compel Roche to produce documents responsive to its Requests for Production as set forth in the Proposed Order accompanying this motion.

Respectfully Submitted,

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By its attorneys,

/s/ M. Gottfried

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