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

PLAINTIFF AMGEN INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR RECONSIDERATION OR CLARIFICATION OF THE NOVEMBER 6, 2006 ORDER

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I. INTRODUCTION

On November 6, 2006, the Court endorsed certain provisions of Amgen's Proposed Protective Order and other provisions of Roche's Proposed Protective Order, and directed the parties to settle the final form of the Order. Since that time, Amgen has attempted to reach agreement with Roche and finalize a Protective Order in accordance with the Court's Order before the parties must produce documents on December 4. While agreement has been reached on some issues, due to widely differing views of what the Court intended in its Order, no agreement has been reached on several key points, including (1) the handling and use of Roche's IND and BLA submissions, (2) Roche's intended redesignation of key portions of its ITC discovery, including its BLA and INDs to "Highly Confidential," (3) the submission of "Confidential" and "Highly Confidential" documents to the Court, and (4) restrictions on the selection of experts and consultants. As described below, Amgen believes that the Court's Order already addressed several of these points, and to the extent not already made plain, Amgen seeks further clarification.

In addition, during attempts to negotiate a mutually acceptable definition for what limited set of documents would be produced as "Highly Confidential" under the two-tier protective order, it has become clear that Roche intends to produce most, if not all, of its relevant documents under the higher designation thereby precluding access to Amgen's in-house counsel. Such actions would abuse the two-tier system and effectively nullify the Court's Order allowing four in-house counsel access to "Confidential" information. Given Roche's apparent intent to game its production of documents and information, and to avoid recurrent disputes down the road as to the propriety of the use of the "Highly Confidential" designation on particular documents, Amgen respectfully asks this Court to reconsider its adoption of a two-tier protective order. Amgen submits that a single-tier "Confidential" order accords the necessary protection to

the parties' confidential business information and avoids the practical difficulties for the litigants, the witnesses and the Court of operating under a two-tier system. Failing reconsideration of the two-tier approach, Amgen requests that the Court adopt a reasonable definition for the limited set of documents to be designated in the top tier.

Contrary to Roche's arguments in its Cross-Motion for a Protective Order that the "Highly Confidential" designation would be used on only the "extremely sensitive" documents, Roche has indicated its intent to redesignate the majority, and certainly the most relevant, documents produced in the ITC proceeding as "Highly Confidential" and has refused to agree to any reasonable limits on the use of this designation for newly produced documents. In its Order, however, this Court expressly rejected Roche's position on redesignation and adopted Amgen's proposal that "all documents produced in the related ITC action will be deemed produced in this action, thus presumably making all such documents immediately accessible to Amgen's in-house counsel."[1] Roche disputes that this Order applies to its BLA and INDs which comprised the vast majority of the documents produced by Roche in the ITC action.

Also in its Cross-Motion in support of its two-tier proposal, Roche asserted that certain Amgen produced documents raised questions as to the actions of Amgen's in-house counsel and their ability to fully comply with the requirements of the protective order in this case. Since the Court acted on Roche's motion before Amgen responded to these assertions, Amgen provides further information herein that should allay any legitimate concerns about the ability of Amgen's in-house counsel to avoid inadvertent disclosure of Roche's confidential information. Given the unique position and experience of Amgen's in-house counsel in litigating the patents-in-suit and related patents and their intended role in this litigation, Amgen's efforts in this case will suffer if its counsel are excluded from the most relevant documents on infringement as Roche intends.

[1] 11/6/06 Order at 6, Docket No. 142.

To assist the Court, attached hereto in the Appendix are tables setting forth the parties' respective positions on the issues sought to be resolved by this motion.

II. THE COURT SHOULD RECONSIDER ITS ORDER ENDORSING A TWO-TIER PROTECTIVE ORDER.

Even though Roche proposed a two-tier protective order, its actions make clear that it intends to designate all of its significant documents as "Highly Confidential," thus making it a single-tier, not out of a legitimate concern for safeguarding the information, but to keep Amgen's in-house counsel from effectively participating in the litigation. While Roche asserted in its Cross-Motion that its BLA and IND submissions to the FDA are "highly sensitive," Roche recently published the centerpiece of that regulatory filing – the results of its Phase III clinical trials – at a medical conference.[2] Having done so, it can no longer rightly claim that its regulatory submissions deserve heightened protection and should be restricted to outside counsel.

Moreover, in its Cross-Motion, Roche created the false impression that Amgen's in-house counsel are susceptible to inadvertent disclosure of Roche's confidential information by drawing incorrect conclusions from historical documents. In reaching its decision, the Court did not have the benefit of the attorney's explanation that she was involved with this business team only to give legal advice. Regardless of whatever role in-house counsel played in the past, Amgen's Proposed Single-Tier Protective Order[3] requires in-house counsel to affirm that (s)he will not be involved in competitive decision making and patent prosecution in certain fields related to the issues here for a time exceeding the pendency of this litigation. In light of these new facts, which were not before the Court at the time of the November 6 Order, Amgen requests that the Court reconsider its adoption of Roche's proposed two-tier protective order, and

[2] 11/20/06 Roche Press Release, "Mircera: first drug to correct anemia in all chronic kidney disease patients with a simple twice-monthly dosing schedule"(www.roche.com/med-cor-2006-11-20), attached hereto as Exh. 1.

[3] Attached hereto as Exh. 2.

instead adopt a single-tier protective order with access for in-house counsel, as such access was ordered previously by the Court.[4]

A. A Two-Tier Protective Order Will Be Abused By Roche.

During the parties' negotiations, Roche has evidenced its intent to collapse the two tiers ordered by this Court into the higher one, thus precluding in-house counsel access to any information produced under the protective order. The best evidence of this is Roche's proposed description of the materials falling within the "Highly Confidential Material" tier. Early in negotiations, counsel for Roche refused to place any categorical limits around the type of information that would be subject to the highest tier of the protective order.[5] After three weeks of exchanged drafts and meet-and-confers, Roche has proposed a definition of "Highly Confidential Material" that is expressly non-limiting and would encompass, at Roche's discretion, essentially every relevant document in its possession. Under Roche's proposal, such materials would include:

> highly sensitive scientific, marketing, sales, financial, customer, accounting and business operations information and materials, ***including*** those relating to any compound, product, material, process or method, pending but not yet approved for sale by a regulatory authority, or for which no regulatory approval has yet been sought ("highly confidential products") ***including without limitation***: (a) Defendants' Biological License Application ("BLA") and Investigational New Drug Applications ("INDs") for CERA; (b) on-going and future, research, basic science, experimentation, pre-clinical experimentation, and clinical trials; (c) and communications or filings with regulatory authorities, customers and researchers, regarding such highly confidential products and research, or internal information and materials relating to such communications or filings; (d) labeling negotiations with any regulatory or review organization for any highly confidential product, and internal information and materials relating to such negotiations for any highly confidential product; (e) any research and development of any highly confidential product for which no regulatory approval has yet been sought; (f)

[4] This Court has the discretion to reconsider and to revise or amend its November 6 Order at any time prior to final judgment in this case. As this Court has noted, "[w]hen faced with a motion for reconsideration, a district court must balance the need for finality against the duty to render just decisions." *Davis v. Lehane*, 89 F. Supp. 2d 142, 147 (D. Mass. 2000).

[5] 11/14/06 D. Fishman letter to T. Fleming, attached hereto as Exh. 3.

> information and materials relating to products not the subject of this action; and (g) any highly sensitive commercial or business method, operation or process of a party, the disclosure of which is likely to have the effect of causing substantial or irreparable harm to the Supplier.[6]

This definition seemingly includes — without limitation — every aspect of Roche's business. Under this definition, any material subjectively deemed by the producing party to be "highly sensitive" or "likely to have the effect of causing substantial or irreparable harm" is subject to designation at the higher tier.

Two-tier protective orders are inherently subject to the abuse of over-designation; while parties may intend a higher tier to be reserved for a very small and discrete set of documents, in practice, a higher tier may be over-used so as to subsume documents that are more appropriately designated at the lower level of confidentiality.[7] In *THK America*, the defendant NSK designated as highly confidential or "Attorneys Eyes Only" documents that were "extremely confidential" in that their disclosure would be competitively damaging. In so doing, the Defendant produced most of its documents designated with the highest degree of confidentiality. The Illinois district court found that the standard articulated for the higher tier was not an appropriate standard and would blanket most information within the higher tier, at odds with the very purpose of a two-tier protective order.[8] Moreover, the court noted that a two-tier protective order requires the court – already overloaded with heavy caseloads and backlogs – to police almost every classification decision unless both parties demonstrate a willingness to adhere to a narrowly tailored highest tier.[9]

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[6] Roche's 11/25/06 Proposed Protective Order (sent to Amgen on 11/29/06) at ¶ 3 (emphasis added), attached hereto as Exh. 4.

[7] *See, e.g.*, *THK Am., Inc. v. NSK Co. Ltd.*,157 F.R.D. 637 (N.D. Ill. 1993); *see also Procter & Gamble Co. v. Nabisco Brands, Inc.*, 111 F.R.D. 326 (D. Del. 1986).

[8] *THK Am., Inc. v. NSK Co. Ltd.*,157 F.R.D. 637, 643-45 (N.D. Ill. 1993).

[9] *Id.*

The problems with a two-tier protective order are exacerbated by Roche's refusal to narrowly tailor the highest tier of confidentiality.[10] Like *THK Americas*' "extremely confidential" definition, Roche's proposed "highly sensitive" definition will create a *de facto* single-tier of over-designated documents. Roche's proposal would effectively preclude Amgen's in-house counsel from participating in, managing, or supervising this litigation.

B. A Single-Tier Protective Order Adequately Protects Roche's Interests.

The only difference between Roche's proposed two-tier protective order adopted by the Court and the single-tier protective order proposed by Amgen is to limit the access of in-house counsel to those documents and information designated as "Highly Confidential." This heightened designation serves no other purpose under the protective order. In contrast, Amgen's proposed single-tier would eliminate the attempt to disable in-house counsel and allow access to in-house counsel from both Amgen and Roche to all confidential information.

In its Cross-Motion, Roche argued that information "related to pending and future FDA filings is extremely sensitive, and deserving of the highest level of protection." But Roche has already publicly disclosed the centerpiece of those FDA filings, i.e., the results of the Phase III clinical trials, designed to establish the safety and efficacy of Roche's EPO product.[11] Roche can no longer claim this information is even "Confidential" let alone "Highly Confidential." While Roche will undoubtedly argue that there was much information about these trials that was not publicly disclosed, the reality is that much has been already disclosed by Roche in an effort to generate interest in its EPO product. It is difficult to see how Roche can disclose what it considers to be the positive parts of its clinical data while seeking to designate as "Highly Confidential" other information, presumably not so favorable.

[10] 11/14/06 D. Fishman letter to T. Fleming (Exh. 3).

[11] *See, e.g.,* the compilation of Abstracts presented at the American Society of Nephrologists in

C. Amgen's In-House Counsel Should Have Access to Confidential Materials For This Litigation And Have Undertaken The Steps Necessary To Protect Roche's Confidential Information.

Under a single-tier protective order, Amgen's designated in-house counsel should be afforded access to all confidential information because they are: (1) actively involved in the conduct of the litigation and are responsible for any major decisions concerning it; (2) in positions at Amgen that would allow them to avoid conflict and inadvertent disclosure; and (3) subject to the same Code of Professional Responsibility as outside counsel.[12]

Amgen's in-house counsel are integral members of its litigation team.[13] They are responsible for making, and are accountable for the results of, all substantive decisions in this case, including the way in which Amgen deploys its resources during the course of the litigation. As in past litigations, they will be actively involved in depositions, the preparation of expert reports, and in drafting briefs to this Court.[14]

In addition, as more fully set forth in Amgen's original Motion for Entry of Protective Order,[15] Amgen's in-house litigation counsel have specialized knowledge that make their involvement indispensable to Amgen's representation and preparation in this case. For example, one or more of Amgen's in-house counsel have been intimately involved in the majority of Amgen's foreign patent proceedings,[16] which were put at issue here by Roche's Answer and

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November 2006, attached hereto as Exh. 5.

[12] *Boehringer Ingelheim Pharms., Inc. v. Hercon Labs. Corp*., No. 89-484, 1990 WL 160666, at *2 (D. Del. 1990).

[13] Unlike any of its outside counsel, Amgen's in-house counsel have participated in Amgen's EPO litigations ***both*** in the U.S. and abroad. *See* 11/6/06 Answer and Counterclaims at Answer ¶ 44, Docket No. 140 (putting at issue Amgen's conduct in its foreign litigations).

[14] Wendy A. Whiteford Declaration at ¶ 2, attached hereto as Exh. 6 (hereinafter "Whiteford Decl.").

[15] *See* 10/23/06 Motion for Protective Order by Amgen, Docket No. 128.

[16] For example, Ms. Whiteford has participated in a majority of Amgen's foreign patent proceedings and litigations regarding these patents and products since 1996. Whiteford Decl. at

Counterclaims.[17] Moreover, each of the identified in-house counsel was selected and recruited to join Amgen for their patent litigation experience and skill and, while at Amgen, these in-house attorneys have gained tremendous expertise.

Roche's proposed two-tier system would prevent Amgen's in-house counsel (but allow Roche's in-house counsel) to be actively involved in discovery, briefing, and preparations for trial of the infringement issues in this case. For instance, Roche has asserted that Amgen's in-house counsel be denied access to Roche's peg-EPO BLA and IND submissions (and indeed, according to Roche, any material about the structure and activity of its peg-EPO).[18] Yet, Amgen's infringement case (including evidence at summary judgment, in expert reports, and at trial) will depend in large measure on the admissions contained in these documents. Roche's proposal to treat its BLA and INDs as a monolithic category deserving the highest tier of confidentiality – rather than a compilation of different kinds of information totaling approximately 275,000 pages[19] – would deny Amgen in-house counsel access to many of the clearest and most direct infringement admissions and, in so doing, would effectively preclude them from contributing to or directing the on-going litigation. Without access to these documents, Amgen's in-house counsel cannot adequately weigh the merits of the parties' positions, supervise the litigation, authorize and participate in the preparation of motions or reports, or help prepare to examine Roche's witnesses.

In addition, Roche's proposal effectively denies Amgen the right to adequate

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¶ 2 (Exh. 6).

[17] *See, e.g.*, 11/06/06 Answer and Counterclaims at ¶ 44, Docket No. 140.

[18] 11/7/06 P. Fratangelo letter to L. Day, attached hereto as Exh. 7; *see also* Roche's 11/29/06 Proposed Protective Order at ¶ 3, attached hereto as Exh. 4 (hereinafter "Roche's 11/29/06 Proposed Protective Order").

[19] In the ITC proceeding, these 275,000 pages represented over 70% of Roche's total document production.

representation and choice of counsel, despite Amgen's making every reasonable precaution to avoid inadvertent disclosure.[20] Where, as here, the litigation presents complex issues and in-house counsel provide valuable litigation input and must make quick and effective pretrial decisions (particularly in the context of a rapid or accelerated case schedule), access should be provided.[21]

In its Cross-Motion for Protective Order, Roche objected to providing Amgen's designated in-house counsel with access to Roche's confidential information based on allegations that (1) each is a patent attorney and/or supervises patents attorneys involved in patent prosecution for Amgen, and (2) each is located in Amgen's headquarters and meets regularly with Amgen's management.[22] Amgen's Proposed Protective Order as well as the declarations of its in-house counsel submitted with this motion and previously address and resolve these purported concerns.

Amgen's in-house counsel are situated in a way to avoid the inadvertent disclosure of Roche's confidential information to competitive decision makers at Amgen. Under Amgen's Proposed Protective Order, each in-house attorney that is designated under that Protective Order must confirm that (s)he will not participate in competitive decision-making or patent prosecution in the relevant field of ESPs (erythropoiesis stimulating proteins) for one year after the conclusion of the lawsuit.[23] Roche specifically objected to providing one in-house attorney, Ms. Whiteford, with access to confidential information based on its assertion that she is involved in

[20] *See generally Rizzo v. Sears, Roebuck and Co.*, 127 F.R.D. 423, 425 (D. Mass. 1989) (citing *Borman v. Borman,* 393 N.E.2d 847 (Mass. 1979) (emphasizing importance of choice of counsel in the context of a motion to disqualify).

[21] *Volvo Penta of the Ams., Inc. v. Brunswick Corp.*, 187 F.R.D. 240, 241-42 (E.D. Va. 1999)

[22] Roche's 11/03/06 Cross-Motion for Protective Order at 10-12, 14-15, Docket No. 136 (hereafter "Roche's Cross-Motion").

[23] *See* Amgen's 11/28/06 Single-Tier and Two-Tier Proposed Protective Orders, Appendix AA, attached hereto as Exhs. 2 and 8, respectively.

and participates in competitive decision-making and, in particular, competitive decision-making vis-à-vis Roche.[24] But, Roche provided the Court no reason to doubt that Ms. Whiteford will take all necessary and reasonable steps to protect against the inadvertent disclosure of Roche confidential information.[25] Rather, Roche's argument relied principally on a document produced by Amgen that listed Ms. Whiteford as a legal representative on Amgen's Competitive Anemia Task Force. This document dates back to the first-half of 2005.[26] At that time and thereafter, Ms. Whiteford's participation and responsibility on the task force were limited to providing legal updates and advice.[27] While Ms. Whiteford's role was purely legal in nature, in an effort to avoid even the appearance of impropriety, she has taken affirmative steps to remove herself from roles that might appear to implicate competitive decision-making related to ESPs.[28]

Finally, each Amgen in-house attorney is subject to the same Code of Professional Responsibility as outside counsel. All are members of a state bar in good standing and have never been the subject of any disciplinary proceedings.[29] As discussed in *U.S. Steel,* the status of an attorney as in-house or outside counsel does not compel the decision on access; rather the decision must be made based on the relevant facts for each attorney signing on to abide by a protective order. In fact, the Federal Circuit, in declining to treat in-house counsel categorically, noted that: "[l]ike retained counsel, however, in-house counsel are officers of the court, are

[24] Roche's Cross-Motion at 9-10.

[25] In fact, both her track record for the past 16 years of practice – including her track record before this Court – should dispel any notion that Ms. Whiteford cannot be trusted with Roche's most sensitive information. 10/23/06 Whiteford Decl. at ¶11, Docket No. 130.

[26] Whiteford Decl. at ¶ 3 (Exh. 6).

[27] Whiteford Decl. at ¶ 4 (Exh. 6).

[28] *Id.* at ¶ 6.

[29] 10/23/06 Whiteford Decl. at ¶ 11, Docket No. 130; 10/24/06 Cordray Decl. at ¶ 11, Docket No. 135; 10/23/06 Dotson Decl. at ¶ 11, Docket No. 131.

bound by the same Code of Professional Responsibility, and are subject to the same sanctions."[30]

For all of these reasons, Amgen's in-house counsel should be given access to all of Roche's confidential information under the Proposed Single-Tier Protective Order.[31]

III. IN THE ALTERNATIVE, AND IN ADDITION, AMGEN MOVES FOR CLARIFICATION OF THE COURT'S NOVEMBER 6, 2006 ORDER.

In the event this Court denies Amgen's request for reconsideration of its Order requiring a two-tier protective order, Amgen requests in the alternative that the Court adopt workable definitions for the two tiers. In addition, Amgen requests that the Court to clarify its Order with respect to access to Roche's BLA and INDs and adopt Amgen's proposal for the qualification of experts. In addition to its unreasonably broad definition of the highest confidentiality tier, Roche also proposes placing unreasonable restrictions on the access and use of its BLA and INDs and unwarranted limitations on the definition of experts and consultants who may be qualified to view Highly Confidential discovery materials. Amgen further requests that the Court adopt its form of Protective Order as to the filing of the parties' confidential information since it faithfully adheres to the Court's November 6 Order.

The parties' principal disputes with respect to finalizing a two-tier protective order are summarized below at Appendix A, second table.

A. If A Two-Tier Protective Order Is Adopted In This Case, It Should Include Amgen's Proposed Definitions For Those Tiers.

Roche has refused Amgen's proposals to more precisely and categorically define the higher tier of confidentiality. In so doing, Roche attempts to create the appearance of imposing categories, but as discussed above,[32] its "categories" are so broad and expressly non-limiting

[30] *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984).

[31] *See* Amgen's Proposed Single-Tier Protective Order (Exh. 2).

[32] *See* Section II.A.

("including without limitation") as to subsume essentially all materials that will be produced in this litigation.

If the Court rejects Amgen's request for reconsideration and finds that a two-tier protective order is appropriate, Amgen believes that its two-tier proposal better balances the need for in-house patent litigation counsel to have access to confidential information to direct the litigation with the sensitivity of Roche's confidential information. Amgen's definition of "Highly Confidential Material" affords heightened protection to the categories of documents that Roche identified as highly sensitive in its Cross-Motion for Protective Order.

In its Cross-Motion, Roche identified the universe of "truly sensitive documents" to include its BLA, on-going discussions with FDA, current clinical trials for the use of peg-EPO, and information related to pending and future FDA filings.[33] With the exception of Roche's BLA and IND documents discussed below, Amgen's proposed definition of "Highly Confidential Material" includes precisely those limited categories of documents:

> (1) the on-going and future clinical trials and communications with regulatory authorities regarding such trials; (2) on-going labeling negotiations for any therapeutic product pending but not yet approved for sale by a regulatory authority (excluding the proposed label submitted with Roche's April 2006 BLA); and (3) active and on-going research and development of any therapeutic product for which no regulatory approval has yet been sought.[34]

This definition includes Roche's on-going and future clinical trials and submissions to FDA with respect to its pending BLA on peg-EPO. It also includes Roche's on-going labeling negotiations with FDA for peg-EPO based on Roche's now-pending BLA.

At the same time, Amgen's proposed definition excludes from "Highly Confidential Material" information about the characterization of Roche's accused product and, in particular,

[33] Roche's Cross-Motion at 7-8.

[34] Amgen's 11/27/06 Proposed Two-Tier Protective Order at ¶ 3 (Exh. 8).

its structure and function because this material is relevant to the issue of Roche's infringement and is not the type of highly sensitive information that justifies limited access. In addition, Amgen has expressly included this material in its proposed definition of information that may be designated as "Confidential Material."[35] Amgen's proposal also excludes from the higher tier information pertaining to the clinical trials that Roche has already completed, submitted to FDA, and presented in public forums.[36] Amgen's proposal, however, includes in the higher tier information about developmental products for which no regulatory approval has been sought.

B. Amgen Seeks the Court's Clarification on In-House Counsel's Access to the BLA and INDs.

While the Court agreed to put certain safeguards on the handling of Roche's BLA and INDs, its November 6 Order deemed all ITC discovery, which Roche advised the Court to include such IND and BLA, as Confidential pursuant to the pending Protective Order:

> Provides that all discovery produced in the related ITC action will be deemed produced in this action, thus presumably making all such documents ***immediately accessible to Amgen's in-house counsel***.[37]

In so ordering, the Court expressly rejected Roche's proposal to permit re-designation of discovery materials produced during the related ITC proceeding to the higher tier.[38] Amgen understands the import of the Court's ruling to mean that all ITC discovery material – specifically including Roche's BLA and INDs – is Confidential and thus accessible to Amgen's in-house counsel subject to the additional safeguards implemented by the Court. By contrast, Roche has taken the position that the Court's Order deemed Roche's BLA and INDs as Highly

[35] *Id.* at ¶ 2.

[36] *See e.g.,* Exh. 5.

[37] 11/6/06 Order at 6, Docket No. 142 (emphasis added).

[38] *Id*.

Confidential and denied Amgen's in-house counsel access to these materials.[39]

The information contained in Roche's BLA and INDs appropriately falls within the scope of "Confidential Material." In fact, much of the information contained in the BLA and INDs has been publicly disclosed by Roche and should not fall under the protective order at all. The BLA and INDs were submitted to the FDA over six months ago, and the six Phase III clinical studies, as well as Phase II clinical trials contained therein are now closed and the trial results have already been publicly presented and discussed.[40] Consequently, contrary to Roche's assertions, the sensitivity of this information is, at best, rapidly waning. Balancing the decreased sensitivity of the BLA and IND information with the need of Amgen's in-house patent litigation counsel to meaningfully participate in the litigation, Roche's BLA and INDs should be deemed "Confidential" and accessible to in-house counsel pursuant to the Protective Order.

Despite Amgen's efforts to reach agreement on this point, the parties are at an impasse predicated on diametrically different interpretations of the Court's Order. Accordingly, Amgen respectfully requests that the Court clarify its November 6 Order to provide that Roche's BLA and INDs produced during the ITC proceeding shall be designated as "Confidential Material" and shall be accessible under the Protective Order to Amgen's designated in-house counsel, subject to the additional safeguards ordered by the Court.

C. Roche's Proposal Also Places Unreasonable Restrictions on the Access to and Use of its BLA and INDs.

In accordance with the Court's November 6 Order, the Protective Order proposed here by Amgen provides that "Roche shall produce one complete hard copy and ten (10) fully searchable

[39] *See* 11/7/06 P. Fratangelo letter to L. Day (Exh. 7). Amgen has agreed to treat Roche's past production as Highly Confidential (that is, Amgen in-house counsel has agreed to refrain from accessing this production) until such time as this issue is resolved. *See also* 11/8/06 K. Carter letter to P. Fratangelo, attached hereto as Exh. 9.

[40] *See, e.g.,* Exh. 5.

electronic copies of its Biological License Application ("BLA") and Investigational New Drug Applications ("INDs") for CERA, to be maintained in accordance herewith on non-networked computers."[41] Roche proposes to impose additional and unreasonable restrictions on the access to and use of its BLA and IND documents. In addition, Roche improperly uses its Proposed Protective Order to suggest – contrary to fact – that it has fulfilled its discovery obligation with respect to its BLA and INDs.

Roche's proposed treatment of the BLA and INDs under its Proposed Protective Order should be rejected because it unjustifiably expands the Court's November 6 Order to (1) impose unnecessary and unduly burdensome restrictions on Amgen's access and use of Roche's BLA and INDs, and (2) discharge Roche's pending and unmet discovery obligation to produce a complete and fully searchable electronic copy of its FDA submissions.

1. The Parties' Treatment of the BLA and INDs in the ITC Proceeding Places Unreasonable Restrictions on the Access and Use of Such Documents Without Justification.

Because of the time constraints imposed in the related ITC proceeding, Amgen agreed under duress to treat Roche's BLA and INDs under the terms of a "Side Agreement," which required Amgen's outside counsel to maintain Roche's BLA and INDs ***in a locked room with a log to identify each person who has been given access*** to the materials.[42] Roche now seeks to impose the ***same*** unreasonable terms of that agreement upon Amgen in its Proposed Protective Order. [43]

The agreement reached by the parties for the ITC proceeding provided no meaningful protection for the materials, but imposed unworkable conditions for Amgen's counsel. Two of

[41] 11/06/06 Order at 7, Docket No. 142.

[42] 6/01/06 K. Stevens letter to C. Gonzalez, attached hereto as Exh. 10.

[43] Roche's 11/29/06 Proposed Protective Order at ¶ 10 (Exh. 4).

the four firms representing Amgen[44] had to separately quarantine the BLA and INDs in locked rooms, provide keys to all attorneys and staff needing access, and keep a running log to track access to the materials. In addition, by requiring counsel to maintain the electronic copies on non-networked computers, attorneys and staff accessing the materials were forced to do so under extremely inconvenient and burdensome conditions, having to either to shuffle back and forth between the quarantined materials and their usual workspace or to set up camp removed from their usual workspace (and network connections) as well as their other daily responsibilities.

Roche has failed to suggest even one credible justification as to why the protections already ordered by the Court are inadequate to safeguard its BLA and INDs, especially where much of the information has been publicly disclosed. Roche offers only its well-worn refrain that Amgen agreed to these terms in the ITC proceeding.

Because the additional safeguards the Court has already endorsed, in addition to the protections provided in either party's Proposed Protective Order, are more than adequate to safeguard the confidential information in Roche's BLA and INDs, and Defendants have offered no evidence to the contrary to warrant such extreme restrictions, they should be rejected.

2. Roche Has Not Fulfilled its Obligation to Produce Fully Searchable or Complete Copies of its BLA and INDs.

Roche has improperly injected into Protective Order negotiations a discovery issue more appropriately addressed in the context of the parties' negotiations concerning document production and, if necessary, in a motion to compel. Specifically, Roche proposes language in the Protective Order providing that "Defendants ***have*** produced" one paper copy and 10 electronically searchable copies of the BLA and INDs to its Proposed Protective Order.[45] This

[44] The ITC Side Agreement also restricted where Roche's BLA and INDs could be located to two locations.

[45] *See* Roche's 11/29/06 Proposed Protective Order at ¶ 10 (emphasis added) (Exh. 4). Roche

language should be rejected because it is simply not true. Roche's intended purpose in proposing this language appears to be to avoid complying with Amgen's pending Requests for Production, which specifically requests a copy of Roche's BLA and IND submissions for peg-EPO in the electronic form and data format provided to the FDA.[46]

Roche's previous production of its BLA and INDs was neither complete nor in a proper, fully text-searchable format. In the ITC proceeding, Roche produced to Amgen a copy of its 150,000 page BLA in scrambled page order, without an index, and containing inactive hyper-text links to external files, data reports, and patient records referenced in the text. Amgen has spent hundreds of hours organizing the materials and still has no way of identifying or locating any one of thousands of references made in the TIFF/OCR version of the BLA.

Because of these deficiencies, Amgen is not able to review the BLA comprehensively, as the inoperable hypertext links prevent Amgen from associating a hyperlink to the appropriate referenced document(s). Nor is Amgen able to confirm the completeness of the BLA. In fact, to the best of Amgen's knowledge, based on an analysis of and representations made in the BLA, Amgen has not received significant portions of Roche's BLA. Amgen has made Roche aware of these deficiencies on numerous occasions and Roche has failed to rectify them.[47]

Amgen recognizes this issue is more appropriately raised in a Motion to Compel, but based on Roche's Proposed Protective Order, requests that the Court reject any provision in an order that would exempt Roche from complying with its pending discovery obligations.

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also deleted "fully" from the Court's endorsed provision that the 10 electronic copies of the BLA and INDs be "fully text searchable," presumably because it knew that the previously produced electronic copy of the BLA was not ***fully*** text searchable.

[46] *See* Amgen's 10/30/06 First Set of Requests for Production of Documents and Things (Nos. 1-224), Request Nos. 137-141 at 13, attached hereto as Exh. 11.

[47] *See e.g.*, 11/14/06 and 11/21/06 D. Fishman letters to T. Fleming, attached hereto as Exhs. 3 and 12, respectively.

D. Roche's Proposal Regarding the Filing of Confidential Information Is Unworkable.

The November 6 Order plainly provides for the procedure whereby the parties may file confidential information:

> "Designating party must seek leave of court for opposition's papers to be filed under seal; **burden on Court** to grant leave to file under seal within 3 days or documents will be made public."

Roche has resisted this directive and proposes instead that the Court adopt a proposal that would require a party to identify the other party's confidential documents seven days in advance of serving (but not filing) its papers, give the designating party three days in which to object, and then, after the Court has ruled, give the designating party an additional three day in which to file a motion for reconsideration before a paper could be filed with the Court. Roche's proposal effectively denies this Court access to the confidential information supporting a brief (or the brief itself if it contains reference to such confidential information) for a period of nine business days.

Based on the expedited schedule set for this case, such delay simply makes no sense. In contrast, Amgen's proposal would require that a party provide the designating party notice of its intent to use the designating party's confidential information pursuant to Local Rule 7.2, give such party two days in which to file a motion, and allow filing of the information as soon as the Court rules. Because Amgen's proposal more faithfully adheres to the procedure already outlined by the Court, Amgen requests that its proposal be adopted.

E. Roche's Proposal Places Unwarranted Restrictions on the Definition of Experts and Consultants and is Unnecessary in Light of Other Provisions in the Protective Order.

Finally, Amgen and Roche have also been unable to reach agreement on the definition of experts and consultants who may be provided access to each party's Highly Confidential Material. Both parties agree that neither the party's employees nor employees of their licensees should be qualified as experts or consultants with access under the Protective Order. However,

Roche proposes further limiting the qualification of an expert or consultant to exclude any individual "affiliated with any domestic or foreign manufacturer, wholesaler, retailer, or distributor of products and pharmaceutical compositions containing recombinant human erythropoietin, or competitors of the Parties in the markets which are the subject of this action."

The term "affiliated with" is vague and ambiguous and Roche's proposed category of excluded experts is unduly broad. Not every affiliation or relationship creates a risk of disclosure or competitive disadvantage. Further, Roche's definition may very well exclude from the bevy of experts physicians who have administered human erythropoietin or PEG-EPO or dialysis centers that have used such products. Both types of experts or consultants may well be necessary for Amgen to effectively respond to Roche's antitrust counterclaims and to address the issue of public interest.

Beyond that, Roche's proposed exclusion is also unnecessary in light of other provisions of Amgen's Proposed Protective Order. In particular, Amgen's proposal provides a method for identification of an expert, disclosure of his or her current C.V., an agreement to be bound by the protective order, and an identification of all current consulting arrangements.[48] Each party is also afforded the opportunity to object to the provision of its confidential information to a designated expert or consultant and state the basis for its objection.[49] Finally, the burden to share confidential information with an expert or consultant is placed firmly on the party designating such expert or consultant.[50] These provisions are more than adequate to prevent disclosure of confidential information to an expert or consultant where there is basis for cause to prevent such disclosure.

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[48] Amgen's Proposed Two-Tier Protective Order at ¶ 12 and Appendix A (Exh. 8).
[49] *Id*. at ¶ 12.
[50] *Id.*

IV. CONCLUSION

For each of the foregoing reasons, Amgen respectfully requests that the Court adopt the Single-Tier Protective Order as attached hereto as Exhibit 2. In the alternative, Amgen requests that the Court endorse the circumscribed Two-Tier Protective Order proposed by Amgen and attached hereto as Exhibit 8.

Respectfully Submitted,

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By its attorneys,

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November 29, 2006

Appendix A

IF SINGLE-TIER PROTECTIVE ORDER:		
ISSUE	**AMGEN'S POSITION**	**ROCHE'S POSITION[1]**
Handling and Use Restrictions on Defendants' BLA and IND Documents	Roche has produced one complete hard copy of the IND and BLA and must still produce ten fully searchable electronic copies of the IND and BLA. Amgen and its counsel shall maintain the electronic copies only on non-networked computers.	Roche has fulfilled its production obligation by producing one complete hard copy and 10 electronic copies in TIFF/OCR form, which must be maintained on non-networked computers. The electronic copies to be maintained in a locked room by outside counsel with a log maintained to identify each person who has been given access to the materials. Counsel for Amgen are not permitted to make electronic copies of the BLA or IND documents.
Filing of Confidential Documents	Any party seeking to file an opposing party's Confidential Material with the Court shall meet and confer with the opposing party pursuant to L.R. 7.2 in an effort to reach agreement on the appropriate method and manner for filing such papers with the Court. Failing such agreement, the moving party shall serve its papers on the Supplier and shall file a notice of service with the Court. The Supplier shall then have two (2) Court days in which to either consent to the request to file said information in the public file or to seek leave of Court pursuant to Local Rule 7.2 to file such papers under seal. Unless leave of Court is	Any party seeking to file an opposing party's Confidential Material [~~or Highly Confidential Material~~][2] with the Court shall meet and confer with the opposing party pursuant to L.R. 7.2 (at least seven days before the filing of said papers) in an effort to reach agreement on the appropriate method and manner for filing such papers with the Court. Failing such agreement, the moving party shall serve its papers on the Supplier and shall file a notice of service with the Court. The Supplier shall then have three (3) Court days in which to either consent to the request to file said information in the public file or to seek leave of Court pursuant to

[1] Roche's position is taken from its 11/29/06 Proposed Protective Order (Exh. 4).

[2] Amgen has lined-out reference to "Highly Confidential Material" in this Single-Tier Table.

	obtained by the Supplier to file such Confidential Material under seal within three (3) Court days, the opposing party may file said papers in the public file of the Court.	Local Rule 7.2 to file such papers under seal; and the filing party agrees not to oppose said motion. The proposed filing party shall take no further action, unless leave of Court is obtained by the Supplier to file such Confidential Material [~~or Highly Confidential Material~~] under seal within three (3) Court days, and no motion for reconsideration or renewal is made by the Supplier which would extend this period until three (3) days after the Court decides any such motion.
Exclusion Criteria for Experts and Consultants	Experts, consultants, and their staff may not be employed by a party to this proceeding or by a licensee of a party to this proceeding.	Experts, consultants, and their staff may not be employed by a party to this proceeding or by a licensee of a party to this proceeding. In addition, they may not be affiliated with any domestic or foreign manufacturer, wholesaler, retailer, or distributor of products and pharmaceutical compositions containing recombinant human erythropoietin, or competitors of the Parties in the markets which are the subject of this action.

IF TWO-TIER PROTECTIVE ORDER:		
ISSUE	**AMGEN'S POSITION**	**ROCHE'S POSITION**
Scope of Two-Tier Protective Order	"Highly Confidential Material" shall be limited to (a) on-going and future clinical trials and communications with regulatory authorities regarding such trials; (b) on-going labeling negotiations for any therapeutic product pending but not yet approved for sale by a regulatory authority (excluding the proposed label submitted with Roche's April 2006 BLA); and (c) active and on-going research and development of any therapeutic product for which no regulatory approval has yet been sought. Non-public information regarding the structure and activity of any accused product is expressly excluded from materials that may be designated as "Highly Confidential Materials."	"Highly Confidential Material" shall refer to a party's highly sensitive scientific, marketing, sales, financial, customer, accounting and business operations information and materials, including those relating to any compound, product, material, process or method, pending but not yet approved for sale by a regulatory authority, or for which no regulatory approval has yet been sought ("highly confidential products"), including without limitation: (a) Defendants' Biological License Application ("BLA") and Investigational New Drug Applications ("INDs") for CERA; (b) on-going and future, research, basic science, experimentation, pre-clinical experimentation, and clinical trials; (c) and communications or filings with regulatory authorities, customers and researchers, regarding such highly confidential products and research, or internal information and materials relating to such communications or filings; (d) labeling negotiations with any regulatory or review organization for any highly confidential product, and internal information and materials relating to such negotiations for any highly confidential product; (e) any research and development of any highly confidential product for which no regulatory approval has yet been sought; (f) information and materials relating to products not the subject of this action; and (g) any highly sensitive commercial or business method, operation or process of a party, the disclosure of which is

IF TWO-TIER PROTECTIVE ORDER:		
ISSUE	**AMGEN'S POSITION**	**ROCHE'S POSITION**
		likely to have the effect of causing substantial or irreparable harm to the Supplier.
	"Confidential Material" may include non-public information relating to trade secrets, processes, operations, style of work, communications or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, the disclosure of which information is likely to have the effect of causing harm to the Supplier (producing party). Confidential Material expressly includes all non-public information regarding the structure and function of any accused product.	"Confidential Material" includes non-public information relating to trade secrets, processes, operations, style of work, communications or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, the disclosure of which information is likely to have the effect of causing harm to the Supplier (producing party).
Designation of and In-House Counsel Access to Defendants' BLA and IND Documents	Defendants' BLA and IND documents produced in the related ITC investigation shall be treated as "Confidential Material" and shall be made accessible to designated in-house counsel with access under the Protective Order.	Defendants' BLA and IND produced in the related ITC investigation are designated "Highly Confidential Material" under a two-tier Protective Order and not available to designated in-house counsel.
Handling and Use Restrictions on Defendants' BLA and IND Documents	Roche has produced one complete hard copy of the IND and BLA and must still produce ten fully searchable electronic copies of the IND and BLA. Amgen and its counsel shall maintain the electronic copies only on non-networked computers.	Roche has fulfilled its production obligation by producing one complete hard copy and 10 electronic copies in TIFF/OCR form, which must be maintained on non-networked computers. The electronic copies to be maintained in a locked room by outside counsel with a log maintained to

IF TWO-TIER PROTECTIVE ORDER:		
ISSUE	**AMGEN'S POSITION**	**ROCHE'S POSITION**
		identify each person who has been given access to the materials. Counsel for Amgen are not permitted to make electronic copies of the BLA or IND documents.
Filing of Confidential and Highly Confidential Documents	Any party seeking to file an opposing party's Confidential Material or Highly Confidential Material with the Court shall meet and confer with the opposing party pursuant to L.R. 7.2 in an effort to reach agreement on the appropriate method and manner for filing such papers with the Court. Failing such agreement, the moving party shall serve its papers on the Supplier and shall file a notice of service with the Court. The Supplier shall then have two (2) Court days in which to either consent to the request to file said information in the public file or to seek leave of Court pursuant to Local Rule 7.2 to file such papers under seal. Unless leave of Court is obtained by the Supplier to file such Confidential Material under seal within three (3) Court days, the opposing party may file said papers in the public file of the Court.	Any party seeking to file an opposing party's Confidential Material or Highly Confidential Material with the Court shall meet and confer with the opposing party pursuant to L.R. 7.2 (at least seven days before the filing of said papers) in an effort to reach agreement on the appropriate method and manner for filing such papers with the Court. Failing such agreement, the moving party shall serve its papers on the Supplier and shall file a notice of service with the Court. The Supplier shall then have three (3) Court days in which to either consent to the request to file said information in the public file or to seek leave of Court pursuant to Local Rule 7.2 to file such papers under seal; and the filing party agrees not to oppose said motion. The proposed filing party shall take no further action, unless leave of Court is obtained by the Supplier to file such Confidential Material or Highly Confidential Material under seal within three (3) Court days, and no motion for reconsideration or renewal is made by the Supplier which would extend this period until three (3) days after the Court decides any such motion.
Exclusion Criteria for	Experts, consultants, and their staff may not be employed by a party to this proceeding or by a	Experts, consultants, and their staff may not be employed by a party to this proceeding or by a

IF TWO-TIER PROTECTIVE ORDER:		
ISSUE	**AMGEN'S POSITION**	**ROCHE'S POSITION**
Experts and Consultants	licensee of a party to this proceeding.	licensee of a party to this proceeding. In addition, they may not be affiliated with any domestic or foreign manufacturer, wholesaler, retailer, or distributor of products and pharmaceutical compositions containing recombinant human erythropoietin, or competitors of the Parties in the markets which are the subject of this action.

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the Plaintiff has attempted to confer with counsel for the Defendants, F. Hoffman-La Roche Ltd., Hoffman La Roche Inc. and Roche Diagnostics GmbH, in an attempt to resolve or narrow the issues presented by this motion and that no agreement could be reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on November 29, 2006.

/s/ Michael R. Gottfried
Michael R. Gottfried