

From: DLopez@kayescholer.com [mailto:DLopez@kayescholer.com]
Sent: Friday, October 20, 2006 7:26 PM
To: Fishman, Deborah
Cc: Thomas Fleming; Howard Suh
Subject: Fw: 2006-10-20 ltr to Fishman re Protective Order

Please see attached.

Denise Lopez

----- Original Message -----

From: Denise Lopez
Sent: 10/20/2006 06:38 PM
To: Denise Lopez
Subject: 2006-10-20 ltr to Fishman re Protective Order

(See attached file: 2006-10-20 ltr to Fishman re Protective Order.pdf)

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* * * *

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October 20, 2006

Via Email

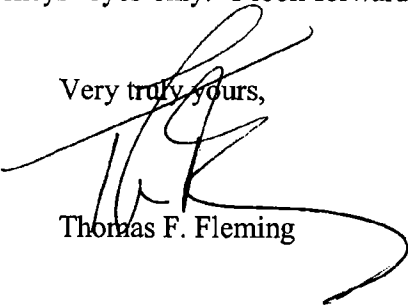
Deborah E. Fishman, Esq.
Day Casebeer Madrid
& Batchelder LLP
20300 Stevens Creek Blvd.
Suite 400
Cupertino, CA 95014

Re: Amgen Inc. v. F. Hoffmann LaRoche Ltd, et al. (05-CV-12237WGY)

Dear Deborah:

As promised, I enclose a revised draft protective order for you to consider. I have tried to hue to the terms of the protective order from the the ITC proceeding and side agreement as much as possible, incorporating where I could the salient paragraphs from your draft. Having reached agreement on terms of a protective order already (the one in the ITC with side letter), it made more sense to us to use that model. Among the provisions is a restriction that confidential information be restricted to outside attorneys' eyes only. I look forward to setting up a time to discuss this draft with you.

Very truly yours,


Thomas F. Fleming

TFF/jm

cc: Leora Ben-Ami
Lee Carl Bromberg
Julia Huston

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**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
v.)	Civil Action No.: 05 Civ. 12237 WGY
)	
F. HOFFMANN-LAROCHE LTD., ROCHE)	
DIAGNOSTICS GmbH, and HOFFMANN)	
LAROCHE INC.,)	
Defendants.)	
)	
)	

ORDER NO. : STIPULATED PROTECTIVE ORDER

WHEREAS, documents and information may be sought, produced or exhibited by and among the parties to the above captioned proceeding, which materials relate to trade secrets or other confidential research, development or commercial information, Plaintiff AMGEN INC. (“Amgen”), and Defendants F. HOFFMANN-LAROCHE LTD., ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. (“Defendants”) (hereinafter, collectively “the Parties”), hereby agree that the following Stipulated Protective Order be entered to provide access by the parties to such confidential information, subject to certain protective provisions set forth herein.

IT IS HEREBY ORDERED THAT:

1. Confidential business information is information which has not been made public and which concerns or relates to the 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

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expenditures of any person, firm, partnership, corporation, or other organization, the disclosure of which information is likely to have the effect of causing substantial harm to the competitive position of the Parties, person, firm, partnership, corporation, or other organization from which the information was obtained (hereinafter collectively referred to as "confidential business information").

2. Any information submitted, either voluntarily or pursuant to order, in this action, which is asserted by any party or non-party providing information to this litigation "supplier" to contain or constitute confidential business information shall be so designated by such supplier in writing, or orally at a deposition (to be confirmed in writing in five (5) days), conference or hearing, and shall be segregated from other information being submitted. Documents shall be clearly and prominently marked on their face with the legend: "**[supplier's name] CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER,**" or a comparable notice. Information obtained during discovery and asserted by the supplier to be confidential under this order will be deemed to be confidential business information and treated as such unless the Court rules that it is not. The parties shall file confidential business information with the Court only in accordance with Local Rule 7.2, and the Court's Electronic Case Filing Administrative Procedures. Before seeking such relief relating to the other party's confidential business information, under Local Rule 7.2, the filing party shall first confer with the other party at least three (3) business days before the motion is filed. Then, confidential business information whether submitted in writing or in oral testimony shall be disclosed at a hearing only on the *in camera* record and shall not be made part of the public record of this proceeding. The Court may determine that information alleged to be confidential is not confidential. If such a determination is made by the Court, opportunity shall

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be provided to the supplier of such information to argue its confidentiality, prior to the time that such ruling becomes final. If a party or non-party thereafter determines that it inadvertently failed to designate information or testimony as containing confidential information, it may do so by giving notice to all parties, who shall thereafter treat the materials pursuant to the provisions of this Order. Any transcript portion that contains testimony so designated shall be labeled in a visible manner with the CONFIDENTIAL legend (or comparable notice).

3. In the absence of written permission from the supplier or an order by the Court, any confidential documents or business information submitted in accordance with the provisions of paragraph 2 above **shall not be disclosed to any person** other than: (a) outside counsel of record for parties to this action, including necessary secretarial and clerical personnel assisting such counsel, (b) qualified persons taking testimony involving such documents or information and necessary stenographic and clerical personnel thereof, (c) technical experts and their staff who are employed by outside counsel under 3(a) above for the purposes of this litigation (unless they are otherwise employed by, consultants to, or otherwise affiliated with a non-governmental party, or are employees of any domestic or foreign manufacturer, wholesaler, retailer, or distributor of certain products and pharmaceutical compositions containing recombinant human erythropoietin, or competitors of the Parties which are the subject of this action), and (d) the Court and the Court staff, in accordance with the Court's rules, procedures and orders for handling confidential information.

4. Confidential business information submitted in accordance with the provisions of paragraph 2 above shall not be made available to any person designated in paragraph 3(a) and (c) unless he or she shall have first read this order and shall have agreed, by letter served on outside counsel of record (letter of acknowledgment): (i) to be bound by the terms thereof; (ii) not to

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reveal such confidential business information to anyone other than another person designated in paragraph 3; and (iii) to utilize such confidential business information solely for purposes of this action. Such letter shall also acknowledge that the signatory(ies) has (have) read the order. Such letter shall further state which parties the person filing the letter is involved with and shall state in what capacity he or she is a signatory to the Protective Order (e.g., as an attorney under Paragraph 3(a), or technical expert under Paragraph 3(c) and, in the case of an attorney, in what jurisdictions he or she is admitted to practice. Each outside attorney seeking access to confidential business information shall sign such letter individually, but clerical and support personnel (including law clerks and paralegals) of that attorney need not sign. All letters of acknowledgment of this Protective Order shall be served on all non-parties who have theretofore submitted confidential business information in accordance with the provisions of paragraph 2, above.

5. Any party or non-party may designate deposition or other testimony in whole or in part as containing confidential information by so stating on the record during the deposition (to be confirmed in writing as in 2 above), or thereafter by notifying the other party in writing of the portions of such testimony to be so designated within twenty (20) days of receipt of the transcript. If a party or non-party thereafter determines that it inadvertently failed to designate testimony as containing confidential information, it may do so by giving notice to all parties, who shall thereafter treat the materials pursuant to the provisions of this Order.

6. This Stipulated Protective Order permits a party or non-party to refuse to disclose information properly subject to the attorney-client privilege or the attorney work product doctrine. To that end, each party or non-party may produce its documents in redacted form, redacting only information which is irrelevant or is subject to a claim of attorney-client privilege

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or work-product immunity. The party or non-party so producing a document in redacted form shall make the notation "REDACTED" (or comparable notice) on each redacted portion of the document. In addition, each "REDACTED" (or comparable) notation must include a separate notation identifying the basis for that redaction (*i.e.*, privilege or relevance). Inspecting counsel shall not have the right to custody of the original un-redacted documents or a copy thereof. In the event of disagreement, inspecting counsel shall identify those redacted areas of the documents which should not be redacted and shall state why such areas should not be redacted. In the even the producing party or non-party continues to refuse to produce the document(s) in unredacted form, counsel of the inspecting party may seek a determination by the Court that such documents or portions thereof should be produced in unredacted form.

7. If the Court orders, or if the supplier and all parties to the action agree, that access to, or dissemination of, information submitted as confidential business information shall be made to persons not included in paragraphs 3, 4 above, such matter shall only be accessible to, or disseminated to, such persons based on the conditions pertaining to, and obligations arising from, this order, and such persons shall be considered subject to it unless the Court finds that the information is not confidential business information as defined in paragraph 1 hereof.

8. When any confidential business information submitted in accordance with paragraph 2 above is included in an authorized transcript of a deposition or exhibits thereto, arrangements shall be made with the court reporter taking the deposition to bind such confidential portions and separately label them "[supplier's name], **CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER.**" Before a court reporter receives any such information, he or she shall have first read this order and shall have agreed in writing to be bound by the terms thereof. Alternatively, he or she shall sign the agreement included as

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Attachment A hereto. Copies of each such signed agreement shall be provided to the supplier of such confidential business information and to the Court. If a party or non-party thereafter determines that it inadvertently failed to designate testimony as containing confidential information, it may do so by giving notice to all parties, who shall thereafter treat the materials pursuant to the provisions of this Order.

9. The restrictions upon, and obligations accruing to, persons who become subject to this order shall not apply to any information submitted in accordance with paragraphs 1 and 2 above to which the person asserting the confidential status thereof agrees in writing, or the Court rules, after proper notice and hearing, was publicly known at the time it was supplied to the receiving party or has since become publicly known through no fault of the receiving party.

10. The Court acknowledges that any document or information submitted as confidential business information pursuant to paragraph 2 above is to be treated as such subject to a challenge by any party pursuant to paragraph 15 below or to a final ruling by the Court, or by appeal of such a ruling, interlocutory or otherwise.

11. If no determination has been made by the Court that the information designated as confidential business information by the submitter is not confidential, the persons who are recipients of such information shall take all necessary and proper steps to preserve the confidentiality of, and to protect each supplier's rights with respect to any confidential business information designated by the supplier in accordance with paragraph 2 above.

12. If a party or non-party inadvertently produces or discloses information that is subject to attorney-client privilege and/or attorney-work product immunity, it may request in writing within ten business (10) days of learning of such inadvertent production or disclosure that the information inadvertently produced or disclosed be returned or destroyed. Such inadvertent

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production shall not be or constitute a waiver of any applicable privilege either to the information or subject matter of the disclosure. The request must state the nature of the privilege and/or immunity claimed for the inadvertently produced or disclosed information. Upon receipt of such request, the party or non-party in receipt of such information shall in good faith attempt to retrieve all copies of such information and shall return or destroy the information (and shall to the extent possible destroy any notes relating to the information subject to the request). No party or non-party that received the inadvertently produced or disclosed information under the provisions of this Order may argue that the privilege or immunity has been waived as a result of the inadvertent production or disclosure, nor may that party use any information contained in or obtained from such inadvertent production in this action. If the receiving party or non-party wishes to challenge the propriety of the claim of privilege or immunity, it may do so only after first fully complying with the requirements of this paragraph.

13. This is to confirm the agreement reached by outside counsel for Defendants and outside counsel for Amgen regarding the confidentiality of the Roche Biological License Application ("BLA") and the INDs. This agreement is to provide additional protection for the BLA and INDs. It was agreed and is ordered that this provision supercedes any other paragraph of this order to the contrary:

- (1) Roche has produced one paper copy of the subject INDs and BLA,
- (2) Roche has produced 10 electronically searchable CD copies of the INDs and BLA (which Amgen's counsel will not electronically reproduce),
- (3) the CD's and single hard copy will be maintained by outside counsel in a locked room and a log will be maintained to identify each person who has been given access to the materials,
- (4) the CDs will be reviewed on stand-alone, non-networked computers, and

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(5) individuals qualified as outside counsel under the Protective Order in paragraph 3(a) now in place may access and use the information contained in Roche's INDs and BLA subject to the provisions and restrictions of the Order.

14. Only a party may move to declassify the protections of this Order.

15. If a party to this order who is a recipient of any business information designated as confidential and submitted in accordance with paragraph 2, disagrees with respect to such a designation, in full or in part, it shall notify the supplier in writing, and they will thereupon confer as to the status of the subject information proffered within the context of this order. If prior to, or at the time of, such a conference, the supplier withdraws its designation of such information as being subject to this order, but nonetheless submits such information for purposes of the action, such supplier shall express the withdrawal in writing and shall serve such withdrawal upon outside counsel of record for all parties. If the recipient and supplier are unable to concur upon the status of the subject information submitted as confidential business information within ten (10) business days from the date of notification of such disagreement, any party to this Order may raise the issue of the designation of such a status to the Court, and the Court may raise the issue of designation of the confidential status without any request from a party. Upon notice that such confidential status of information is at issue, the party to the action which submitted the information and designated it as confidential shall have the burden of proving such confidential status.

16. No less than ten (10) business days (or any other period of time designated by the Court) prior to the initial disclosure to the proposed expert of any confidential information submitted in accordance with paragraphs 2 and 3, the party proposing to use such expert shall submit in writing the name of such proposed expert and his or her educational and employment history to the supplier. If the supplier objects to the disclosure of such confidential business

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information to such proposed expert as inconsistent with the language or intent of this order or on other grounds, it shall notify the recipient in writing of its objection and the grounds therefore prior to the initial disclosure. If the dispute is not resolved on an informal basis within ten (10) days of receipt of such notice of objection, motion may be made to the Court for a ruling on such objection. The submission of such confidential business information to such proposed expert shall be withheld pending the ruling of the Court.

17. If confidential business information submitted in accordance with paragraph 2 is disclosed to any person other than in the manner authorized by this protective order, the party responsible for the disclosure must immediately bring all pertinent facts relating to such disclosure to the attention of the supplier and, without prejudice to other rights and remedies of the supplier, make every effort to prevent further disclosure by it or by the person who was the recipient of such information.

18. Nothing in this Order shall be deemed to place any restrictions on any party, non-party or its attorneys with respect to access and use and disposition of a party's own confidential business information, nor abridge the right of any person to seek judicial review or to pursue other appropriate judicial action with respect to any ruling made by the Court concerning the issue of the status of confidential business information. The denial of a motion under Local Rule 7.2 shall not be deemed a waiver of protection for said confidential business information by the supplier and shall not entitle the filing party to place that confidential business information in the public record.

19. Upon final termination of this action, including any appeal thereof, each party that is subject to this order shall destroy or return to the supplier all items containing confidential business information submitted in accordance with paragraph 2 above, including all copies of

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such materials or information which may have been made, but not including copies containing notes or other attorney's work product that may have been placed thereon by counsel for the receiving party. All copies containing such notes or other attorney's work product shall be destroyed. Receipt of material returned to the supplier shall be acknowledged in writing. This paragraph shall not apply to the Court, which may in its discretion, retain such material, destroy them or return them to the parties.

20. If any confidential business information which is supplied in accordance with paragraph 2 above is supplied by a non-party to this action, such a non-party shall be considered a "supplier" within the meaning of that term as it is used in the context of this order.

21. At or before the final termination of the action, copies of confidential information that was in the hands of expert witnesses must be retrieved or destroyed.

22. The Court retains jurisdiction for purposes of enforcing the terms of this Order at any time.

23. The parties may move to amend this order, but any proposed amendment that would broaden the range of persons having access to confidential business information must be proposed and adopted before such information is supplied in reliance upon the terms of this order, unless all suppliers of confidential information consent to the amendment.

Dated: October __, 2006

SO ORDERED:

[SIGNATURE LINES FOR ALL PARTIES]

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ATTACHMENT A

NONDISCLOSURE AGREEMENT FOR REPORTER STENOGRAPHER TRANSLATOR

I, _____, do solemnly swear that I will not divulge any information communicated to me in any confidential portion of the action or hearing in the above action except as permitted in the protective order issued in this case. I will not directly or indirectly use, or allow the use of such information for any purpose other than that directly associated with my official duties in this case.

Further, I will not by direct action, discussion, recommendation, or suggestion to any person reveal the nature of content of any information communicated during any confidential portion of the action or hearing in this case.

I also affirm that I do not hold any position or official relationship with any of the participants in said action.

Signed _____

Dated _____

Firm or affiliation

