

**EXHIBIT A**

**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.	)	
	)	
	)	

**DEFENDANTS' PROPOSED PROTECTIVE ORDER**

**WHEREAS**, documents and information may be sought, produced or exhibited by and among the parties to the above captioned proceeding, which relate to trade secrets or other confidential research, development or commercial information, the Court finds that good cause exists for the entry of the following protective order in this action pursuant to Rule 26(c) of the Federal Rules of Civil Procedure in order to provide access by the parties to such confidential information, subject to certain protective provisions set forth herein. The parties to this action are Plaintiff AMGEN INC. (“Amgen”), and Defendants F. HOFFMANN-LAROCHE LTD., ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. (“Defendants”) (hereinafter, collectively “the Parties”).

**IT IS HEREBY ORDERED THAT:**

1. This Protective Order shall apply to all information, including but not limited to deposition testimony, documents and things subject to discovery and produced by or otherwise obtained from either a party or non-party (“Supplier”) in discovery in this action (“Discovery Materials”).

2. Discovery Materials that contain confidential business information shall be referred to as “Confidential Material.” 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 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.

3. Discovery Materials that contain highly confidential business information shall be referred to as “Highly Confidential Material.” Highly confidential business information is information which has not been made public and which is highly sensitive including, but not limited to, highly sensitive scientific, technical, business, commercial, financial, marketing, customer, cost, profit and pricing information, the disclosure of which information is likely to have the effect of causing substantial or irreparable harm to the Supplier.

4. Any Discovery Materials submitted, either voluntarily or pursuant to order, in this action, which are asserted by any Supplier to contain or constitute either Confidential Material or Highly Confidential Material shall be so designated by such Supplier, as set forth in subparagraphs (a)–(d) below and shall be segregated from other information being submitted.

- a. Documents designated as Highly Confidential Material shall be clearly and prominently marked on their face with the legend: “**HIGHLY CONFIDENTIAL– OUTSIDE COUNSELS’ EYES ONLY**” or a comparable notice. Documents designated as Confidential Material shall be clearly and prominently marked on their face with the legend “**CONFIDENTIAL**” or a comparable notice.
- b. Interrogatory answers and information contained therein shall be designated as Confidential Material or Highly Confidential Material by means of a statement at the conclusion of each answer specifying the

Confidential or Highly Confidential Material contained therein or by other means that clearly indicate what portion of the answer or information is considered Confidential or Highly Confidential Material and by placing the legend referenced in subpart (a) above on the front of any set of interrogatory answers containing such Confidential or Highly Confidential Material.

- c. Deposition testimony and transcripts thereof shall be treated as Highly Confidential Material for a period of twenty (20) days following receipt of the transcript by counsel for the deponent. Within said time, deposition testimony may be designated Confidential or Highly Confidential by identifying the transcript containing such Confidential or Highly Confidential Material.
- d. In the event that a Supplier produces or discloses Confidential or Highly Confidential business information without designating it as Confidential or Highly Confidential Material prior to or contemporaneously with such production or disclosure, and thereafter determines that it inadvertently failed to designate Discovery Material as Confidential or Highly Confidential Material, it may do so by giving notice to all receiving parties, who thereafter shall treat the Confidential or Highly Confidential Material as such pursuant to the provisions of this Order. Notwithstanding the provisions of the preceding sentence, no receiving party shall have any obligation or liability to seek return of any disclosure of the Discovery Material that may have occurred in good faith and consistent with the terms of this Order prior to the receipt of such notice.

5. Any Discovery Materials designated as Confidential or Highly Confidential Material pursuant to paragraph 4 above are to be treated as such until and unless the parties agree in writing to the contrary or there is a final ruling by the Court pursuant to a challenge to the designation pursuant to Paragraph 17 below, including any appeal of such a ruling, interlocutory or otherwise.

6. In the absence of written permission from the Supplier or an order by the Court, any Highly Confidential Material designated in accordance with the provisions of paragraph 4 above **shall not be disclosed to any person** other than:

- a. outside counsel of record for parties to this action, including necessary paralegal, litigation support, secretarial and clerical personnel assisting such counsel;

- b. qualified persons translating, recording or transcribing testimony involving Highly Confidential Material and necessary stenographic and clerical personnel thereof;
- c. technical experts and their staff who are employed by outside counsel under 6(a) for the purposes of this litigation (provided that they are not employed by, consultants to, or otherwise affiliated with a party to this proceeding, a licensee of a party to this proceeding, any domestic or foreign manufacturer, wholesaler, retailer, or distributor of 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.

7. In the absence of written permission from the Supplier or an order by the Court, any Confidential Material designated in accordance with the provisions of paragraph 4 above **shall not be disclosed to any person** other than:

- a. the persons identified in subparagraphs 6(a)–(d) above; and
- b. no more than four (4) in-house counsel for each party who have made an appearance in this action (and their paralegal, litigation support, secretarial and clerical personnel).

8. Roche's pending Biological License Application ("BLA") for CERA and Investigational New Drug Applications ("INDs") for CERA are to be provided additional protection. It was previously agreed by the Parties in a related proceeding, and is hereby Ordered, that this provision supercedes any other paragraph of this Order to the contrary:

- a. Defendants have produced one paper copy of the subject INDs and BLA;
- b. Defendants have produced 10 electronically searchable CD copies of the INDs and BLA (which Amgen's counsel will not electronically reproduce);
- c. the CDs 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;

- d. the CDs will be reviewed on stand-alone, non-networked computers; and
- e. individuals qualified as outside counsel under the Protective Order in paragraph 6(a) now in place may access and use the information contained in Roche's INDs and BLA subject to the provisions and restrictions of this Order.

9. Confidential and Highly Confidential Material designated in accordance with the provisions of paragraph 4 above shall not be made available to any attorney or expert identified in paragraphs 6(a) and (c), or 7(b) unless he or she shall have first read this order and shall have agreed in writing to the terms thereof by completing an agreement in the form set forth in Attachment A to this Order, which shall be served on outside counsel of record. Such agreement shall 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 Paragraphs 6(a), an in-house counsel under Paragraph 7(b), or technical expert under Paragraphs 6(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 agreements to be bound by the terms of this Protective Order shall be served on all non-parties who have theretofore produced Confidential or Highly Confidential Material designated in accordance with the provisions of paragraph 4, above.

10. When any Highly Confidential or Confidential Material designated in accordance with paragraph 4 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 highly confidential or confidential portions and separately label them “[Supplier] **HIGHLY CONFIDENTIAL MATERIAL – OUTSIDE COUNSELS’ EYES ONLY, SUBJECT TO PROTECTIVE ORDER,**” or “[Supplier], **CONFIDENTIAL MATERIAL, SUBJECT TO**

**PROTECTIVE ORDER,**” respectively. Before a court reporter receives any such Confidential or Highly Confidential Material, 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 Attachment B hereto. Copies of each such signed agreement shall be provided to the Supplier of the Discovery Materials at issue.

11. 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 Highly Confidential or Confidential Material designated in accordance with paragraph 4 above, 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 Highly Confidential or Confidential Material to such proposed expert as inconsistent with the language or intent of this Order or on other grounds, it shall notify the other party in writing of its objection and the grounds therefor 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 Highly Confidential or Confidential Material to such proposed expert shall be withheld pending the ruling of the Court.

12. All Highly Confidential or Confidential Material that is filed with the Court, and all pleadings, motions or other papers filed with the Court that contain or disclose Confidential or Highly Confidential Material, shall be filed only in accordance with Local Rule 7.2 and such other Orders as may be entered by the Court. No party shall file another’s Confidential or Highly Confidential Material with the Court, either under seal or in the public record, in the absence of a specific directive from the Court, which shall be sought by motion for good cause

shown. Without limiting the generality of the foregoing, the denial of a motion under Local Rule 7.2 to file documents under seal shall not be deemed a waiver of protection for said Highly Confidential or Confidential Material by the Supplier and shall not entitle any party to file the Highly Confidential or Confidential Material in the public record, absent a specific directive of the Court.

13. If the Court orders, or if the Supplier and all parties to the action agree, that access to, or dissemination of, Highly Confidential or Confidential Material shall be made to persons not included in paragraphs 6 and 7 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 highly confidential business information or confidential business information as defined in paragraphs 2 and 3 hereof.

14. The restrictions upon, and obligations accruing to, persons who become subject to this Order shall not apply to any Confidential or Highly Confidential Material designated in accordance with paragraph 4 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.

15. If no determination has been made by the Court that the Highly Confidential or Confidential Material designated by the Supplier is not highly confidential or confidential, respectively, 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 the confidentiality of such Highly Confidential or Confidential Material designated by the Supplier in accordance with paragraph 4 above.

16. Only a party may move to declassify Highly Confidential or Confidential Material subject to the protections of this Order.

17. If a party to this Order who is a recipient of Highly Confidential or Confidential Material designated in accordance with paragraph 4 disagrees with respect to such a designation, in full or in part, it shall notify the Supplier in writing, and the Supplier and receiving party 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, 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 Discovery Material as Highly Confidential or Confidential Material, any party to this Order may raise the issue of the designation of such status to the Court. The Court also may raise the issue of designation of the confidential status without any request from a party. Upon notice that the confidential status of Discovery Material is at issue, the Supplier shall have the burden of proving such Highly Confidential or Confidential status.

18. If Highly Confidential or Confidential Material designated in accordance with paragraph 4 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 and by the person who was the recipient of such information.



19. This 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 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). Receiving counsel shall not have the right to custody of the original un-redacted documents or a copy thereof. In the event of disagreement, receiving 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 event the producing party or non-party continues to refuse to produce the document(s) in unredacted form, counsel of the receiving party may seek a determination by the Court that such documents or portions thereof should be produced in unredacted form.

20. If a party or non-party inadvertently produces or discloses information that is subject to attorney-client privilege and/or attorney-work product immunity, or other applicable privilege, 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 production shall not constitute or be construed as 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 or for any purpose. 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.

21. 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 highly confidential or 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 Discovery Material designated as Highly Confidential or Confidential Material.

22. 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 within thirty (30) days all Highly Confidential or Confidential Material designated in accordance with paragraph 4 above, including all copies of such materials or information which may have been made. Copies of all pleadings or other papers filed or served in the case containing or disclosing Highly Confidential or Confidential Material shall be destroyed; provided however, that outside counsel of record for each of the parties may retain one (1) paper and one (1) electronic copy of such pleadings or other papers solely for the purpose of preserving a file in this matter. If destroyed rather than

returned, the party destroying shall so verify in writing. Receipt of material returned to the Supplier shall be acknowledged in writing.

23. Within thirty (30) days of the final termination of the action, including any appeal thereof, copies of Highly Confidential or Confidential Material that was in the hands of expert witnesses must be retrieved or destroyed.

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

25. The parties may move to amend this Order, but any proposed amendment that would broaden the range of persons having access to Highly Confidential or Confidential Material must be proposed and adopted before such Discovery Material is produced in reliance upon the terms of this Order, unless all Suppliers of Highly Confidential or Confidential Material consent to the amendment.

SO ORDERED on this \_\_\_\_ day of \_\_\_\_\_, 200\_.

SO ORDERED:

\_\_\_\_\_  
The Honorable William G. Young  
United States District Court  
District of Massachusetts

3099/501 568085

ATTACHMENT A

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.	)	
	)	
	)	

AGREEMENT TO PROTECTIVE ORDER

The undersigned represents that he or she is affiliated with [Plaintiff Amgen, Inc.] [Defendants F. Hoffman-LaRoche Ltd, Roche Diagnostics GmbH, and Hoffman LaRoche Inc.], in the above captioned matter. The undersigned is involved in this litigation as \_\_\_\_\_ [e.g., attorney, expert retained by outside counsel]. If an attorney, the undersigned is admitted in \_\_\_\_\_ [all jurisdictions]. The undersigned has read the Protective Order issued on \_\_\_\_\_ by the Honorable William G. Young in this matter, and in accordance with that Order, hereby agrees:

- (1) To be bound by the terms of the Protective Order;
  - (2) Not to reveal confidential business information or highly confidential business information under the Protective Order to anyone other than another person designated in paragraphs 6 and 7 of the Protective Order;
- and

(3) To use such confidential business information or highly confidential business information solely for purposes of this litigation, unless permission is received from the supplier, or the Court, to use it for other purposes.

Respectfully submitted,

Dated:

\_\_\_\_\_  
Name  
Employer  
Address

ATTACHMENT B

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.	)	
	)	
	)	

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 \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_