

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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

**AMENDED 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-LA ROCHE 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 in discovery in this action (“Discovery Materials”).

For purposes of this Protective Order, any party or non-party producing Discovery Materials in this case shall be known as a "Supplier."

2. Discovery Materials that contain confidential business information may be designated as "Confidential Material." Confidential Material may include 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 may be designated as "Highly Confidential Material" pursuant to the terms of this paragraph. Discovery Materials designated as 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; and (c) active and on-going research and development of any therapeutic product for which no regulatory approval has yet been sought. Defendants may within 10 days of this Order designate as Highly Confidential documents previously produced in the proceeding before the International Trade Commission captioned *In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568, that are within the definition of "Highly Confidential Material" set forth in this paragraph and that are not contained in the BLA and INDs identified in Paragraph 4 and are not duplicative of information contained therein, to the extent that any such documents exist.

4. Defendants' pending Biological License Application ("BLA") for CERA and Investigational New Drug Applications ("INDs") for CERA may be designated as "Restricted Access Confidential BLA/IND Material" and shall not be disclosed except to the persons identified in Paragraph 10 subject to the following procedures and conditions:

- a. Defendants have produced or will produce one paper copy of the subject INDs and BLA;
- b. Defendants have produced or will produce 10 fully text 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 of record and/or designated in-house counsel in one or more locked rooms in one or more office buildings, commercial storage facilities or other secure non-residential facilities not on Amgen's premises, and a log will be maintained to identify each person who has been given access to said materials, which access shall be limited to the individuals identified in paragraph 10; and
- d. the CDs will be reviewed on stand-alone, non-networked computers.

The provisions of this paragraph shall apply to Defendants' prior production of such documents in the proceeding before the International Trade Commission captioned *In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568; and shall also apply to any subsequent productions, if any, of these documents in another form by Defendants.

5. Any Discovery Materials submitted, either voluntarily or pursuant to order, in this action, which are asserted by any Supplier to contain or constitute Confidential Material, Restricted Access Confidential BLA/IND Material, or Highly Confidential Material (collectively, "Confidential Discovery 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 "Restricted Access Confidential BLA/IND Material" shall be clearly and prominently marked on their face with the legend: "**RESTRICTED ACCESS CONFIDENTIAL BLA/IND - LOCKED ROOM ACCESS 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 or other responses to written discovery and information contained therein shall be designated as Confidential Discovery Material by means of a statement at the conclusion of each answer specifying the Confidential Discovery Material contained therein or by other means that clearly indicate what portion of the answer or information is considered Confidential Discovery Material and by placing the legend referenced in subpart (a) above on the front of any set of interrogatory answers containing such Confidential Discovery Material.
- c. Deposition testimony and transcripts including exhibits attached thereto shall be treated as Confidential Material, unless otherwise designated as Highly Confidential or Restricted Access Confidential BLA/IND Material. Counsel may designate all or portions of the transcript and exhibits used therein as Highly Confidential or Restricted Access Confidential BLA/IND Material at any time during the deposition and for a period of five (5) business days following receipt of the transcript by counsel for the deponent. In-house counsel shall not have access to such transcripts or exhibits until after the expiration of said five (5) business days and provided that the designation has not been changed to Highly Confidential or Restricted Access Confidential BLA/IND Material. In-house counsel of a party may attend any deposition of a party or non-party witness, provided that the in-house counsel upon notice will leave the deposition room while another party or non-party's Highly Confidential information or an exhibit containing the same is the subject of the examination or testimony.
- d. In the event that a Supplier produces or discloses Confidential Discovery Material without designating it as Confidential Discovery Material prior to or contemporaneously with such production or disclosure, and thereafter determines that it inadvertently failed to designate Discovery Material as Confidential Discovery Material, it may do so by giving notice to all receiving parties, who thereafter shall treat the Confidential Discovery Material as such pursuant to the provisions of this Order.

6. When any Confidential Discovery Material 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 portions and separately label them “[Supplier] **HIGHLY CONFIDENTIAL MATERIAL – OUTSIDE COUNSELS’ EYES ONLY, SUBJECT TO PROTECTIVE ORDER,**” “[Supplier] **RESTRICTED ACCESS CONFIDENTIAL BLA/IND - LOCKED ROOM ACCESS ONLY**” or “[Supplier], **CONFIDENTIAL MATERIAL, SUBJECT TO PROTECTIVE ORDER,**” respectively. Before a court reporter receives any such Confidential Discovery 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 C hereto. Copies of each such signed agreement shall be provided to the Supplier of the Discovery Materials at issue.

7. Any Discovery Materials designated as Confidential Discovery Material are to be treated as such until and unless the parties agree in writing to the contrary or there is a ruling by the Court pursuant to a challenge to the designation pursuant to Paragraph 8 below.

8. If a party to this Order disagrees, in full or in part, with a Supplier’s designation of Confidential Discovery Material, such party may notify the Supplier in writing stating the basis for its disagreement, and the Supplier shall thereafter state the basis for the designation and confer in good faith as to the designation of the Discovery Material. If the parties are unable to reach agreement on the proper designation of the Discovery Material, either party may move to re-classify Confidential Discovery Material pursuant to the terms of this Order.

9. In the absence of written permission from the Supplier or an order by the Court, any Highly Confidential Material pursuant to Paragraph 3 **shall not be disclosed to any person** other than:

- a. outside counsel of record for parties to this action, including necessary paralegal, litigation support (including outside document management and courtroom graphics consultants), 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. experts, consultants, and their staff who are employed by outside counsel under Paragraph 9(a) for the purposes of this litigation (provided they are not employed by a party to this proceeding or by a licensee of a party to this proceeding); and
- d. the Court and the Court staff, in accordance with the Court's rules, procedures and orders for handling confidential information.

10. In the absence of written permission from the Supplier or an order by the Court, any Confidential Material **shall not be disclosed to any person** other than:

- a. the persons identified in subparagraphs 9(a)-(d) above; and
- b. the following four (4) Amgen in-house counsel who have each been admitted or will be admitted *pro hac vice* in this action (and their paralegal, litigation support, secretarial and clerical personnel):
  1. Wendy A. Whiteford
  2. Monique L. Cordray
  3. Darrell G. Dotson
  4. to be identified at a later date by Amgen
- c. the following four (4) Defendants in-house counsel who have each been admitted or will be admitted *pro hac vice* in this action (and their paralegal, litigation support, secretarial and clerical personnel):
  1. George W. Johnston
  2. Patricia Rocha-Tramaloni
  3. Nancy DiLella
  4. to be identified at a later date by Defendants

11. Confidential Discovery Material shall not be made available to any individual identified in Paragraphs 9(a) and (c), or 10(b) and (c) unless he or she has first read and agreed in writing (as set forth in Attachment A) to be bound to terms of this Order.

12. Each outside counsel seeking access to confidential business information shall agree in writing (per Attachment A) to be bound by the terms of the Protective Order. Outside counsel's clerical and support personnel (other individuals identified in Paragraph 9(a) except any outside litigation support) need not sign. Each in-house counsel who wishes to have access to Confidential Materials shall review and agree in writing (per Attachment B) to be bound by the Protective Order. Notwithstanding the access restrictions in Paragraph 4, in-house counsel may maintain the following documents containing Restricted Access Confidential BLA/IND Material of another party received pursuant to this Protective Order either in a locked room pursuant to Paragraph 4(c) or under lock and key, such as in a locked room or filing cabinet, at any location: documents filed with the Court in this proceeding, deposition transcripts (but not exhibits) in this proceeding, expert reports (but not exhibits) in this proceeding, interrogatory answers in this proceeding, admissions in this proceeding, and drafts of any of the foregoing. All agreements to be bound by the terms of this Protective Order shall be served on all non-parties who have theretofore produced Confidential Discovery Material. Each counsel identified in paragraph 10 above may utilize Discovery Materials produced under the terms of this order for purposes of this litigation, including to generate work product, draft motions, prepare for depositions, work with experts, draft expert reports and to otherwise prepare the case for trial. Without limiting the generality of the foregoing, the parties agree that Restricted Access BLA/IND Material may be shown to Amgen's experts at their offices, consistent with the terms of Paragraph 13 hereof, provided that those materials are not left with the experts and further

provided that such materials remain in the custody and control of Amgen's counsel of record designated pursuant to this Protective Order at all times.

13. Not less than ten (10) business days before the initial disclosure of any Confidential Discovery Material to a proposed expert or consultant in accordance with Paragraph 9(c) above, the party proposing to disclose designated information to said expert or consultant shall notify the Supplier in writing of the name of the expert or consultant, provide a signed copy of Attachment A, and a current curriculum vitae of the expert or consultant. If, within 10 business days of such notice, the Supplier objects to the disclosure of such Confidential Discovery Material to the proposed expert or consultant, it shall notify the other party in writing of its objection and the grounds therefor.<sup>1</sup> The parties will meet and confer in good faith to resolve the dispute within 3 days of notification by the Supplier. If the parties are unable to reach agreement, the party proposing to disclose designated information to the expert or consultant may seek a ruling from the Court permitting such disclosure.

14. No document shall be filed in Court under seal absent allowance of a particularized motion to seal that would be allowed only if the filing includes a trade secret. A party seeking to file another party's Confidential Discovery Material shall serve its papers on the Supplier and shall file a notice of service with the Court. The Supplier shall then have four (4) Court days in which to either consent to the request to file said information in the public record or to seek leave of the Court pursuant to Local Rule 7.2 to file such papers under seal as set forth

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<sup>1</sup> The parties disagree as to whether it would be appropriate to disclose Confidential Discovery Material to a proposed expert or consultant who is employed by or affiliated with (a) a competitor of the Parties in the markets which are the subject of this action, or (b) any domestic or foreign manufacturer, wholesaler, retailer, or distributor of products and pharmaceutical compositions containing recombinant human erythropoietin. Each party preserves its rights with respect to this issue.



above. The parties shall cooperate in good faith to obtain a prompt ruling on any motion for leave to file under seal pursuant to this paragraph, including by filing any opposition within two (2) Court days of the motion.

15. If Confidential Discovery Material 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.

16. This Protective Order does not affect the right of any 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.

17. 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.

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 Discovery Material, 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 Confidential Discovery Material. In addition, nothing in this Order shall place a restriction on either party or its attorneys with respect to

sharing a Supplier's Confidential Discovery Material with a Supplier's current or former employee who was an author or recipient of such documents.

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 within thirty (30) days all Confidential Discovery Material designated in accordance with Paragraphs 2-4 above, including all copies of such materials or information which may have been made. Copies of all pleadings or other papers filed under seal containing or disclosing Confidential Discovery 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.

20. Within thirty (30) days of the final termination of the action, including any appeal thereof, copies of Confidential Discovery Material that is in the hands of experts or consultants under Paragraph 9(c) must be retrieved or destroyed.

21. The parties acknowledge that this Protective Order is binding upon them, and agree to treat any Confidential Discovery Material disclosed to them Pursuant to this Protective Order in accordance with its terms. The parties further agree that this Protective Order may be enforced by a Supplier at any time, including after the termination of this action.

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 for good cause shown at any time.

PLAINTIFF AMGEN INC.  
By its attorneys,

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SO ORDERED on this 7<sup>TH</sup> day of Feb, 2007.

SO ORDERED:

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