

EXHIBIT 4

11/25/06 version
For Discussion Purposes Only; without prejudice

**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.)	
)	
)	

[PROPOSED] STIPULATED 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”) AND HEREBY STIPULATE to the entry of this Protective Order.

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”).

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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 shall 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 designated as “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

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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 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 or other responses to written discovery 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 each page of any such answers containing such Confidential or Highly Confidential Material.
- c. Deposition testimony and transcripts including exhibits attached thereto shall be treated as Confidential Material, unless otherwise designated as Highly Confidential. Counsel may designate all or portions of the transcript and exhibits used therein as Highly Confidential at any time during the deposition and for a period of ten (10) 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 10 business days and provided that the designation of the materials has not been changed to Highly Confidential. In-house counsel of a party or non-party may attend any deposition of a witness employed by that party or non-party, provided that the in-house counsel must leave the deposition room after notice if the testimony pertains to a

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Highly Confidential information or exhibit supplied by another party or non-party.

- 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.

5. When any Highly Confidential Material or Confidential 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 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.

6. Except as already provided with respect to Defendants’ Highly Confidential BLA and INDs for CERA, all other documents and things produced by both parties in the ITC proceeding (“other ITC materials”) shall be deemed Confidential Discovery Materials pursuant to this Order, except as either party may, within 30 days of the date of this Order, re-designate certain information in the other ITC materials consistent with the terms of this Order. In-house counsel shall not have access to any such other ITC materials, that are not otherwise re-designated as Highly Confidential, until after the expiration of the 30-day period.

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7. Any Discovery Materials designated as Confidential Material or Highly Confidential Material 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, including any orders on motions for reconsideration or renewal, 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 Material or Highly Confidential Material, such party may notify the Supplier in writing stating the basis for its disagreement, which shall 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 or Highly Confidential 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 **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 ¶ 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; or 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); and
- d. the Court and the Court staff, in accordance with the Court's rules, procedures and orders for handling confidential information.

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10. 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) from the ITC proceeding with side agreement, 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.

11. 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 made an appearance in this action (and their paralegal, litigation support, secretarial and clerical personnel):
 1. XXX
 2. XXX
 3. XXX
 4. XXX

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c. the following four (4) Defendants in-house counsel who have each made an appearance in this action (and their paralegal, litigation support, secretarial and clerical personnel):

1. XXX

2. XXX

3. XXX

4. XXX

12. Confidential and Highly Confidential 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 or AA), as appropriate, to be bound to terms of this Order.

13. 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 AA) to be bound by the Protective Order. In addition to signing Attachments A or AA, each attorney shall identify the jurisdictions in which he or she is admitted to practice. Each expert or consultant retained by outside counsel for purposes of this litigation (under ¶ 9 (c)) shall review the terms of the protective order, sign the agreement to be bound (Attachment A) and include a current curriculum vitae to be served on each party. All agreements to be bound by the terms of this Protective Order shall be served on all non-parties who have theretofore produced Confidential Material or Highly Confidential Material.

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14. Not less than ten (10) business days before the initial disclosure of any Highly Confidential Material or Confidential 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 and provide a copy of the agreement of the expert or consultant to abide by this Order 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 Highly Confidential Material or Confidential Material to the proposed expert or consultant, it shall notify the other party in writing of its objection and the grounds therefor. 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.

15. 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

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Supplier which would extend this period until three (3) days after the Court decides any such motion.

16. If Confidential Material or Highly Confidential 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.

17. 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.

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18. 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.

19. 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.

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20. 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 under seal 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.

21. Within thirty (30) days of the final termination of the action, including any appeal thereof, copies of Confidential Material and Highly Confidential Material that is in the hands of experts or consultants under ¶ 9 (c) 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 for good cause shown at any time.

[Party signature blocks for stipulations]

SO ORDERED on this ____ day of _____, 200_.

SO ORDERED:

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

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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 OUTSIDE COUNSEL

The undersigned represents that he or she is affiliated with firm [NAME OF FIRM] that is appearing as outside counsel for [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 or consultant 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 Material or Highly Confidential Material under this Protective Order to anyone other than another person designated in paragraphs 9 and 10 of the Protective Order;

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- (3) To use such Confidential Material or Highly Confidential Material solely for purposes of this litigation, unless permission is received from the Supplier, or the Court, to use it for other purposes; and

If the undersigned is an in-house attorney, he or she further agrees:

- (4) Not to participate in or supervise patent prosecution or engage in any competitive decision-making with respect to any ESP (any erythropoiesis-stimulating protein, including EPO, peg-EPO, and EPO analog) for one year after the conclusion of the lawsuit.

Respectfully submitted,

Dated:

Name
Employer
Address

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ATTACHMENT AA

**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 IN-HOUSE COUNSEL

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 or consultant 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 Material under this Protective Order to anyone other than another person designated in paragraphs 9 and 10 of the Protective Order;

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- (3) To use such Confidential Material solely for purposes of this litigation, unless permission is received from the Supplier, or the Court, to use it for other purposes; and
- (4) Acknowledges that he/she is not permitted access to any materials or information designated Highly Confidential under the terms of the Protective Order.

If the undersigned is an in-house attorney, he or she further agrees:

- (5) Not to participate in or supervise patent prosecution or engage in any competitive decision-making with respect to any ESP (any erythropoiesis-stimulating protein, including EPO, peg-EPO, and EPO analog) for one year after the conclusion of the lawsuit.

Respectfully submitted,

Dated:

Name
Employer
Address

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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 reveals 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 _____

