

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of)
)
CERTAIN PRODUCTS AND)
PHARMACEUTICAL COMPOSITIONS)
CONTAINING RECOMBINANT)
HUMAN ERYTHROPOIETIN)

Investigation No. 337-TA-568

2006 MAY 12 PM 5:04
OFFICE OF THE SECRETARY
US INTERNATIONAL TRADE COMMISSION

Order No. 2: 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, as such terms are used in the Commission's Rules, 19 C.F.R. Section 210.34(a)(7),

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, 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 either (1) impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or (2) causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such

information.

2. Any information submitted, either voluntarily or pursuant to order, in this investigation, which is asserted by a supplier to contain or constitute confidential business information shall be so designated by such supplier in writing, or orally at a deposition, 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 unless the administrative law judge or the Commission rules that it is not. When such information is made part of a pleading, or is offered into the evidentiary record, the party offering it must state the basis for its claimed confidentiality. Confidential 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 administrative law judge or the Commission may determine that information alleged to be confidential is not confidential, or that its disclosure is necessary for the proper disposition of the proceeding, at any time before, during or after the close of the hearing herein. If such a determination is made by the administrative law judge, opportunity shall be provided to the supplier of such information to argue its confidentiality, prior to the time that such ruling becomes final.

3. In the absence of written permission from the supplier or an order by the Commission or the administrative law judge, 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: (I) outside counsel for parties to this investigation, including necessary secretarial and clerical personnel assisting such counsel, (ii) qualified persons taking testimony involving such documents or information and necessary stenographic and clerical personnel thereof, (iii) technical experts and their staff who are employed by outside counsel under (I) 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, which are the subject of this investigation), and (iv) the Commission, the administrative law judge, the Commission staff, and personnel of any governmental agency as authorized by the Commission. However see Commission rule 210.5 (b) which conforms to 19 U.S.C. § 1337(n)(2), which clarifies the list of government officers and employees who may have access to confidential business information, and (c) which alerts suppliers to the possibility that confidential business information may be transmitted to a federal district court, subject to such protective order as the district court determines necessary. This result might occur in a limited class of cases because of 28 U.S.C. § 1659. Past Commission practice has been to permit the transfer of confidential business information to another court only with permission of the supplier of the information. Particularly where the supplier is a third party who is involved in neither the Commission investigation nor the district court case, it is important that the supplier be made aware that treatment of confidential information would be governed by the district court's protective order and not that of the Commission following transmittal of the record under this provision. See also

Commission rule 210.39 which outlines the circumstances in which the Commission's record, including the in camera record, may be transmitted to a federal district court, subject to such protective order as the district court determines necessary. In addition, referring to Commission Administrative Order No. 97-06, dated February 4, 1997, information submitted under this Protective Order may be disclosed to technical contract personnel who are acting in the capacity of Commission employees, for developing or maintaining the records of this investigation or related proceedings, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3. Any contract personnel will sign appropriate non-disclosure agreements.¹ Where the supplier of information under this order is a third party who is not involved in the Commission investigation, it is important that the supplier be made aware of the disclosure of such information to contract personnel by being provided a copy of the protective order.

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(I) and (iii) unless he or she shall have first read this order and shall have agreed, by letter filed with the Secretary of this Commission (letter of acknowledgment): (I) to be bound by the terms thereof; (ii) not to 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 investigation. Such letter shall also acknowledge that the signatory(ies) has

¹ A supplier of confidential business information may request that the administrative law judge identify said contract personnel.

(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(I) or technical expert under Paragraph 3(iii) and, in the case of an attorney, in what jurisdictions he or she is admitted to practice. Each 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. Confidential business information obtained in the Commission proceeding may be used with the consent of the supplier in a parallel district court proceeding under a protective order issued by the district court without losing its confidential status under the protective order in this proceeding as long as the information is not made public in the district court proceeding or by someone who obtains the information from that source or by anyone else.

6. Confidential business information furnished by a supplier may lose its protection under this order if it is disseminated to anyone not authorized to see it either by this protective order or by a protective order issued by a district court in a parallel proceeding protecting confidential business information obtained by the parties under the Commission's protective order. Information obtained pursuant to the Commission's protective order, however, may be produced to the district court under the district court protective order only with the consent of the

suppliers of that information.

7. If the Commission or the administrative law judge orders, or if the supplier and all parties to the investigation agree, that access to, or dissemination of, information submitted as confidential business information shall be made to persons not included in paragraphs 3, 5 or 6 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 Commission or the administrative law judge finds that the information is not confidential business information as defined in paragraph 1 hereof.

8. Any confidential business information submitted to the Commission or the administrative law judge in connection with a motion or other proceeding within the purview of this investigation shall be submitted under a designation that confidential information is contained or attached therein, pursuant to paragraph 2 above. 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 Attachment A hereto. Copies of each such signed agreement shall be provided to the supplier of such confidential business information and to the

Secretary of the Commission.

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 paragraph 2 above to which the person asserting the confidential status thereof agrees in writing, or the Commission or the administrative law judge 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 administrative law judge acknowledges that any document or information submitted as confidential business information pursuant to paragraph 2 above is to be treated as such within the meaning of 5 U.S.C. § 522(b)(4) and 18 U.S.C. § 1905, subject to a challenge by any party pursuant to paragraph 12 below or to a final ruling by the Commission, the administrative law judge or its Freedom of Information Act Officer to the contrary, or by appeal of such a ruling, interlocutory or otherwise.

11. If no determination has been made by the administrative law judge or the Commission that the information designated as confidential 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. The supplier of any confidential information is hereby notified that Commission regulations 19 C.F.R. § 201.19(c) through (e) generally require that the Commission will give notice to a submitter of confidential information upon the Commission's receipt of an FOIA request.

13. The supplier of any confidential information is put on notice that Commission rule 210.20 provides that only a party may move to declassify and that only then are such motions, whether brought at any time during or after the conclusion of an investigation, addressed to and ruled upon by an administrative law judge. Other requests to declassify made by non-parties, such as an FOIA request, will not be referred to the administrative law judge for consideration under the protective order.

14. 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 investigation, such supplier shall express the withdrawal in writing and shall serve such withdrawal upon all parties, the administrative law judge, and the Commission investigative attorney. If the recipient and supplier are unable to concur upon the status of the subject information submitted as confidential business information within ten 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 Commission or to the administrative law judge, and the Commission or the administrative law judge 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 investigation which submitted the information and designated it as confidential shall have the burden of proving such confidential status.

15. No less than ten days (or any other period of time designated by the administrative law judge) prior to the initial disclosure to the proposed expert of any confidential information submitted in accordance with paragraph 2, 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 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 therefor prior to the initial disclosure. If the dispute is not resolved on an informal basis within ten days of receipt of such notice of objection, motion may be made to the administrative law judge 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 administrative law judge. The terms of this paragraph shall be inapplicable to experts within the Commission or to experts from other governmental agencies who are consulted with, or used by, the Commission.

16. 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 the administrative law judge 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.

17. Nothing in this order shall 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 Commission, its Freedom of Information Act Officer, or the administrative law judge concerning the issue of the status of confidential business information.

18. Upon final termination of this investigation, 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 such matter 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 Commission, including its investigative attorney, and the administrative law judge, which shall retain such material pursuant to statutory requirements and for other recordkeeping purposes, but may destroy those additional copies in its possession which are regarded as surplusage.

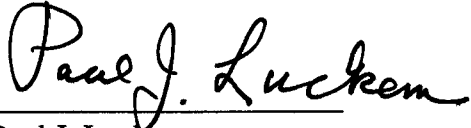
19. If any confidential business information which is supplied in accordance with paragraph 2 above is supplied by a non-party to this investigation, such a non-party shall be considered a "supplier" within the meaning of that term as it is used in the context of this order.

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

21. Except as provided in Commission rule 210.20, the jurisdiction of the administrative law judge over this order terminates upon filing of the initial determination issued at the end of the case. After that date, the Commission has jurisdiction to enforce this order and to issue reprimands and other sanctions.

22. 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.

23. The Secretary shall serve a copy of this order upon all parties.


Paul J. Luckern
Administrative Law Judge

Issued: May 12, 2006

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 investigation or hearing in Certain Products And Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, Inv. No. 337-TA-568, 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 investigation 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 investigation.

I am aware that the unauthorized use or conveyance of information as specified above is a violation of the Federal Criminal Code and punishable by a fine of up to \$10,000, imprisonment of up to ten (10) years, or both.

Signed _____

Dated _____

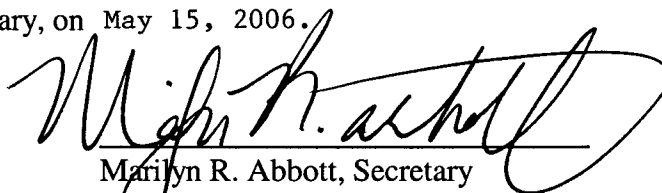
Firm or affiliation

**CERTAIN PRODUCTS AND
PHARMACEUTICAL COMPOSITIONS
CONTAINING RECOMBINANT
ERYTHROPOIETIN**

Investigation No. 337-TA-568

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **Order** was served by hand upon Commission Investigative Attorney Anne Goalwin, Esq. and upon the following parties via first class mail, and air mail where necessary, on May 15, 2006.



Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW - Room 112
Washington, DC 20436

For Complainant Amgen, Inc.:

Lloyd R. Day, Jr., Esq.
**DAY CASEBEER MADRID &
BATCHELDER LLP**
20300 Stevens Creek Blvd., Suite 400
Cupertino, CA 95014

Cecilia H. Gonzalez, Esq.
HOWREY LLP
1299 Pennsylvania Avenue, NW
Washington, DC 2000

Respondents:

Roche Holding Ltd.
Grenzacherstrasse 124, CH-4070
Basel, Switzerland

F. Hoffmann-La Roche, Ltd.
Grenzacherstrasse 124, CH-4070
Basel, Switzerland

Roche Diagnostics GmbH
Sandhofer Strasse 116, D-68305
Mannheim, Germany

**CERTAIN PRODUCTS AND
PHARMACEUTICAL COMPOSITIONS
CONTAINING RECOMBINANT
ERYTHROPOIETIN**

Investigation No. 337-TA-568

Certificate of Service page 2

Respondents:

Hoffmann La Roche, Inc.
340 Kingsland Street
Nutley, New Jersey 07110

Morgan & Finnegan, L.L.P.

A REGISTERED LIMITED LIABILITY PARTNERSHIP
1775 EYE STREET, NW, SUITE 400
WASHINGTON, DC, 20006-2401

Kent Stevens
(202) 857-8019
kstevens@morganfinnegan.com

TEL: 202-857-7887
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www.morganfinnegan.com

June 1, 2006

BY HAND DELIVERY

Cecilia H. Gonzales, Esq.
Howrey LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004

Re: CERTAIN PRODUCTS AND PHARMACEUTICAL COMPOSITIONS
CONTAINING RECOMBINANT HUMAN ERYTHROPOIETIN,
Investigation No. 337-TA-568

Dear Cecilia:

This is to confirm the agreement reached by outside counsel for Roche and outside counsel for Amgen regarding the confidentiality of the Roche Biological License Application ("BLA") and the IND. This agreement is a side agreement to the Protective Order in the above-captioned investigation to provide additional protection for the BLA and IND. We have agreed that:

- (1) Roche to produce one paper copy of the subject INDs and BLA,
- (2) Roche to produce 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
- (5) individuals qualified under the Protective Order 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.

Letter to Cecilia H. Gonzalez, Esq.
June 1, 2006
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We are preparing the paper copy and will have a copy as soon as possible given capacity. Also, this is to confirm that while the searchable copies are being made, Roche will produce five of the electronic copies previously made in tiff format. These five copies will not be electronically copied and will be promptly returned to Roche when the searchable copies are delivered.

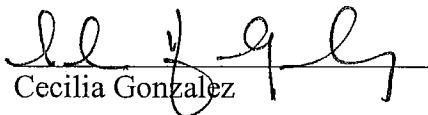
Please confirm.

Sincerely

A handwritten signature in black ink, appearing to be 'KRS', written over a horizontal line.

Kent Stevens, Esq.

Agreed on this 1 day of June, 2006:

A handwritten signature in black ink, appearing to be 'C. Gonzalez', written over a horizontal line.
Cecilia Gonzalez

cc: Lloyd R. Day, Jr. Esq.
Anne Goalwin, Esq.
Leora Ben-Ami, Esq.

KRS:rxp