UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

DECLARATION OF RENEE DUBORD BROWN
IN SUPPORT OF AMGEN INC.'S MEMORANDUM TO ITS
MOTION TO DISMISS ROCHE'S COUNTERCLAIMS COUNTS I – IX AND XII

I, Renee DuBord Brown, declare as follows:

1. I am a partner at the law firm of Day Casebeer Madrid & Batchelder LLP, counsel for plaintiff Amgen, Inc. I am admitted to practice law before this Court (pro hac vice) and all of the Courts of the State of California.

2. I make this declaration of my own personal knowledge. If called to testify as to the truth of the matters stated herein, I could and would testify competently.

3. Attached hereto as Exhibit 1 is a true and correct copy of *In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568, ("*In re EPO*") Notice of Investigation, issued on May 9, 2006 by the United States International Trade Commission.

4. Attached hereto as Exhibit 2 is a true and correct copy of *In re EPO*, Commission Investigative Staff's Response to Complainant's Motion for an Extension of the Briefing Schedule for Response to Respondents' Motion for Summary Determination so as to Allow for Discovery, issued on May 25, 2006.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Signed this 27th day of November, 2006.

By: /s/ Renee DuBord Brown
Renee DuBord Brown

EXHIBIT 1

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN PRODUCTS AND PHARMACEUTICAL COMPOSITIONS CONTAINING RECOMBINANT HUMAN ERYTHROPOIETIN	**Inv. No. 337-TA-568**

NOTICE OF INVESTIGATION

AGENCY: U.S. International Trade Commission

ACTION: Institution of investigation pursuant to 19 U.S.C. § 1337

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on April 11, 2006, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, on behalf of Amgen Inc. of Thousand Oaks, California. Amgen filed an amended complaint and a supplement on April 27, 2006. The amended complaint alleges violations of section 337 in the importation into the United States of certain products and pharmaceutical compositions containing recombinant human erythropoietin by reason of infringement of claims 1 and 2 of U.S. Patent No. 5,441,868, claims 3, 4, 5, and 11 of U.S. Patent No. 5,547,933, claims 4-9 of U.S. Patent No. 5,618,698, claims 4 and 6 of U.S. Patent No. 5,621,080, claim 7 of U.S. Patent No. 5,756,349, and claim 1 of U.S. Patent No. 5,955,422. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The amended complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Room 112, Washington, D.C. 20436, telephone 202-205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at

202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server at http://www.usitc.gov. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at http://edis.usitc.gov.

FOR FURTHER INFORMATION CONTACT: Anne Goalwin, Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2574.

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.10 (2005).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on May 8, 2006, ORDERED THAT –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products and pharmaceutical compositions containing recombinant human erythropoietin by reason of infringement of one or more of claims 1 and 2 of U.S. Patent No. 5,441,868, claims 3, 4, 5, and 11 of U.S. Patent No. 5,547,933, claims 4-9 of U.S. Patent No. 5,618,698, claims 4 and 6 of U.S. Patent No. 5,621,080, claim 7 of U.S. Patent No. 5,756,349, and claim 1 of U.S. Patent No. 5,955,422, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(2) In instituting this investigation, the Commission is mindful of the provision of 35 U.S.C. § 271(e), which states that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . ." Accordingly, the Commission directs the presiding administrative law judge to consider at an early date any motions for summary determination based upon 35 U.S.C. § 271(e). Any decision granting or denying such motions should be issued in the form of an initial determination (ID) under Rule 210.42(c), 19 C.F.R. § 210.42(c). The ID will become the Commission's final determination 45 days after the date of service of the ID unless the Commission determines to review the ID. Any such review will be conducted in accordance with Commission Rules 210.43, 210.44 and 210.45, 19 C.F.R. §§ 210.43, 210.44, and 210.45.

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is –

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

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

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

(c) The Commission investigative attorney, party to this investigation, is Anne Goalwin, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and

(4) For the investigation so instituted, the Honorable Paul J. Luckern is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.13. Pursuant to 19 C.F.R. §§ 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to

appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondents, to find the facts to be as alleged in the complaint and this notice and to enter a final determination containing such findings, and may result in the issuance of a limited exclusion order or cease and desist order or both directed against the respondent.

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: May 9, 2006

EXHIBIT 2

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before Paul J. Luckern
Administrative Law Judge

In the Matter of **CERTAIN PRODUCTS AND PHARMACEUTICAL COMPOSITIONS CONTAINING RECOMBINANT HUMAN ERYTHROPOIETIN**	**Inv. No. 337-TA-568**

COMMISSION INVESTIGATIVE STAFF'S RESPONSE TO COMPLAINANT'S MOTION FOR AN EXTENSION OF THE BRIEFING SCHEDULE FOR RESPONSE TO RESPONDENTS' MOTION FOR SUMMARY DETERMINATION S0 AS TO ALLOW FOR DISCOVERY

On May 19, 2006, Respondents Roche Holding Ltd., F. Hoffmann-La Roche, Ltd., Roche Diagnostics GmbH, and Hoffmann La Roche, Inc. (collectively, "Roche") filed a motion for summary determination of no violation of Section 337 (Mtn. Dkt. 568-1). Respondents assert that there has been no violation of Section 337 because the importations of the accused products to date were solely for uses reasonably related to the Food and Drug Administration ("FDA") approval process and thus within the safe harbor created by 35 U.S.C.

§ 271(e).[1] Roche Memo. at 1. Responses to Roche's motion for summary determination are due on May 31, 2006.

On May 24, 2006, Complainant Amgen Inc. ("Amgen") filed a motion (Mtn. Dkt. 568-2) to extend the time to reply to Roche's motion until June 26, 2006 to allow for discovery on the factual assertions in Roche's motion. Amgen Motion at 2. Amgen cites some specific examples of substantive issues raised in Roche's motion that Amgen argues it cannot respond to without the benefit of discovery. Amgen Memo. at 4. The Commission Investigative Staff ("Staff") supports Complainant's motion for an extension of the time until June 26, 2006 to respond to Roche's motion. The Staff also specifically requests that its time to respond to Roche's motion be similarly extended until June 26, 2006.

This extension is necessary to allow the non-moving parties to properly respond to Roche's motion. Under the Commission's Rules of Practice and Procedure:

> a party opposing the motion may not rest upon the mere allegations or denials of the opposing party's pleading, but the opposing party's response, by affidavits, answers to interrogatories, or as otherwise provided in this section, must set

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[1] Pursuant to Section 271(e)(1):

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

> forth specific facts showing that there is a genuine issue of fact for the evidentiary hearing under Section 210.36(a)(1) or (2).

19 C.F.R. § 210.18. However, because Respondents' motion was filed only a week after this investigation was instituted, Complainant and the Staff have not yet had the opportunity to complete the discovery necessary to test Respondents' assertions and possibly identify "specific facts" on the Section 271(e) issue in opposition to those set forth in Roche's motion. It has been held that a motion for summary determination should not be granted if a patent-holder has not had an opportunity to conduct discovery related to the Section 271(e) defense. *Ventrassist Pty Ltd. v. Heartware Inc.*, 377 F.Supp.2d 1278, 1287-88 (S.D. Fla. 2005) (allowing discovery related to Section 271(e) issue).

An opportunity to conduct discovery is particularly important in this instance because the declarations filed in support of Roche's motion are conclusory in nature. For example, the Char declaration indicates only that the accused products have been imported into the United States for use in non-clinical studies "to generate information relevant to the U.S. Food and Drug Administration's decision of whether to approve CERA for marketing" and "to generate information of potential relevance to the FDA approval process." Char Declaration at ¶¶ 3, 7. There is no other support in the Char declaration or elsewhere in Roche's motion for this conclusion. In particular, no supporting documents were included with Roche's motion, although it could be expected that documents would exist such as statements of the research objectives for the referenced studies, reports of the studies' conclusions, and filings made with the FDA. Accordingly, discovery is needed.

The Staff believes that the extension should be used for targeted discovery efforts focused on the Section 271(e) issue. Based on the correspondence attached to Amgen's motion, the Staff understands that the production of relevant documents should be completed around the end of May. The Staff agrees that the requested extension represents an appropriate length of time to analyze the document productions and take depositions related specifically to the Section 271(e) issue. Accordingly, the Staff supports Complainant's motion for an extension of time to respond to Roche's motion and seeks a similar extension for its own response.

Respectfully submitted,

/s/ Anne Goalwin

Lynn I. Levine, Director
T. Spence Chubb, Supervisory Attorney
Anne Goalwin, Investigative Attorney
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U.S. International Trade Commission
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Washington, D.C. 20436
(202) 205-2574
(202) 205-2158 (Facsimile)

May 25, 2006

Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin **Inv. No. 337-TA-568**

CERTIFICATE OF SERVICE

The undersigned certifies that on May 25, 2006, she caused the foregoing **COMMISSION INVESTIGATIVE STAFF'S RESPONSE TO COMPLAINANT'S MOTION FOR AN EXTENSION OF THE BRIEFING SCHEDULE FOR RESPONSE TO RESPONDENTS' MOTION FOR SUMMARY DETERMINATION SO AS TO ALLOW FOR DISCOVERY** to be served by hand upon the Hon. Paul J. Luckern (two copies) and upon the parties below in the manner indicated:

For Complainant Amgen Inc.:

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Cecilia H Gonzalez, Esq. **BY EMAIL AND FIRST CLASS MAIL**
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For Respondents Roche Holding Ltd., F. Hoffmann-La Roche, Ltd., Roche Diagnostics GmbH, and Hoffmann La Roche, Inc.:

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May 25, 2006