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