

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of

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

Investigation No. 337-TA-568

**NOTICE OF COMMISSION DECISION TO GRANT AMGEN INC.'S MOTION FOR
PARTIAL TERMINATION; NOTICE OF REQUEST FOR WRITTEN SUBMISSIONS
RELATING TO SUMMARY DETERMINATION AND TO REMEDY, THE PUBLIC
INTEREST, AND BONDING**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to grant Amgen Inc.'s motion for partial termination of the above-referenced investigation and that the Commission is requesting briefing on issues relating to summary determination and to remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Michelle Walters Klancnik, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be 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., Washington, D.C. 20436, telephone (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>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: On May 12, 2006, the Commission instituted an investigation under section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) based on a complaint filed by Amgen, Inc. ("Amgen") of Thousand Oaks, California. 71 *Fed. Reg.* 27742 (May 12, 2006). The complaint asserted a violation of section 337 in the importation into the

United States, sale for importation, or sale within the United States after importation 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 (“the ‘868 patent”), claims 3, 4, 5, and 11 of U.S. Patent No. 5,547,933 (“the ‘933 patent”), claims 4-9 of U.S. Patent No. 5,618,698 (“the ‘698 patent”), claims 4 and 6 of U.S. Patent No. 5,621,080 (“the ‘080 patent”), claim 7 of U.S. Patent No. 5,756,349 (“the ‘349 patent”), and claim 1 of U.S. Patent No. 5,955,422 (“the ‘422 patent”). The notice of investigation named Roche Holding Ltd. of Basel, Switzerland; F. Hoffman-La Roche, Ltd. of Basel, Switzerland; Roche Diagnostics GmbH of Mannheim, Germany; and Hoffman La Roche, Inc. of Nutley, New Jersey (collectively, “Roche”) as respondents.

On August 31, 2009, after a remand of the original investigation from the United States Court of Appeals for the Federal Circuit, Amgen moved for summary determination that Roche violated section 337 by importing and using a pegylated erythropoietin product, which according to Amgen infringes claims 1 and 2 of the ‘868 patent, claim 3 of the ‘933 patent, claims 6-9 of the ‘698 patent, and claim 1 of the ‘422 patent. Amgen also requested a limited exclusion order that would preclude importation of Roche’s product regardless of the party seeking to import such product. Roche does not oppose Amgen’s motion for purposes of this investigation. The Commission investigative attorney (“IA”) also does not oppose Amgen’s motion, but indicated that the motion does not resolve asserted claim 7 of the ‘349 patent or asserted claims 4, 5, and 11 of the ‘933 patent.

On December 22, 2009, Amgen moved to terminate the investigation with respect to claims 4, 5, and 11 of the ‘933 patent, claims 4 and 6 of the ‘080 patent, and claims 4 and 5 of the ‘698 patent. In addition, on December 31, 2009, Amgen filed a supplemental motion for summary determination with respect to claim 7 of the ‘349 patent. Roche does not oppose these motions. The IA also does not oppose Amgen’s motion to terminate the investigation in part, but does oppose Amgen’s supplemental motion for summary determination.

The Commission has determined to grant Amgen’s motion to terminate the investigation with respect to claims 4, 5, and 11 of the ‘933 patent, claims 4 and 6 of the ‘080 patent, and claims 4 and 5 of the ‘698 patent. The Commission has determined that further briefing is necessary to decide the motion for summary determination.

The parties are requested to brief their positions on the following issues with reference to the applicable law and evidence:

1. How does the United States Court of Appeals for the Federal Circuit’s decision in *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340 (Fed. Cir. 2009), vacating certain aspects of the decision by the United States District Court of Massachusetts in *Amgen Inc. v. F. Hoffman-La Roche, Ltd.*, No. 05-12237-WGY (D. Mass. Oct. 2, 2008), affect Amgen’s original motion for summary determination filed on August 31, 2009, for each asserted claim? Please address the Commission’s February 3, 2009 opinion in *Certain*

Semiconductor Integrated Circuits Using Tungsten Metallization and Products Containing Same, Inv. No. 337-TA-648.

2. If the Commission can proceed with respect to any claim(s), please explain whether the Commission should apply the principles of claim or issue preclusion to the district court case and what standard the Commission should apply.
3. Can the Commission apply claim or issue preclusion to the permanent injunction order issued by the district court on December 22, 2009, and if so, to what effect? Does the stipulation, which is signed by the parties and which appears before the permanent injunction, form part of the district court's judgment? If so, does Amgen rely on the stipulation for claim or issue preclusion? Please provide case law supporting your positions.
4. If the Commission denies Amgen's motions for summary determination with respect to any claims, how should the Commission proceed with respect to those claims?

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 *Fed. Reg.* 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Complainants and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the dates that the patents expire and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on May 7, 2010. Reply submissions must be filed no later than the close of business on May 21, 2010. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in sections 210.18, 210.21, and 210.50 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.18, 210.21, and 210.50).

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: April 6, 2010