UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

NOTICE OF COMMISSION DECISION TO TERMINATE AN INVESTIGATION ON THE BASIS OF SETTLEMENT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to terminate the above-captioned investigation on the basis of settlement between the private parties.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-2532. 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: This investigation was instituted on May 12, 2006, based on a complaint filed by Amgen Inc. ("Amgen") of Thousand Oaks, California. 71 *Fed. Reg.* 27,742 (May 12, 2006). The complaint alleged a violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) 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 various claims of six United States patents: U.S. Patent Nos. 5,441,868; 5,547,933 ("the '933 patent"); 5,618,698 ("the '698 patent"); 5,621,080 ("the '080 patent"); 5,756,349; and 5,955,422. The complaint 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.

After separate remands by the Court of Appeals for the Federal Circuit of this investigation and a parallel civil action involving many of the same patents asserted in this investigation, on December 18, 2009, the private parties executed a settlement agreement that allows Roche to begin selling accused products in the United States in mid-2014. Form 10-K, Amgen Inc., at 8 (Mar. 1, 2010); *see also* Settlement Agreement (Dec. 18, 2009). On December 21, 2009, Amgen and Roche submitted a proposed consent order to the district court in that parallel civil action, and on December 22, 2009, the district court entered judgment.

On December 22, 2009, Amgen moved to withdraw certain patent claims from this investigation that had not been asserted in the district court. Unopposed Compl't Amgen Inc.'s Mot. to Terminate Investigation as 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 (Dec. 22, 2009). The Commission granted that motion. 75 *Fed. Reg.* 18,548 (Apr. 12, 2010).

Also on December 22, 2009, Amgen moved the Commission to terminate this investigation by entry of an exclusion order based on preclusion caused by the district court judgment. Addendum to August 24, 2009 Stipulation (Dec. 22, 2009). Two Amgen motions regarding claim 7 of the '349 patent followed. By notice on April 6, 2010, the Commission sought clarification from the parties about, among other things, the effect of the stipulated district court judgment on this investigation. 75 *Fed. Reg.* 18,548 (Apr. 12, 2010).

On March 11, 2011, the Commission issued an order to show cause why the investigation should not be terminated in view of the parties' settlement. In response, Amgen and Roche declined to pursue their request for an exclusion order and instead requested the issuance of a consent order. In support of their proposed consent order, Amgen and Roche stated that "the Commission has previously terminated investigations when there is both a settlement agreement and an executed consent order stipulation." Joint Response of Complainant and Respondents to the Commission's Order to Show Cause and Request for Termination on the Basis of a Consent Order 2-3 (Apr. 21, 2011) ("Joint Response") (citing Notices, *Certain Digital Multimeters and Products with Multimeter Functionality*, Inv. No. 337-TA-588 (May 31, 2007 and July 3, 2007)). In a corrected response that the Commission hereby grants leave to file, the Commission investigative attorney did not object to the issuance of a consent order.

As will be discussed further in an accompanying opinion, the facts of the 588 investigation are readily distinguished from the facts here. Amgen and Roche have offered no basis, in law or policy, to support the Commission's issuance of a consent order under the unusual facts of this investigation. Nor is the Commission itself aware of any such basis. Accordingly, the Commission terminates this investigation on the basis of the settlement agreement between the private parties. 19 U.S.C. § 1337(c); 19 C.F.R. §§ 210.21(b), 210.41.

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 Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

/s/
James R. Holbein
Secretary to the Commission

Issued: October 14, 2011