

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

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**In the Matter of**

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

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) **Inv. No. 337-TA-568**  
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**NOTICE OF COMMISSION DECISION TO EXTEND DEADLINE FOR  
DETERMINING WHETHER TO REVIEW AN INITIAL DETERMINATION**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to extend the deadline for determining whether to review a summary initial determination (“ID”) issued by the presiding administrative law judge (“ALJ”) finding no violation of section 337 until September 5, 2006.

**FOR FURTHER INFORMATION CONTACT:** Christal A. Sheppard, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-2301. 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 (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>. 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 9, 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. of Thousand Oaks, California. 71 *Fed. Reg.* 27742-43 (May 12, 2006). The complaint asserted a violation of

section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, 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. 71 *Fed. Reg.* 27742-43 (May 12, 2006). 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 as respondents. *Id.*

On May 19, 2006, respondents moved for summary determination of no violation of section 337, stating that their activities fell within the safe harbor created by 35 U.S.C. section 271(e)(1) which provides 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 or veterinary biological products.” The Commission investigative attorney supported the motion. On July 7, 2006, the ALJ issued an ID (Order No. 6) granting respondents’ motion. The Commission has extended the date for determining whether to review the ID to Tuesday, September 5, 2006. No other dates are affected by this notice.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, and Commission Rule 210.42, 19 C.F.R. § 210.42(h)(3).

By order of the Commission.

/s/  
Marilyn R. Abbott  
Secretary to the Commission

Issued: August 3, 2006