

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

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<b>In the Matter of</b>	)	
	)	
	)	<b>Inv. No. 337-TA-568</b>
<b>CERTAIN PRODUCTS AND</b>	)	
<b>PHARMACEUTICAL COMPOSITIONS</b>	)	
<b>CONTAINING RECOMBINANT</b>	)	
<b>HUMAN ERYTHROPOIETIN</b>	)	

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**NOTICE OF COMMISSION DECISION NOT TO REVIEW AN INITIAL DETERMINATION GRANTING RESPONDENTS' MOTION FOR SUMMARY DETERMINATION THAT THERE IS NO VIOLATION OF SECTION 337**

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

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined not to review the initial determination (“ID”) issued by the presiding administrative law judge (“ALJ”) granting respondents’ motion for summary determination that there is no violation of section 337 in the above-captioned investigation. The investigation is terminated.

**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 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 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 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 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 May 19, 2006, Roche moved for summary determination of no violation of section 337, stating that its activities fell within the safe harbor created by 35 U.S.C. § 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.” Amgen opposed the motion. The Commission investigative attorney (“IA”) supported the motion. On July 7, 2006, the ALJ issued an ID (Order No. 6) granting Roche’s motion. Amgen filed a petition for review of the ID. Respondents and the IA filed oppositions to the petition for review. Amgen also filed a motion for leave to reply to the oppositions to its petition for review.

Having considered the petition for review, the oppositions thereto, and the relevant portions of the record, the Commission has determined not to review the ID and to deny Amgen’s motion for leave.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, and section 210.42(h) of the Commission’s Rules of Practice and Procedure, 19 C.F.R. § 210.42(h).

By order of the Commission.

/s/  
Marilyn R. Abbott  
Secretary to the Commission

Issued: August 31, 2006