

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

In the Matter of)

CERTAIN TADALAFIL OR ANY SALT OR)
SOLVATE THEREOF AND PRODUCTS)
CONTAINING SAME)

Inv. No. 337-TA-539

**NOTICE OF COMMISSION ISSUANCE OF GENERAL EXCLUSION ORDER;
DECISION TO GRANT MOTION TO FILE A SURREPLY; TERMINATION OF THE
INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, and has issued a general exclusion order under section 337(g)(2), 19 U.S.C. § 1337(g)(2), and terminated the investigation. The Commission has decided to grant complainant's motion to file a surreply.

FOR FURTHER INFORMATION CONTACT: Jean Jackson, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3104. 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://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 by the Commission based on a complaint filed by Lilly ICOS LLC ("Lilly") of Wilmington, Delaware, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. 70 *Fed. Reg.* 25601 (May 13, 2005). The complainant alleged violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain tadalafil or any salt or solvate thereof, and products containing same by reason of infringement of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006 ("the '006 patent"). The complaint and notice of investigation named ten respondents.

On September 12, 2005, the Commission issued a notice indicating that it had determined not to review an initial determination (“ID”) (Order No. 5) finding respondents Santovittorio Holdings Ltd. d/b/a Inhousepharmacy.co.uk of El Dorado, Panama; Stop4Rx of Port-au-Prince, Haiti, Rx Mex-Com, S.A. de C.V. of Colonia Las Brisas, Mexico; and www.Nudewfds.info of New Orleans, Louisiana; in default. The ID further found that respondent Express Generic had not been properly served with the complaint.

On November 17, 2005, the Commission issued a notice that it had determined not to review an ID (Order No. 9) finding an additional five of the originally named respondents in default. The additional five respondents are Budget Medicines Pty Ltd., of Sydney, Australia; Generic Cialis Pharmacy of Managua, Nicaragua; Cutprice Pills of Scottsdale, Arizona; Allpills.us of Beverly Hills, California; and Pharmacy4u.us of New York, New York.

On October 28, 2005, Lilly filed a motion for summary determination on the issues of the existence of a domestic industry and violation of section 337 by reason of patent infringement with respect to the nine respondents that were found in default. On November 14, 2005, the Commission investigative attorney (“IA”) filed a response in support of Lilly’s motion.

On December 6, 2005, the presiding administrative law judge (“ALJ”) issued an ID (Order No. 10) granting Lilly’s motion for a summary determination of violation of section 337. At the same time the ALJ made his recommendations on remedy and the amount of bond to be imposed during the Presidential period of review provided for in section 337(j), 19 U.S.C. § 1337(j). No party petitioned for review of the ID. On January 4, 2006, the Commission determined not to review the ID, thereby allowing it to become the Commission’s final determination on violation. *71 Fed. Reg.* 1452 (Jan. 9, 2006). With respect to remedy, the ALJ recommended the issuance of a general exclusion order under section 337(g)(2), 19 U.S.C. § 1337(g)(2). The ALJ also recommended that the bond permitting importation during the Presidential review period be set at 100 percent of the value of the infringing imported products.

Pursuant to the Commission’s notice, Lilly and the IA submitted main briefs on the issues of remedy, the public interest, and bonding on January 17, 2006, with draft general exclusion orders attached. The IA filed a reply submission on January 24, 2006. Lilly filed a motion to file a surreply with surreply attached on February 9, 2006. The Commission has determined to grant Lilly’s motion to file a surreply.

Having reviewed the record in this investigation, including the recommended determination of the ALJ and the written submissions of the parties, the Commission has determined that the public interest factors listed in section 337(d)(2) do not preclude issuance of a general exclusion order that prohibits the unlicensed entry for consumption of tadalafil salt or solvate thereof and products containing same that infringe one or more of claims 1-4, 6-8, 12, and 13 of the ‘006 patent during the term of that patent. The Commission has further determined that the appropriate bond during the period of Presidential review pursuant to section 337(j) should be set at 100 percent of the value of the infringing products. The Commission’s general

exclusion order was delivered on the date of its issuance to the President and to the United States Trade Representative, pursuant to the Presidential Memorandum of July 21, 2005. *70 Fed. Reg.* 43251 (July 26, 2005).

This action is taken under authority of section 337 of the Tariff Act of 1930, 19 U.S.C. §1337, and sections 210.41, 210.49, and 210.50 of the Commission's Rules of Practice and Procedure, 19 C.F.R. §§ 210.41, 210.49, and 210.50.

By order of the Commission.

/s/
Marilyn R. Abbott
Secretary to the Commission

Issued: June 13, 2006