

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 DECISION NOT TO REVIEW AN INITIAL
DETERMINATION FINDING A VIOLATION OF SECTION 337; SCHEDULE FOR
WRITTEN SUBMISSIONS ON REMEDY, 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 not to review an initial determination (“ID”) (Order No. 10) issued by the presiding administrative law judge (“ALJ”) finding a violation of section 337 in the subject investigation.

FOR FURTHER INFORMATION CONTACT: Steven Crabb, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5432. 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, DE 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 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 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, LA, in default. The ALJ also 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 were Budget Medicines Pty Ltd., of Sydney, Australia, Generic Cialis Pharmacy of Managua, Nicaragua, Cutprice Pills of Scottsdale, AZ, Allpills.us of Beverly Hills, CA, and Pharmacy4u.us of New York, NY.

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 with respect to the nine respondents that were found in default. On November 14, 2005, the Commission Investigative Attorney (“IA”) filed a response to Lilly’s motion.

On December 6, 2005, the ALJ issued the subject ID (Order No. 10) granting Lilly’s motion for a summary determination of a violation of section 337. With respect to the 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. No party petitioned for review of the subject ID. The Commission has determined not to review this ID with respect to the finding of a violation of section 337, and to request written submissions with respect to remedy, bonding, and the public interest.

In connection with the final disposition of this investigation, the Commission may issue an order that could result in the exclusion of the subject articles from entry into the United States. 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, it 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).

When 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 in this investigation include the effect that an exclusion order 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 President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a 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.

WRITTEN SUBMISSIONS: The parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on remedy, bonding, and the public interest. Such submissions should address the December 6, 2005, recommended determination (Order No. 10) by the ALJ on remedy and bonding. Complainants and the Commission's investigative attorney are also requested to submit proposed orders for the Commission's consideration. Complainants are further requested to state the expiration date of the patent at issue and the HTSUS numbers under which the infringing goods are imported. Main written submissions and proposed orders must be filed no later than close of business on January 17, 2006. Reply submissions, if any, must be filed no later than the close of business on January 24, 2006. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) 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 that the Commission should grant such treatment. *See* section 201.6 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 201.6. 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 section 210.42 and 210.50 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.42 and 210.50).

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: January 4, 2006