

UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.

In the Matter of	)	
	)	
CERTAIN SILDENAFIL OR ANY	)	Inv. No. 337-TA-489
PHARMACEUTICALLY ACCEPTABLE	)	
SALT THEREOF, SUCH AS SILDENAFIL	)	
CITRATE, AND PRODUCTS	)	
CONTAINING SAME	)	

**NOTICE OF COMMISSION DECISION NOT TO REVIEW AN INITIAL  
DETERMINATION FINDING A VIOLATION OF SECTION 337 AND THAT THE  
DOMESTIC INDUSTRY REQUIREMENT IS MET; 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. 19) issued by the presiding administrative law judge ("ALJ") finding a violation of section 337 and that the domestic industry requirement has been met in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Wayne Herrington, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-3090. Copies of all nonconfidential 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 the matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on March 6, 2003, based on a complaint filed by Pfizer, Inc. ("Pfizer") of New York, New York. 68 Fed. Reg. 10749 (March 6, 2003). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, sale for importation, and sale within the United States after importation of certain sildenafil or any pharmaceutically acceptable salt thereof, including sildenafil citrate,

and products containing same by reason of infringement of claims 1-5 of Pfizer's U.S. Patent No. 5,250,534 ("the '534 patent").

Fifteen respondents were named in the Commission's notice of investigation. Of these, eleven were found to be in default. Two other respondents were never found to have been served with the complaint and notice of investigation, and have not otherwise participated in the investigation. Another respondent has been terminated from the investigation on the basis of a settlement agreement. One respondent is the subject of a motion to terminate the investigation on the basis of a consent order, which the ALJ has granted and which is currently before the Commission.

On October 6, 2003, Pfizer filed a motion pursuant to Commission rule 210.18 (19 C.F.R. § 210.18) for summary determination on the issues of the existence of a domestic industry and violation of section 337. Pfizer's motion sought a general exclusion order and a cease and desist order against respondent #1 Aabaaca Viagra LLC ("Aabaaca"). On October 16, 2003, the Commission investigative attorney filed a response in support of Pfizer's motion. No other responses to the motion were filed.

On October 27, 2003, the ALJ issued the subject ID finding that Pfizer has demonstrated that there is a violation of section 337 by reason of the defaulting respondents' importation and sale of sildenafil, sildenafil salts, or sildenafil products that infringe one or more of claims 1-5 of the '534 patent. He also found the domestic industry requirement satisfied. As to remedy, the ALJ found that the legal framework for considering whether to issue a general exclusion order in the circumstances of this case is section 337(g)(2), not section 337(d)(2). He recommended the issuance of a general exclusion order, but did not recommend the issuance of a cease and desist order against respondent Aabaaca. He also recommended that the bond permitting temporary importation during the Presidential review period be set at 100 percent of entered value. No party petitioned for review of the ID.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or issue one or more cease and desist orders that could result in respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. 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). The Commission considers the question of remedy to include the ALJ's finding that the legal framework for considering whether to issue a general exclusion order in the circumstances of this case is section 337(g)(2), not section 337(d)(2).

If 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 a remedial 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 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, the public interest, and bonding. Such submissions should address the October 27, 2003, recommended determination by the ALJ on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed orders for the Commission's consideration. The written submissions and proposed orders must be filed no later than close of business on December 12, 2003. Reply submissions, if any, must be filed no later than the close of business on December 19, 2003. 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 why 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.

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

By order of the Commission.

Marilyn R. Abbott  
Secretary

Issued: November 24, 2003