

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 TERMINATING INVESTIGATION AS TO ONE RESPONDENT ON
THE BASIS OF A SETTLEMENT AGREEMENT; NOTICE OF ISSUANCE OF
GENERAL EXCLUSION ORDER; 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 determined not to review an initial determination (Order No. 22) issued by the presiding administrative law judge (“ALJ”) terminating the investigation as to respondent Biovea on the basis of a settlement agreement. Notice is also hereby given that, having previously found a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, the Commission has issued a general exclusion order under section 337(d)(2) and terminated the 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, such as 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. Thirteen of these were successfully served with the complaint and notice of investigation. One respondent has previously been terminated from the investigation on the basis of a settlement agreement.

Eleven respondents were found to be in default, including respondent #1 Aabaaca Viagra LLC ("Aabaaca"). On October 27, 2003, the ALJ issued an initial determination ("ID") (Order No. 19) finding that Pfizer had 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 that Pfizer had established the existence of a domestic industry. He recommended the issuance of a general exclusion order, but did not recommend the issuance of a cease and desist order against defaulting respondent Aabaaca, as had been requested by Pfizer. The ALJ also recommended that the bond permitting temporary importation during the Presidential review period be set at 100 per cent of entered value. On November 24, 2003, the Commission issued notice that it had determined not to review the ALJ's ID and set a schedule for written submissions on remedy, the public interest, and bonding. Both Pfizer and the Commission investigative attorney timely filed initial submissions on remedy, the public interest, and bonding. The Commission investigative attorney filed a reply submission.

On January 6, 2004, the ALJ issued an initial determination (Order No. 22) terminating respondent Biovea on the basis of a settlement agreement. No petitions for review of Order No. 22 were filed.

Having reviewed the record in this investigation, including the recommended determination of the ALJ and the written submissions of the parties, the Commission determined (1) to not review Order No. 22, terminating respondent Biovea on the basis of a settlement agreement and (2) to terminate the investigation with the issuance of a general exclusion order under section 337(d)(2) prohibiting the unlicensed entry for consumption of sildenafil or any pharmaceutically acceptable salt thereof, such as sildenafil citrate, and products containing same which infringe one or more of claims 1-5 of the '534 patent.

The Commission also determined that the public interest factors enumerated in section 337(d) do not preclude the issuance of the aforementioned general exclusion order and that the bond during the Presidential review period shall be 100 percent of the entered value of the articles in question.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, the Administrative Procedure Act, and sections 210.41-51 of the Commission's Rules of Practice and Procedure, 19 C.F.R. §§ 210.41-51.

By order of the Commission.

/s/

Marilyn R. Abbott
Secretary

Issued: February 6, 2004