

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

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 TO REVIEW AN INITIAL DETERMINATION
TERMINATING THE INVESTIGATION AS TO TWO RESPONDENTS**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the presiding administrative law judge's ("ALJ's") initial determination ("ID") terminating the investigation as to respondent Ezee Soulnature Healthcare Pvt. Ltd. ("Ezee") on the basis of a settlement agreement and as to respondent Biovea on the basis of a consent order.

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 the ALJ's ID and all other 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-ON-LINE) 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: 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 Commission's notice of investigation named Ezee and Biovea among the respondents.

On June 13, 2003, complainant Pfizer filed a single motion pursuant to Commission rules 210.21(b) and (c) to terminate the investigation as to respondent Ezee on the basis of a settlement agreement and as to respondent Biovea on the basis of a consent order.

On June 30, 2003, the ALJ issued the subject ID (Order No. 16) terminating the investigation as to respondent Ezee on the basis of a settlement agreement and as to respondent Biovea on the basis of a consent order, subject to deletion of a term in the consent order.

On July 24, 2003, the Commission issued a notice extending the deadline for determining whether to review the ID to permit respondent Ezee, who could only be served with the public version of the ID, an opportunity to file a petition for review.

No petitions for review of the ID have been filed.

Having examined the record in this investigation, including the ALJ's ID, the Commission, on its own motion, has determined (1) to waive its rule requiring that a motion terminating a respondent on the basis of a consent order include that respondent as a moving party, and (2) to review the ID in its entirety.

On review, the Commission requests briefing based on the record. While the Commission has determined to review the ID in its entirety, it is particularly interested in receiving answers to the following questions:

1. To what acts in paragraph 15 of the Biovea consent order stipulation and paragraph 1 of the proposed Biovea consent order does the language "via the Internet or electronic mail" apply? Given that the quoted language appears to extend the consent order to acts performed outside the United States (*e.g.*, offers to sell or advertising via an Internet site located outside the United States), what jurisdictional basis does the Commission have for the issuance of a consent order with such language? How does the quoted language (which appears in both the proposed Biovea consent order and the Ezee settlement agreement) affect consideration of the public interest factors set out in section 337(d) and (f)?
2. Is there any reason paragraph 4 of the proposed Biovea consent order should not be amended so that it (a) applies to both Pfizer and Biovea, (b) states that the referenced information gathering efforts are those of the "Commission," as

opposed to “Pfizer and/or the Commission Staff,” and (c) states that Pfizer and Biovea will cooperate with, as well as not impede, the Commission’s information gathering efforts, as required by the Commission’s rules?

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues under review. The written submissions must be filed no later than close of business on September 2, 2003. Reply submissions must be filed no later than the close of business on September 9, 2003. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 14 true copies thereof on or before the deadlines stated above with the Office of the Secretary. 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, as amended (19 U.S.C. § 1337), and sections 210.42-.44 of the Commission’s Rules of Practice and Procedure (19 C.F.R. §§ 210.42-.44).

By order of the Commission.

Marilyn R. Abbott
Secretary

Issued: August 13, 2003