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

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In the Matter of	)	
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CERTAIN MALE PROPHYLACTIC	)	Inv. No. 337-TA-546
DEVICES	)	
	)	

NOTICE OF COMMISSION DETERMINATION TO REVIEW A
FINAL INITIAL DETERMINATION IN PART; SCHEDULE FOR FILING WRITTEN
SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY,
THE PUBLIC INTEREST, AND BONDING; EXTENSION OF TARGET DATE

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on June 30, 2006, in the above-captioned investigation. The Commission has also determined to extend the target date for completion of the investigation until December 5, 2006.

FOR FURTHER INFORMATION CONTACT: Mark B. Rees, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3116. The public version of the ALJ's final 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 (<a href="http://www.usitc.gov">http://www.usitc.gov</a>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS-ON-LINE) at <a href="http://edis.usitc.gov">http://edis.usitc.gov</a>. 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 on August 5, 2005, based on a complaint filed on behalf of Portfolio Technologies, Inc., of Chicago, Illinois. 70 *Fed. Reg.* 45422. The complaint, as amended and supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27, 31-33, and 36 of U.S. Patent No. 5,082,004 ("the '004 patent"). The respondents named in the investigation are Church & Dwight Co., Inc., of Princeton, New Jersey; Reddy Medtech, Ltd., of Tamil Nadu, India; and Intellx, Inc., of Petoskey, Michigan.

On June 30, 2006, the ALJ issued a final ID in which he ruled that there is no violation of section 337 of the Tariff Act of 1930, as amended. All parties have petitioned for review of various parts of the final ID.

Having examined the record in this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the issues of claim construction, invalidity due to anticipation, infringement, and domestic industry.

On review, the Commission requests briefing on these issues based on the evidentiary record. The Commission is particularly interested in briefing on the following subissues: (1) the proper treatment of functional limitations in the asserted claims of the '004 patent, (2) whether the use of "theoretical constructs" to construe claim terms is appropriate, including whether the use of theoretical constructs to interpret claims would raise any issues under 35 U.S.C. § 112, second paragraph; (3) the effect that the parties' proposed claim constructions may have on the resolution of issues concerning anticipation, infringement, and the technical prong of the domestic industry; (4) whether the ID properly applied Commission precedent to determine that complainant had not met the economic prong of the domestic industry requirement; and (5) whether the ID gave appropriate weight to the evidence complainant proffered to prove that a domestic industry exists under the economic prong. The Commission also requests that the parties include responses to the following question in their submissions:

- 1. Whether the ID's construction of "elongated tubular portion" to consist of both a physical tube-like structure and a theoretical tube-like structure improperly reads out of the claims the limitation that the "tubular portion" be "formed of thin membrane."
- 2. Whether a finding that the preferred embodiment depicted in Figure 10 of the '004 patent is not covered by any of the patent claims, as argued by Respondents, is permissible given the Federal Circuit's statement that a claim interpretation that altogether excludes a preferred embodiment from practicing any claims of the patent is "rarely, if ever, correct." <u>Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.</u>, 429 F. 3d 1364, 1374 (Fed. Cir. 2005) (internal quotes omitted).
- 3. Whether the ID, in finding no infringement of claims 22 or 25, took into consideration all the undisputed evidence in the record regarding the thickness of the Twisted Pleasure.
- 4. Whether the undisputed evidence in the record (whether or not credited by the ALJ), in addition to the facts found by the ALJ that go to the existence of a domestic industry, are sufficient to support a finding that Complainant satisfied the economic prong of the domestic industry requirement.

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 (2) 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, the party 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).

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 include the effect that an exclusion order and/or cease and desist orders 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 are requested to file written submissions on the issues under review. The submissions should be concise and thoroughly referenced to the record in this investigation. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the June 30, 2006, recommended determination by the ALJ on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the expiration date of the '004 patent and state the HTSUS number under which the accused articles are imported. The written submissions and proposed remedial orders must be filed no later than close of business on October 16, 2006. Reply submissions must be filed no later than the close of business on October 23, 2006. 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 12 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.

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 sections 210.42-.46 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.42-.46).

By order of the Commission.

/s/ Marilyn R. Abbott Secretary to the Commission

Issued: September 29, 2006