UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN IN VITRO FERTILIZATION PRODUCTS, COMPONENTS THEREOF, AND PRODUCTS CONTAINING THE SAME	**Inv. No. 337-TA-1196**

NOTICE OF COMMISSION DECISION TO REVIEW IN PART AN INITIAL DETERMINATION GRANTING IN PART COMPLAINANT'S MOTION FOR SUMMARY DETERMINATION OF A VIOLATION OF SECTION 337

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 an initial determination ("ID") (Order No. 10) of the presiding Chief Administrative Law Judge ("Chief ALJ") granting in part Complainant's motion for summary determination of a violation of section 337 by respondents Fast IVF of Scottsdale, Arizona and Hermes Ezcanesi of Istanbul, Turkey (collectively, the "Defaulting Respondents").

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov* . General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.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: On April 16, 2020, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), based on a complaint filed by complainant EMD Serono, Inc. of Rockland, Massachusetts ("Complainant"). *See* 85 FR 21267-68 (Apr. 16, 2020). The complaint, as amended and supplemented, alleges a violation of section 337 based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain *in vitro* fertilization products, components thereof, and products containing same (collectively, "Gray Market IVF Products"), by reason of: (1) infringement of U.S. Trademark Registration Nos. 4,689,651; 1,772,761; 3,777,170; 3,389,332; 3,816,320; 1,972,079; 3,604,207; and 3,185,427; (2) unfair methods of competition and unfair acts in the importation and sale of Gray Market IVF Products by reason of false designation of source; and (3) unfair methods of competition and unfair acts in the importation and sale of the Gray Market IVF Products by reason of false

advertising. *See id.* In addition to the Defaulting Respondents, the notice of investigation also names General Plastik Drug Stores of Istanbul Suadiye, Turkey ("Unserved Respondent") as a respondent in this investigation. *See id.* The Office of Unfair Import Investigations ("OUII") is also a party to the investigation. *See id.*

On September 24, the Commission found each of the Defaulting Respondents in default. *See* Order No. 6 (Sept. 1, 2020), *unreviewed by* Comm'n Notice (Sept. 24, 2020). On October 26, 2020, the Commission terminated the Unserved Respondent from the investigation based on the withdrawal of the complaint allegations as to that respondent. *See* Order No. 8 (Oct. 13, 2020), *unreviewed by* Comm'n Notice (Oct. 26, 2020).

On December 2, 2020, Complainant filed a motion for summary determination of a violation of section 337 by the Defaulting Respondents. On December 22, 2020, OUII filed a response to Complainant's motion. No other responses were filed.

On April 16, 2021, the Chief ALJ issued the subject ID (Order No. 10) granting in part pursuant to Commission Rule 210.18 (19 CFR 210.18) Complainant's motion for summary determination of violation of section 337 by the Defaulting Respondents. Specifically, the Chief ALJ granted the motion with respect to Complainant's trademark infringement claim under section 337(a)(1)(C) but denied the motion with respect to Complainant's unfair competition claims under section 337(a)(1)(A). Order No. 10, insofar as it denies summary determination, is not an ID and is not subject to Commission review at this time. In addition, the Chief ALJ recommended that the Commission issue a GEO and set a bond at 100 percent during the period of Presidential review. No petition for review of the subject ID was filed.

The Commission has determined to review the ID in part. Specifically, the Commission has determined to review the ID's findings with respect to the economic prong of the domestic industry requirement. The Commission has determined not to review any other findings in the ID.

In connection with its review, the Commission is interested in briefing on the following issues:

1. Where are the domestic industry products manufactured? What activities related to the domestic industry products take place outside the United States?

2. Are each of the claimed domestic industry activities of the sort that the Commission has credited under section 337(a)(3)(C)?

3. Please discuss Complainant's domestic industry investments under Section 337(a)(3)(A), (B), or (C) that are related to products that practice the Gonal-f and Ovidrel registered trademarks and explain whether such investments are significant or substantial under each subsection in light of Commission and Federal Circuit precedents. Please include in your response a contextual discussion of the relevant marketplace, *e.g.*, a discussion of Complainant's foreign investments relative to its domestic industry expenditures in these statutory categories and/or a discussion of the

value added to the product from Complainant's activities in the United States. *See*, *e.g.*, *Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op., 2019 WL 5622443, *12 (Oct. 28, 2019).

4. The Federal Circuit has stated that section 337 does not protect mere importers. *See, e.g., Schaper Mfg. Co. v. Int'l Trade Comm'n*, 717 F.2d 1368, 1372-73 (Fed. Cir. 1983). Please explain whether Complainant's asserted domestic industry differs from that of a mere importer, including by discussing: (A) how the Commission and the Federal Circuit have considered such investments in prior investigations, and (B) how the facts of this investigation should be assessed in light of applicable precedent. Also address the extent to which the activities relied upon to show satisfaction of the economic prong (*e.g.*, payment of FDA fees) need to take place in the United States either as a legal or a practical matter, such that those activities would not distinguish a domestic industry from a mere importer.

The parties are invited to brief only the discrete issues described above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues, which are adequately presented in the parties' existing filings. As Complainant's section 337(a)(1)(A) claims are outstanding, the Commission does not seek briefing at this time concerning the appropriate remedy and bonding, or on the public interest.

WRITTEN SUBMISSIONS: The Commission requests that the parties to the investigation file written submissions on the issues identified in this notice. The initial written submissions must be filed no later than close of business on June 1, 2021. Reply submissions must be filed no later than the close of business on June 8, 2021. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 C.F.R. 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1196) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and

operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission's vote for this determination took place on May 18, 2021.

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 part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: May 18, 2021