PUBLIC VERSION

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**

ORDER NO. 10: INITIAL DETERMINATION GRANTING-IN-PART COMPLAINANT EMD SERONO'S MOTION FOR SUMMARY DETERMINATION OF VIOLATION BY THE DEFAULTING RESPONDENTS

(April 16, 2021)

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I. INTRODUCTION

On December 2, 2020, Complainant EMD Serono, Inc. ("EMD Serono") moved (1196-005) for a summary determination of violation by Respondents FastIVF and Hermes Eczanesi and requested entry of a general exclusion order ("GEO"). On December 22, 2020, the Commission Investigative Staff ("Staff") filed a response in support of the motion as to the (a)(1)(C) trademark infringement claims, but opposed the motion as to the (a)(1)(A) claims. On December 30, 2020, EMD Serono filed a reply in support of the motion. To date, no other party has filed a response.

A. Procedural History

On March 11, 2020, EMD Serono filed a Complaint alleging a violation of section 337 of the Tariff Act of 1930, as amended, in 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 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 (collectively, "the Asserted Trademarks"). 85 Fed. Reg. 21,267-268 (Apr. 16, 2020). The Complaint also alleged a violation of section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1). *Id.* EMD Serono filed a supplement and an amendment to the Complaint on March 27, 2020. *Id*.

On April 10, 2020, the Commission determined to institute this Investigation. *Id.* Specifically, the Commission instituted this Investigation to determine:

> Whether there is a violation of subsection (a)(1)(C) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of [prescription in vitro fertilization drugs, components thereof, and products containing the same labeled, in whole or in part, Gonal-f, Ovidrel, or Ovitrelle] by reason of infringement of one or more of the [Asserted Trademarks] and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

Id. The Commission also instituted this Investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(A) of section 337 in the unfair methods of competition and unfair acts in the importation and sale of the Gray Market IVF Products through the false designation as to source, the threat or effect of which is to destroy or substantially injure an industry in the United States; and

Id. Finally, the Commission instituted this Investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(A) of section 337 in the unfair methods of competition and unfair acts in the importation and sale of the Gray Market IVF Products through false advertising, the threat or effect of which is to destroy or substantially injure an industry in the United States.

Id.

The Notice of Investigation named three respondents: FastIVF, Hermes Eczanesi, and General Plastik Drug Stores. *Id.* The Office of Unfair Import Investigations was also named as a party to the Investigation. *Id.*

During the course of this Investigation, FastIVF and Hermes Eczanesi (collectively, "Defaulting Respondents") were found to be in default. Order No. 6 (Sept. 1, 2020); *see also* Notice of a Comm'n Decision Not to Review an Initial Determination Finding Certain Respondents in Default (Sept. 24, 2020). On October 13, 2020, the undersigned issued an Initial Determination granting EMD Serono's motion to terminate the Investigation as to the remaining respondent based on withdrawal of the Complaint. *See* Order No. 8; *see also* Notice of a Comm'n Decision Not to Review an Initial Determination Partially Terminating the Investigation as to an Unserved Respondent (Oct. 26, 2020). None of the Defaulting Respondents have contested EMD Serono's allegations that they have violated and continue to violate section 337.

B. The Parties

i. Complainant

1. EMD Serono, Inc.

EMD Serono is a biopharmaceutical company located in Rockland, Massachusetts and is a subsidiary of Merck KGaA, Darmstadt, Germany ("MKDG"). Compl. at ¶ 4. Among other things, EMD Serono specializes in providing fertility drugs, devices, therapies, and services to its customers. *Id.* MKDG is the owner of the Asserted Trademarks and EMD Serono is the exclusive licensee. *Id.*

ii. The Defaulting Respondents

1. FastIVF[1]

Respondent FastIVF operates the website https://fastivf.com/ (also known as www.fastivf.com). *Id.* ¶ 16. FastIVF's domain name is registered by Domains By Proxy, LLC, whose principal place of business and address is 14455 N. Hayden Road, Scottsdale, AZ 85260. *Id.* FastIVF sells the Gray Market IVF Products on its website. *Id.* at ¶ 107.

2. Hermes Eczanesi

Respondent Hermes Eczanesi is a Turkish corporation with its principal place of business located at 105/A Abide-I Hurriyet Cad., Sisli, Istanbul, Turkey 34381. *Id.* ¶ 17. Hermes Ezcanesi sells and/or imports the Gray Market IVF Products from Turkey to the U.S. *Id.* at ¶ 108.

C. The Asserted Trademarks

The Asserted Trademarks are:

Trademark	Reg. No.	Issue Date	Exhibit
Gonal-f RFF RediJect	4,689,651	Feb. 17, 2015	Compl., Ex. 1
GONAL-F	1,772,761	May 25, 1993	Compl., Ex. 2

[1] Both EMD Serono and Staff use "Fast IVF" and "FastIVF" interchangeably in their briefs. The undersigned follows the spelling used in the Notice of Investigation.

Trademark	Reg. No.	Issue Date	Exhibit
	3,777,170	Apr. 20, 2010	Compl., Ex. 3
	3,389,332	Feb. 26, 2008	Compl., Ex. 4
	3,816,320	Jul. 13, 2010	Compl., Ex. 5
Ovidrel	1,972,079	May 7, 1996	Compl., Ex. 6
OVIDREL	3,604,207	Apr. 7, 2009	Compl., Ex. 7
	3,185,427	Dec. 19, 2006	Compl., Ex. 8

See Staff Resp. at 4-5. Registration Nos. 4,689,651; 1,772,761; 1,972,079; and 3,604,207 are word marks. The remaining trademarks are design marks. Additionally, Registration Nos. 1,772,761; 3,777,170; 3,389,332; and 3,816,320 are referred to herein as the "Gonal-f Trademarks" and Registration Nos. 1,972,079; 3,604,207; and 3,185,427 are referred to as the "Ovidrel Trademarks."

D. Products at Issue

The products at issue in this Investigation are prescription in vitro fertilization drugs, components thereof, and products containing the same labeled, in whole or in part, Gonal-f, Ovidrel, or Ovitrelle. 85 Fed. Reg. at 21,268. EMD Serono sells both the Gonal-f and Ovidrel products through its fertility business. Mem. at 1.

The Gray Market IVF products are IVF products bearing the Asserted Trademarks but intended for sale outside of the United States. Compl. at ¶ 39.

II. LEGAL STANDARDS

A. Summary Determination

Summary determination is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to a determination as a matter of law. *See* 19 C.F.R. § 210.18(b). In determining whether there is a genuine issue of material fact, "the evidence must be

viewed in the light most favorable to the party opposing the motion with doubts resolved in favor of the non-movant." *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (citations omitted); *see also Paragon Podiatry Lab., Inc. v. KLM Labs, Inc.*, 984 F.2d 1182, 1185 (Fed. Cir. 1993) ("In other words, '[s]ummary judgement is authorized when it is quite clear what the truth is, and the law requires judgment in favor of the movant based upon facts not in genuine dispute.") (citations omitted).

B. Default

Commission Rule 210.16(b)(4) states: "A party found in default shall be deemed to have waived its right to appear, to be served with documents, and to contest the allegations at issue in the investigation." 19 C.F.R. § 210.16(b)(4). Commission Rule 210.16(c) further provides that "[t]he facts alleged in the complaint will be presumed to be true with respect to the defaulting respondent." 19 C.F.R. § 210.16(b)(4).

C. Trademark Infringement

Trademark infringement is analyzed under a two-prong test: First, courts look to see whether the mark merits protection, and second, whether the respondent's use of a similar mark is likely to cause consumer confusion. *Certain Handbags, Luggage, Accessories, & Packaging Thereof*, Inv. No. 337-TA-754, Order No. 16 at 6 (Mar. 5, 2012) ("*Handbags*").

In a traditional trademark case, to determine consumer confusion, the Commission applies the following factors: (1) the degree of similarity between the designation and the trademark in appearance, the pronunciation of words used, verbal translation of pictures or designs involved, and suggestion; (2) the intent of the actor in adopting the designation; (3) the relation in use and manner of marketing between the goods and services marked by the actor and those by the other; and (4) the degree of care likely to be exercised by purchasers. *Certain Ink Markers & Packaging*

Thereof, Inv. No. 337-TA-522, Order No. 30 at 36 (July 25, 2005). The Commission may also consider additional factors, such as the strength of the mark or actual confusion. All factors must be evaluated in the context of the ultimate question of likelihood of confusion as to the source or sponsorship of the product. *Handbags*, Order No. 16 at 9.

In cases involving gray market goods, a different analysis is applied. "The principle of gray market law is that the importation of a product that was produced by the owner of the United States trademark or with its consent, but not authorized for sale in the United States, may, in appropriate cases, infringe the United States trademark." *Gamut Trading Co. v. Int'l Trade Comm'n*, 200 F.3d 775, 777 (Fed. Cir. 1999). In determining whether gray market products infringe, courts have considered "whether the imported goods bearing the foreign mark are the same as (or not materially different from) the goods that are sold under the United States trademark." *Id.* at 778. "The courts have applied a low threshold of materiality, requiring no more than showing that consumers would be likely to consider the differences between the foreign and domestic products to be significant when purchasing the product, for such differences would suffice to erode the goodwill of the domestic source." *Id.* at 779. Thus, even "[d]ifferences in labeling and other written materials have been deemed material, on the criteria of likelihood of consumer confusion and concerns for the effect of failed consumer expectations on the trademark holder's reputation and goodwill." *Id.* at 781.

A complainant must also establish "that all or substantially all of its sales are accompanied by the asserted material difference in order to show that its goods are materially different." *SKF USA Inc. v. Int'l Trade Comm'n*, 423 F.3d 1307, 1315 (Fed. Cir. 2005). This "benchmark recognizes that something less than 100% compliance will suffice and certainly permits a small amount of nonconforming goods." *Id.* at 1316.

D. Domestic Industry

In a patent-based complaint, a violation of section 337 can be found "only if an industry in the United States, relating to the articles protected by the . . . trademark . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Under Commission precedent, this "domestic industry requirement" of section 337 consists of an economic prong and a technical prong. *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 12-14, 2009 WL 5134139 (U.S.I.T.C. Dec. 2009). The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, Final Initial Determination at 294, 2002 WL 31556392 (U.S.I.T.C. June 21, 2002) (unreviewed by Commission in relevant part).

i. Technical Prong

Where registered trademark rights are asserted, "[t]he test for determining whether the technical prong is met through the practice of a trademark is plain use of the trademark on products and packaging." *Certain Protective Cases and Components Thereof,* Inv. No. 337-TA-780, Initial Determination at 90 (June 29, 2012).

ii. Economic Prong

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such investigations:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
> (B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *Certain Integrated Circuit Chipsets and Prods. Containing Same*, Inv. No. 337-TA-428, Order No. 10, Initial Determination (May 4, 2000) (unreviewed).

E. Causes of Action Under Section 43(a) of the Lanham Act

i. False Representation of Source

Under the Lanham Act, it is unlawful to use in commerce, in connection with goods or services, any "false or misleading description of fact, or false or misleading representation of fact, which . . . is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person." 15 U.S.C. § 1125(a)(1)(A). "In the gray market context, violation of 15 U.S.C. § 1125(a)(1)(A) . . . 'turns on the existence vel non of material differences between the products of a sort likely to create consumer confusion." *Certain Bearings & Packaging Thereof*, Inv. No. 337-TA-469, Initial Determination, 2003 WL 21056379, *141 (Apr. 10, 2003). The "existence of material differences creates a legal presumption that consumers are likely to be confused as to the source of the gray market product." *Id.*

ii. False Advertising

A complainant engages in false advertising if "in commercial advertising or promotion," it "misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B).

To prove a violation based on false advertising, a complainant must show that:

(1) The respondent made false or misleading statements about his own or another person's product;

(2) There is actual deception or at least a tendency to deceive a substantial portion of the intended audience;

(3) The deception is material in that it is likely to influence purchasing decisions;

(4) The advertised good traveled in interstate commerce; and

(5) There is a likelihood of injury to the complainant in terms of declining sales, loss of good will, etc.

Certain Food Processing Equip. & Packaging Materials Thereof, Inv. No. 337-TA-1161, Initial Determination, 2020 WL 1504748, at *9 (Feb. 18, 2020).

iii. Injury to a Domestic Industry

When asserting the claims related to unfair methods of competition, a complainant must show that the "threat or effect" of the action is "(i) to destroy or substantially injure an industry in the United States; (ii) to prevent the establishment of such an industry; or (iii) to restrain or monopolize trade and commerce in the United States." 19 U.S.C. § 1337(a)(1)(A). "Injury determinations are highly fact specific." *Certain Foodservice Equip. & Components Thereof*, Inv. No. 337-TA-1166, Comm'n Op. at 10 (Dec. 16, 2020). In making this determination, the Commission considers "a broad range of indicia, including the volume of imports and their degree of penetration, complainant's lost sales, underselling by respondents, reductions in complainant's declining production, profitability and sales, and harm to complainant's good will or reputation." *Id.* Additionally, "[t]he injury requirement in section 337(a)(1)(A)(i) can . . . be met by demonstrating a threat of substantial injury when an assessment of the market in the presence of the accused imported products demonstrates relevant conditions or circumstances from which probable future injury can be inferred." *Id.*

III. IMPORTATION

Section 337(a)(1) prohibits, *inter alia*, "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that . . . infringe a valid and enforceable United States patent" or trademark. 19 U.S.C. § 1337(a)(1)(B)–(C). Complainant need only prove importation of a single accused product to satisfy the importation element. *Certain DC-DC Controllers and Prods. Containing the Same*, Inv. No. 337-TA-698, Order No. 29 at 3 (June 18, 2010); *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Order No. 17 at 5 (Sept. 23, 2004).

EMD Serono asserts that "[t]he evidence demonstrates that the Gray Market IVF Products were imported, sold for importation, or sold after importation into the United States." Mem. at 9. EMD Serono explains it hired an investigative agency to make two monitored purchases in July 2017 and April 2019. *Id.* at 4. In July 2017, "the investigative agency hired by EMD Serono visited www.fastivf.com and documented that the website offers various Gray Market IVF products for sale, including Gonal-f® and Ovidrel®." *Id.* at 4-5 (citing Compl. Ex. 63 at 3-4). The investigative agency "ordered various Gray Market IVF Products and, on July 18, 2017, the investigative agency received a package in the mail that was sent from" Hermes Eczanesi. *Id.* at 5 (citing Compl. Ex. 63 at 22-27, 40). "The package included Gary-Market Gonal-f® (450 IU/0/.75ml) and Gray Market Ovitrelle® (250 µg/0/5 ml)." *Id.* (citing Compl. Ex. 63 at 45-48, 51-52).

In April 2019, "[t]he investigative agency emailed info@fastivf.com seeking to place an order for certain Gray Market IVF products, including Ovitrelle® 250 mcg/0.5 ml and Follitropin Alfa 900 IU." *Id.* (citing Compl. Ex. 64 at 9). EMD Serono explains that the investigative agency "communicated with an individual identified as 'Mary' at the email address mary@fastivf.com, and completed the purchase by wiring payment to a bank in Istanbul, Turkey." *Id.* (citing Compl.

Ex. 64 at 18). The investigative agency received the Gray Market IVF products in the mail on April 9, 2019. *Id.* (citing Compl. Ex. 64 at 25). "Unlike the first monitored purchase, which was fulfilled directly from Istanbul, Turkey, the second monitored purchase was routed through a separate location in the United States." *Id.* "The only information disclosed to the recipient on the United States Postal Service packing slip was the name 'Mary Fast.'" *Id.* at 5-6 (citing Compl. Ex. 64 at 25).

Staff agrees that there is no factual dispute related to importation of most of the accused products by the Defaulting Respondents. Staff Resp. at 15. Staff "does not believe the evidence shows that any product bearing the Gonal-f RFF RediJect mark" has been imported.[2] *Id.*

The undersigned finds that EMD Serono has established that the importation requirement of section 337 is satisfied. In the Complaint, EMD Serono identified an instance of importation by each of the Defaulting Respondents. *See* Compl. at ¶¶ 40-47, Ex. 63 at 3-4, 22-27, 40, 45-48, 51-52; Ex. 64 at 25; Ex.65. Specifically, the evidence shows that the Defaulting Respondents imported Gray Market Gonal-f (450 IU/0/.75 ml), Gray Market Ovitrelle (250 µg//0/5 ml), and Gray Market Ovitrelle 250 mcg/0.5 ml. *Id*. Because the Commission presumes the facts alleged in the Complaint to be true, EMD Serono has satisfied their burden of demonstrating importation. Additionally, the undersigned is not aware of any evidence to the contrary with respect to importation by the Defaulting Respondents.

IV. JURISDICTION

A. Subject Matter Jurisdiction

Section 337 confers subject matter jurisdiction on the Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the

[2] The undersigned addresses the issue of whether the imported products infringe this trademark in Section V.B.

importation, the sale for importation, or the sale after importation of articles into the United States. *See* 19 U.S.C. §§ 1337(a)(1)(C) and (a)(2). EMD Serono filed a complaint alleging a violation of this subsection. Accordingly, the Commission has subject matter jurisdiction over this Investigation under section 337 of the Tariff Act of 1930. *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

Personal jurisdiction is not required so long as the products are being imported. *See Sealed Air Corp. v. U.S. Int'l Trade Comm'n*, 645 F.2d 976, 985-89 (C.C.P.A. 1981). The undersigned has determined hereinabove that the accused products have indeed been imported into the United States. *See* Section III. Furthermore, by defaulting, the Defaulting Respondents have waived their right to contest that *in personam* jurisdiction exists. *See Certain Protective Cases and Components Thereof,* Inv. No. 337-TA-780, Initial Determination at 46 (June 29, 2012).

C. In Rem Jurisdiction

The Commission has *in rem* jurisdiction by virtue of the fact that accused in vitro fertilization drugs have been imported into the United States. *See Sealed Air Corp. v. U. S. Int'l Trade Comm'n*, 645 F.2d 976, 985 (C.C.P.A. 1981).

V. TRADEMARK INFRINGEMENT

EMD Serono contends that the Defaulting Respondents infringe the Asserted Trademarks. Mem. at 10. Staff supports a finding of infringement for all of the Asserted Trademarks, except for the Gonal-f RFF RediJect mark. Staff Resp. at 16.

A. Validity

Under the Lanham Act, federal registration is prima facie evidence of validity. 15 U.S.C. § 1057(b); *Handbags,* Order No. 16 at 6. The undersigned is not aware of any evidence to the

contrary with respect to validity. *See also* Staff Resp. at 16 (agreeing that the Asserted Trademarks are valid, enforceable, and incontestable).

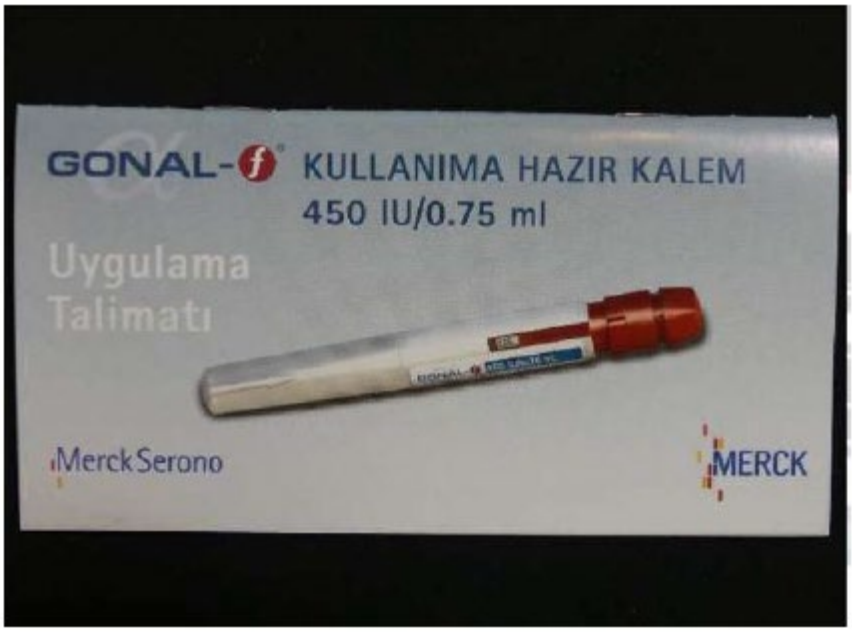
B. Infringement of Gonal-f Trademarks

EMD Serono asserts that the Defaulting Respondents import gray market goods that infringe its Gonal-f Trademarks. Mem. at 10. Staff "believes EMD [Serono] has proven trademark infringement for all the Asserted Trademarks (except the Gonal-f RFF RediJect mark, Reg. No. 4,689,651 . . .)." Staff Resp. at 16.

The undersigned first agrees with Staff that EMD Serono has not established that the Gray Market IVF Products infringe the word mark "Gonal-f RFF RediJect." There is no evidence that any of the imported products include the name "Gonal-f RFF RediJect." Additionally, although EMD Serono filed a reply brief on this issue, it did not cite to any evidence that shows that any of the imported Gray Market IVF Products actually bear this mark. As such, the undersigned finds that there is no infringement of U.S. Registration No. 4,689,651.[3]

The evidence shows, however, that the Defaulting Respondents sell for importation and/or import Gonal-f (450 IU/0/.75 ml) affixed with a foreign Gonal-f trademark:

[3] The fact that any products bearing the words "Gonal-f" would infringe other Asserted Trademarks is not reason to find that these products also infringe the "Gonal-f RFF RediJect" mark. *See* Reply at 1-2 (argument by EMD Serono that the fact that the Gray Market IVF Products infringe other marks demonstrates infringement of the "Gonal-f RFF RediJect" mark.)



Compl. Ex. 30. This trademark is the same as EMD Serono's Gonal-f Trademarks registered in the United States. *See* U.S. Registration No. 1,772,761 (word mark for Gonal-f); U.S. Registration Nos. 3,777,170; 3,389,332; and 3,816,320 (design marks). As such, it qualifies as a gray market good and "the basic question [to analyze is] whether there are differences between the foreign and domestic product and if so whether the differences are material." *Gamut Trading,* 200 F.3d at 779.

Here, the undersigned finds that there are material differences between the Gray Market IVF Products and the genuine U.S. IVF Products. First, there are differences in the labeling of the products. Specifically, the evidence shows that the labeling of the Gray Market IVF Products is written entirely (or in part) in Turkish or another foreign language, whereas the labeling of the genuine products is in English. Compl. Exs. 14-15, 30. Additionally, the prescribing instructions are in Turkish instead of English. Mem. at 12; Compl. Exs. 19-20, 30. The product cartons of the Gray Market IVF Products also include contact information for a foreign distributor, rather than a U.S. distributor, and do not include the FDA required information on side effects or adverse events.

Mem. at 12; Mot. Ex A at ¶ 13; Compl. Ex. 30. Second, the evidence shows that the Gray Market IVF Products are not subject to the strict temperature monitoring and control processes that the U.S. IVF Products are subject to when shipped from abroad. Mem. at 15; Compl. Ex. 23-29, 63, 64; Mot Ex A. at ¶¶ 16-22. The evidence also shows that the Gray Market IVF Products are not subject to FDA-approved drug supply chain regulations. *See* Mem. at 16. The evidence further shows that consumers would consider these differences to be significant when purchasing the product. Mot. Ex. A at ¶¶ 15-16 (testimony from EMD Serono's Head of Channel Account Management and Customer Operations that consumers would expect an IVF drug's label and instructions to be in English and further expect that pharmaceutical companies "manufacture and distribute the company's products under a rigorous quality management system").

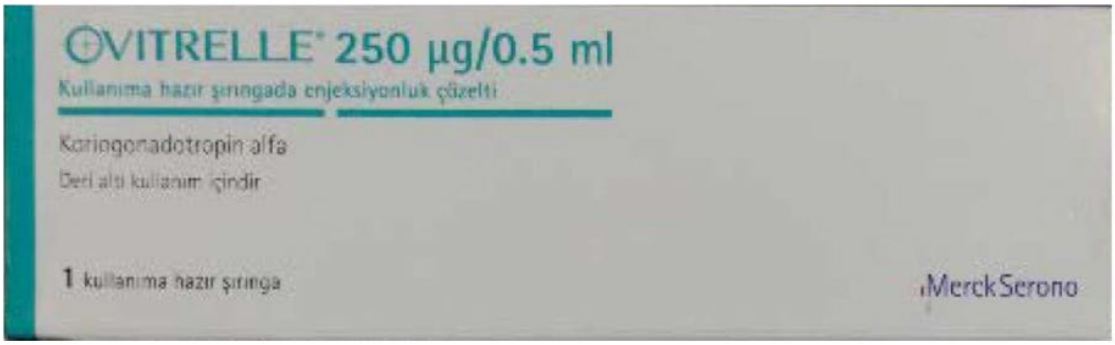
The undersigned also finds that EMD Serono has shown that all or substantially all of the U.S. IVF Products are materially different than the Gray Market IVF Products. The evidence shows that the law requires that all genuine U.S. IVF Products include labeling in English and that they are subject to quality control processes. *See* Mot. Ex. A at ¶¶ 6-22. There is no evidence that any of the U.S. IVF Products fail to meet these legal requirements. There is also no evidence that any of the Defaulting Respondents import any Gray Market IVF Products that include English labels or that are subject to strict temperature controls.

For these reasons, the undersigned finds that the gray market Gonal-f (450 IU/0/.75 ml) infringes the Gonal-f Trademarks.

C. Infringement of Ovidrel Trademarks

EMD Serono asserts that the Defaulting Respondents import gray market goods that infringe its Ovidrel Trademarks. Mem. at 10, 21-22. Staff agrees. Staff Resp. at 21.

Unlike with the Gonal-f trademark, the trademarks on the imported products are not identical to the Ovidrel Trademarks. The U.S. trademarks spell the name as "Ovidrel," whereas the imported products include a different spelling: "Ovitrelle."



Compl. Ex. 31. Thus, these products do not necessarily qualify as gray market goods.[4]

The undersigned finds, however, that there is infringement of the Ovidrel Trademarks under a traditional trademark infringement analysis. Specifically, the undersigned finds that the Defaulting Respondents' use of the similar mark is likely to cause consumer confusion. First, the marks themselves are very similar, including the spelling, pronunciation, and the distinctive "O" element. Compl. Exs. 16, 63. The two marks also use similar fonts. *Id.* Second, the evidence shows that the Defaulting Respondents intend for consumers to believe they are purchasing products with the Ovidrel trademark. Hermes Eczanesi use the name "Ovidrel" on the invoicing and paperwork included in the shipment. Compl. Ex. 63 at 35; Ex. 64 at 13. FastIVF uses the names "Ovidrel" and "Ovitrelle" interchangeably on its website, specifically listing "Ovidrel" under "Other Names" for Ovitrelle. Compl. Ex. 63 at 10.

[4] Staff agrees that there "is some question about whether the imported Gray Market IVF Products that allegedly infringe the 'Ovidrel Marks' are gray market goods." Staff Resp. at 19. Staff ultimately finds, however, that "EMD [Serono] has shown that consumers would likely be confused by the Defaulting Respondents' sale and importation of 'Ovitrelle.'" *Id.* at 21.

For these reasons, the undersigned finds that Gray Market Ovitrelle (250 µg//0/5 ml) and Gray Market Ovitrelle 250 mcg/0.5 ml. infringe the Ovidrel Trademarks.

VI. DOMESTIC INDUSTRY

A. Technical Prong

EMD asserts that it "is and has been at all times, the exclusive licensee of each of the Asserted [Trademarks] in the United States with respect to the U.S. IVF Products, and the Asserted [Trademarks] are displayed on the U.S. IVF Products." Mem. at 17-18. Staff agrees that the technical prong of the domestic industry requirement is met. Staff Resp. at 24-25.

The undersigned finds that the technical prong of the domestic industry is met. The evidence shows that EMD Serono's U.S. IVF Products bear the Asserted Trademarks on the product packaging. Compl. Exs. 13-16. Specifically, the Asserted Trademarks appear on: Gonal-f RFF Redi-ject, Gonal-f RFF 75 IU, Gonal-f Multi-dose 1050 IU, and Ovidrel 250 µg/0.5 mL. *Id.*

B. Economic Prong

EMD Serono states that it "has made significant investments in plant and equipment under section 337(a)(3)(A)." Mem. at 18. It further states that it "has made, and continues to make, significant, substantial investments in labor and research and development under section 337(a)(3)(B) and (C) related to the domestic industry articles." *Id.* at 18. Staff agrees that EMD Serono has shown "the existence of a domestic industry under Section 337(a)(3)(C)." Staff Resp. at 27. Staff asserts, however, that the current record does not support a showing that EMD Serono has established a domestic industry under Section 337(a)(3)(A) or (B). *Id.* at 29-32.

The undersigned finds that EMD Serono has adduced substantial, reliable, and probative evidence to support a finding that it satisfies the economic prong of the domestic industry

requirement under § 337(a)(3)(C). The evidence shows that EMD Serono made the following investments[5]:

Staff Resp. at 27. The undersigned finds that these investments are properly considered investments in the Asserted Trademarks' exploitation. In other investigations, investments in "functions related to regulatory affairs and quality assurance, scientific affairs, clinical education . . . , research and development, [and] medical and scientific operations" have been considered under subsection (C). *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Order No. 17, 2004 WL 2330140, *5-6 (Sept. 23, 2004), *unreviewed*; *see also Certain Endoscopic Probes for Use in Argon Plasma Coagulation Sys.*, Inv. No. 337-TA-569, Initial Determination, 2008 WL 274869, at *46 (Jan. 16, 2008), *unreviewed*. Similarly, investments in efforts to seek FDA approval have

[5] These investments are from 2018-2019. EMD Serono allocates [redacted] of its investments to Gonal-f and Ovidrel based on a sales-allocation method. Staff asserts that this allocation method is reasonable and the undersigned agrees. *See* Staff Resp. at 26; *see also Certain Collapsible Sockets for Mobile Elec. Devices & Components Thereof*, Inv. No. 337-TA-1056, Comm'n Op. at 16 (July 9, 2018) ("A sales-based allocation may be applied to determine, under each subsection, the investments relating to the articles protected by the patent.").

been considered as part of this subsection. *See, e.g.*, *Certain Strontium-Rubidium Radioisotope Infusion Sys. & Components Thereof Including Generators*, Inv. No. 337-TA-1110, Initial Determination, 2019 WL 8752807, *94-*95 (Aug. 1, 2019), *unreviewed in relevant part*; *Certain Diltiazem Hydrochloride & Diltiazem Preparations*, Inv. No. 337-TA-349, Initial Determination, 1995 WL 945191, at *167 (Feb. 1, 1995), *unreviewed in relevant part*.

The undersigned further finds that these investments are substantial. They total [redacted] over a three-year period and are significant to EMD Serono's business. For example, the investments in quality control, medical studies, and FDA fees are necessary in order for EMD Serono to sell its IVF products in the United States. Compl. Ex. 66 at ¶¶ 7-8.

For these reasons, no genuine issue of material fact remains and a summary determination that the economic prong of the domestic industry requirement is satisfied is appropriate.[6]

VII. UNFAIR COMPETITION

A. False Representation of Source

EMD Serono asserts that the Defaulting Respondents use a false designation of origin for the Gray Market IVF Products. Mem. at 25. Specifically, EMD Serono states "Respondent Fast IVF's website makes express and/or implied claims that the products sold on their website . . . are 'European,' and are regulated by the European Medicines Agency ('EMA'), when in fact the Gray Market IVF Products are not regulated by the EMA and are sourced from Turkey." *Id.* According to EMD Serono, such statements "are false designation of origin that constitute unfair methods of competition and unfair acts pursuant to section 337(a)(1)(A)." *Id.* at 27.

[6] The undersigned has already determined that EMD Serono satisfies the economic prong under section 337(a)(3)(C.) Accordingly, the undersigned need not decide whether EMD Serono meets the economic prong under sections 337(a)(3)(A) or (B).

Staff asserts that "EMD's claim of false representation of source . . . will succeed or fail in tandem with EMD's claim of trademark infringement." Staff Resp. at 32. Staff believes that "[t]he evidence of material differences discussed [in relation to trademark infringement] demonstrates that the Defaulting Respondents have engaged in false representation of source." *Id.* at 33.

Staff also "notes that the MSD appears to argue for the existence of a false designation of geographic origin." *Id.* Staff recognizes, however, that "the Commission's [Notice of Investigation] institutes the Investigation as to 'false designation of source[,]' not geographic origin." *Id.* The undersigned agrees with Staff that it would be inappropriate to address EMD Serono's false designation of geographic origin argument.

The undersigned finds that the Defaulting Respondents have engaged in false representation with respect to the Gonal-f trademark. The Commission has previously noted that the "existence of material differences between an authorized domestic product and a gray market product creates a legal presumption of consumer confusion as to source." *Certain Cigarettes & Packaging Thereof*, Inv. No. 337-TA-424, Init. Det., 2000 WL 1089576, at *18 (Jun. 22, 2000). As noted above, the undersigned found that there are material differences between the Gray Market IVF Products and the genuine IVF Products.

The undersigned also finds that the Defaulting Respondents have engaged in false representation with respect to the Ovidrel trademark. As noted above, the undersigned found that the Defaulting Respondents intend for consumers to believe they are purchasing Ovidrel and that consumers are likely to be confused between the Ovidrel and Ovitrelle products.

For these reasons, the undersigned finds that Defaulting Respondents have engaged in false representation of source in violation of Section 337(a)(1)(A).

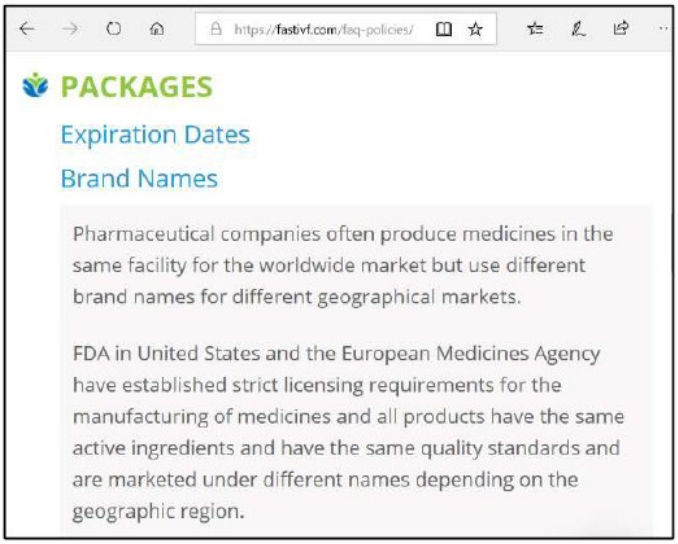
B. False Advertising

EMD Serono asserts that the Defaulting Respondents also violate Section 337(a)(1)(A) by using false advertising to promote the Gray Market IVF Products. Mem. at 31. EMD Serono asserts, for example, that "Fast IVF's website makes literally false, false by necessary implication, and/or misleading statements that the Gray Market IVF Products sold on their website . . . are the 'same' as EMD Serono's FDA-approved products meant for distribution in the U.S." *Id.* at 33. EMD Serono also asserts that FastIVF falsely claims that the Gray Market IVF Products are approved by European regulators. *Id.*

Staff agrees with EMD Serono that FastIVF has engaged in false advertising. Staff Resp. at 34. Staff does not, however, support a finding that Hermes Ezcanesi committed false advertising. *Id.* at 35.

The evidence shows that FastIVF[7] meets four of the five elements of false advertising. As to the first element, FastIVF made a false statement when it alleged that it was selling EMD Serono's products that are the same as EMD Serono's FDA-approved IVF Products when, as noted above, the products are materially different:

[7] The undersigned agrees with Staff that EMD Serono has not established that Hermes Eczanesi has engaged in false advertising. As Staff notes: EMD Serono's "evidence related to false advertising is directed solely to FastIVF." Staff Resp. at 35. There is no evidence in the record that Hermes Eczanesi engaged in false advertising with respect to the Gray Market IVF Products.



Compl. Ex. 39.[8] *see also Certain Woven Textile Fabrics & Prods. Containing Same*, Inv. No. 337-TA-976, Initial Determination at 8 (Nov. 10, 2016) (noting that a false statement is one that is either literally false or "literally true or ambiguous but likely to mislead or deceive consumers").

Second, because its statement is literally false, FastIVF is presumed to have deceived its customers. *Woven Textile Fabrics*, Initial Determination at 9 (explaining that, if a statement is literally false, a judge "may grant relief without considering evidence of consumer reaction").

Third, FastIVF's deception is material in that it is likely to influence purchasing decisions. The undersigned agrees that consumers of prescription drugs are likely to take into consideration whether a drug purchased online is the same as the FDA approved drug in the United States. *See* Staff Resp. at 37 ("The Staff agrees with EMD that consumers are likely influenced by FastIVF's deceptive statements given the sensitive nature of an FDA regulated fertility drug.").

[8] EMD Serono asserts that FastIVF "makes express and/or implied claims" that its products are European, and thus regulated by the EMA. Mem. at 37. EMD Serono does not, however, cite to any exhibit that shows where FastIVF made a claim that its products were regulated by the EMA.

Fourth, the Gray Market IVF Products were imported into the United States, thus meeting the "interstate commerce" element. *Certain Food Processing Equip.*, at *19 (explaining that interstate commerce includes "United States import or export trade that can be regulated by Congress").

The undersigned finds that the final element is not met. As explained below, EMD Serono has not established that there is a likelihood of injury in terms of declining sales, loss of good will, etc. As such, the undersigned must find that EMD Serono has not established that FastIVF engaged in false advertising.[9]

C. Injury to a Domestic Industry

EMD Serono asserts that "[t]he importation and sale of Respondents' Gray Market IVF Products have injured EMD Serono's domestic industry or threatened it with injury by (i) causing lost sales and lost market share; (ii) price underselling, [and] (iii) damaging the EMD Serono brand in various ways" by "undermining and circumventing . . . EMD Serono's quality control management systems." Mem. at 27.

Staff "does not believe the MSD provides substantial, reliable, and probative evidence that any injury to EMD [Serono's] domestic industry is 'substantial.'" Staff Resp. at 38.

The undersigned agrees with Staff that EMD Serono has not established that any injury it suffers is substantial. As Staff notes, "[t]he only evidence of importation by the Defaulting Respondents, and thus the only quantifiable evidence of sales lost to the products, are the units imported at behest of EMD's counsel for this case." Staff Resp. at 39.[10] Additionally, "[t]hose

[9] Although Staff states that it "agrees with EMD that FastIVF has engaged in false advertising," it notes that it "cannot identify any evidence that the Defaulting Respondents' . . . have caused *any* injury to EMD's domestic quality control industry, let alone a 'substantial' injury." Staff Resp. at 34, 40 (emphasis in original).

[10] EMD Serono presents evidence of other importations of Gray Market IVF Products, but there is no evidence that these imported goods can be tied to either of the Defaulting Respondents. Mot. Ex. B at ¶ 8; Compl. Exs. 56, 59-61; *see* Staff Resp. at 39-40.

shipments appear to be a [redacted] Staff Resp. at 40 (citing Compl. Ex. 66 at ¶ 4.) Without any other evidence that shows that EMD Serono actually lost sales or that the Defaulting Respondents are impacting the price of EMD Serono's products, the undersigned cannot find injury on these grounds.

Nor does the evidence show that there is a future threat to EMD Serono's domestic industry due to the Defaulting Respondents' lack of quality controls. EMD Serono asserts that the failure of the Defaulting Respondents to conduct quality control checks on the Gray Market IVF Products [redacted] Mem. at 28. By its own admission, this threat of injury is speculative. EMD Serono does not argue that such a [redacted] *will* occur, only that it *might*. Nor does EMD Serono explain how any [redacted]

EMD Serono next asserts that the lack of quality controls may damage its brand if a customer experiences a serious quality event after receiving imported Gray Market IVF Products. EMD Serono asserts that [redacted][11] In its reply, EMD Serono argues that "[i]n recent years, FDA has repeatedly warned the public that 'foreign and unlicensed sources' have been responsible for distributing counterfeit prescription drugs in the U.S." Reply at 5. While

[11] EMD Serono cites to paragraph 12 of the supplemental declaration of Robert Truckenmiller. Mr. Truckenmiller's statements are conclusoryand are not supported by any additional evidence as to [redacted]

the FDA has issued such warnings, these warnings are directed to the health of the public, and do not support the assertion that the brands' goodwill will be damaged. *See, e.g.*, Compl. Ex. 34 at 2 ("Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patent's health at risk, as patients may not be getting proper treatment.") Without evidence that directly supports the assumption that EMD Serono's brand will be damaged, the undersigned cannot find that EMD Serono has established injury. *See Foodservice Equip.*, Comm'n Op. at 13 ("[S]ubstantial harm or threat thereof to the U.S. industry found to exist cannot be assumed; it must be proven by a preponderance of the evidence.")

Accordingly, for these reasons, the undersigned finds that EMD Serono has not established an injury to its domestic industry.

VIII. REMEDY AND BONDING[12]

A. General Exclusion Order

Section 337(d)(2) provides that a general exclusion order may issue in cases where (a) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named respondents; or (b) there is a widespread pattern of violation of Section 337 and it is difficult to identify the source of infringing products. 19 U.S.C. § 1337(d)(2). The statute essentially codifies Commission practice under *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, Comm'n Op. at 18-19, USITC Pub. 119 (Nov. 1981) ("*Spray Pumps*"). *See Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing the Same,* Inv. No. 337-TA-372 ("*Magnets*"), Comm'n Op. on Remedy, the Public Interest and Bonding at 5 (USITC Pub. 2964 (1996)) (statutory standards "do not differ significantly" from the standards set forth in *Spray Pumps*). In *Magnets*, the Commission

[12] EMD Serono did not request cease and desist orders against either of the Defaulting Respondents.

confirmed that there are two requirements for a general exclusion order: [1] a "widespread pattern of unauthorized use;" and [2] "certain business conditions from which one might reasonably infer that foreign manufacturers other than the respondents to the investigation may attempt to enter the U.S. market with infringing articles." *Id.* The focus now is primarily on the statutory language itself and not an analysis of the *Spray Pump* factors. *Ground Fault Circuit Interrupters and Prods. Containing Same*, Inv. No. 337-TA-615, Comm'n Op. at 25 (Mar. 9, 2009).

EMD Serono and Staff both submit that a GEO is appropriate in this Investigation.

i. Circumvention of a Limited Exclusion Order

EMD Serono asserts that "[a] GEO is necessary to prevent circumvention of an exclusion order limited to the Gray Market IVF Products to the Defaulting Respondents." Mem. at 39. EMD Serono explains: "Because they frequently have no 'bricks and mortar' facilities, an internet pharmacy that is found to violate section 337 can shut down its website and re-establish another web presence under a different name overnight at virtually no cost." *Id.*

Staff agrees that a GEO is necessary. Staff Resp. at 42. Staff explains that "the sale of the Gray Market IVF Products through semi-anonymous internet pharmacies makes it difficult to identify and serve these entities with legal process." *Id.* Staff also argues that "the internet pharmacies source their products from foreign brick-and-mortar pharmacies," which, given the volume of such pharmacies, "would make it easy to circumvent an LEO by sourcing products from a different brick-and-mortar pharmacy." *Id.* at 43. Staff also notes that "the importation of the Gray Market IVF Products is profitable." *Id.*

The undersigned agrees that the evidence shows that a GEO is necessary to prevent circumvention of an LEO. First, the evidence shows that FastIVF has taken steps to conceal its identity. FastIVF registered with the Internet Corporation for Assigned Names and Numbers

("ICAAN") through GoDaddy.com, LLC. Mot. Ex. D. By doing this, FastIVF requested that its own contact information not appear in the publicly available WHOIS database, and that Domains by Proxy's address be used instead. This made it difficult for EMD Serono to locate FastIVF for service of the complaint in this Investigation. *See* Mem. at 40-41. FastIVF could also use the services of a registrar like GoDaddy to change its website domain to circumvent an LEO.

The undersigned further finds that FastIVF could easily use a different pharmacy to fulfil its online orders. The evidence shows that there are numerous pharmacies in Turkey. *See* Tekiner, Halil, "Pharmacy in Turkey: Past, present, and future," Die Pharmazie, v. 69: 477-480, at 478 (2014) (2013 study indicating that there are more than 5,000 pharmacies in Istanbul alone). FastIVF could therefore switch to a pharmacy other than Hermes Ezcanesi to fulfill its online orders.

Finally, the evidence shows that the importation of the Gray Market IVF Products is profitable. EMD Serono's profit margin for the genuine IVF products was approximately [redacted] in 2018. Compl. Ex. 67. Additionally, FastIVF makes a significant profit when it sells the Gray Market IVF Products:

[redacted]

Staff Resp. at 44. The evidence also shows that the IVF Products are in high demand. Compl. Ex. 58; *see also Certain Inkjet Ink Supplies & Components Thereof*, Inv. No. 337-TA-730, Comm'n Op. at 4-5 (Feb. 24, 2012) (explaining that evidence of "a strong demand" for the infringement

products shows conditions ripe for circumvention). Thus, FastIVF has an incentive to continue to sell the Gray Market IVF Products after an LEO issues.

For these reasons, the undersigned finds that a general exclusion order is necessary to prevent circumvention of an LEO directed to the Defaulting Respondents.

ii. Widespread Pattern of Unauthorized Use

EMD Serono asserts that there is "a widespread pattern of illegal distribution activity that is similar to Respondents' conduct." Mem. at 42. EMD Serono explains: "Gray market versions of EMD Serono's products are being illegally shipped into the United States – at a minimum – from Israel, Bulgaria, and/or Romania (via the United Kingdom), and Turkey." *Id.* at 47-48. It also argues that "internet pharmacies, particularly those that use proxy or privacy services providers, are uniquely able to mask the identity of their principals and the source of the infringing articles." *Id.* at 48. Staff agrees that there is a pattern of violation and that it is difficult to identify the source of infringing Gray Market IVF Products. Staff Resp. at 45.

The evidence shows multiple instances of the importation of Gray Market IVF Products. *See* Mot. Ex. E (evidence of the importation of gray market Gonal-f imported from Romania or Bulgaria); Mot. Ex. F (evidence of gray market Ovidrel and Gonal-f imported from Turkey); Mot. Ex. G (evidence of gray market Ovidrel and Gonal-f imported from Israel). The evidence also shows that [redacted] Compl. Exs. 59-61, 67 at ¶ 24.

The evidence further shows that it is difficult to identify the source of the Gray Market IVF Products. As explained above, internet pharmacies can easily switch domain names and use different brick and mortar pharmacies to fulfill online orders. Additionally, as EMD Serono notes,

there is "a byzantine distribution network" with online pharmacies." *See* Mem. at 48. For example, in one of EMD Serono's monitored purchases, the payee was listed as [redacted] Mot. Ex. G at 21-22. In other monitored purchases, names did not match listed addresses. *See* Mot. Ex. F at 2, 16 (identifying the IVF Pharmacy as [redacted] but including an address for a different company).

For these reasons, the undersigned finds there is a widespread pattern of violation of section 337.

iii. Conclusion

For the above reasons, the undersigned recommends that in the event the Commission finds a violation of section 337, the appropriate remedy is a GEO that encompasses the Gray Market IVF Products. The undersigned also finds that the additional requirements of section 337(g)(2) have been satisfied in this Investigation.

B. Bonding

Pursuant to section 337(j)(3), the Administrative Law Judge and the Commission must determine the amount of bond to be required of a respondent during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. 19 U.S.C. § 1337(j)(3). The purpose of the bond is to protect the complainant from any injury. 19 C.F.R. § 210.42(a)(1)(ii), § 210.50(a)(3).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Microsphere Adhesives, Processes for Making Same, and Prods. Containing Same*, *Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. 2949, Comm'n Op. at 24 (Dec.

8, 1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See, e.g.*, *Certain Integrated Circuit Telecomm. Chips and Prods. Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm'n Op. at 41, 1993 WL 13033517, at *24 (U.S.I.T.C. June 22, 1993). A 100 percent bond has been required when no effective alternative existed. *See, e.g.*, *Certain Flash Memory Circuits and Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (imposing a 100% bond when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimus* and without adequate support in the record).

EMD Serono submits that the bond be set at 100 percent for all infringing goods entered during the Presidential review period. Mem. at 49. It explains that "Fast IVF's prices are one-half to one-fifth the WAC prices charged by EMD Serono." *Id.* at 49-50. Staff also believes that a bond of 100% is appropriate. Staff Resp. at 48 (explaining that the Defaulting Respondents did not provide discovery but that the prices on FastIVF's website support a finding that the prices range from one-half to one-fifth of EMD Serono's prices).

With little information on pricing or royalty information, it is impossible to calculate a bond rate based on the average price differential between EMD Serono's genuine IVF Products and the Gray Market IVF Products. The undersigned therefore agrees with EMD Serono and Staff that the Commission set the bond value at 100%. *See Certain Digital Photo Frames and Image Display Devices and Components Thereof,* Inv. No. 337-TA-807, Comm'n Op. at 17, U.S.I.T.C. 4549 (July 2015) ("The Commission finds that there is little or no evidence in the record of this investigation as to pricing of the defaulting respondents' products. . . . The Commission has

traditionally set a bond of 100 percent of the entered value of the products under these circumstances.").

IX. INITIAL DETERMINATION

For the foregoing reasons, it is the INITIAL DETERMINATION of the undersigned that EMD Serono has shown by reliable, probative, and substantial evidence that a domestic industry exists and a violation of section 337 has occurred with respect to U.S. Trademark Registration Nos. 1,772,761, 3,777,170, 3,389,332, 3,816,320, 1,972,079, 3,604,207, and 3,185,427. The undersigned further finds that there is no violation of section 337 with respect to U.S. Trademark No. 4,689,651 or for EMD Serono's claims of unfair methods of competition. Accordingly, EMD Serono's motion for summary determination of violation (1196-005) is hereby granted-in-part.

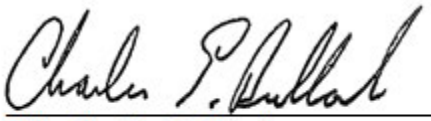
In addition, the undersigned recommends that the Commission issue a general exclusion order issue prohibiting the entry of all in vitro fertilization drugs, components thereof, and products containing the same labeled, in whole or in part, Gonal-f, Ovidrel, or Ovitrelle that infringe U.S. Trademark Registration Nos. 1,772,761, 3,777,170, 3,389,332, 3,816,320, 1,972,079, 3,604,207, and 3,185,427, and that a 100 percent bond be imposed during the Presidential review period.

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation. A public version will be served at a later date upon all parties of record.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within ten days of the date of this document, the parties shall submit to the Office of Administrative Law Judges a joint statement regarding whether or not they seek to have any portion of this document deleted from the public version. The parties' submission shall be made by hard copy and must include a copy of this Initial Determination with red brackets indicating any portion asserted to contain confidential business information to be deleted from the public version. The parties' submission shall include an index identifying the pages of this document where proposed redactions are located. The parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.



Charles E. Bullock
Chief Administrative Law Judge

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

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served via EDIS upon the Commission Investigative Attorney, **W. Peter Guanieri, Esq.** and the following parties as indicated, on **April 28, 2021.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainant EMD Serono, Inc.:

Jeffrey M. Telep, Esq.
KING & SPALDING L.L.P.
901 New York Ave. NW
Washington, DC 20001
Email: jtelep@kslaw.com

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