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**

COMMISSION OPINION

On April 16, 2021, the presiding Chief Administrative Law Judge ("Chief ALJ") issued an initial determination ("ID") (Order No. 10) granting in part the motion for summary determination of a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), filed by complainant EMD Serono, Inc. of Rockland, Massachusetts ("EMD Serono" or "Complainant") against defaulting respondents FastIVF c/o Domains by Proxy LLC of Scottsdale, Arizona and Hermes Eczanesi of Istanbul, Turkey (collectively, "the Defaulting Respondents"). 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).[1] The Chief ALJ recommended that the Commission issue a general exclusion order ("GEO") and set a bond at 100 percent during the period of Presidential review.[2]

On May 18, 2021, the Commission determined to review the ID in part. *See* Comm'n Notice (May 18, 2021). Specifically, the Commission determined to review the ID's findings

[1] The Chief ALJ's denial of summary determination as to Complainant's section 337(a)(1)(A) claims is not subject to Commission review. *See* 19 C.F.R. § 210.42(c)(1).

[2] Complainant did not request a cease and desist order against any of the Defaulting Respondents.

with respect to the economic prong of the domestic industry requirement. The Commission also requested briefing from Complainant and the Commission Investigative Attorney ("IA") on the issue under review.

Having reviewed the parties' submissions and responses thereto relating to the May 18, 2021 Notice, as well as the record in this investigation, the Commission has determined that genuine issues of material fact remain as to whether Complainant satisfied the economic prong of the domestic industry requirement. Thus, the Commission has determined to vacate in part the ID. Specifically, the Commission vacates the ID's findings as to the issue under review, *i.e.*, the economic prong of the domestic industry requirement. Consequently, the Commission also vacates the ID's finding of a violation of section 337. The Commission has further determined to remand the investigation for further proceedings consistent with this opinion.[3]

I. BACKGROUND

A. Procedural Background

On April 16, 2020, the Commission instituted this investigation based on a complaint filed by Complainant EMD Serono. *See* 85 FR 21267-68 (Apr. 16, 2020). The complaint, as amended and supplemented, alleges a violation of section 337 based on: (1) 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, the "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"); (2) unfair methods of competition and

[3] Commissioners Schmidtlein and Karpel dissent from the Commission's decision and have filed a separate opinion explaining their views.

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 named General Plastik Drug Stores of Istanbul Suadiye, Turkey ("Unserved Respondent") as a respondent. *See id.* The Office of Unfair Import Investigations is also a party to the investigation. *See id.*

On September 1, 2020, the Chief ALJ issued an ID finding each of the Defaulting Respondents in default. *See* Order No. 6 (Sept. 1, 2020), *unreviewed by* Comm'n Notice (Sept. 24, 2020). On October 13, 2020, the Chief ALJ also issued an ID terminating the Unserved Respondent from the investigation based on the withdrawal of the complaint 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.[4] On December 22, 2020, the IA filed a response to Complainant's motion.[5] No other responses were filed.

On April 16, 2021, the Chief ALJ issued the subject ID (Order No. 10) granting in part Complainant's motion for summary determination of violation of section 337 by the Defaulting Respondents. 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). In addition, the Chief ALJ

[4] *See* Complainant EMD Serono's Motion for Summary Determination of Violation by the Defaulting Respondents and for Recommended Determination on Remedy and Bonding (Dec. 2, 2020) (hereinafter, "Complainant's Mot.").

[5] *See* Commission Investigative Staff's Response to Complainant EMD Serono, Inc.'s Motion for Summary Determination of Violation and for Recommended Determination on Remedy and Bonding (Dec. 22, 2020) (hereinafter, "IA's Resp.").

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.

On May 18, 2021, the Commission determined to review the ID in part. *See* Comm'n Notice (May 18, 2021). Specifically, the Commission determined to review the ID's findings with respect to the economic prong of the domestic industry requirement. *See id.* The Commission requested briefing on several issues, including: (1) where the domestic industry products are manufactured; (2) whether the claimed domestic industry activities are of the sort that the Commission has credited under subsection 337(a)(3)(C); (3) whether the claimed domestic industry investments are significant or substantial, including a contextual discussion of the relevant marketplace, *e.g.*, Complainant's foreign investments relative to its domestic industry expenditures and/or the value added to the product from Complainant's activities in the United States; and (4) whether Complainant's asserted domestic industry differs from that of a mere importer. *See id.*

On June 1, 2021, Complainant and the IA filed submissions in response to the Commission's May 18, 2021 Notice.[6] On June 8, 2021, the IA filed a response to Complainant's submission.[7] No other responses were filed.

B. The Asserted Trademarks

The Asserted Trademarks are:

[6] *See* Complainant's Brief to the Commission on Issues under Review (June 1, 2021) (hereinafter, "Complainant's Br."); The Office of Unfair Import Investigations' Responses to the Commission's Questions (June 1, 2021) (hereinafter, "IA's Br.").

[7] *See* Office of Unfair Import Investigations' Reply to Complainant's Brief to the Commission on Issues under Review (June 8, 2021) (hereinafter, "IA's Reply").

Registration No.	Trademark
4,689,651	**Gonal-f RFF RediJect**
1,772,761	**GONAL-F**
3,777,170	
3,389,332	
3,816,320	
1,972,079	**Ovidrel**
3,604,207	**OVIDREL**
3,185,427	

See ID at 3-4 (citing Compl., Exs. 1-8).

C. Domestic Industry Products and Accused Products

The notice of investigation defines the scope of the investigation as "prescription in vitro fertilization drugs, components thereof, and products containing the same labeled, in whole or in part, Gonal-f, Ovidrel, or Ovitrelle." *See* 85 FR at 21268 (Apr. 16, 2020).

The domestic industry products are prescription IVF products sold in the United States under the names Gonal-f or Ovidrel. *See* ID at 4; Compl., ¶ 28. Complainant does not sell its products under the Ovitrelle mark in the United States.

The accused Gray Market IVF Products are gray market IVF products bearing the Asserted Trademarks or marks that are confusingly similar and intended for sale outside of the United States (*e.g.*, Turkey). *See* ID at 4; Compl., ¶¶ 39, 47. Gray market goods are "produced by the owner of the United States trademark or with its consent, but not authorized for sale in the United States.'" *Bourdeau Bros., Inc. v. ITC*, 444 F.3d 1317, 1320 (Fed. Cir. 2006) (citation omitted).

II. LEGAL STANDARDS

A. Standard on Review

Commission Rule 210.45(c) provides that "[o]n review, the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge" and that "[t]he Commission also may make any findings or conclusions that in its judgment are proper based on the record in the proceeding." *See* 19 C.F.R. § 210.45(c). In addition, as explained in *Certain Polyethylene Terephthalate Yarn and Products Containing Same*, "[o]nce the Commission determines to review an initial determination, the Commission reviews the determination under a *de novo* standard." Inv. No. 337-TA-457, Comm'n Op., 2002 WL 1349938, at *5 (June 18, 2002) (citations omitted). This is "consistent with the Administrative Procedure Act which provides that once an initial agency decision is taken up for review, 'the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule.'" *Id.* (citing 5 U.S.C. § 557(b)).

B. Summary Determination Standard

Under Commission Rule 210.18, summary determination "shall be rendered if pleadings and any depositions, answers to interrogatories, and admissions on file, together with the

affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a summary determination as a matter of law." 19 C.F.R. § 210.18(b).

"[I]n deciding a motion for summary judgment, 'the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1377 (Fed. Cir. 2007) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)). "The summary judgment movant has the initial responsibility of identifying the legal basis of its motion, and of pointing to those portions of the record that it believes demonstrate the absence of a genuine issue of material fact." *Novartis Corp, v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)).[8]

C. Violation of Section 337(a)(1)(C)

"[A] violation of section 337 may not be found unless supported by 'reliable, probative, and substantial evidence.'" *Certain Sildenafil or any Pharmaceutically Acceptable Salt Thereof, Such as Sildenafil Citrate and Products Containing Same*, USITC Inv. No. 337-TA-489, Comm'n Op. at 4-5 (July 26, 2004) (citing 5 U.S.C. § 556). Because no respondent appeared and participated in the investigation, section 337(g)(2) governs the Commission's analysis of whether to issue a GEO. *See* 19 U.S.C. § 1337(g)(2) (requiring a violation to be established by

[8] The standard for summary judgment in district courts applies to summary determination at the U.S. International Trade Commission. *See Amgen Inc. v. ITC*, 565 F.3d 846, 849 (Fed. Cir. 2009) (citing *Hazani v. USITC*, 126 F.3d 1473, 1476 (Fed. Cir. 1997)).

"substantial, reliable, and probative evidence" where "no person appears to contest an investigation concerning a violation of the provisions of this section").[9]

Section 337(a)(1)(C) provides that the Commission has authority to investigate and adjudicate unfair trade practices relating to "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation . . . of articles that infringe a valid and enforceable [registered] United States trademark." 19 U.S.C. § 1337(a)(1)(C). Thus, a violation of section 337(a)(1)(C) requires a showing of: (1) importation; (2) infringement of a valid and enforceable registered trademark; and (3) an industry in the United States relating to the articles protected by the asserted trademark. *See* 19 U.S.C. § 1337(a)(1)(C), (a)(2), and (a)(3).

D. Domestic Industry

For claims based on infringement of a registered trademark under 19 U.S.C. § 1337(a)(1)(C), 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). Section 337(a)(3) provides that a domestic "industry . . . shall be considered to exist . . . with respect to the articles protected by the . . . trademark . . ." if there is:

(A) Significant investment in plant and equipment;

[9] The Dissent states that "[g]iven that this is a default case in which no respondent has appeared and the Office of Unfair Import Investigations supports the motion and the ID granting summary determination, no party has raised a dispute as to any material facts." Dissent at 2 n.1. Under section 337(g)(2), however, Complainant bears the burden to establish a violation by "substantial, reliable, and probative evidence." 19 U.S.C. § 1337(g)(2). Moreover, complainant must prove in any section 337 investigation that it has the required domestic industry, and the Commission must make a determination on the issue, regardless of whether respondents are in default. In the absence of sufficient evidence regarding the domestic industry here, we remand the investigation to the ALJ for further proceedings.

(B) Significant employment of labor or capital; or

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

19 U.S.C. § 1337(a)(3). In assessing the significance or substantiality of a complainant's domestic investments, the Commission "place[s] the value of domestic investments in the context of the relevant marketplace, such as by comparing a complainant's domestic expenditures to its foreign expenditures or considering the value added to the product from a complainant's activities in the United States." *See Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op., 2019 WL 5622443, at *12-13 (Oct. 28, 2019) ("*Carburetors*"); *see also Lelo Inc. v. ITC*, 786 F.3d 879, 883 (Fed. Cir. 2015) (requiring "a quantitative analysis" in determining whether a complainant satisfies the domestic industry requirement under section 337(a)(3) and reasoning that "the terms 'significant' and 'substantial' refer to an increase in quantity, or to a benchmark in numbers."). Moreover, section 337 does not protect mere importers. *See, e.g., Schaper Mfg. Co. v. USITC*, 717 F.2d 1368, 1372-73 (Fed. Cir. 1983) ("Congress did not mean to protect American importers (like Schaper) who cause the imported item to be produced for them abroad and engage in relatively small nonpromotional and non-financing activities in this country.").

III. DISCUSSION

The ID grants Complainant's motion for summary determination and finds that a violation of section 337 has occurred. The Commission determined to review the ID's finding that Complainant satisfied the economic prong of the domestic industry requirement. In view of the record before the Commission, including the ID and Complainant's and the IA's submissions in response to the Commission's May 18, 2021 Notice, the Commission has determined that genuine issues of material fact remain as to whether Complainant met the economic prong of the

domestic industry requirement. Therefore, the Commission has determined to vacate in part the ID and to remand the investigation for further proceedings consistent with this opinion.

A. The ID's Findings

The ID determines that Complainant satisfied the economic prong of the domestic industry under subsection 337(a)(3)(C), that is, through "substantial investment in [the] exploitation, including engineering, research and development, or licensing," of the Asserted Trademarks. *See* 19 U.S.C. § 1337(a)(3)(C); ID at 17-19. The ID considers the following investments under subsection 337(a)(3)(C):

Investment	2017	2018	2019[11]	Evidence
"non-promotional education of third-party health care providers on the science of fertility drugs"		[ ]		Compl., Conf. Ex. 66, ¶ 7
"medical grants to support the U.S. IVF Products"				*Id.*
"FDA fees, including New Drug Application maintenance fees to support the U.S. IVF Products.				*Id.*
"quality assurance and other activities"				*Id.* at ¶ 8
"third-party logistics company, to ensure compliance with its quality control program"				*Id.*
Totals				[ ]

See id. at 18.

The ID reasons that "investments in 'functions related to regulatory affairs and quality assurance, scientific affairs, clinical education . . . , research and development, [and] medical and scientific operations" can be considered under subsection 337(a)(3)(C). *Id.* (citing *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Initial Determination, 2004 WL 2330140, at *5-6 (Sept. 23, 2004), *unreviewed by* Comm'n Notice (Oct. 19, 2004)). The ID also notes that

"investments in efforts to seek FDA[10] approval have been considered as part of [section 337(a)(3)(C)]." *See id.* at 18-19 (citing, *inter alia*, *Certain Strontium-Rubidium Radioisotope Infusion Sys. & Components Thereof Including Generators*, Inv. No. 337-TA-1110, Initial Determination, 2019 WL 8752806, at *94-95 (Aug. 1, 2019), *unreviewed in relevant part by* Comm'n Op., 2019 WL 9596567 (Dec. 11, 2019)).

The ID finds that Complainant's investments are substantial because "[ ] and are significant to EMD Serono's business," at least in part because Complainant's investments are "necessary in order for EMD Serono to sell its IVF products in the United States." *See* ID at 19 (citing Compl. Ex. 66).

B. Submissions on Review

1. Question 1: Where the DI Products Are Manufactured.

Both Complainant and the IA respond that the active pharmaceutical ingredient, the drug product, and the finished DI product are manufactured and packaged outside the United States. *See* Complainant's Br. at 3-4; *accord* IA's Br. at 4-5.

2. Question 2: Whether the Claimed DI Activities Are Properly Credited under Section 337(a)(3)(C).

Complainant identifies five categories of activities that are alleged to be properly credited under subsection 337(a)(3)(C). *See* Complainant's Br. at 8-9. However, the categories of investments set forth in Complainant's brief differ somewhat from those identified in the ID:

Categories Identified in ID	Categories Identified in Complainant's Brief
"non-promotional education of third-party health care providers on the science of fertility drugs"	"Research and development"

[10] "FDA" refers to the U.S. Food and Drug Administration.

Categories Identified in ID	**Categories Identified in Complainant's Brief**
"medical grants to support the U.S. IVF Products"	
"FDA fees, including New Drug Application maintenance fees to support the U.S. IVF Products"	"FDA-related activities (including compliance costs)"
"quality assurance and other activities"	"Quality assurance/control"
"third-party logistics company, to ensure compliance with its quality control program"	
	"Promotion and sales, marketing, and advertising"
	"Product support (including customer education activities, patient assistance programs, and patient injection training)"

Compare ID at 18 *with* Complainant's Br. at 8-9; *see also* Complainant's Br. at 5 ("EMD Serono's substantial investments in the United States include (1) FDA compliance costs; (2) quality control costs, (3) medical grants; (4) labor costs on promotion and sales; and (5) internal program and third-party costs for marketing, advertising, promoting, and providing support."). Complainant cites Commission authority in connection with each category. *See* Complainant's Br. at 8-9. The cited precedent, however, is distinguishable based on the details of the investments and/or the statutory category under which the activities were credited (discussed in more detail below). On reply, the IA supports Complainant's reliance on these additional categories of investments. IA's Reply at 2 (citing *Certain Solid State Storage Drives, Stacked Elecs. Components, & Prod. Containing Same*, Inv. No. 337-TA-1097, Comm'n Op., 2018 WL 4300500, at *13 (June 29, 2018)).

3. Question 3: Whether Complainant's Investments are Significant or Substantial under Section 337(a)(3)(A), (B), or (C), and Contextual Discussion of the Relevant Marketplace.

In response to the Commission's questions, Complainant argues it has established significant or substantial investments under each of subsections 337(a)(3)(A), (B), and (C). *See* Complainant's Br. at 12-19.

a) Subsection 337(a)(3)(A) (Plant & Equipment)

Complainant argues it has made significant investments in plant and equipment in the United States in the form of [ ] for its Rockland, Massachusetts location. Complainant's Br. at 12. Specifically, Complainant contends that it spends approximately [ ] "dedicated just to the IVF Products." *Id.* (citing Compl. Ex. 66, ¶ 6). Complainant offers no contextual analysis through which the Commission might determine the significance of these expenditures, that, on their face, appear minimal given the facts of this investigation.

b) Subsection 337(a)(3)(B) (Employment of Labor or Capital)

Complainant identifies four categories of expenses in support of its purported "significant employment of labor":

Description	2018 Investments	Jan-Oct. 2019 Investments
"non-promotional education of third-party health care providers on the science of fertility drugs"	[ ]	[ ]
"medical grants to support the U.S. IVF Products"	[ ]	[ ]
"promotion of the U.S. IVF Products"	[ ]	[ ]

Description	2018 Investments	Jan-Oct. 2019 Investments
"sales of the U.S. IVF Products"	[ ]	[ ]

Complainant's Br. at 12-13.

c) Subsection 337(a)(3)(C) (Exploitation of the Asserted Trademarks)

In response to Question 3, Complainant appears to claim six categories of investments under subsection 337(a)(3)(C). *See* Complainant's Br. at 14-19. First, as part of "FDA-Related Activities," Complainant identifies expenditures of [ ] for "New Drug Application maintenance fees." *Id.* at 14. Complainant also refers to clinical trials and other regulatory activities, but given these expenses were incurred nearly two decades ago, do not quantify these investments for purposes of the current analysis. *See id.*

Second, Complainant points to expenditures of [ ] towards "quality assurance and other activities." *Id.* at 15 (citing Compl. Ex. 66, ¶ 8). The supporting documentation includes standard operating procedures for, as examples, ensuring temperature controls during transport and proper labeling of the U.S. IVF Products. *See* Compl. Ex. 66, ¶ 8; Compl. Exs. 23-27.

Third, Complainant identifies expenditures of [ ] towards a contract with a [ ]." Complainant's Br. at 15.[11]

Fourth, Complainant offers expenditures of [ ] towards "an array of product support and customer education activities." Complainant's Br. at

[11] Applying the [ ] percent allocation ratio used by Complainant to the asserted "Compliance" expenditures in 2018 results in [ ].

16. As examples, Complainant specifies "an unbranded patient website, a customer call center, patient assistance programs, and patient injection training." *Id.*; *see also* Compl. Ex. 66, ¶¶ 10-11. These expenditures were not credited in the ID.

Fifth, Complainant identifies [ ] towards promotion, and [ ] towards sales of the U.S. IVF Products. Complainant's Br. at 16. The supporting declaration explains the "promotion" costs consist of "[ ]." Compl. Ex. 66, ¶ 9. These expenditures were not credited in the ID.

Sixth, Complainant argues it has engaged in other activities to "improve, develop, or otherwise take advantage of the [Asserted Trademarks]." Complainant's Br. at 16. Complainant does not detail or quantify these activities, apart from asserting it has "buil[t] a portfolio of complementary products and devices to use during a fertility treatment cycle," and pointing to its sales figures.

d) <u>Contextual Analysis</u>

Complainant contends that its domestic industry investments "relative to total sales, are significant and substantial in context," explaining its claimed expenses total [ ].[12] Complainant's Br. at 17. Complainant does not offer any comparison to its foreign expenditures. *Id.* at 17-19. Instead, Complainant argues its domestic activities add value to the U.S. IVF Products insofar as they are "foundational to [Complainant's] ability to maintain customer confidence." *Id.* at 18.

[12] Given the discrepancies between the investments credited by the ID and those discussed in Complainant's Brief, the percent of sales figures also differ.

4. Question 4: Whether the DI Activities Differ from Those of a Mere Importer.

Both Complainant and the IA argue that Complainant's DI activities in the United States are not those of a mere importer. *See* Complainant's Br. at 19-25; IA's Br. at 20-30. Complainant argues that its responses to Questions 2 and 3 show that Complainant has made substantial investments in the United States and that its categories of investment have been recognized as proper investments by the Commission under subsection 337(a)(3)(C). *See* Complainant's Br. at 21-25; *accord* IA's Br. at 24-25. Complainant attempts to distinguish itself from *Schaper*, in which "the entire manufacturing of the toy vehicles occurs in Hong Kong, as does most of the packaging and quality control." *See* Complainant's Br. at 23 (citing *Schaper*, 717 F.2d at 1373). Complainant concedes that the protections of section 337 do not extend to "importers (like Schaper) who cause the imported item to be produced for them abroad and engage in relatively small nonpromotional and non-financing activities in this country—*i.e.*, [the importers in *Schaper*] engage in design and a small amount of inspection and packaging in this country." *Id.* Complainant argues it has "extensive quality controls and standard operating procedures to ensure the quality and traceability of the U.S. IVF Products". *Id.* at 23-24.

Similarly, the IA argues that Complainant's activities are distinct from those of a mere importer. For example, the IA reasons that "Complainant's investments in clinical education and medical research grants related to the domestic industry products do not appear to be activities that a 'mere importer' would engage in." *See* IA's Br. at 21. The IA continues, "Complainant's investments in quality control appear to go beyond the quality control measures taken by other importers, . . . includ[ing] 'Inspection and Disposition of Products, Distribution Management, Management of Shipping Routes, Warehousing, Monitoring of Temperature Sensitive Products During Shipments, and product-specific 'release criteria." *Id.* at 22. In contrast, Complainant

and the IA note that that the "gray market importers perform little or no quality control when importing products." *See id.* at 24; *accord* Complainant's Br. at 22. The IA admits that in determining whether Complainant's activities are those of a mere importer, the Commission considers whether the "investment is commonly made by both importers and domestic manufacturers." *See* IA's Br. at 26; *but see* Complainant's Br. at 24 ("[B]ut for [Complainant's] investments in quality assurance, its IVF Products would not be saleable in the United States."). The IA recommends, however, that the Commission adopt a flexible, case-by-case, approach and consider the activities of the complainant as whole as well as the extent of those activities. *See* IA's Br. at 29-30.

C. Analysis

The Commission has determined to vacate in part the ID and remand the investigation for further proceedings consistent with this opinion. The Commission finds that many of Complainant's investments are those of a mere importer and do not qualify as expenses under section 337(a)(3)(C). The Commission also finds that the ID lacks a meaningful contextual analysis as to the substantiality of Complainant's investments, as required under section 337(a)(3)(C). *See Carburetors*, 2019 WL 5622443, at *12. To the extent some of Complainant's claimed expenses may qualify under section 337(a)(3)(C), and considering the contextual analysis proffered by Complainant on review, the Commission finds that the value of those expenditures in the context of this investigation is not sufficiently substantial to satisfy section 337(a)(3)(C). Thus, the Commission finds that genuine issues of material fact remain in this investigation.

Before addressing Complainant's expenditures in particular, some statutory context is useful. Section 337(a)(3)(C) provides for a domestic industry if a complainant shows

"substantial investment in [the] exploitation [of the asserted marks], including engineering, research and development, or licensing." 19 U.S.C. § 1337(a)(3)(C); *see*, *e.g.*, *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Order No. 17, 2004 WL 2330140, at *6 (Sept. 23, 2004), *unreviewed by* Comm'n Notice (Oct. 19, 2004) (crediting investments in research and development and testing equipment); *Certain Toner Cartridges and Components Thereof*, Inv. No. 337-TA-829, Order No. 24, 2013 WL 1098164, at *3 (Feb. 26, 2013), *unreviewed by* Comm'n Notice (Mar. 27, 2013) (crediting engineering and quality assurance activities in support of manufacturing in the United States). The legislative history of section 337(a)(3)(C) indicates that it was added to allow intellectual property owners (such as universities) to qualify as a domestic industry by relying on licensing and other non-manufacturing activities, such as research and development. *See Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm'n Op., 2009 WL 5134139, at *11 (Dec. 1, 2009) ("*Stringed Instruments*").

The record before the Commission does not demonstrate any recent investments in [ ] during the relevant time, *i.e.*, 2017 through October 2019. We address below the categories credited in the ID, and the additional expenditures put forth in Complainant's Brief.

"*Non-promotional education of third-party health care providers on the science of fertility drugs*" and "*medical grants to support the U.S. IVF Products.*" The Commission has previously indicated that medical education expenses may be credited under appropriate circumstances, but those expenses must at least be "sufficiently related to the domestic industry that [complainant] seeks to protect from unfair imports." *Certain Bone Cements, Components Thereof & Prods. Containing the Same*, Inv. No. 337-TA-1153, Comm'n Op., 2021 WL 287860,

at *15 (Jan. 25, 2021) ("*Bone Cements*"); *see id.* (affirming determination not to credit education expenses absent evidence they were sufficiently related to bone cement products at issue).[13] Complainant's investments in education of health care providers on the science of fertility drugs have an obvious relationship to the domestic industry products, and the ID properly credited those investments.[14] The same cannot be said of Complainant's grants to "Continuing Medical Education providers with respect to fertility issues." Compl. Ex. 66, ¶ 7. The record before the Commission lacks any evidence as to how, if at all, these grants relate to the U.S. IVF Products in particular, and as such, they were not properly credited.[15]

"*FDA fees, including New Drug Application maintenance fees to support the U.S. IVF Products.*" The Commission has in the past credited some FDA-related expenses, such as research and development and salaries for employees in connection with FDA regulatory approval and related compliance activities, depending on the specific facts of those investigations. *See Certain Strontium-Rubidium Radioisotope Infusion Sys. & Components Thereof*, Inv. No. 337-TA-1110, Comm'n Op., 2019 WL 9596567, at *23 (Dec. 11, 2019) ("*Strontium-Rubidium Systems*") (crediting towards section 337(a)(3)(B) the salaries of employees supporting FDA regulatory approval activities); *Certain Salinyomycin Biomass and*

[13] In *Bone Cements*, Chair Kearns stated "[i]n considering whether to credit education and training expenditures toward a domestic industry, Chair Kearns also considers whether they are of the sort that a mere importer would engage in, and whether they are activities that must by their nature be performed in the United States." *Bone Cements*, 2021 WL 287860, at *15 n.28.

[14] Chair Kearns does not credit these investments at this time, as the record is devoid of information regarding whether they are of the sort that a mere importer would engage in and whether they are of a sort that must be performed in the United States.

[15] The Dissent would credit these expenses based on a statement in a supporting declaration that the grants "support the U.S. IVF Products." Dissent at 17 n.17. This conclusory statement, however, is not sufficient to satisfy Complainant's burden, including under section 337(g)(2).

Preparations Containing Same, Inv. No. 337-TA-370, Initial Determination, 1996 WL 1056309, at *157 (Nov. 6, 1995) *unreviewed by,* Comm'n Notice (Feb. 9, 1996) (crediting expenses associated with converting salinyomycin into a useable pharmaceutical product); *Certain Diltiazem Hydrochloride and Diltiazem Preparations Containing Same*, Inv. No. 337-TA-349, Initial Determination, 1995 WL 945191, at *166-68 (Feb. 1, 1995), *unreviewed in relevant part by* Comm'n Notice (Mar. 30, 1995) (crediting expenses associated with converting bulk diltiazem into dosage form).[16] The Commission, however, has never credited bare fees paid to the FDA that any importer would be required to pay in order to sell its products in the United States.[17] Here, the two domestic industry products received FDA approval in 1997 (Gonal-f) and 2000 (Ovidrel Pre-Filled Syringe).[18] *See* Compl., ¶ 14. The only recent FDA-related expenses specifically identified by Complainant are the payment of New Drug Application maintenance fees. In this context, these fees are not properly considered towards a domestic industry under section 337(a)(3)(C).

"*Quality assurance and other activities*" and "*third-party logistics company, to ensure compliance with its quality control program*." In some circumstances, the Commission has

[16] Chair Kearns has noted that "efforts to obtain FDA regulatory approval may not on their own distinguish a complainant's activities from those of an importer." *Strontium-Rubidium Sys.*, 2019 WL 9596567, at *24 n.27; *see also Certain Elec. Nicotine Delivery Sys. & Components Thereof*, Inv. No. 337-TA-1139, Comm'n Op., 2020 WL 4500718, at *6 n.6 (May 5, 2020).

[17] The IA argues that FDA fees are akin to property and payroll taxes, which the Commission has credited in some past cases. IA's Br. at 11-12 (citations omitted). In the cases cited by the IA, however, the Commission credited such taxes as investments in plant and equipment or labor and capital under section 337(a)(3)(A) or (B). Thus, those taxes were directly related to employment of capital and labor. The FDA fees here are akin to taxes that any participant in the market, including a mere importer, would have to pay to sell its products. In addition, these FDA fees do not appear to be related to engineering or research and development under section 337(a)(3)(C).

[18] The FDA granted subsequent new drug approvals for additional categories of Gonal-f, but the latest was in 2004. *See* Compl., Exs. 9, 11.

credited quality control expenses, for example, in connection with some level of domestic production or packaging activity. *See, e.g.*, *Certain Personal Computers & Components Thereof*, Inv. No. 337-TA-140, Comm'n Op., 1984 WL 15659, at *16 (Mar. 9, 1984) (crediting quality control and packaging activities where the complainant also engaged in some domestic production); *Certain Cube Puzzles*, Inv. No. 337-TA-112, Comm'n Op., 1982 WL 974906, at *12-13 & nn.109-13 (Dec. 30, 1982) (finding a domestic industry based in part on extensive packaging, testing operations, and repair in conjunction with the quality control process, as well as the production of molds and efforts to improve design and materials, where production activities in the United States accounted for approximately 50 percent of the end product's value). In most cases, the Commission has declined to credit general quality assurance and logistics activities because these are expenditures "that would be expected of any commercial purchaser." *Bone Cements*, 2021 WL 287860, at *5 (quoting *Certain Toy Vehicles*, Inv. No. 337-TA-122, Comm'n Op., 0082 WL 941575, at *5 (Oct. 1, 1982)). Complainant argues that its activities and expenses in these areas are more extensive than those of the Defaulting Respondents, but that does not change the fundamental nature of the activities.

Complainant also emphasizes that its domestic activities are necessary to ensure the products are stored within the narrow temperature range required by the FDA. Complainant's Br. at 5-6. Complainant cites *Certain Male Prophylactic Devices* for the proposition that "a domestic industry exists when the domestic activities contribute to making a foreign-manufactured article suitable for sale in the United States." Complainant's Br. at 6; *see id.* ("'[I]f the product is not saleable without the domestic activities, this factor supports finding a domestic industry.'") (quoting *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op., 2007 WL 9772268, at *24 (Aug. 1, 2007)). One key difference between *Male*

Prophylactic Devices and this investigation is that in the former, the complainant imported an unfinished product that was subjected to processing and packaging in the U.S. before it could be used by the consumer. *See* 2007 WL 9772268, at *24-25. Here, Complainant imports the final, packaged product in the form it is ultimately provided to the consumer. Moreover, the additional processing of the unfinished products in the U.S. in *Male Prophylactic Devices* was directed to practicing certain claims of an asserted patent. *Id.* at *25. None of Complainant's activities are directly related to the exploitation of the Asserted Trademarks. Ultimately, the fact that the product requires refrigeration does not transform shipping expenses into the type of activities Congress envisioned would constitute a domestic industry under section 337(a)(3)(C).[19]

"Product Support," "*Sales*," and "*Promotion*." The Commission declines Complainant's and the IA's invitation to credit marketing, promotion, and sales expenses in this investigation. The legislative history of section 337(a)(3)(C) expressly states that "[m]arketing and sales in the United States alone would not . . . be sufficient to meet this test." *See Stringed Instruments*, 2009 WL 5134139, at *11 (citing H. Rep. 100-40 at 157 (1987)); *see also id.* (citing S. Rep. 100-71 at 129 (1987)). While some Commission decisions allowed consideration of marketing and sales expenses, the Commission did so in conjunction with crediting more

[19] Neither *Male Prophylactic Devices* nor *Certain Encapsulated Integrated Circuit Devices*, Inv. No. 337-TA-501, Comm'n Op., 2014 WL 12935964 (Apr. 28, 2014) (cited by Complainant for the same point) found a domestic industry under section 337(a)(3)(C).

traditional section 337(a)(3) expenses.[20] No Commission precedent allows Complainant to rely substantially on such promotion, marketing, and sales expenses to satisfy section 337(a)(3).[21]

Complainant points to expenditures relating to "product support (including customer education activities, patient assistance programs, and patient injection training)." *See* Complainant's Br. at 16. The claimed activities include "an unbranded patient website, a customer call center, patient assistance." Compl. Ex. 66, ¶ 10. The specific breakdown of expenses provided in the supporting documentation include entries for marketing samples, demos, online advertising, promotional materials, advisory boards, and speaker programs." *Id.*,

[20] The Dissent states that "[t]he activities asserted disseminate the asserted trademarks and reinforce the connection between the marks and the goods, which constitute an 'exploitation' of the asserted marks within the meaning of section 337(a)(3)(C)." Dissent at 15; *see id.* at 15-16 (citing *Certain Energy Drink Prods.*, Inv. No. 337-TA-678, Initial Determination at 17-18, 2010 WL 1502174 (Mar. 30, 2010) ("*Energy Drink*"); *Certain Ink Markers & Packaging Thereof*, Inv. No. 337-TA-522, Initial Determination at 51-52, 2005 WL 6964314 (July 25, 2005) ("*Ink Markers*")). We note that in both cases there was also domestic production of the goods bearing the asserted marks. *Energy Drink*, 2010 WL 1502174, at *7; *Ink Markers*, 2005 WL 6964314, at *27-28. Moreover, neither Complainant nor the IA made this argument, and accordingly there is no record evidence (or argument) demonstrating that the sales and promotional expenses claimed by Complainants are analogous to those credited in prior cases, or otherwise showing that such expenditures "exploit" the trademark as required to be cognizable under section 337(a)(3)(C). We also note that *Energy Drink* and *Ink Markers* were decided before *Lelo*, *i.e.*, before the Federal Circuit made it clear that section 337(a)(3) requires a quantitative analysis. In light of *Lelo*, the Commission must determine whether expenses are cognizable under section 337(a)(3) because that determination could significantly affect the required contextual or quantitative analysis.

The Dissent also notes that courts often consider advertising expenditures in evaluating the strength of a mark. Dissent at 15 n.14. Again, neither Complainants nor the IA made this argument, and as such, there is no record evidence demonstrating that any of the expenditures in this case are analogous to those considered in the cases cited by the Dissent. Nor does the record contain any evidence or argument demonstrating that expenses relevant to validity should also be cognizable as part of the domestic industry.

[21] Chair Kearns notes that, in his view, it is generally not appropriate to consider such expenses, which are those that would be borne by a mere importer, regardless of what other types of expenses are present.

¶ 11. Complainant also seeks to credit the labor expenses for its internal marketing team and its sales force. Compl. Ex. 66, ¶ 9. In this investigation, the asserted promotion, marketing, and sales expenses are not merely supplementing Complainant's domestic industry investments, but instead represent a substantial portion of those investments.[22]

Even assuming some of Complainant's alleged expenses qualify under section 337(a)(3)(C) (excluding FDA fees, quality assurance, promotion, marketing, and sales expenses), and taking into consideration the nature of the activities and the claims asserted by Complainants in this investigation, the remaining expenses are not "substantial" as required by the statute in the context of total sales, the only quantitative context available on the current record.[23]

The Dissent states that we have engaged in "a line-by-line approach" and that under such approach, "a complainant with a U.S. industry deserving of protection could nonetheless have its domestic activities discounted if, when the activities are individually considered, they are deemed in isolation to be akin to activities of a 'mere importer.'" Dissent at 12. In the analysis above, however, the Commission has assessed the categories of expenses set forth by Complainant itself in its efforts to show satisfaction of the domestic industry requirement. Moreover, the Commission must, as a practical matter, review expenses in some detail to determine whether they are cognizable under section 337(a)(3)(C) or whether they are activities of a mere importer. Consistent with Commission precedent, the Commission does not credit expenses that are not cognizable under section 337(a)(3) or that are not sufficiently related to the

[22] Certain product support activities may be cognizable under section 337(a)(3)(C), but the specific examples provided in the declaration submitted by Complainant appear to be typical advertising and marketing activities.

[23] As discussed *supra* note 13, Chair Kearns does not credit any of the claimed non-promotional education expenses, and therefore finds that credited expenses account for an even lower percentage of total sales.

protected article. *See*, *e.g.*, *Bone Cements*, 2021 WL 287860, at *15 (affirming determination not to credit education expenses absent evidence they were sufficiently related to bone cement products at issue); *see also* 19 U.S.C. § 1337(a)(2) (requiring the domestic industry to "relat[e] to the articles protected by the patent, copyright, trademark, mask work, or design concerned"). This type of analysis, moreover, provides guidance to parties as to which sorts of expenses are cognizable and which are generally not. The Dissent's approach invites parties to assert a broad group of expenses, some of which have generally not been cognizable under section 337(a)(3), and apparently would recognize those expenses in some investigations but not others. This provides much less certainty to parties as to what expenses to rely on and on the Commission's analysis.

Here, the Commission properly declines to credit non-cognizable expenses and determines that Complainant failed to establish substantial activities beyond those of a mere importer. Accordingly, genuine issues or material fact remain as to whether a domestic industry exists in this case.

IV. CONCLUSION

For the foregoing reasons, the Commission has determined that genuine issues of material fact remain as to whether the economic prong of the domestic industry requirement is satisfied in this investigation. Thus, the Commission has determined to vacate in part the ID. Specifically, the Commission vacates the ID's findings as to the issue under review, *i.e.*, the economic prong of the domestic industry requirement. Consequently, the Commission also vacates the ID's finding of a violation of section 337. The Commission has also determined to remand the investigation for further proceedings consistent with this opinion. The Commission has further determined to extend the target date until December 16, 2021.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 28, 2021