PUBLIC VERSION

In the Matter of

CERTAIN IN VITRO FERTILIZATION PRODUCTS, COMPONENTS THEREOF, AND PRODUCTS CONTAINING THE SAME

Inv. No. 337-TA-1196

DISSENTING VIEWS OF COMMISSIONERS SCHMIDTLEIN AND KARPEL

We respectfully dissent from the Majority's decision to vacate the summary determination that the economic prong of the domestic industry requirement is satisfied under section 337(a)(3)(C) related to the complainant's trademark infringement claim. In our view, the ALJ's summary determination should be affirmed on modified grounds. In particular, and as explained below, we do not agree with the Majority's "line-by-line" approach to the "mere importer" test, whereby a complainant's domestic investments are discounted or rejected entirely if, when individually considered, the investments are deemed to be with respect to activities of a "mere importer." Rather, a more consistent interpretation of the applicable statutory provision, legislative history, and relevant caselaw is that determining whether a complainant is a "mere importer" involves consideration of the complainant's domestic activities as a whole. When EMD Serono's activities are considered as a whole, the nature and extent of its activities distinguish it from a mere

importer.[1] Therefore, together with our finding below that investments in these activities are substantial, we would affirm the determination that EMD Serono established the domestic industry requirement under section 337(a)(3)(C) based on substantial, reliable, and probative evidence.

I. PROCEDURAL BACKGROUND

On December 2, 2020, Complainant EMD Serono, Inc. moved for a summary determination of a violation by Respondents FastIVF and Hermes Eczanesi (collectively, "Defaulting Respondents") and requested entry of a general exclusion order ("GEO"). EMD Serono's motion sought a violation determination as to its registered trademark infringement claim under section 337(a)(1)(C) and its unfair competition claims under section 337(a)(1)(A). Prior to moving for summary determination, the Commission found the Defaulting Respondents to be in default for failing to respond to the complaint, notice of investigation, and failing to show cause why they should not be found in default. Order No. 6 (Sept. 1, 2020), *unreviewed by* Comm'n Notice (Sept. 24, 2020). The Defaulting Respondents have therefore waived their right to appear, be served with documents, and to contest the allegations at issue in this Investigation. Accordingly, the Defaulting Respondents have not contested EMD Serono's allegations or evidence that they have

[1] Given 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. *See* OUII Resp. at 14 ("Thus, no party has raised any genuine issue as to any material facts that would prevent the CALJ from granting the MSD."). Under the relevant standard, the movant is entitled to summary determination if there is no genuine issue as to any material fact and the movant is entitled to summary determination as a matter of law. 19 C.F.R. § 210.18 (b) ("The determination sought by the moving party 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."). In this investigation, there is "no genuine issue as to any material fact" and the Majority Opinion does not identify any.

violated section 337 and that a domestic industry exists.[2] The Office of Unfair Import Investigations, which is a party to the investigation, filed a response in support of EMD Serono's motion as to the section 337(a)(1)(C) trademark infringement claims, including supporting the allegation EMD Serono satisfied the domestic industry requirement.

On April 16, 2021, the presiding Chief Administrative Law Judge issued the subject initial determination ("ID") (Order No. 10) granting in part the motion for summary determination of a section 337 violation. Specifically, the Chief ALJ granted the motion with respect to EMD Serono's trademark infringement claim under section 337(a)(1)(C). The Commission determined to review the ID's findings with respect to the economic prong of the domestic industry requirement. No other issues were reviewed by the Commission.

Because no respondent appeared and participated in the investigation and EMD Serono seeks a GEO, section 337(g)(2) governs the evidentiary standard for this matter. Section 337(g)(2) requires that a violation be established by "substantial, reliable, and probative evidence" where "no person appears to contest an investigation concerning a violation of the provisions of this section" and the complainant seeks a GEO as remedial relief. 19 U.S.C. § 1337(g)(2).

II. EMD SERONO'S ASSERTED DOMESTIC ACTIVITIES

EMD Serono is a biopharmaceutical company located in Rockland, Massachusetts. It provides fertility drugs, therapies, and related services. *See* Compl., ¶ 4. EMD Serono's U.S. administrative, commercial, supply chain, and regulatory activities, among other

[2] Respondent General Plastik Drug Stores was terminated from the investigation based on withdrawal of the complaint due to the inability to serve this respondent with the complainant and notice of investigation. *See* Order No. 8 (Oct. 13, 2020), *unreviewed by* Comm'n Notice (Oct. 26, 2020).

business services, take place in its Rockland, Massachusetts location.[3] Compl. Ex. 66 (Truckenmiller Decl.) at ¶ 6; Ex. B to MSD at ¶ 2. The domestic industry articles, which are manufactured outside the United States, are prescription IVF products sold in the United States under the names Gonal-f or Ovidrel. *See* ID at 4; Compl., ¶ 28. The record reflects that the domestic industry products display one or more of the asserted trademarks on the product carton, product label, and other packaging or informational materials that may accompany the products, such as instructions for use. *See id*., ¶ 23. Historically, EMD Serono assisted in developing the products, conducted clinical trials, and gathered, analyzed, and reported relevant clinical trial data to the FDA. *Id*., ¶ 32.; Ex. 66 (Truckenmiller Decl.) at ¶ 7. In seeking FDA approval for each of the products, EMD Serono incurred the associated expenses to establish the safety and efficacy of the products. *Id.* More recently, EMD Serono has expenditures in the United States on FDA fees, including New Drug Application maintenance fees related to the domestic industry products.

The domestic industry products are temperature-sensitive, and thus require refrigeration and handling protocols. *See id*., ¶ 34. Failure to meet those protocols can compromise the safety and efficacy of the drug. *Id.; see* MSD at 3. EMD Serono developed and implements extensive protocols to ensure its products' quality and to comply with FDA requirements. Compl. Ex. 24 at 5; Compl. Ex. 66 (Truckenmiller Decl.) at ¶ 8. In addition, EMD Serono has developed a portfolio of educational tools and support programs for physicians and patients on the science of fertility drugs and the domestic industry products,

[3] The record shows that EMD Serono dedicates [ ] Rockland, Massachusetts facility to the domestic industry products.

including a patient call center, in-person patient injection training, product websites, information guides, patient brochures and instructional videos as to how to safely inject the products. Compl., ¶ 23; Compl. Ex. 66 (Truckenmiller Decl.) at ¶¶ 7, 10. EMD Serono has also made investments in medical grants to support the domestic industry products. Compl. Ex. 66 (Truckenmiller Decl.) at ¶ 7. EMD Serono also invests in labor for the promotion and sales of the domestic industry products. *Id*. at ¶ 9. EMD Serono alleges that through its activities relating to the DI products, U.S. customers have come to recognize the registered marks and it has acquired a valuable reputation and goodwill in its registered marks among the U.S. public as a result of such consumer association. Compl. ¶ 23.

In its motion for summary determination, EMD Serono asserts investments associated with eight discrete activities during 2018-2019, which are summarized in the following table.[4]

Activity	**2018**	**2019**	**Total**
(1) Non-promotional physician education	[ ]	[ ]	[ ]
(2) Medical grants	[ ]	[ ]	[ ]
(3) FDA fees	[ ]	[ ]	[ ]

[4] EMD Serono also asserts the same categories of investments for 2017 in its complaint. *See* Compl. Ex. 66 (Truckenmiller Decl.) at ¶ ¶7-11. However, the investments for 2017 do not appear to be asserted in the motion for summary determination. *See* MSD at 18-20 (applying [ ] asserted investments to account for fact that domestic industry articles Gonal-f and Ovidrel account for [ ] of EMD Serono's U.S. IVF products; no allocation was applied to 2017 investments asserted in the complaint); *see* Ex. B to MSD at ¶ 4. The ID reproduces a summary table from OUII's response to the motion, which includes the 2017 investments together with the 2018 and 2019 investments and notes the [ ]. *See* ID at 18 & n.5. Notably, OUII's summary table omits line items (6) through (8) that were claimed as investments toward domestic industry in EMD Serono's motion.

Activity	2018	2019	Total
(4) Quality assurance	[ ]	[ ]	[ ]
(5) Compliance with quality control[5]	[ ]	[ ]	[ ]
(6) Promotion	[ ]	[ ]	[ ]
(7) Sales and marketing	[ ]	[ ]	[ ]
(8) Product support and patient assistance	[ ]	[ ]	[ ]
Total Investments[6]	[ ]	[ ]	[ ]

See MSD at 17-21 (citing Declaration of Robert Truckenmiller); Complainant's Br. at 17. EMD Serono alleges in its motion that based on these investments it has proven a domestic industry exists under section 337(a)(3), subparagraphs (A), (B), and (C). *See* MSD at 17-21. The ID credited the first five activities, but it did not consider promotion, sales and marketing, or product support and patient assistance activities. *See* ID at 17-19. The ID concluded that EMD Serono satisfied the domestic industry requirement under section 337(a)(3)(C), and it did not reach EMD Serono's arguments concerning subparagraphs (A) and (B). *Id.* at 19 n.6.

III. DISCUSSION

A. Determining Whether a Complainant is Merely an Importer Involves Consideration of the Domestic Activities as a Whole

To prevail at the Commission for a claim based on infringement of a registered trademark, amongst other things, a complainant must show that it has a domestic industry related to the articles protected by the trademark:

[5] For 2018, EMD Serono's brief appears to contain a computational error of roughly [ ]. This amount is not material to the analysis.

[6] EMD Serono's brief appears to contain computational errors for 2018 and 2019. The discrepancies are not material to the analysis.

> (2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.

19 U.S.C. § 1337(a)(2). Paragraph (3) explains how a complainant may satisfy paragraph (2):

> (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.

Id. at § 1337(a)(3). Paragraph (3) was added to the statute in 1988, in part, "to strengthen the effectiveness of section 337 in addressing the growing problems being faced by U.S. companies from the importation of articles which infringe U.S. intellectual property rights." H.R. REP. No. 100-40, at 155-56 (1987).

Under the pre-1988 version of the statute, the Federal Circuit held that Congress did not intend to protect mere importers under section 337. *Schaper Mfg. Co. v. U.S. Int'l Trade Comm'n*, 717 F.2d 1368, 1373 (Fed. Cir. 1983). This principle still holds true under

the current version of the statute.[7] *See, e.g.*, *Certain Electronic Candle Products and Components Thereof*, Inv. No. 337-TA-1195, Comm'n Op. at 8 (Sept. 13, 2021) (explaining that under the post-1988 version of the statute "Congress did not intend to protect mere importers under section 337"). Accordingly, if the complainant is simply an importer, and nothing more, it cannot establish the domestic industry requirement.

Based on the principle articulated in *Schaper*, the Commission has considered whether a complainant is a "mere importer" in situations where complainant's domestic industry products are made overseas and imported into the United States, and the

[7] Although the legislative history associated with the 1988 amendments to section 337 rejected the "inconsistent and unduly narrow" view of domestic industry reflected in certain pre-1988 Commission decisions, specifically citing the Commission's decision in *Certain Miniature, Battery-Operated, All Terrain, Wheeled Vehicles*, Inv. No. 337-TA-122 that was affirmed by the Federal Circuit in *Schaper*, there is no dispute that the 1988 amendments did not reject the principle that section 337 does not protect mere importers. *See* H.R. REP. No. 99-581, at 112 (1986); H.R. REP. No. 100-40, at 157; *see also Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing the Same*, Inv. No. 337-TA-1097, Commission Op. at 9, n.6 (June 29, 2018). Except to the extent noted in footnote 10, there is no need at this time to decide, and we do not decide at this time, what specific aspects of *Wheeled Vehicles* and *Schaper* may have been superseded by the 1988 amendments. It is sufficient to simply conclude that even after the 1988 amendments to the domestic industry requirement, section 337 does not protect mere importers.

complainant otherwise engages in activities in the United States.[8, 9] *See Certain Beverage Dispensing Systems and Components Thereof*, Inv. No. 337-TA-1130, Comm'n Op. at 20 (Mar. 26, 2020) (affirming the final ID's determination that even though licensee Hopsy imported the domestic industry beer dispensers and beer containers it was not a "mere importer" because it relied on domestic labor for filling and completing the beer containers prior to sale).

The Majority concludes that many of the investments asserted in EMD Serono's motion for summary determination are those of a mere importer. In reaching this conclusion, the Majority adopts the "line-by-line" approach mentioned above to the mere importer test whereby each domestic activity is considered individually to assess whether each activity on its own is the type of activity an importer would perform. Under this approach, for example, a complainant with domestic manufacturing or other operations in the United States would not be allowed to count sales or marketing expenditures or expenditures in other activities that an importer might also engage in – including activities

[8] Commissioner Schmidtlein observes that recently the Commission has expanded the use of the mere importer test to include a line-by-line examination of investments and expenditures in cases where the complainant was not just an importer. *See Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same,* Inv. No. 337-TA-1145, Comm'n Op. at 45, n.32; 51, n.39, n.40 (Jan. 13, 2021) (the majority examined individual categories of investments even though the complainant was not just an importer and had invested billions of dollars in the United States in domestic manufacturing of active pharmaceutical ingredient, R&D, FDA clinical trials and other FDA-related activities, physician education, and sales and marketing activities for the commercialization of the BOTOX product); *Certain Bone Cements and Components Thereof*, Inv. No. 337-TA-1153, Comm'n Op. at 28-34 (Jan. 25, 2021) (examining whether the individual activities of the complainant are akin to a mere importer where the complainant asserted expenditures related to education and training, domestic labor, regulatory activities, and manufacture of components). She believes that the current investigation is the latest example of that trend.

[9] Commissioner Karpel observes that the Commission's recent determination in *Bone Cements* involved trade secret claims under section 337(a)(1)(A). The language pertaining to the domestic industry requirement is different in section 337(a)(1)(A) than in section 337(a)(3), which applies to patent, trademark and other statutory IP claims brought under section 337(a)(1)(B)-(E). Section 337(a)(3) provides for the establishment of a domestic industry based on investments in "(A) plant and equipment;" "(B) labor or capital;" or "(C) substantial investments in [the relevant IP right's] exploitation". Under section 337(a)(3), a complainant must show that its claimed investments are properly categorized as such and that the investments in such activities are "significant" (or "substantial" in the case of (3)(C)). Unlike statutory IP claims subject to section 337(a)(3), section 337(a)(1)(A) does not identify categories of investments that may qualify toward the domestic industry. Rather, as explained in *Bone Cements,* the Commission examines the "nature and significance of complainants' business activities in the United States that relate to complainants' domestic industry products to determine whether there are sufficient qualifying activities to constitute an industry in the United States or whether complainants' activities are those of a mere importer." *Bone Cements,* Comm'n Op. at 22. The Commission's application of this rule to examine one-by-one complainants' activities for which they claimed investments to determine if they constituted qualifying activities, is not unlike the Commission's approach in statutory IP cases to examine each of complainants' claimed activities to determine if they are properly categorized under section 337(a)(3)(A), (B), or (C). In the absence of specific categories of investments that may qualify toward establishing a domestic industry under section 337(a)(1)(A), some analysis is required to determine whether investments in activities asserted by complainant are properly categorized as qualifying investments under section 337(a)(1)(A). The Commission's line-by-line approach in *Bone Cements* was one way to undertake that analysis given the facts of that investigation including the unclear nature of many of complainants' claimed investments; an approach that instead examined complainants' claimed investments in activities as a whole, would not have changed the result in that investigation. Commissioner Karpel disagrees, however, that in examining whether complainants have established a domestic industry in statutory IP investigations under section 337(a)(3), complainants' activities should be assessed line-by-line to determine whether each activity is an activity an importer would also perform (and if so, discredited) and then the remaining activities considered to determine if they properly fall within (A), (B), or (C). This is not what the statute requires. Rather, as explained above, the concept of "mere importer" is applied by examining the nature and extent of complainants' activities as a whole to determine if they are more than a mere importer's involvement with imports to ensure, consistent with Congressional intent and Federal Circuit and Commission precedent, that section 337 protections are not being extended to "mere importers." In addition, complainants must show their investments are properly categorized under (A), (B), or (C) as investments in "plant and equipment;" "labor or capital;" or "exploitation" of the relevant IP right. Commissioner Karpel notes that in *Botulinum Toxins* in determining to credit complainants' expenditures in R&D, the Commission observed that complainants' various activities in R&D were "not the sort of activities that a 'mere importer' would conduct in the United States." *Botulinum Toxins* at 51 n.39. Commissioner Karpel does

in which complainant may engage to a far greater extent than a mere importer – toward demonstrating that its investments are significant or substantial.

Neither the applicable statutory provision nor the Federal Circuit's decision in *Schaper*, however, require or suggest such an approach.[10] Rather, in our view, and similar

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not consider that observation an example of the line-by-line approach taken by the Majority in this investigation, although agrees that considering whether complainants' activities go beyond those of a mere importer is unnecessary in investigations such as *Botulinum Toxins* where complainant had substantial investments in domestic manufacturing.

[10] The Majority rejects EMD Serono's promotion and sales investments on the ground that "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." Majority Op. at 23 (citing *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))). We note that the legislative history does not categorically reject consideration of all marketing and sales activities and investments. Instead, the legislative history indicates that a domestic industry cannot be established based on "marketing and sales in the United States ***alone***." H.R. REP. 100-40 at 157 (emphasis added); S. REP. No. 100-71 at 129 (1987); *see Certain Collapsible Sockets for Mobile Electronic Devices and Components Thereof*, Inv. No. 337-TA-1056, Comm'n Op at 19-20 (July 9, 2018). *See also Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing the Same*, Inv. No. 337-TA-1097, Commission Op. at 22 (June 29, 2018) ("The Commission, however, has stated that '[w]hile marketing and sales activity, alone, may not be sufficient to meet the domestic industry test, those activities may be considered as part of the overall evaluation of whether or not a Complainant meets the economic prong.'") (quoting *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Order No. 24 at 34 (Apr. 21, 2010), *rev 'd on other grounds*, Comm'n Op. at 30-31 (Feb. 17, 2011); S. REP. No. 100-71, at 129 (1987)). This is consistent with the principle that section 337 does not protect mere importers. It also suggests that the Commission should be considering the domestic industry as whole when determining if the complainant is just an importer and that sales and marketing is not a line item that needs to be deducted in every case. We also observe that while the Court in *Schaper* declined to credit advertising and promotion toward establishing a domestic industry, the Court did so in view of its understanding that the domestic industry requirement under the pre-1988 version of the statute required a showing of production in the United States. 171 F.2d at 1372-1373 (declining to consider complainant's investments in advertising and promotion because those activities "cannot be considered part of the production process."). But as the post-1988 amendments and subsequent determinations of the Commission and the Federal Circuit have made clear, production in the United States is no longer required to establish the existence of a domestic industry. *See InterDigital Commc'ns, LLC v. ITC,* 707 F.3d 1295, 1300 (Fed. Cir. 2013).

to OUII's position in its brief to the Commission,[11] consideration of the domestic activities as a whole, as well as the extent of those activities is more consistent with the purpose of the 1988 amendments as reflected in their legislative history. *See* Complainant's Br. at 22-25; IA's Br. at 29-30. The "fundamental purpose" of the 1988 amendments to the domestic industry requirement for IP cases "was to strengthen the effectiveness of section 337 in addressing the growing problems being faced by U.S. companies from the importation of articles which infringe U.S. intellectual property rights." H.R. REP. No. 100-40, at 155; *see also* S. REP. No. 100-71, at 127 (1987). Consideration of the domestic industry as a whole adheres to this purpose by recognizing the marketplace reality of the domestic industry being asserted and avoiding the potential to discount cognizable domestic investments made by a complainant. Under a line-by-line 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." This makes it more difficult and less predictable for complainants with legitimate domestic industries to meet the requirements of section 337 and obtain relief, which we believe is inconsistent with the goal of strengthening section 337's effectiveness. There is nothing in the legislative history that suggests that the Commission should be looking at investments individually and excluding those that are deemed to be akin to an activity an importer would perform. We therefore do not agree with the Majority's adoption of a "line-by-line" approach to the mere importer test.

[11] OUII argues for a flexible, market-oriented approach, favoring a case-by-case determination of "the nature and significance of a complainant's domestic activities in the context of the realities of the marketplace." OUII Br. at 13, n.6; 26-27, 30.

B. EMD Serono is Not a "Mere Importer"

As explained above, EMD Serono is a biopharmaceutical company located in Rockland, Massachusetts. The undisputed record shows that EMD Serono has a domestically-facing business model. It engages in a variety of domestic activities to support the domestic industry articles after they are imported and has invested [ ] of dollars in the United States related to those activities.

Specifically, the record shows that EMD has invested [ ] in domestic educational, regulatory, quality assurance and quality control, promotion, sales and product support and patient assistance activities. As Robert Truckenmiller, EMD Serono's Senior Vice President of U.S. Fertility and Endocrinology, explained, EMD Serono educates third-party health care providers about the science of fertility drugs. Compl., Ex. 66 (Truckenmiller Decl.), ¶ 7. EMD Serono also awards medical grants to independent continuing medical education providers that focus on fertility issues. *Id.* Given the standards governing the U.S. drug supply chain and distribution of temperature-sensitive prescription drugs that require refrigeration and special handling, EMD Serono has made large investments in the United States related to the domestic industry products through sophisticated quality assurance and other related activities.[12] *Id.* at 8. With respect to regulatory activity, EMD Serono has invested [ ] of dollars maintaining FDA approval for the DI products. *Id.* EMD Serono also operates an unbranded patient website,

[12] By contrast, the record reflects that Respondent FastIVF shipped the accused gray market IVF products in a cardboard box with an ice pack. *See* Compl., Conf. Ex. 64, at 25-26. Other record evidence similarly suggests that gray market importers perform little or no quality control when importing IVF products. Compl. Conf. Ex. 55, at 3-5. This evidence suggests that EMD Serono's extensive quality control and other related activities, even if individually considered, are not the type of activities that a mere importer would perform.

a customer call center, patient assistance programs, and patient injection training. Compl., Ex. 66 (Truckenmiller Decl.), ¶ 10. It also invests in labor for the promotion and sale of the domestic industry products, which display one or more of the asserted trademarks. *Id*. at ¶ 9. Taken as a whole, the nature and extent of these activities are not those that a mere importer would perform. We therefore conclude that EMD Serono is not just an importer.

In addition, we find that Complainant's asserted investments can properly be considered under section 337(a)(3)(C). Section 337(a)(3)(C) states that a domestic industry shall be considered to exist if there is in the United States with respect to the domestic industry articles "substantial investment in [the trademark's] exploitation." "'Exploitation' is a generally broad term that encompasses activities such as efforts to improve, develop, or otherwise take advantage of the asserted" IP right. *Certain Integrated Circuit Chips & Prods. Containing the Same*, Inv. No. 337-TA-859, Comm'n Op., 2014 WL 12796437, *22 (Aug. 22, 2014). A complainant can establish the existence of a domestic industry based on the exploitation of registered trademarks in connection with articles protected by those marks, for example, through substantial investments in "advertising, marketing, and promoting" the domestic industry products bearing the registered marks. *See, e.g., Certain Energy Drink Products*, 337-TA-678, Initial Determination, at 17-18 (March 30, 2010), *unreviewed by* Comm'n Notice (May 14, 2010) *see also* 2 *McCarthy on Trademarks and Unfair Competition* § 11:81 (5th ed.) ("Determining the strength of any mark requires weighing circumstantial evidence of advertising, promotion, recognition and any direct evidence of consumer perception, such as by a survey."). The registered trademarks communicate to consumers the quality and consistency of EMD Serono's domestic

industry products.[13] EMD Serono has spent considerable time, money, effort, and resources developing and marketing its U.S. IVF Products in association with its Gonal-f® and Ovidrel® marks and ensuring that such products are safely delivered to its customers. The 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).[14]

Similar activities have been found by the Commission in prior investigations to be investments in the exploitation of a trademark. For example, in *Certain Energy Drink Products*, Inv. No. 337-TA-678, in which complainant Red Bull was seeking to block gray market energy drinks, the Commission found a domestic industry under section 337(a)(3)(C) and credited as an "exploitation" of the asserted registered trademarks the expenditure of substantial sums in domestic quality assurance, advertising, marketing and promotion of Red Bull energy drink products featuring the marks. Initial Determination, at

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[13] *See* 1 *McCarthy on Trademarks and Unfair Competition* § 2:4 (5th ed.) ("An important purpose underlying trademark law is the protection of the trademark owner's investment in the quality of the mark and the quality of the goods or services the mark identifies."); *Certain Cube Puzzles*, Inv. No. 337-TA-112, USITC Pub. No. 1334, Comm'n Op. at 4 (Jan. 1983) ("A trademark indicates origin or ownership, guarantees quality or constancy, and entitles the owner to advertise goods bearing the mark.") & 28 n.109 (crediting "extensive quality control" for products bearing the asserted trademark).

[14] In our view, the strength of the trademark allows the owner to exploit the mark in commerce and both the courts and the Commission regularly consider the amount and manner of advertising as one factor in weighing the mark's strength. *See, e.g., Converse, Inc. v. ITC*, 909 F.3d 1110, 1120 (Fed. Cir. 2018) (explaining that the Federal Circuit considers the amount and manner of advertising, among other factors, in considering the strength of a trademark); *Variety Stores, Inc. v. Wal-Mart Stores, Inc.*, 888 F.3d 651, 663 (4th Cir. 2018) ("We consider many factors to determine a mark's commercial strength [including] . . . advertising expenditures."); *AutoZone, Inc. v. Strick*, 543 F.3d 923, 926-27, 933 (7th Cir. 2008) (concluding that a reasonable juror could find that the AutoZone mark was strong based on its prominent display at more than 3,000 stores and "hundreds of millions of dollars' worth of advertising").

17-18 (March 30, 2010), *unreviewed by* Comm'n Notice (May 14, 2010). Similarly, in *Certain Ink Markers and Packaging Thereof,* Inv. 337-TA-522, the Commission found that "Sanford ***exploits*** the trademarks [under section 337(a)(3)(C)] through various advertising campaigns which include the SHARPIE® internet website, numerous television advertisements, and product give-a-ways." Initial Determination, at 51-52 (July 25, 2005) (emphasis added), *unreviewed by* Comm'n Notice (Sept. 8, 2005).[15]

Further, the ID correctly concluded that "the investments in quality control, medical studies, and FDA fees are necessary for EMD Serono to sell its IVF products in the United States." ID at 19 (citing Compl. Ex. 66 at ¶¶ 7-8). The asserted investments reflect expenditures that enable EMD Serono to market the domestic industry products in the United States,[16] ensure the products are safely delivered for injection in U.S. customers, and reinforce the connection between the trademarks and the goods and the value associated with those trademarks. We, therefore, find that the asserted investments

[15] While *Certain Energy Drink Products* and *Certain Ink Markers* did involve the domestic production of the goods bearing the asserted marks, we observe that production in the United States is not required to establish the existence of a domestic industry. *See InterDigital*, 707 F.3d at 1300; H.R. Rep. 100-40 at 157 ("This definition does not require actual production of the article in the United States if it can be demonstrated that significant investment and activities of the type enumerated are taking place in the United States."). Further, the fact that there was domestic production at issue in *Certain Energy Drink Products* and *Certain Ink Markers* does not discount the findings made by the Commission in those cases that investments in quality assurance, advertising, marketing, and promoting the domestic industry products bearing the marks constituted exploitation of the marks under section 337(a)(3)(C).

[16] In our view, the FDA-related fees should be counted since they are necessary to allow EMD Serono to exploit its registered trademarks in the United States. *See* OUII Br. at 12.

constitute "exploitation" of the asserted marks.[17]

We observe that the Commission has previously considered quality control, FDA-related expenditures, and training expenditures to constitute qualifying investments under section 337(a)(3)(A) and (B) in patent cases. *See, e.g., Certain Sleep-Disordered Breathing Treatment Systems & Components Thereof*, Inv. No. 337-TA-890, ID at 168 (Sept. 16, 2014), *unreviewed in relevant part by* Comm'n Notice (Oct. 16, 2014) (in a patent-based investigation, crediting investments providing for a clinical education group to train medical providers how to "configure ResMed devices and select appropriate masks for patients"); *Certain Road Milling Machines*, Inv. No. 337-TA-1067, ID at 429-34 (Oct. 31, 2018), *unreviewed in relevant part by* Comm'n Notice (Apr. 17, 2019) (in a patent-based investigation, crediting investments oriented to instructing customers on how to use the domestic industry products); *Certain Strontium-Rubidium Radioisotope Infusion Sys. and Components Thereof Including Generators*, Inv. No. 337-TA-1110, ID at 140-43 (Aug. 13, 2019) (crediting labor expenditures of employees who worked on the FDA approval process and explaining that efforts to obtain FDA approval were "*central to enabling exploitation*" of the asserted IP) (emphasis added), *aff'd* Comm'n Op. at 40-42 (Dec. 11, 2019).

Further, quality control activities have been found to constitute an industry in the

[17] The Majority declines to credit EMD Serono's investments in medical grants because they conclude the record lacks any evidence as to how the grants relate to the U.S. IVF Products. However, the Truckenmiller Declaration states that the asserted investments in medical grants reflect amounts spent "to support the U.S. IVF Products." Compl. Ex. 66 (Truckenmiller Decl.) at ¶ 8. EMD Serono then applies an [ ] to the medical grant investments to account for fact that domestic industry articles sold under the Gonal-f® and Ovidrel® marks account for [ ] of sales of EMD Serono's U.S. IVF products. MSD at 19. We therefore find that EMD Serono has established that the medical grants relate to the domestic industry products.

United States under the pre-1988 version of the statute in an investigation involving trademark infringement, which is consistent with our approach in the current investigation. *See Certain Cube Puzzles*, Inv. No. 337-TA-112, USITC Pub. No. 1334, Comm'n Op. at 26-30 (Jan. 1983) (finding that quality control activities involving imported cube puzzles, in connection with other ancillary activities, constituted a domestic industry).

In sum, because we conclude that EMD Serono is not just an importer, and the investments asserted are cognizable under section 337(a)(3)(C), we find that all of the activities EMD Serono asserts should be credited. Having determined to credit activities (1) through (8), we next consider whether the investments are substantial.

B. EMD Serono's Investments are Substantial

We find that the investments made related to activities (1) through (8) are quantitatively substantial in the context of record evidence as to the magnitude of the investments and the size of EMD Serono's fertility business in the United States. EMD Serono's total [ ]. *See* Compl. Ex. 66 (Truckenmiller Decl.) at ¶ 4. [

]. *See* 19 U.S.C. § 1337(a)(3) ("an industry in the United States shall be considered to exist" if the complainant introduces evidence of significant or substantial investment). The investments are qualitatively substantial in view of the contribution the activities make to enhance the value of the Gonal-f ® and Ovidrel ® marks and the association of those marks with EMD Sorono's DI fertility drugs.

IV. CONCLUSION

For the reasons explained above, we would affirm on modified grounds the ALJ's summary determination that EMD Serono established based on substantial, reliable, and probative evidence the existence of a domestic industry under section 337(a)(3)(C). Given this conclusion and the Commission's decision not to review the other violation findings related to the trademark infringement claim, we would find a violation of section 337 based on trademark infringement.