**PUBLIC VERSION**

**UNITED STATES INTERNATIONAL TRADE COMMISSION**

**Washington, D.C.**

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| **In the Matter of**<br><br>**CERTAIN PRODUCTS CONTAINING TIRZEPATIDE & PRODUCTS PURPORTING TO CONTAIN TIRZEPATIDE** | **Inv. No. 337-TA-1377** |

**ORDER NO. 26: INITIAL DETERMINATION GRANTING-IN-PART SUMMARY DETERMINATION ON VIOLATION OF SECTION 337; PRELIMINARY RECOMMENDED DETERMINATION ON REMEDY AND BOND**

Administrative Law Judge Monica Bhattacharyya

(December 6, 2024)

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## I. INTRODUCTION

On July 12, 2024, complainant Eli Lilly and Company ("Lilly") moved for summary determination of violation (Mot. No. 1377-016, EDIS Doc ID 825878 ("Lilly Br.")) by Respondents Audrey Beauty Co. ("Audrey Beauty"), Biolabshop Limited ("Biolabshop"), Mew Mews Company Limited ("Mew Mews"), Strate Labs LLC ("Strate Labs"), Super Human Store ("SHS"), Triggered Supplements LLC (d/b/a The Triggered Brand) ("Triggered Brand"), Paradigm RE LLC (d/b/a Paradigm Peptides) ("Paradigm Peptides"), Fibonacci Sequence LLC (d/b/a GenX Peptides) ("GenX Peptides"), Total Compounding Pharmaceuticals ("Total Compounding"), Xiamen Austronext Trading Co., Ltd. (d/b/a AustroPeptide) ("AustroPeptide"), and Arctic Peptides LLC ("Arctic Peptides") (collectively, "Respondents") for trademark infringement, false designations of origin, and/or false and misleading advertising. Lilly Br. at 1. On July 30, 2024, the Commission Investigative Staff ("Staff") filed a response, supporting the motion in part ("Staff Br.").[1] EDIS Doc. ID 827644. On August 9, 2024, Lilly filed a reply ("Lilly Reply").[2] EDIS Doc. ID 829168. On August 15, 2024, Staff filed a sur-reply ("Staff Sur-Reply"). EDIS Doc. ID 829661. No other responses were filed.

For the reasons set forth below, the motion for summary determination on violation is GRANTED-IN-PART. Further, based on the findings of violation herein, the undersigned recommends issuance of a general exclusion order based on Lilly's trademark infringement and false designation of source claims, certain limited exclusion orders based on Lilly's false

[1] On July 23, 2024, the undersigned granted Staff's motion for an extension of time to respond to Lilly's motion. See Order No. 20 (July 23, 2024).

[2] On August 6, 2024, the undersigned granted Lilly's motion for an extension of time to file a reply and permitted Staff to file a sur-reply.

advertising claims, certain cease and desist orders, and a bond of 100 percent of entered value during the Presidential review period.[3]

### A. Procedural History

On October 19, 2023, Lilly 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 products containing tirzepatide and products purporting to contain tirzepatide by reason of trademark infringement, false designation of origin, and false and misleading advertising. 88 Fed. Reg. 82914 (Nov. 27, 2023) ("Notice of Investigation"). A supplement to the Complaint was filed on November 10, 2023. *Id*. The investigation was instituted upon publication of the Commission's Notice of Investigation in the *Federal Register* on November 27, 2023. *Id*. The Notice of Investigation named 11 entities as Respondents. *Id*. The Office of Unfair Import Investigation was also named as a party to the Investigation. *Id.*

On March 7, 2024, the undersigned granted Lilly's motion to terminate the investigation in part by withdrawing the Complaint as to respondents Unewlife, Supopeptide, and Steroide Kaufen, who Lilly represented were unable to be served with the Complaint and Notice of Investigation. *See* Order No. 8 (March 7, 2024), *unreviewed by* Comm'n Notice (March 21, 2024).

On March 26, 2024, in response to a corrected motion filed by Lilly (Mot. No. 1377-004), and pursuant to Commission Rule 210.16, the undersigned issued a "show cause" order

[3] The undersigned will request, by separate Order, the parties' positions as to whether further proceedings are warranted as to issues where summary determination was not granted. To the extent additional evidence is introduced, it is possible that the recommended determination on remedy will need to be updated.

requiring Respondents Arctic Peptides, Audrey Beauty, Biolabshop, Mew Mews, Strate Labs, SHS, Triggered Brand, and AustroPeptide to show why they should not be found in default for failure to respond to the Complaint and Notice of Investigation. *See* Order No. 10 (March 26, 2024). Because these Respondents did not respond to the show cause order and did not respond to the Complaint and Notice of Investigation, the undersigned issued an initial determination on April 22, 2024, finding these Respondents in default. *See* Order No. 13 (April 22, 2024), *unreviewed by* Comm'n Notice (May 15, 2024).

On March 15, 2024, Lilly moved to amend its complaint to add four additional Respondents: Total Compounding, GenX Peptides, Singularity Marketing Limited (d/b/a Swiss Chems) ("Swiss Chems"), and Paradigm Peptides. Mot. No. 1377-005, EDIS Doc ID 816239 (Mar. 15, 2024). On April 22, 2024, the undersigned granted the motion as to GenX Peptides and Paradigm Peptides, but denied the motion without prejudice as to Total Compounding and Swiss Chems. *See* Order No. 12 (April 22, 2024) ), *unreviewed by* Comm'n Notice (May 21, 2024).

On May 15, the undersigned granted Lilly's motion for alternative service for Total Compounding. *See* Order No. 14 (May 13, 2024). On May 17, the undersigned granted Lilly's motion to make a second amendment to the Complaint and Notice of Investigation to add Total Compounding. See Order No. 16 (May 8, 2024), *unreviewed by* Comm'n Notice (June 13, 2024). This second amended complaint ("Second Am. Compl.") is the operative complaint in this investigation.

On August 7, 2024, in response to a motion filed by Lilly (Mot. No. 1377-014), and pursuant to Commission Rule 210.16, the undersigned issued a show cause order requiring Respondent GenX Peptides to show why it should not be found in default for failure to respond to the Complaint and Notice of Investigation. *See* Order No. 22 (August 7, 2024). Lilly's motion

for a show cause order was denied as to Total Compounding and Paradigm Peptides because Lilly had not shown that service had been effected on either Respondent. *Id*. Because GenX Peptides did not respond to the show cause order and did not respond to the Complaint and Notice of Investigation, the undersigned issued an initial determination on August 27, 2024, finding GenX Peptides in default. *See* Order No. 23 (August 27, 2024), *unreviewed by* Comm'n Notice (October 16, 2024).

As detailed *supra*, Lilly moved for summary determination on July 12, 2024. Briefing was complete by August 15, 2024.[4]

On October 18, 2024, the undersigned extended the target date by approximately four weeks to March 25, 2025. Order No. 24 (October 18, 2024). On November 14, 2024, the undersigned extended the target date by two weeks to April 8, 2025. Order No. 25 (November 14, 2024).

### B. The Private Parties

#### 1. The Moving Complainant

Lilly is a global pharmaceutical company incorporated and headquartered in Indiana. Second Am. Compl. at ¶ 21.

#### 2. The Defaulting Respondents

As discussed in Section I.A *supra*, each of the following Respondents have been found in default and are referenced as the "Defaulting Respondents."

[4] The summary determination filing occurred after several extensions of the deadline for this filing. *See generally* Order No. 24.

**a. Audrey Beauty**

According to the Complaint, Audrey Beauty Co., Ltd. is a Chinese business entity with its principal place of business at Flat C 23/F Lucky Plaza, 315-321 Lockhart Road, Wan Chai, Hong Kong, China. Second Am. Compl. ¶ 28.; Ex. 10.[5]

**b. AustroPeptide**

According to the Complaint, Xiamen Austronext Trading Co., Ltd. (d/b/a AustroPeptide) is a Chinese business entity with its principal place of business at Room 3001, No. 5998 Maqing Rd., Haicang District, Xiamen, Fujian, China 361026. Second Am. Compl. at ¶ 38; Exs. 11–12.

**c. Biolabshop**

According to the Complaint, Biolabshop Limited is a UK business entity with its principal place of business at 25 Scotforth Road, Lancaster, PR1 4XX, United Kingdom. Second Am. Compl. at ¶ 42; Ex. 14.

**d. GenX Peptides**

According to the Complaint, Fibonacci Sequence LLC (d/b/a GenX Peptides) is a Texas limited liability company with its principal place of business at 1415 N. Loop W, Houston, Texas 77008. Second Am. Compl. at ¶ 48; Ex. 15 at LILLY_ITC_0002824.

**e. Mew Mews**

According to the Complaint, Mew Mews Company Limited is a Chinese business entity with a principal place of business at RM C1 11/F Blk 1, 152 Tai Pai Road, Golden Dragon IND Ctr., Kwai Chung, New Territories, Hong Kong, China. Second Am. Complaint at ¶ 30, Ex. 24.

[5] Unless otherwise specified, the exhibit numbers referenced in this order refer to the exhibits attached to Lilly's motion for summary determination (Mot. No. 1377-016).

#### f. Strate Labs

According to the Complaint, Strate Labs LLC is a Delaware limited liability company with a principal place of business at 18482 Kuykendahl Road #123, Spring, Texas, 77379-8123. Second Am. Complaint at ¶ 36, Ex. 37 at 1.

#### g. SHS

According to the Complaint, Super Human Store is a Spanish business entity with a principal place of business at Passeig Del Taulat 267, 5O 4A Barcelona 08019, Spain. Second Am. Compl. at ¶ 26, Ex. 20 at 3.

#### h. Triggered Brand

According to the Complaint, Triggered Supplements LLC (d/b/a The Triggered Brand) is a Florida limited lability company with a principal place of business at 1361 S. Martin Luther King Jr. Avenue, Clearwater, Florida 33756. Second Am. Compl.at ¶ 34, Exh. 31 at 1.

#### i. Arctic Peptides

According to the Complaint, Artic Peptides is an Iowa limited liability company with its principal place of business at 2104 NE Oak Drive, Ankeny, Iowa 50021. Second Am. Compl. at ¶ 44, Ex. 58.

### 3. The Terminated Respondents

Apart from the Defaulting Respondents, certain other Respondents in the investigation have been terminated based on withdrawal of the Complaint based on difficulty of service. *See* Order No. 8 (March 7, 2024), *unreviewed by* Comm'n Notice (March 21, 2024).

#### a. Unewlife

According to the Complaint, Unewlife is a Chinese business company with its principal place of business at 371 Little Falls Road, Ste 4, Cedar Grove, NJ 07009. Second Am. Compl. at ¶ 24, Ex. 17.

**b. Supopeptide**

According to the Complaint, Supopeptide is a Chinese business company with its principal place of business at 371 Little Falls Road, Ste 4, Cedar Grove, NJ 07009. Second Am. Compl. at ¶ 40, Ex. 48.

**c. Steroide Kaufen**

According to the Complaint, Supopeptide is a Polish business entity with its principal place of business at W. Polna 2017, 15-698 Bialystok, Poland. Second Am. Compl. at ¶ 32, Ex. 27.

**4. Non-Served Respondents**

Under 19 U.S.C. § 1337, a determination of violation requires appropriate notice and opportunity for a hearing. 19 U.S.C. § 1337(c). Lilly has not shown that service has been effected upon Respondents Paradigm Peptides and Total Compounding Pharmaceuticals. *See* Order No. 22 (August 7, 2024). Therefore, on the current record, there is no showing of a violation of section 337 with respect to these Respondents.

**a. Paradigm Peptides**

According to the Complaint, Paradigm RE LLC (d/b/a Paradigm Peptides) is a U.S. business entity with a place of business at 1511 N. Convent Street, Suite 700-156, Bourbonnais, Illinois 60914. Second Am. Compl. at ¶ 50, Exs. 84 at 14, 89C.

**b. Total Compounding Pharmaceuticals**

According to the Complaint, Total Compounding Pharmaceuticals ("TCP" or "Total Compounding") is an Australian business entity that claims to have a place of business at 20 N. Gould Street, Suite R, Sheridan, Wyoming 82801. Second Am. Compl. at ¶ 46, Exh. 71. However, this address appears to belong to a different entity with no ties to TCP. SX-0001C (Email to Lilly Counsel).

### C. The Asserted Trademark

Lilly owns U.S. Trademark Registration No. 6,809,369 for the mark "Mounjaro," a mark that "consists of standard characters, without claim to any particular font style, size, or color." Ex. 24 at Lilly_ITC_0000685–86; Lilly Br. at 5. On November 5, 2019, Lilly filed an intent-to-use application with the United States Patent and Trademark Office ("PTO") to register MOUNJARO as a standard character word mark in connection with "[p]harmaceutical preparations—namely, pharmaceutical preparations for the treatment of . . . diabetes." Lilly Br. at 5; Ex. 24.

### D. The Products at Issue

#### 1. The Accused Products

Lilly alleges that the Respondents import, sell for importation, or sell after importation, into the United States certain products that contain or purport to contain tirzepatide and in connection with which Lilly asserts claims of trademark infringement, false designation of origin, and/or false advertising. Lilly Br. at 14.

#### 2. The Domestic Industry Product

Lilly identifies its MOUNJARO products as the domestic industry products. Lilly Br. at 14. The MOUNJARO trademark is used by Lilly in connection with the sale of its MOUNJARO products containing tirzepatide. *See*, *e.g.*, Second Am. Compl. ¶ 328; Ex. A (Potts Decl.) ¶ 6.

The MOUNJARO products are sold in auto-injector pens in doses ranging from 2.5 mg to 15 mg. Second Am. Compl. ¶ 329; Lilly Br. at 16. Each auto-injector pen is marked with the MOUNJARO mark:


*Id*.

## II. LEGAL STANDARDS

### A. Summary Determination

Commission Rule 210.18 governing summary determination states, in pertinent part:

> 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.

19 C.F.R. § 210.18(b). By analogy to Fed. R. Civ. P. 56 (a), in deciding whether to grant summary determination the evidence "must be viewed in the light most favorable to the party opposing the motion . . . with doubts resolved in favor of the nonmovant." *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (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, if a complainant seeks "immediate entry of relief against the respondent in default," the "facts alleged in the complaint will be presumed to be true with respect to the defaulting respondent."

19 C.F.R. § 210.16(c)(1). However, in order for a general exclusion order to issue, a violation must be proven by substantial, reliable, and probative evidence. *See* 19 C.F.R. § 210.16(c)(2); *Certain LED Lighting Devices and Components Thereof*, Inv. No. 337-TA-1107, Comm'n Op., 2019 WL 9596566, at *4 (Sept. 11, 2019).

Here, with respect to its trademark infringement and false designation of origin claims, Complainant seeks a general exclusion order or, in the alternative a limited exclusion order against the relevant Defaulting Respondents and any affiliates, subsidiaries, and assigns. Lilly Br. at 128, 148. With respect to its false advertising claim, Complainant only seeks a limited exclusion order and does not seek a GEO. *See* Lilly Br. at 128 ("***Complainant does not rely on the violation of Section 337(a)(1)(A) based on false advertising to support entry of a GEO***.") (emphasis added); *see also id.* at 148 (requesting an LEO against False Advertising Respondents).

### C. Trademark Infringement

The Lanham Act prohibits the "use in commerce" of

> any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive.

15 U.S.C. § 1114(1)(a). Trademark infringement is recognized as a basis for violation under 19 U.S.C. § 1337(a)(1)(C). To establish trademark infringement, Complainant must show that Complainant owns the asserted trademark; the asserted trademark is valid and legally protectable; and respondents' use of an allegedly similar mark to identify goods and services causes a likelihood of consumer confusion. *See Certain Casual Footwear and Packaging Thereof*, 337-TA-1270, Comm'n Op. at 14 (Oct. 4, 2023) ("*Casual Footwear*") (EDIS Doc. ID 805361) (citing *Converse, Inc. v. Int'l Trade Comm'n*, 909 F.3d 1110, 1116 (Fed. Cir. 2018)).

Likelihood of consumer confusion is assessed using the "DuPont factors" set out in *In re E.I. DuPont DeNemours & Co.*, 476 F.2d 1357 (C.C.P.A. 1973):

> (1) The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression.
>
> (2) The similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use.
>
> (3) The similarity or dissimilarity of established, likely-to-continue trade channels.
>
> (4) The conditions under which and buyers to whom sales are made, i.e. "impulse" vs. careful, sophisticated purchasing.
>
> (5) The fame of the prior mark (sales, advertising, length of use).
>
> (6) The number and nature of similar marks in use on similar goods.
>
> (7) The nature and extent of any actual confusion.
>
> (8) The length of time during and conditions under which there has been concurrent use without evidence of actual confusion.
>
> (9) The variety of goods on which a mark is or is not used (house mark, "family" mark, product mark).
>
> (10) The market interface between applicant and the owner of a prior mark ....
>
> (11) The extent to which applicant has a right to exclude others from use of its mark on its goods.
>
> (12) The extent of potential confusion, i.e., whether de minimis or substantial.
>
> (13) Any other established fact probative of the effect of use.

*Swagway, LLC v. Int'l Trade Comm'n*, 934 F.3d 1332, 1338–39 (Fed. Cir. 2019). "The Commission need not consider every DuPont factor[,] . . . only those factors which are supported by evidence in the record." *Id*. at 1339. The likelihood of confusion analysis is not a simple tally of the DuPont factors as each factor is accorded different weights in different circumstances. *Id.* at 1340. "Consumer survey evidence is not required to show a likelihood of confusion." *Id.* Likelihood of confusion is ultimately a legal conclusion based on factual findings. *Id*. at 1338.

### D. False Designation of Origin

The Lanham Act further prohibits the use in commerce of "any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin . . . 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). To establish such a cause of action, it is also necessary to show likely damage. *See id*; *see generally Meenaxi Enterprise, Inc. v. Coca-Cola Co.*, 38 F.4th 1067, 1074-77 (Fed. Cir. 2022).

With respect to likelihood of confusion, "[t]he factors relevant to establishing false designation of origin . . . are identical to the factors for evaluating likelihood of confusion with respect to trademark infringement (15 U.S.C. § 1114)." *Casual Footwear*, Comm'n Op. at 34 (citing *Ross Bicycles, Inc. v. Cycles USA, Inc.*, 765 F.2d 1502, 1503–04 (11th Cir. 1985)); *see also Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 780 (1992) (Stevens, J., concurring) ("Under the Lanham Act § 43(a), the ultimate test is whether the public is likely to be deceived or confused by the similarity of the marks. . . . Whether we call the violation infringement, unfair competition or false designation of origin, the test is identical—is there a 'likelihood of confusion?'" (quoting *New W. Corp. v. NYM Co. of California*, 595 F.2d 1194, 1201 (9th Cir. 1979)).

### E. False Advertising

A party engages in false advertising if in commercial advertising or promotion, it misrepresents the nature, characteristics, qualities, or geographic origin of its or another's goods, services, or commercial activities and thereby causes or is likely to cause injury to another. 15

U.S.C. § 1125(a)(1)(B). False advertising can constitute the basis of a violation under 19 U.S.C. § 1337(a)(1)(A). *See Certain Raised Garden Beds and Components Thereof*, Inv. No. 337-TA-1334, Comm'n Op. at 20 (EDIS Doc. ID 817237) (March 21, 2024).

The elements of a false advertising claim are:

(1) The respondent made false or misleading statements about their 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 entry of the false advertisement into interstate commerce; and

(5) There is a likelihood of injury to the complainant because of the false statement.

*See Certain Cigarettes and Packaging Thereof*, Inv. No. 337-TA-424, USITC Pub. No. 3366, Initial Determination at 43 (Jun. 22, 2000), *unreviewed*, Comm'n Notice (EDIS Doc. ID 52778) (Aug. 28, 2000).

### F. Domestic Industry

#### 1. Section 337(a)(1)(C)

A violation of section 337(a)(1)(C) 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, the domestic industry requirement of section 337 consists of a "technical prong" and an "economic prong." *See, e.g., Alloc, Inc. v. Intl Trade Comm'n,* 342 F.3d 1361, 1375 (Fed. Cir. 2003); *Certain Stringed Musical Instruments & 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. *John Mezzalingua Assocs., Inc. v. Int'l Trade Comm'n*, 660 F.3d 1322, 1331 (Fed. Cir. 2011).

Where registered trademark rights are asserted, the technical prong can be met through "plain use of the trademark on products and packaging." *Certain Protective Cases & Components Thereof*, Inv. No. 337-TA-780, ID at 90 (EDIS Doc. ID 485078) (June 29, 2012).

With respect to the "economic prong," subsection (3) of Section 337(a) provides:

> 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.

19 U.S.C. § 1337(a)(3).

Expenditures may be counted toward satisfaction of the domestic industry requirement "as long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted IP rights." *Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *36 (Oct. 30, 2015); *accord, e.g., Certain Marine Sonar Imaging Devices, Including Downscan & Sidescan Devices, Prods. Containing the Same, & Components Thereof*, Inv. No. 337-TA-921, Comm'n Op., 2016 WL 10987364, at *40 (Jan. 6, 2016) ("Navico's allocation methodology reasonably approximates the warranty and technical customer support expenditures relating to the LSS-1 product.") (*citing Certain Ground Fault Circuit Interrupters & Prods. Containing Same,* Inv. No. 337-TA-739, Comm'n Op. at 74-75, 79-81 (June 8, 2012)). Subsections (A), (B), and (C) are listed in the disjunctive, and accordingly, the domestic industry investments in plant

and equipment or labor and capital can include expenditures that relate to engineering or research and development. *Certain Solid State Storage Drives, Stacked Electronics Components, & Prods. Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 14 (EDIS Doc. ID 649139) (June 29, 2018) ("[T]he text of the statute, the legislative history, and Commission precedent do not support narrowing subsections (A) and (B) to exclude non-manufacturing activities, such as investments in engineering and research and development.").

Whether a complainant satisfies the economic prong is not analyzed according to a rigid mathematical formula. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (EDIS Doc. ID 279161) (Aug. 1, 2007). The decision is made on a case-by-case basis and requires "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* Although Section 337(a)(3) describes the economic activities as "significant" and "substantial," a complainant does not need to show any "minimum monetary expenditure," and a complainant does not "need to define or quantify the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 26 (EDIS Doc. ID 300615) (May 16, 2008). "A precise accounting [of the complainant's domestic investments] is not necessary, as most people do not document their daily affairs in contemplation of possible litigation." *Id.*

**2. Section 337(a)(1)(A)**

Commission investigations involving false advertising and false designation of origin are assessed under 19 U.S.C. § 1337(a)(1)(A), which declares unlawful:

> Unfair methods of competition and unfair acts in the importation of articles (other than articles provided for in subparagraphs (B), (C), (D), and (E)) into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which 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).

For complaints alleging a violation of section 337(a)(1)(A), the statute requires an "industry in the United States." 19 U.S.C § 1337(a)(1)(A). "[T]here is no bright-line rule for determining whether a domestic industry exists under section 337(a)(1)(A)." *Certain Foodservice Equip. and Components Thereof*, Inv. No. 337-TA-1166, Comm'n Op. at 6 (EDIS Doc. ID 755527) (Oct. 29, 2021). The Commission "has historically considered the 'nature and significance' of the complainant's activities that allegedly form the domestic industry." *Certain Bone Cements and Components Thereof*, Inv. No. 337-TA-1153, Comm'n Op. at 8-9 (EDIS Doc. ID 731649) (Jan. 25, 2021); *see also Schaper Mfg. Co. v. Int'l Trade Comm'n*, 717 F.2d 1368, 1372 (Fed. Cir. 1983) (finding that the "nature and extent" of complainant's activities were insufficient to constitute an industry in the United States). In assessing the existence of a domestic industry, the Commission first considers the nature of the alleged activities in the United States to determine whether they "are of the nature of activities that contribute to an 'industry in the United States' under section 337(a)(1)(A)(i). Then, the Commission considers the extent of the investments in the context of the investigation to determine whether they are sufficient to establish "an industry in the United States." *Foodservice Equip.*, Inv. No. 337- TA-1166, Comm'n Op. at 6-7, 13.

In addition to establishing the existence of an industry in the United States and unfair acts in the importation of articles, "a complainant must show that those unfair acts have substantially injured or threatened to injure the domestic industry." *Bone Cements*, Inv. No. 337-TA-1153, Comm'n Op. at 11; *Certain Rubber Resins and Processes for Mfg. Same,* Inv. No. 337-TA-849,

Comm'n Op. at 10 (EDIS Doc. ID 528759) (Feb. 26, 2014) ("Therefore, there is a requirement not only that the complainant demonstrate the existence of a domestic industry, but also that there be actual substantial injury or the threat of substantial injury to a domestic industry"). Evidence for such injury may include "the volume of imports and their degree of penetration, complainant's lost sales, underselling by respondents, reductions in complainants' declining production, profitability and sales, and harm to complainant's good will or reputation." *Rubber Resins*, Inv. No. 337-TA-849, Comm'n Op. at 60-61.

## III. STATUTORY AUTHORITY AND IMPORTATION

### A. Statutory Authority

The Commission has statutory authority over the present investigation, which includes the authority to investigate a particular respondent's accused articles that are imported into the United States or sold after importation, and the authority to investigate the importation into the United States or the sale of such articles. *See Certain Video Security Equip. and Sys., Related Software, Components Thereof, and Prods. Containing Same*, Inv. No. 337-TA-1281, Comm'n Op. at 9-10 (EDIS Doc. ID 794569) (Apr. 19, 2023); *Certain Portable Battery Jump Starters and Components Thereof (III)*, Inv. No. 337-TA-1360, Comm'n Notice at 3 (EDIS Doc. ID 826741) (July 22, 2024). The Commission likewise has authority to investigate allegations of false advertising based on importation of accused products and injury to a domestic industry where the advertising "was disseminated online and viewed by U.S. customers." *Certain Raised Garden Beds*, Inv. No. 337-TA-1334, Comm'n Op., 2024 WL 1434222, at *10 (Apr. 1, 2024).

### B. Importation

A complainant generally need only prove importation of a single accused product to satisfy the importation element. *Certain Chem. Mech. Planarization Slurries & Components*

*Thereof*, Inv. No. 337-TA-1204, Comm'n Op. at 10 (EDIS Doc. ID 759875) (Jan. 6, 2022); *Certain DC-DC Controllers & Prods. Containing the Same*, Inv. No. 337-TA-698, Order No. 29at 3 (EDIS Doc. ID 428773) (June 18, 2010); *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Order No. 17at 5 (EDIS Doc. ID 215648) (Sept. 23, 2004).[6]

As discussed below, summary determination is warranted with respect to the importation requirement for all Defaulting Respondents except GenX Peptides.

**1. Audrey Beauty and Mew Mews**

According to the complaint and supporting documents, Lilly purchased three 10 mg vials of "Tirzepatide 10mg Mounjaro Raw Powder" from Audrey Beauty through the website https://www.ec21.com. Ex. 10. The packaging of the product received indicates it originated in Hong Kong. Ex. 16 (packaging). The commercial invoice indicates the shipment was exported from Hong Kong by Mew Mews Company Limited. Ex. 17 (commercial invoice).

The evidence shows that Audrey Beauty and Mew Mews meet the importation requirement. *See* Lilly Br. at 33-35; Staff Br. at 25-26.

**2. AustroPeptide**

According to the complaint and supporting documents, Lilly purchased ten 10 mg vials of tirzepatide from AustroPeptide through the website http://austropeptide.com. Ex. 29; Second Am. Compl. at ¶¶ 304–05. The package was received from an address in Linden, New Jersey.

[6] The Commission has further held that in instances with multiple product categories, the importation of a representative product within each product category is sufficient to satisfy the importation requirement for all products in each of the representative categories. *See Certain Elec. Connectors and Cages, Components Thereof, and Prods. Containing the Same*, Inv. No. 337-TA-1241, Comm'n Op. at 10-11 (EDIS Doc. ID 781376) (Sept. 30, 2022) ("In other words, because the parties have treated all of the products within the QSFP 1x1 SMT and OSFP product categories, respectively, the same for purposes of infringement and the Commission has found that at least one product from each product category has been imported, the importation requirement for all products in those categories has been met.") (citing *Certain Chem. Mech. Planarization Slurries*, Comm'n Op. at 10-11).

Ex. 30. The packaging does not identify the sender. *Id.* However, Lilly states that its order from AustroPeptide was the only pending order for ten 10 mg vials of tirzepatide at the time of delivery. Second Am. Compl. at ¶ 304.

Because the products arrived from New Jersey, Lilly relies on other documentary evidence to demonstrate AustroPeptide imports its products into the United States. According to its own website, AustroPeptide has production facilities in in Hong Kong, China, Vietnam, and Europe. Ex. 31; Second Am. Compl. at ¶ 305. Furthermore, AustroPeptide boasts "on time delivery" when "exporting" to the United States:

On time delivery
24/7/360 after sales services for all of our products
Exporting to South America (Brazil, ...) , Australia, Middle East ( , Europe (Austria, Germany, Italy,...), USA, Asia (Vietnam, India, Thailand,...), Africa

Ex. 29 at LILLY_ITC_0001043.

Accordingly, the evidence shows that AustroPeptide meets the importation requirement. *See* Lilly Br. at 35-36; Staff Br. at 26-27.

**3. Biolabshop**

According to the complaint and supporting documents, Lilly purchased six 5 mg vials of tirzepatide from Biolabshop through the website https://biolabshop.eu/. Ex. 32; Second Am. Compl. at ¶ 310. The package was received from an address in Poland. Ex. 33.

The evidence shows that Biolabshop meets the importation requirement. *See* Lilly Br. at 37-38; Staff Br. at 27.

**4. GenX Peptides**

According to the complaint, Lilly purchased six 5 mg vials of tirzepatide from GenX Peptides through the website https://genx.bio/. Exs. 15 (website product info), 34 (website order

receipt); Second Am. Compl. at ¶¶ 317–319. The package was received from an address in Spring, Texas. Ex. 35 (shipping label).

Lilly contends that documents produced by GenX Peptides "confirm[] that the tirzepatide products sold were imported and/or sold for importation into the United States from a business entity in China." Lilly Br. at 39; Lilly Reply at 2–3. Lilly served a subpoena on GenX Peptides seeking, among other things:

> B. Documents sufficient to identify the source or sources of tirzepatide that Fibonacci Sequence LLC sells in any tirzepatide product.
>
> C. Documents sufficient to identify the manufacturer or manufacturers of the API in the tirzepatide products of Fibonacci Sequence LLC.

Lilly Reply, Ex. 1 at 11 (subpoena). Lilly states that GenX Peptides produced a document, the substance of which is reproduced in its entirety here:

Ex. 36; Lilly Br. at 39.

Staff argues that the evidence is insufficient to show the lack of a genuine issue of material fact regarding importation:

> The document itself is not self-explanatory. It is undated. There is nothing on the face of this document indicating who or what entity prepared it or for what reason. There is also no indicia indicating that this is a document prepared and kept in the ordinary course of business.

Staff Br. at 23–29; *see also* Staff Sur-Reply at 2–3.

Lilly argues in reply that "there is no other logical reason for GenX to have provided this information except in response to Lilly's request[s]" B and C above. Lilly Reply at 3. Lilly

argues that Staff does not allege the document is not what it purports to be or that it is inauthentic. *Id.*

Upon consideration of the evidence of record, the undersigned agrees with Staff that summary determination is not warranted. The document relied upon does not appear to be one kept in the ordinary course of business and there is no evidence of record indicating, for example, who provided the information and their relationship with the company. *See* Staff Br. at 23-29; Staff Sur-Reply at 2-3.[7] Accordingly, summary determination regarding importation as to GenX Peptides is denied because Lilly has not shown substantial, reliable, and probative evidence of importation.[8]

**5. Paradigm Peptides**

According to the complaint and supporting documents, Lilly purchased six 5 mg vials of tirzepatide from Paradigm Peptides through the website https://www.paradigmpeptides.com/. Exs. 18, 37; Second Am. Complaint at ¶¶ 320–22. The package was received from an entity named Paradigm RE LLC with an address in Michigan City, Indiana. Ex. 38. The packing slip inside the package indicates Paradigm Peptides and the order number matches the information on the online receipt. *Compare id*. at LILLY_ITC_0002729 *with* Ex. 37 at LILLY_ITC_0002841. An invoice dated December 8, 2022, indicates Paradigm RE LLC purchased 500 units of 5 mg

[7] Moreover, although GenX Peptides appears to be a domestic company, and although Lilly's subpoena sought testimony regarding any documents produced (*see* Lilly Reply Ex. 1), it does not appear that Lilly made efforts to enforce the subpoena or to obtain a declaration from any person with knowledge. The mere fact that GenX Peptides defaulted after being named as a Respondent does not provide substantial, reliable, and probative evidence of importation.

[8] The undersigned notes that, to the extent no additional evidence is introduced, the same conclusion would be reached in a Final ID. However, this issue may be immaterial as any imports by GenX Peptides could still be covered by the recommended GEO for trademark infringement and false designation of origin. *See* Section IVC., V, VIII.A *infra*. Indeed, the fact that GenX Peptides (in addition to all other served Respondents) defaulted is a factor supporting issuance of a GEO.

tirzepatide from a business entity in China. Ex. 39. This indicates Paradigm Peptides imports tirzepatide into the United States.

The evidence shows that Paradigm Peptides meets the importation requirement. *See* Lilly Br. at 40-41; Staff Br. at 29. As discussed *supra*, however, there can be no violation as to Paradigm Peptides because there is insufficient evidence that Paradigm Peptides was properly served. *See* discussion *supra*; Order No. 22.

**6. Strate Labs**

According to the complaint and supporting documents, Lilly purchased three 10 mg of tirzepatide from Strate Labs through the website https://www.stratelabs.com. Ex. 40; Second Am. Compl. at ¶ 302. The package was received from an address in Spring, Texas. Ex. 19 at LILLY_ITC_0001030. The order number on the packing slip matches the order number of the purchase receipt indicating the product was received from Strate Labs. *Compare* Ex. 40 at LILLY_ITC_0001025 *with* Ex. 19 at LILLY_ITC_0001030. The packaging on the products received identify the contents as tirzepatide 10 mg vials produced by Semathin Ltd of Ontario, Canada. Ex. 19 at LILLY_ITC_0001032–33.

The evidence shows that Strate Labs meets the importation requirement. *See* Lilly Br. at 41-43; Staff Br. at 30.

**7. SHS**

According to the complaint and supporting documents, Lilly purchased six 5 mg vials of tirzepatide from SHS through the website https://www.superhumanstore.com/. Ex. 41; Second Am. Compl. at ¶ 292. The package was shipped from an address in Barcelona, Spain, and identifies the contents as a "Vitamin supplement" from Austria. Ex. 20 at LILLY_ITC_0000894, 896.

The evidence shows that SHS meets the importation requirement. *See* Lilly Br. at 43-44; Staff Br. at 30.

**8. Triggered Brand**

According to the complaint and supporting documents, Lilly purchased three 10 mg vials of tirzepatide from Triggered Brand on June 9, 2023, and another three vials on June 14, 2023, through the website https://thetriggeredbrand.store/. Second Am. Complaint at ¶¶ 299–300; Lilly Br. at 44–45. The packages were received from an address in Largo, Florida. Exs. 44, 45. Lilly contacted Triggered Brand through an email to support@triggeredbrand.store inquiring about the source of the tirzepatide. Ex. 46. The response from [redacted] indicated "all of our tirzepatide is from outside the US." *Id*.

The evidence shows that Triggered Brand meets the importation requirement. *See* Lilly Br. at 44-45; Staff Br. at 30.

**9. TCP**

According to the complaint and supporting documents, TCP advertises the sale of tirzepatide through a website, https://www.totalcompoundingpharmaceuticals.com, and flyers. Exs. 47, 48; Second Am. Compl. ¶¶ 315–16. Lilly purchased two 15 mg vials of tirzepatide from TCP. Ex. 49 (order receipt). The package was received in Miami, Florida from an address in Brisbane, Queensland, Australia. Ex. 50.[9]

The evidence shows that TCP meets the importation requirement. *See* Lilly Br. at 31; Staff Br. at 46. As discussed *supra*, however, there can be no finding of violation as to TCP

[9] Exhibit 50 to the present motion is nearly illegible. However, a legible version of the same exhibit was attached to Motion No. 1377-005 as Exhibit 76. EDIS Doc ID 816239 (Mar. 15, 2024).

because there is insufficient evidence that TCP was properly served. *See* discussion *supra*; Order No. 22.

#### 10. Arctic Peptides

According to the complaint and supporting documents, Lilly purchased three 10 mg vials of tirzepatide from Arctic Peptides through the website https://arcticpeptides.com. Ex. 52; Second Am. Compl. at ¶¶ 311–314; Lilly Br. at 47–48. The package was received in Lake Ridge, Virginia from an address in Ankeny, Iowa. Ex. 23. Lilly contacted Artic Peptides through an email to support@arcticpeptides.com inquiring about the source of the tirzepatide. Ex. 7. The response from [redacted] stated "[o]ur peptides, along with every other manufacturer we have ever located are sourced in the China/Hong Kong area." *Id*.

The evidence shows that Arctic Peptides meets the importation requirement. *See* Lilly Br. at 47-48; Staff Br. at 31.

## IV. TRADEMARK INFRINGEMENT

To establish trademark infringement under the Lanham Act, Complainant must show that Complainant owns the asserted trademark; the asserted trademark is valid and legally protectable; and respondents' use of an allegedly similar mark to identify goods or services causes a likelihood of consumer confusion. *Casual Footwear*, Comm'n Op. at 14 (EDIS Doc. ID 805361).

Lilly asserts Accused Products from Audrey Beauty, Mew Mews, Strate Labs, SHS, Triggered Brand, Paradigm Peptides, GenX Peptides, and Total Compounding (collectively, "Trademark Respondents") infringe Lilly's Mounjaro mark under 15 U.S.C. § 1114(1)(a). Lilly Br. at 3, 49. Staff agrees with Lilly that summary determination of trademark infringement is warranted. Staff Br. at 3, 32–80.

As discussed below, Lilly has presented substantial, reliable, and probative evidence to demonstrate it owns a valid and legally protectable the trademark and that use of the Asserted Trademark by Audrey Beauty, Mew Mews, SHS, Triggered Brand, Paradigm Peptides, GenX Peptides, and Total Compounding is likely to cause consumer confusion.[10] The evidence of record is insufficient, however, to show the lack of a genuine issue of material fact as to trademark infringement by Strate Labs.

### A. Trademark Ownership and Validity

Lilly owns U.S. Trademark Registration No. 6,809,369 for the mark "Mounjaro," a mark that "consists of standard characters, without claim to any particular font style, size, or color." Ex. 24 at Lilly_ITC_0000685–86; Lilly Br. at 5. No party challenges Liily's assertion of ownership or validity of the asserted mark. Lilly Br. at 49–50; Staff Br. at 32–33. 15 U.S.C. § 1057(b) provides:

> A certificate of registration of a mark upon the principal register provided by this chapter shall be prima facie evidence of the validity of the registered mark and of the registration of the mark, of the owner's ownership of the mark, and of the owner's exclusive right to use the registered mark in commerce on or in connection with the goods or services specified in the certificate, subject to any conditions or limitations stated in the certificate.

15 U.S.C. § 1057(b). The undersigned finds there is substantial, reliable, and probative evidence that Lilly owns the Asserted Trademark and the registration shows it is *prima facie* valid.

### B. Likelihood of Confusion Factors

Lilly analyzed likelihood of confusion using the following five factors:

(1) the degree of similarity between the Complainant's mark and/or designations and the mark and/or designation used by Respondents;
(2) the strength of the mark and/or designations;
(3) the similarity in the nature and channels of trade of the goods;

[10] As discussed in Section II.B *supra*, Lilly seeks a general exclusion order based on its trademark infringement claims.

(4) the intent of the accused infringer in adopting its mark and/or designation
(5) the presence or absence of similar marks in use with similar goods

Lilly Br. at 20–21 (citing *Swagway, LLC v. Int'l Trade Comm'n*, 934 F.3d 1332, 1338-39 (Fed. Cir. 2019)). At Staff's request, Lilly provided a mapping correlating these factors to the full set of factors set forth in *E.I. DuPont DeMours & Co*., 476 F.2d 1357 (C.C.P.A. 1973)—and recognized in *Swagway*[11]— which Staff represents as follows:

| ***Swagway*/*DuPont* Factors** | **Applicable Section of Complainant's MSD** |
|---|---|
| **Factor 1**: "The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." 934 F.3d at 1338. | **Section VI.A.b.ii**: The Similarity of the Marks Favors Lilly. MSD at 53-56 (discussing similarity in appearance, sound, and connotation) |
| **Factor 2**: "The similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Id*. | **Section VI.A.b.iii**: The Similarity in Goods and Channels of Trade Favors Lilly. MSD at 56-57 (discussing similarity in goods) |
| **Factor 3**: "The similarity or dissimilarity of established, likely-to- continue trade channels." *Id*. | **Section VI.A.b.iii**: The Similarity in Goods and Channels of Trade Favors Lilly. MSD at 57-58 (discussing similarity in channels of trade) |
| **Factor 4**: "The conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." Id. | N/A |
| **Factor 5**: "The fame of the prior mark (sales, advertising, length of use)." *Id*. | **Section VI.A.b.i**: The Mounjaro® Mark Is Strong. MSD at 50-52 (discussing inherent and acquired distinctiveness). |
| **Factor 6**: "The number and nature of similar marks in use on similar goods." *Id*. | **Section VI.A.b.v**: The Lack of Similar Marks in Use on Similar Goods Favors Lilly. MSD 59–60 (discussing lack of similar marks in use on similar goods) |

[11] In *Swagway*, the Federal Circuit identified the *DuPont* factors as the relevant set of factors, but noted that the five factors identified by Lilly, in addition to a sixth factor not identified by Lilly ("the degree of care likely to be exercised by purchasers") were "nearly identical to those outlined in *DuPont*." 934 F.3d at 1339.

| ***Swagway*/*DuPont* Factors** | **Applicable Section of Complainant's MSD** |
|---|---|
| **Factor 7**: "The nature and extent of actual confusion." *Id.* | N/A |
| **Factor 8**: "The length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Id.* | N/A |
| **Factor 9**: "The variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Id*. | ***See* Section VI.A.a**: The Mounjaro® Mark Is Valid and Enforceable by Lilly. MSD at 49-50 (discussing use of Mounjaro® in connection with type 2 diabetes medication).<br>***See also* Section D.2**: The Domestic Industry Products – Lilly's Mounjaro®. MSD at 14-18 (discussing use of Mounjaro® on domestic products)<br>***See also* Section VII.A.**: Technical Prong. MSD at 92- 95 (discussing use of Mounjaro® on products and packaging) |
| **Factor 10**: "The market interface between applicant and the owner of a prior mark." *Id*. at 1339. | N/A |
| **Factor 11**: "The extent to which applicant has a right to exclude others from use of its mark on its goods." *Id*. | ***See* Section VI.A.a**: The Mounjaro® Mark Is Valid and Enforceable by Lilly. MSD at 49-50 (discussing federal registration of Mounjaro®) |
| **Factor 12**: "The extent of potential confusion, i.e., whether de minimis or substantial." *Id*. | ***See* Section VI.A.b.ii**: The Similarity of the Marks Favors Lilly. MSD at 55-56 (discussing supporting survey evidence of substantial confusion) |
| **Factor 13**: "Any other established fact probative of the effect of use." *Id.* | **Section VI.A.b.iv**: The Trademark Respondents' Manifest Bad Intent Favors Lilly. MSD at 58 – 59 (discussing Respondents' bad intent in adopting the mark) |

Staff Br. at 34–36.[12] The table indicates that Lilly believes factors 4, 7, 8, and 10 to be inapplicable to the present analysis. *Id*. Staff agrees that factors 8 and 10 are not applicable to assessing the likelihood of confusion in this investigation but contends that factors 4 and 7 are. *Id*. at 34.

As discussed in Section II.C *supra*, "[t]he Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record." *Swagway*, 934 F.3d at 1339. Because no party has presented evidence or argument concerning factors 8 and 10, those two factors will not be considered in the analysis of the likelihood of confusion. The remaining DuPont Factors are addressed below with respect to each of the Trademark Respondents.

### C. Respondents' Use of Lilly's Trademark

#### 1. SHS

SHS advertises a product on its website titled "Tirzepatide 5 mg GLP-1 receptor agonist obesity, weight loss, diabetes (mounjaro) EU stock." Ex. 56 at LILLY_ITC_0000857.

Lilly argues SHS' "unauthorized use of 'Mounjaro' is likely to confuse consumers and cause them to mistakenly believe that the Unapproved Drug Products derive from the same source as and/or are affiliated with MOUNJARO®." Lilly Br. at 53–55. Staff argues "there is sufficient undisputed substantial, reliable, and probative evidence to find that SHS' use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 56.

For the reasons discussed below, substantial, reliable, and probative evidence shows a likelihood of consumer confusion. Summary determination of trademark infringement is warranted with respect to SHS.

[12] Lilly does not dispute this table in its Reply. *See* Lilly Reply.

### a. DuPont Factor 1

DuPont Factor 1 concerns the "similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." *Swagway*, 934 F.3d at 1338–39. SHS advertises a product on its website titled "Tirzepatide 5 mg GLP-1 receptor agonist obesity, weight loss, diabetes (mounjaro) EU stock."


Ex. 56 at LILLY_ITC_0000857 (excerpt). As shown above the term "mounjaro" is used in the product description on SHS's website. Based on the advertising image, the product is provided in an unmarked vial. Ex. 56 at LILLY_ITC_0000857.

Lilly argues SHS's designation is "not just similar but actually ***identical*** to MOUNJARO® in appearance, sound, and connotation, cutting strongly in favor of a likelihood of confusion." Lilly Br. at 53–54 (emphasis in original). Staff agrees, arguing the use of the same mark "strongly favors a likelihood of confusion." Staff Br. at 51.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 1 weighs in favor of a likelihood of confusion. SHS includes "mounjaro" as part of the product description. Ex. 56 at LILLY_ITC_0000857. Moreover, "mounjaro" is the only identifiable branding included in the title. *See id*. The evidence shows that the use of the term "mounjaro," considered in context, indicates a likelihood of consumer confusion. *See Swagway*, 934 F.3d at 1338–39.

### b. DuPont Factor 2

DuPont Factor 2 concerns the "similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Swagway*, 934 F.3d at 1338–39. Lilly registered Mounjaro in connection with pharmaceutical preparations—namely, pharmaceutical preparations for the treatment of diabetes—and uses the mark in for its tirzepatide product to treat type-2 diabetes. *See* Ex. 24 at Lilly_ITC_0000685–86; Lilly Br. at 5, 13-14. SHS advertises its tirzepatide product in connection with weight loss and diabetes. Ex. 56 at LILLY_ITC_0000857. Lilly argues that SHS sells its product in a dosage that matches one of FDA-approved dosage of Mounjaro. Lilly Br. at 57; Ex. 90 at 2 (Mounjaro is available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg dosages.). Staff agrees that this factor favors a likelihood of confusion. Staff Br. at 51–52.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 2 weighs in favor of a likelihood of confusion. Both Lilly's and SHS's products contain tirzepatide and are marketed for treatment of diabetes.

### c. DuPont Factor 3

DuPont Factor 3 concerns the "similarity or dissimilarity of established, likely-to-continue trade channels." *Swagway*, 934 F.3d at 1338–39. SHS markets and sells its products through online websites. Ex. 56. Lilly argues generally that its marketing of Mounjaro thorough its websites, www.mounjaro. lilly.com and www.lilly.com, targets the same channels and class of consumers as the Trademark Respondents. Lilly Br. at 57–58 (citing Ex. A ¶ 8; Second Am. Compl. ¶¶ 66, 72). Staff states Mounjaro requires a prescription and is purchased through pharmacies—not from Lilly through its websites—arguing this reduces the likelihood of confusion by consumers. Staff Br. at 52.

The evidence of record shows that this factor weighs somewhat against a likelihood of confusion. As Staff notes, Complainant's product requires purchase through prescription whereas the evidence fails to show that this is the case for SHS. *See* Staff Br. at 52; Lilly Br. at 4, 55 (noting that consumers who buy Respondents' products may believe they are getting it "without the required prescription and consultation with a healthcare professional"). Moreover, as courts have recognized, "[t]oday, it would be the rare commercial retailer that did not advertise online, and the shared use of a ubiquitous marketing channel does not shed much light on the likelihood of consumer confusion." *Network Automation, Inc. v. Advanced Sys. Concepts, Inc.*, 638 F.3d 1137, 1151 (9th Cir. 2011). However, this factor does not necessarily determine the analysis. *See* MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 24:53 (5th ed., 2024 update) ("[T]he fact that the marks appear on products sold in different channels of distribution, or at different distribution levels, or in different geographical markets, does not necessarily dictate that confusion is unlikely.").

**d. DuPont Factor 4**

DuPont Factor 4 concerns the "conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." *Swagway*, 934 F.3d at 1338–39. Lilly argues this DuPont factor is not applicable to the analysis. *See* Section IV.B.

Staff argues the significantly higher price point of Mounjaro and Lilly's prominent use of the Mounjaro mark on the label for its products is different from the lower-priced, unlabeled vial sold by SHS, weighing against a likelihood of confusion under DuPont Factor 4. *Id*. at 52–53 (citing *Casual Footwear*, Comm'n Op. at 20). Staff cites documents indicating that SHS's product is $129 per 5 mg vial and provided in a labelled vial. *Id*.; Ex. 56 at

LILLY_ITC_0000857. Lilly sells Mounjaro in packaging displaying the Mounjaro mark priced at $267.27 per dose. Ex. 3 at LILLY_ITC_0000164; Ex. 90 at 1–2.[13]

The present evidence of record shows that DuPont Factor 4 weighs against a likelihood of confusion. The lack of branding on SHS's product and packaging, as shown in SHS's advertising, weighs against a likelihood of confusion among consumers. *See* Ex. 56; *Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."). [14] Moreover, at least for certain customers utilizing a 2.5 or 5 mg dose, Mounjaro is sold at a significantly higher price point. *See* Ex. 90 at 2; Ex. B ¶ 99. In addition, as noted above regarding DuPont Factor 3, the evidence indicates that the conditions under which sales are typically made differ with respect to whether a prescription is required.

**e. DuPont Factor 5**

DuPont Factor 5 concerns the "fame of the prior mark (sales, advertising, length of use)." *Swagway*, 934 F.3d at 1338–39. The evidence shows that the fame of the Mounjaro mark weighs in favor of a likelihood of confusion. According to Lilly's Vice President of Marketing, Janet Potts, Lilly released Mounjaro in 2022, proceeded to advertise and market it extensively, and spent more than $280 million on television and digital advertising in 2023. Ex. A ¶¶ 6–8; Lilly Br. at 51; Ex. 53 (Facebook and Instagram paid influencer posts); Ex. 53 (Facebook and

[13] The list price of Mounjaro is $1,069.08 "per fill" which contains four weekly injections. Ex. B ¶ 99; Ex. 90 at 1–2; Staff Br. at 128. This results in a list price for a single dose of $267.27 ($1,069.08 / 4). The price of Mounjaro does not appear to vary with the dosage, *i.e.*, a 5 mg and 15 mg dose are the same price. Ex. B ¶ 99; Ex. 90 at 1–2 (only noting insurance, eligibility for the Mounjaro Savings Program, and pharmacy charges as affecting the price a patient pays); Staff Br. at 128 n.36.

[14] Both Lilly and Staff appear to agree that buyers take care with these purchases. See Lilly Reply at 6 n.7 (rejecting concept that people "are buying injections on a whim"); Staff Sur-Reply at 4 ("Staff agrees that a buyer of drugs for obesity or diabetes would be a careful purchaser").

Instagram paid influencer posts); Ex. 54 (YouTube video post template). In 2023, Mounjaro sold more than 60 million units generating approximately $4.7 billion in revenue. Ex. A ¶ 9. Lilly argues that the Trademark Respondents seek to exploit the reputation of the Asserted Trademark "by causing consumers to mistakenly believe those products share a source or affiliation" with Mounjaro produced by Lilly. Lilly Br. at 55.

Staff agrees that the fame of the Mounjaro mark "weighs heavily in favor of a likelihood of confusion." Staff Br. at 53–54.

The evidence of record shows no genuine issue of material fact that the level of fame of the Mounjaro mark weighs in favor of a likelihood of confusion.

**f. DuPont Factor 6**

DuPont Factor 6 concerns "[t]he number and nature of similar marks in use on similar goods." *Swagway*, 934 F.3d at 1338–39*; see also Palm Bay Imps., Inc. v. Veuve Clicquot Ponsardin Maison Fondee en 1772*, 396 F.3d 1369, 1373 (Fed. Cir. 2005) ("Evidence of third-party use of similar marks on similar goods is relevant to show that a mark is relatively weak and entitled to only a narrow scope of protection."). Lilly uses the Mounjaro mark in connection with certain of its tirzepatide-containing products, and related advertisements. *See* Lilly Br. at 50–52. Staff states that the use of Mounjaro by Lilly and SHS favors a finding of likelihood of confusion. Staff Br. at 54.

There is no genuine issue of material fact that DuPont Factor 6 weighs in favor of a likelihood of confusion. The evidence indicates that there no other similar marks used on similar goods that would weaken the strength of the Mounjaro trademark. *See* Potts Decl. (Appendix A) ¶ 12; c*f. Palm Bay Imps.*, 396 F.3d at 1374 (finding substantial evidence that the strength of the mark at issue "was not undermined by third-party use").

### g. DuPont Factor 7

DuPont Factor 7 concerns "[t]he nature and extent of actual confusion." *Swagway*, 934 F.3d at 1338–39. Lilly relies on surveys by Dr. Isaacson to demonstrate confusion by consumers. Lilly Br. at 55–56. Dr. Isaacson's surveys show the "[SHS] web page communicates to substantial percentages of survey respondents that the accused product sold on the web page . . . is called Mounjaro, and is the same as Mounjaro." Isaacson Report ¶¶ 79, 81; *see also id*. ¶ 76. Staff credits Dr. Isaacson's survey results as support for a likelihood of confusion, but notes "a substantial number of consumers do not believe the product sold by SHS is made by Complainant." *Id*. at 54; Isaacson Report ¶ 76 (showing only 6% of respondents thought Eli Lilly made the product).[15]

The evidence of record shows that this factor is neutral, as the survey evidence relates to potential confusion (DuPont Factor 12) rather than actual confusion. *See Certain Casual Footwear*, at 22-31 (discussing "actual confusion" separately from survey results); MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32.184 (5th ed., 2024 update) ("Survey Results are Not Evidence of 'Actual Confusion'").

### h. DuPont Factor 8

DuPont Factor 8 concerns "[t]he length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 8, this factor will not be

[15] To show likelihood of confusion, it is sufficient that survey respondents believe the products came from the same source. *See, e.g., Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand Mngmt, Inc*., 618 F.3d 1025, 1036-1038 (9th Cir. 2010) (crediting survey for purposes of denying summary judgment where questions were directed to whether the products at issue "came from the same company").

considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**i. DuPont Factor 9**

DuPont Factor 9 concerns "[t]he variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark for its tirzepatide product to treat diabetes and uses a separate mark—Zepbound—for its tirzepatide product related to weight loss. Lilly Br. at 4–6. Staff argues "SHS's use of the Asserted Trademark, widely known as a diabetes medication, for the incorrect indication (weight loss) in addition to diabetes would tend to slightly favor a finding of a likelihood of confusion or be neutral at best." Staff Br. at 54.

The evidence of record shows that DuPont Factor 9 is neutral. *See Certain Casual Footwear*, Comm'n Op. at 32 (where Complainant does not use asserted mark on a "variety of goods," the factor is neutral).

**j. DuPont Factor 10**

DuPont Factor 10 concerns "[t]he market interface between applicant and the owner of a prior mark." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 10, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

### k. DuPont Factor 11

DuPont Factor 11 concerns "[t]he extent to which applicant has a right to exclude others from use of its mark on its goods." *Swagway*, 934 F.3d at 1338–39. Lilly refers in its briefing to the registration of Mounjaro as evidence to consider for Dupont Factor 11. *See* Section IV.B *supra*; Lilly Br. at 49–50. Staff notes that Lilly has registered a separate mark, Zepbound, in connection to its tirzepatide-based product for weight loss. Staff Br. at 42. Staff argues that this factor is neutral or inapplicable because Lilly "has not presented evidence to show how broadly the right to exclude the use of Mounjaro® should extend." *Id*.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 11 weighs in favor of a likelihood of confusion based on Lilly's possession of a registered mark for diabetes treatment.

### l. DuPont Factor 12

DuPont Factor 12 concerns "[t]he extent of potential confusion, i.e., whether de minimis or substantial." *Swagway*, 934 F.3d at 1338–39. Lilly cites Dr. Isaacson's surveys to argue that there is substantial confusion among survey participants about whether the SHS product is Mounjaro. Lilly Br. at 55–56. Staff argues this DuPont factor only minimally favors a likelihood of confusion because the products themselves sold by SHS are vials that do not have a mark or label. Staff Br. at 55.[16]

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 12 weighs in favor of a likelihood of confusion. The survey evidence (discussed above in connection with DuPont Factor 7) indicates that a substantial portion of survey participants mistakenly believed SHS to be selling Mounjaro based on SHS's website (which the record

[16] Issues regarding the use of unmarked vials are taken into account through DuPont Factor 4.

indicates has been used by SHS for marketing and sales). Isaacson Report ¶¶ 79, 81; *see also id*. ¶ 76 (showing 35.7% "net measure" of respondents stating the product is called Mounjaro).[17] The undersigned credits Dr. Isaacson's survey results as substantial, reliable, and probative evidence of potential confusion by consumers. *See generally J&J Snack Foods Corp. v. McDonald's Corp*., 932 F.2d 1460, 1463-64 (Fed. Cir. 1991) (citing survey finding 30% of respondents were confused in upholding likelihood of confusion); MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32.184 (5th ed., 2024 update) ("While survey percentages demonstrating confusing levels over 50% are almost always viewed by courts as persuasive evidence of likely confusion, figures in the range of 25% to 50% have often been relied upon as support for a finding of a likelihood of confusion."); *see also id.* (noting cases where evidence that 11% or 16% of respondents were likely to be confused constituted an "appreciable" number of customers); *id.* § 32.188 ("Generally, figures in the range of 25% to 50% have been viewed as solid support for a finding of a likelihood of confusion.").

**m. DuPont Factor 13**

DuPont Factor 13 concerns "[a]ny other established fact probative of the effect of use." *Swagway*, 934 F.3d at 1338–39. With respect to all Trademark Respondents, Lilly argues use of the Mounjaro mark, marketing products as suitable for the same or similar purposes as Mounjaro, and selling products in the same dosages as Mounjaro are sufficient to infer intent to benefit from the reputation of the Mounjaro mark. Lilly Br. at 58–59. Staff disagrees that such an

[17] Survey respondents were chosen, among other qualification criteria, on the basis that "they had purchased medication for weight loss or type 2 diabetes in the past 12 months or were likely to purchase such medications in the next 12 months; and that they would consider purchasing such medications online, such as through a website." Issacson Report ¶ 35.

inference is appropriate here, where the Trademark Respondents defaulted before providing and discovery. *See, e.g.*, Staff Br. at 43, 49–50, 55–56.

Lilly cites *Nautilus Group, Inc. v. ICON Health & Fitness, Inc.* for the proposition that:

> The law has long been established that if an infringer "adopts his designation with the intent of deriving benefit from the reputation of the trade-mark or trade name, its intent may be sufficient to justify the inference that there are confusing similarities."

372 F.3d 1330, 1337 (Fed. Cir. 2004) (quoting *Brookfield Commc'ns, Inc. v. W. Coast Ent. Corp.*, 174 F.3d 1036, 1059 (9th Cir. 1999)); Lilly Br. at 58. However, in the same opinion, the Federal Circuit recognized that the Ninth Circuit had "de-emphasized" intent in the likelihood of confusion analysis, giving it "minimal importance" in later cases. *Nautilus*, 372 F.3d at 1337; *Brookfield*, 174 F.3d at 1059 ("[T]his factor is only relevant to the extent that it bears upon the likelihood that consumers will be confused by the alleged infringer's mark (or to the extent that a court wishes to consider it as an equitable consideration)."); *GoTo.com, Inc. v. Walt Disney Co*., 202 F.3d 1199, 1208 (9th Cir. 2000) ("[w]e have previously emphasized the minimal importance of the intent factor").

Based on the record evidence, DuPont Factor 13 carries little weight in the analysis in view of the other evidence relating to the presence or absence of consumer confusion.

**n. Conclusion**

As discussed above, there is substantial, reliable, and probative evidence of likelihood of confusion as to SHS. In particular, Factors 1, 2, 5, 6, 11, and 12 weigh in favor of a likelihood of confusion, Factors 7, 8, 9, 10, and 13 are neutral or are not considered, and Factors 3 and 4 weigh against a likelihood of confusion. Based *inter alia* on the similarity of the marks, the survey evidence, and the lack of dispute, the evidence does not show a genuine issue of material fact as to the likelihood of confusion based on SHS's use of the Mounjaro trademark and

summary determination is warranted. *See Swagway*, 450 F.3d at 1340 ("Our precedent supports the Commission's finding that the strength of the asserted trademark, along with the comparable similarity of the asserted and allegedly infringing marks, can weigh strongly in favor of a likelihood of confusion.").

### 2. TCP[18]

TCP uses the term Mounjaro in its advertisement flyer selling "tirzepatide 15 mg/ml known as (MOUNJARO)." Ex. 48. TCP's website advertises "Tirzepatide 15 mg/ml L-Carnitine" that includes the following description: "Tirzepatide was approved by the FDA on May 13, 2022, under the brand name MOUNJARO by the FDA." Ex. 47 at LILLY_ITC_0002638–39.

Lilly argues TCP's "unauthorized use of 'Mounjaro' is likely to confuse consumers and cause them to mistakenly believe that the Unapproved Drug Products derive from the same source as and/or are affiliated with MOUNJARO®." Lilly Br. at 53–55. Staff argues "there is sufficient undisputed substantial, reliable, and probative evidence to find that TCP's use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 80.

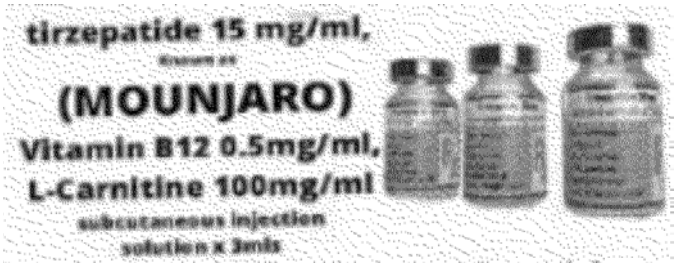
For the reasons discussed below, substantial, reliable, and probative evidence shows that TCP's use of Mounjaro in its advertised goods creates a likelihood of confusion. Summary determination of trademark infringement is warranted with respect to TCP.

#### a. DuPont Factor 1

DuPont Factor 1 concerns the "similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." *Swagway*, 934 F.3d at 1338–

[18] Although there is no violation as to TCP based on lack of proof of service (*see* Section I.B.4), likelihood of confusion is assessed for purposes of the GEO analysis. *See* Section VIII.A *infra*.

39. TCP uses the term Mounjaro as shown in the following excerpt from a TCP advertisement flyer selling "tirzepatide 15 mg/ml known as **(MOUNJARO)**."




Ex. 48 (excerpt).[19] TCP's website advertises "Tirzepatide 15 mg/ml L-Carnitine" that includes the following description: "Tirzepatide was approved by the FDA on May 13, 2022, under the brand name MOUNJARO by the FDA." Ex. 47 at LILLY_ITC_0002638–39.

Lilly argues TCP's designation is "not just similar but actually ***identical*** to MOUNJARO® in appearance, sound, and connotation, cutting strongly in favor of a likelihood of confusion." Lilly Br. at 53–54 (emphasis in original). Staff agrees, arguing the use of the same mark "strongly favors a likelihood of confusion." Staff Br. at 75.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 1 weighs strongly in favor of a likelihood of confusion. TCP includes "MOUNJARO" in a larger font than the surrounding text, bolded, and entirely in capitalized letters. Ex. 48. The inclusion of "known as" immediately before Mounjaro further links the advertised product to Mounjaro. The evidence shows that the use of the term "Mounjaro," considered in context, indicates a likelihood of consumer confusion. *See Swagway*, 934 F.3d at 1338–39.

[19] Exhibit 48 of the present motion is nearly illegible but it appears to be the same document as exhibit 73 attached to Complaint's second amended complaint. EDIS Doc ID 816439 (public version). In that slightly clearer version of the flyer, most of the text can be discerned upon close inspection.

**b. DuPont Factor 2**

DuPont Factor 2 concerns the "similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Swagway*, 934 F.3d at 1338–39. Lilly registered Mounjaro in connection with pharmaceutical preparations—namely, pharmaceutical preparations for the treatment of diabetes—and uses the mark in for its tirzepatide product to treat type-2 diabetes. *See* Ex. 24 at Lilly_ITC_0000685–86; CIB at 13-14. TCP primarily advertises its tirzepatide product in connection with weight loss but also refers to its use for diabetes. Ex. 47 at Lilly_ITC_0002638–39. In addition to noting that TCP also markets a tirzepatide-containing product, Lilly argues that TCP sells its product in a 15 mg dosage, which is also an FDA-approved dosage of Mounjaro. Lilly Br. at 56–57; Ex. 90 at 2 (Mounjaro is available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg dosages.). Staff argues this factor favors a likelihood of confusion. Staff Br. at 51–52.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 2 weighs, on balance, in favor of a likelihood of confusion. Both Lilly's and TCP's products contain tirzepatide. TCP refers to use of tirzepatide for diabetes (although focusing on weight loss). The similarity of the underlying goods and the fact they are both marketed for pharmaceutical-type applications, including diabetes, weighs in favor of a likelihood of confusion.

**c. DuPont Factor 3**

DuPont Factor 3 concerns the "similarity or dissimilarity of established, likely-to-continue trade channels." *Swagway*, 934 F.3d at 1338–39. TCP markets and sells its products through online websites. Ex. 47. Lilly argues generally that its marketing of Mounjaro thorough its websites, www.mounjaro.lilly.com and www.lilly.com, targets the same channels and class of

consumers as the Trademark Respondents. Lilly Br. at 57–58 (citing Ex. A ¶ 8; Second Am. Compl. ¶¶ 66, 72). Staff states Mounjaro requires a prescription and is purchased through pharmacies—not from Lilly through its websites—arguing this does not favor a likelihood of confusion by consumers. Staff Br. at 76.

The evidence of record shows that this factor weighs in favor of a likelihood of confusion as to TCP. As Staff notes, Complainant's product requires purchase through prescription. *See* Staff Br. at 76; Lilly Br. at 4, 55. TCP also appears to require a prescription before it will ship its products. Ex. 47 at LILLY_ITC_0002639 ("How to Order[:] Email us a script with patient's contacts and we will contact the patient for shipping and payment information within an hour, we won't ship without a valid doctor's prescription order."); Ex. 48 ("Fax or Email us a script"). The overlap of trade channels and requirements for prescriptions favors a likelihood of confusion under DuPont Factor 3.

**d. DuPont Factor 4**

DuPont Factor 4 concerns the "conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." *Swagway*, 934 F.3d at 1338–39. Lilly argues this DuPont factor is not applicable to the analysis. *See* Section IV.B.

Staff argues the higher price point of Mounjaro and Lilly's prominent use of the Mounjaro mark on the label for its products weighs against a likelihood of confusion under DuPont Factor 4 when compared to the lower-priced vial with a different label sold by TCP. Staff Br. at 76–77. TCP's product is $250 per 15 mg vial and provided in a labelled vial that does not contain the Mounjaro mark. Ex. 47 at LILLY_ITC_0002638–39; Lilly Br. at 46 ("Lilly

purchased two 15 mg vials of tirzepatide"); Ex. 49 ($500 invoice for order quantity of two).[20] Lilly sells Mounjaro in packaging displaying the Mounjaro Mark priced at $267.27 per dose. *See* Section IV.C.1.d n.13; Ex. 3 at LILLY_ITC_0000164.

The present evidence of record shows that DuPont Factor 4 weighs against a likelihood of confusion. The lack of branding on TCP's product and packaging, as shown in TCP's advertising, weighs against a likelihood of confusion among consumers. *See* Ex. 48; *Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."); Section IV.C.1.d *supra*.

**e. DuPont Factor 5**

DuPont Factor 5 concerns the "fame of the prior mark (sales, advertising, length of use)." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the evidence of record shows no genuine issue of material fact that the level of fame of the Mounjaro mark favors a likelihood of confusion.

**f. DuPont Factor 6**

DuPont Factor 6 concerns "[t]he number and nature of similar marks in use on similar goods." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark in connection with its tirzepatide-containing products, and related advertisements. *See* Lilly Br. at 50–52. TCP uses the Mounjaro mark when advertising its tirzepatide-containing product. Ex. 47 at

[20] Staff states TCP sells its product for $83.33 per 15 mg vial. Staff Br. at 77. This statement appears to be based on the image of three vials shown next to $250 in the TCP flyer ($250 divided by three vials is $83.33). Ex.48. Based on Lilly's statements that it purchased two vials, and supporting receipts showing a $500 price, this indicates TCP's advertised price of $250 refers to a single 15 mg vial. *See* Lilly Br. at 46; Ex. 49; *see also* Staff Br. at 122 (listing TCP's product as "$250 per 15 mg vial"). Even under Staff's larger price differential—which would counsel against a likelihood of confusion—Staff ultimately concludes "there is sufficient undisputed substantial, reliable, and probative evidence to find that TCP's use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 80.

LILLY_ITC_0002638–39. Staff agrees that the use of Mounjaro by Lilly and TCP favors a finding of likelihood of confusion. Staff Br. at 78.

There is no genuine issue of material fact that DuPont Factor 6 weighs in favor of a likelihood of confusion for the same reasons set forth above for SHS.

**g. DuPont Factor 7**

DuPont Factor 7 concerns "[t]he nature and extent of actual confusion." *Swagway*, 934 F.3d at 1338–39. Lilly relies on surveys by Dr. Isaacson to demonstrate confusion by consumers. Lilly Br. at 55–56.

Dr. Isaacson' surveys show the "[TCP] web page communicates to substantial percentages of survey respondents that the accused product sold on the web page . . . is called Mounjaro." Isaacson Report ¶ 82; *see also id*. ¶ 76 (showing 45.0% of respondents stating the product is called Mounjaro). Staff credits Dr. Isaacson's survey results as support for a likelihood of confusion, but notes "a substantial number of consumers do not believe the product sold by TCP is made by Complainant." Staff Br. at 78; Isaacson Report ¶ 76 (showing only 2.9% of respondents thought Eli Lilly made the product).

For the reasons discussed above with respect to SHS, the evidence of record shows that DuPont Factor 7 is neutral with respect to actual confusion. The survey results are discussed below in connection with DuPont Factor 12.

**h. DuPont Factor 8**

DuPont Factor 8 concerns "[t]he length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 8, this factor will not be

considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**i. DuPont Factor 9**

DuPont Factor 9 concerns "[t]he variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark for its tirzepatide product to treat diabetes and uses a separate mark—Zepbound—for its tirzepatide product related to weight loss. Lilly Br. at 4–6. TCP advertises its tirzepatide product using the mark Mounjaro primarily in connection with weight loss. Ex. 47 at LILLY_ITC_0002638–39 ("Tirzepatide for Weight Loss"). Staff argues "TCP's use of the Asserted Trademark, widely known as a diabetes medication, for the incorrect indication (weight loss) in addition to diabetes would tend to slightly favor a finding of a likelihood of confusion or be neutral at best." Staff Br. at 78.

The evidence of record shows that DuPont Factor 9 is neutral for the reasons set forth in Section IV.C.1.i.

**j. DuPont Factor 10**

DuPont Factor 10 concerns "[t]he market interface between applicant and the owner of a prior mark." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 10, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

### k. DuPont Factor 11

DuPont Factor 11 concerns "[t]he extent to which applicant has a right to exclude others from use of its mark on its goods." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the record evidence shows that DuPont Factor 11 weighs in favor of a likelihood of confusion.

### l. DuPont Factor 12

DuPont Factor 12 concerns "[t]he extent of potential confusion, i.e., whether de minimis or substantial." *Swagway*, 934 F.3d at 1338–39. Lilly cites Dr. Isaacson's surveys to argue that there is substantial confusion among survey participants about whether the TCP product is Mounjaro. Lilly Br. at 55–56. Staff argues this DuPont factor only minimally favors a likelihood of confusion because the products themselves sold by TCP are vials that do not have the Mounjaro mark on the label. Staff Br. at 79.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 12 weighs in favor of a likelihood of confusion. The evidence indicates a substantial proportion of survey participants mistakenly believed that TCP was selling Mounjaro based on material which the record indicates has been used by TCP for marketing and sales. *See* Isaacson Report ¶¶ 76, 82.

### m. DuPont Factor 13

DuPont Factor 13 concerns "[a]ny other established fact probative of the effect of use." *Swagway*, 934 F.3d at 1338–39. With respect to all Trademark Respondents, Lilly argues use of the Mounjaro mark, marketing products as suitable for the same or similar purposes as Mounjaro, and selling products in the same dosages as Mounjaro are sufficient to infer intent to benefit from the reputation of the Mounjaro mark. Lilly Br. at 58–59.

For the reasons discussed above in Section IV.C.1.m, DuPont Factor 13 carries little weight in the analysis.

**n. Conclusion**

As discussed above, there is substantial, reliable, and probative evidence of likelihood of confusion as to TCP. In particular, Factors 1, 2, 3, 5, 6, 11, and 12 weigh in favor of a likelihood of confusion, Factors 7, 8, 9, 10, and 13 are neutral or are not considered, and Factor 4 weighs against a likelihood of confusion. Based *inter alia* on the similarity of the marks, the survey evidence, and the lack of dispute, the evidence does not show a genuine issue of material fact as to the likelihood of confusion based on TCP's use of the Mounjaro trademark. *See Swagway*, 450 F.3d at 1340.

**3. Strate Labs**

Strate Labs posted a test report online in a reddit thread titled "Semathin Tirzepatide (Generic Mounjaro) 10mg – Janoshik Test Report – 9.58mg Tirzepatide@ 99.629% Purity." Ex. 55 at LILLY_ITC_0001014. On its own website, Strate Labs does not use the Mounjaro mark. *See generally* Ex. 58.

Lilly argues Strate Labs' "unauthorized use of 'Mounjaro' is likely to confuse consumers and cause them to mistakenly believe that the Unapproved Drug Products derive from the same source as and/or are affiliated with MOUNJARO®." Lilly Br. at 53–55. Staff argues "there is sufficient undisputed substantial, reliable, and probative evidence to find that Strate Lab's use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 62.

For the reasons discussed below, the undersigned finds that there is at least a genuine issue of material fact as to trademark infringement by Strate Labs. Accordingly, summary determination is not warranted with respect to Strate Labs.

### a. DuPont Factor 1

DuPont Factor 1 concerns the "similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." *Swagway*, 934 F.3d at 1338–39. Lilly's only evidence of trademark infringement is a posting by Strate Labs, on a reddit site, of a test report entitled "Semathin Tirzepatide (Generic Mounjaro) 10mg – Janoshik Test Report – 9.58mg Tirzepatide@ 99.629% Purity":


Ex. 55 at LILLY_ITC_0001014. On its own website, Strate Labs does not use the Mounjaro mark. *See generally* Ex. 58. Instead, the evidence indicates that it markets a tirzepatide product under the name SEMATHIN and a stylized "T" logo:


Ex. 58 at LILLY_ITC_0001006 (excerpt). The product is titled "TIRZEPATIDE BY SEMATHIN | 10MG" and has a description including "Tirzepatide injection is used to treat type 2 diabetes" and "[i]n the SURMOUNT-1 clinical trial, the average weight loss with tirzepatide after 72 weeks was 15% for the 5mg dose, 19.5% for the 10mg dose, and 20.9% for the 15mg dose." *Id*. at LILLY_ITC_0001006–07.

Lilly argues Strate Labs' designation is "not just similar but actually ***identical*** to MOUNJARO® in appearance, sound, and connotation, cutting strongly in favor of a likelihood of confusion." Lilly Br. at 53–54. Staff argues that Strate Labs' use of the "Mounjaro" mark to describe its product "strongly favors a likelihood of confusion." Staff Br. at 56-57.

The undersigned does not find this evidence persuasive. The evidence fails to show that use of the term "Generic Mounjaro," without more, favors a likelihood of confusion. An analysis of DuPont factor 1 takes into account the similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation, and commercial impression. *Swagway*, 934 F.3d at 1338–39. Moreover, ownership of a trademark does not preclude use of that mark by others for all purposes. Companies are permitted to use the trademark of another, for example, in comparative advertising. *Cf. LTJ Enters., Inc. v. Custom Mktg. Co.,* LLC, 168 F. Supp. 3d 1202,

1215 (D. Minn. 2016) (granting summary judgment of no trademark infringement and noting that "[t]he use of the mark at trade shows is permissible comparative advertising unless sufficient customer confusion is demonstrated"); *Calvin Klein Cosms. Corp. v. Lenox Labs., Inc.*, 815 F.2d 500, 503 (8th Cir. 1987) ("A trademark is not a monopoly on the use of a name or a phrase. Rather, the legal relevance of a trademark is to show the source, identity, sponsorship, or origin of the product."); *Sykes Lab. Inc. v. Kalvin*, 610 F. Supp. 849, 851-856 (C.D. Cal. 1985) (granting summary judgment against plaintiff on unfair competition claim that product labeled "the GENERIC BRAND Version of Sykes' Perfect Nail" misappropriated plaintiff's mark "Perfect Nail"); *Waco Int'l, Inc. v. KHK Scaffolding Houston Inc.*, 278 F.3d 523, 534 (5th Cir. 2002) ("Thus, use of 'Waco-style' is not identifying the good as a 'Waco' good (i.e., use of the Waco mark 'as a mark'), but rather *describes* the good as being similar to or compatible with Waco's products."); *August Storck K.G. v. Nabisco, Inc.*, 59 F.3d 616, 618 (7th Cir. 1995) ("Both the FTC and the FDA encourage product comparisons. The FTC believes that consumers gain from comparative advertising, and to make the comparison vivid the Commission 'encourages the naming of, or reference to competitors'") (citing 16 C.F.R. § 14.15(b)).[21]

On the present record, the evidence regarding Strate Labs' limited use of the Mounjaro mark does not show the absence of a genuine issue of material fact regarding likelihood of confusion. Lilly cites a single reference by Strate Labs to "Generic Mounjaro" in a reddit post, which follows the words "Semanthin Mounjaro." Ex. 55. The evidence indicates that Semanthin is used as a brand name by Strate Labs. *See* Ex. 58. There is insufficient evidentiary support that this juxtaposition of Semathin with "Generic Mounjaro" creates a likelihood of confusion among

[21] To the extent Lilly seeks to argue that the Strate Labs product is not actually a "generic" version of Mounjaro, that issue goes to false advertising (which was not asserted against Strate Labs), not likelihood of confusion.

consumers (or, *e.g.*, whether use of the term "Generic Mounjaro" would be viewed as a type of comparison). On the current record, there is a genuine issue of material fact as to whether DuPont Factor 1, which takes into account the overall "commercial impression," supports a likelihood of confusion.

**b. DuPont Factor 2**

DuPont Factor 2 concerns the "similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Swagway*, 934 F.3d at 1338–39. Lilly registered Mounjaro in connection with pharmaceutical preparations—namely, pharmaceutical preparations for the treatment of diabetes—and uses the mark in for its tirzepatide product to treat type-2 diabetes. *See* Ex. 24 at Lilly_ITC_0000685–86. Strate Labs explains on its website that "[t]irzepatide injection is used to treat type 2 diabetes" and showed weigh loss results in the Surmount-1 clinical trial. Ex. 58 at LILLY_ITC_0001007–08. In addition to noting that Strate Labs also markets a tirzepatide-containing product, Lilly argues that Strate Labs sells its product in a 10 mg dosage, which is also an FDA-approved dosage of Mounjaro. Lilly Br. at 56–57; Ex. 90 at 2 (Mounjaro is available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg dosages.). Staff argues this factor favors a likelihood of confusion. Staff Br. at 57.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 2 weighs in favor of a likelihood of confusion. Both Lilly's and Strate Labs' products contain tirzepatide and are marketed for treatment of diabetes.

**c. DuPont Factor 3**

DuPont Factor 3 concerns the "similarity or dissimilarity of established, likely-to-continue trade channels." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, this factor weighs somewhat against a likelihood of confusion.

**d. DuPont Factor 4**

DuPont Factor 4 concerns the "conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." *Swagway*, 934 F.3d at 1338–39. Lilly argues this DuPont factor is not applicable to the analysis. *See* Section IV.B.

Staff argues the higher price point of Mounjaro, Lilly's prominent use of the Mounjaro mark on the label for its products, and separate labelling by Strate Labs on its product weighs against a likelihood of confusion under DuPont Factor 4. *Id.* at 58–59. Strate Labs' product is $224.95 per 10 mg vial and provided in a vial labelled with a stylized "T" logo and the name Semathin. Ex. 58 at LILLY_ITC_0001006–07. Lilly sells Mounjaro in packaging displaying the Mounjaro Mark priced at $267.27 per dose. *See* Section IV.C.1.d n.13; Ex. 3 at LILLY_ITC_0000164.

The present evidence of record shows that DuPont Factor 4 weighs against a likelihood of confusion. As shown in Strate Labs' advertising,the branding and packaging of Strate Labs' product does not resemble Lilly's Mounjaro branding and packaging. Strate Labs displays Semathin on both the package and vial label and does not include Mounjaro on either. Ex. 58 at LILLY_ITC_0001006; *see also Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."); Section IV.C.1.d *supra*. In addition, as noted above

regarding DuPont Factor 3, the evidence shows that the conditions under which sales are made (in terms of prescription requirements) differ.

**e. DuPont Factor 5**

DuPont Factor 5 concerns the "fame of the prior mark (sales, advertising, length of use)." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the evidence of record shows no genuine issue of material fact that the level of fame of the Mounjaro mark favors a likelihood of confusion.

**f. DuPont Factor 6**

DuPont Factor 6 concerns "[t]he number and nature of similar marks in use on similar goods." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark in connection with its tirzepatide-containing products, and related advertisements. *See* Lilly Br. at 50–52. Strate Labs uses the term "Generic Mounjaro" in connection with its tirzepatide-containing product. Ex. 47 at LILLY_ITC_0002638–39. Staff contends that the use of Mounjaro by Lilly and Strate Labs for tirzepatide-based products favors a finding of likelihood of confusion. Staff Br. at 60.

There is no genuine issue of material fact that DuPont Factor 6 weighs in favor of a likelihood of confusion for the same reasons as set forth above for SHS.

**g. DuPont Factor 7**

DuPont Factor 7 concerns "[t]he nature and extent of actual confusion." *Swagway*, 934 F.3d at 1338–39. Lilly does not present survey results for Strate Labs; however, Lilly seeks to extend Dr. Isaacson's opinions to apply to other Trademark Respondents. Lilly Br. at 55–56. Staff disagrees stating Lilly "has not submitted any evidence of actual confusion due to Strate Labs' advertising. Thus, this factor does not weigh in favor of a likelihood of confusion." Staff Br. at 60.

The evidence of record shows that this factor is neutral, as the survey evidence at issue relates to potential confusion (DuPont Factor 12) rather than actual confusion. *See Certain Casual Footwear*, at 22-31 (discussing "actual confusion" separately from survey results); MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32.184 (5th ed., 2024 update) ("Survey Results are Not Evidence of 'Actual Confusion'").

**h. DuPont Factor 8**

DuPont Factor 8 concerns "[t]he length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning Factor 8, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**i. DuPont Factor 9**

DuPont Factor 9 concerns "[t]he variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark for its tirzepatide product to treat diabetes and uses a separate mark—Zepbound—for its tirzepatide product related to weight loss. Lilly Br. at 4–6. Strate Labs' markets its product in connection with type 2 diabetes and weight loss. *See* Ex. 58 at LILLY_ITC_0001007–08. Staff argues "Strate Labs' use of the Asserted Trademark, widely known as a diabetes medication, for the incorrect indication (weight loss) in addition to diabetes would tend to slightly favor a finding of a likelihood of confusion or be neutral at best." Staff Br. at 60.

The evidence of record shows that DuPont Factor 9 is neutral for the reasons set forth in Section IV.C.1.i.

**j. DuPont Factor 10**

DuPont Factor 10 concerns "[t]he market interface between applicant and the owner of a prior mark." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 10, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**k. DuPont Factor 11**

DuPont Factor 11 concerns "[t]he extent to which applicant has a right to exclude others from use of its mark on its goods." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the record evidence shows that DuPont Factor 11 weighs in favor of a likelihood of confusion.

**l. DuPont Factor 12**

DuPont Factor 12 concerns "[t]he extent of potential confusion, i.e., whether de minimis or substantial." *Swagway*, 934 F.3d at 1338–39. Lilly argues there is similarity in the marks and cites Dr. Isaacson's surveys to argue that there is substantial confusion among survey participants about whether the TCP product is Mounjaro. Lilly Br. at 55–56. Staff argues this DuPont factor only minimally favors a likelihood of confusion because the products sold by Strate Labs have their own branding on the label and do not contain the Mounjaro mark. Staff Br. at 61.

The evidence of record fails to show substantial potential confusion. There is insufficient evidence that Strate Labs' reference to "Generic Mounjaro" in a reddit post would cause a likelihood of confusion in an appreciable number of people. *See Nautilus Grp., Inc. v. ICON Health & Fitness, Inc.*, 372 F.3d 1330, 1338 (Fed. Cir. 2004) ("[T]rademark infringement is only actionable when a mark is likely to confuse an *appreciable* number of people as to the source of the product." (emphasis in original, internal quotations omitted)). Lilly cites a single reference by Strate Labs of "Generic Mounjaro" in a reddit post that is not mentioned or hyperlinked on the Strate Labs website. There is no evidence regarding the likelihood that consumers or potential consumers of Strate Labs' product will view the forum post. Moreover, in its reddit forum post, Strate Labs refers to "Semathin Tirzepatide (Generic Mounjaro)." Ex. 55. As discussed above regarding DuPont Factor 1, there is also insufficient evidentiary support that this juxtaposition of "Generic Mounjaro" with Semathin creates a likelihood of confusion among consumers.

Dr. Isaacson's opinions do not bolster Lilly's position. Dr. Isaacson reviewed the advertisements of all the Trademark Respondents and acknowledges he did not conduct surveys concerning respondents other than SHS and TCP. Isaacson Report ¶ 121. He also makes qualified statements about the applicability of his results to the other respondents:

> I have not conducted a survey measuring other web pages operated by other Respondents. However, to the extent that those other web pages *contain similar elements in a similar presentation* to those of the web pages measured in my survey, I have no reason to expect that the results of a survey measuring those other web pages would be different from the measures presented in this report.

*Id*. (emphasis added). Lilly has not persuasively explained if or how Strate Labs' advertisement contains "similar elements in a similar presentation" to the TCP or SHS websites.

Accordingly, on the evidence of record, there is a genuine issue of material fact as to whether this factor favors a finding of likelihood of confusion.

**m. DuPont Factor 13**

DuPont Factor 13 concerns "[a]ny other established fact probative of the effect of use." *Swagway*, 934 F.3d at 1338–39. With respect to all Trademark Respondents, Lilly argues use of the Mounjaro mark, marketing products as suitable for the same or similar purposes as Mounjaro, and selling products in the same dosages as Mounjaro are sufficient to infer intent to benefit from the reputation of the Mounjaro mark. Lilly Br. at 58–59.

For the reasons discussed above in Section IV.C.1.m, DuPont Factor 13 carries little weight in the analysis.

**n. Conclusion**

As discussed above, there is insufficient substantial, reliable, and probative evidence of likelihood of confusion as to Strate Labs. Factors 2, 5, 6, and 11 weigh in favor of a likelihood of confusion, Factors 7, 8, 9, 10, and 13 are neutral or are not considered, Factors 3 and 4 weigh against a likelihood of confusion, and there are at least genuine issues of material fact as to whether Factors 1 and 12 weigh against a likelihood of confusion. Based on the factors considered above, including in particular the issues regarding DuPont Factors 1 and 12, there exists at least a genuine issue of material fact regarding likelihood of confusion. *Cf. Swagway*, 934 F.3d at 1340 ("[T]he likelihood-of-confusion analysis cannot be reduced to a simple tally of the factors. The factors are accorded different weights in different circumstances."). Accordingly, summary determination on likelihood of confusion as to Strate Labs is not warranted.

#### 4. Audrey Beauty and Mew Mews[22]

Audrey Beauty advertises a product on its website titled "Tirzepatide 10mg Mounjaro Raw Powder Weight Loss Therapy CAS: 2023788-19-2." Ex. 28 at LILLY_ITC_0000903. Audrey Beauty's website also lists "Related Keywords" that include "Tirzepatide, Mounjaro." *Id*.

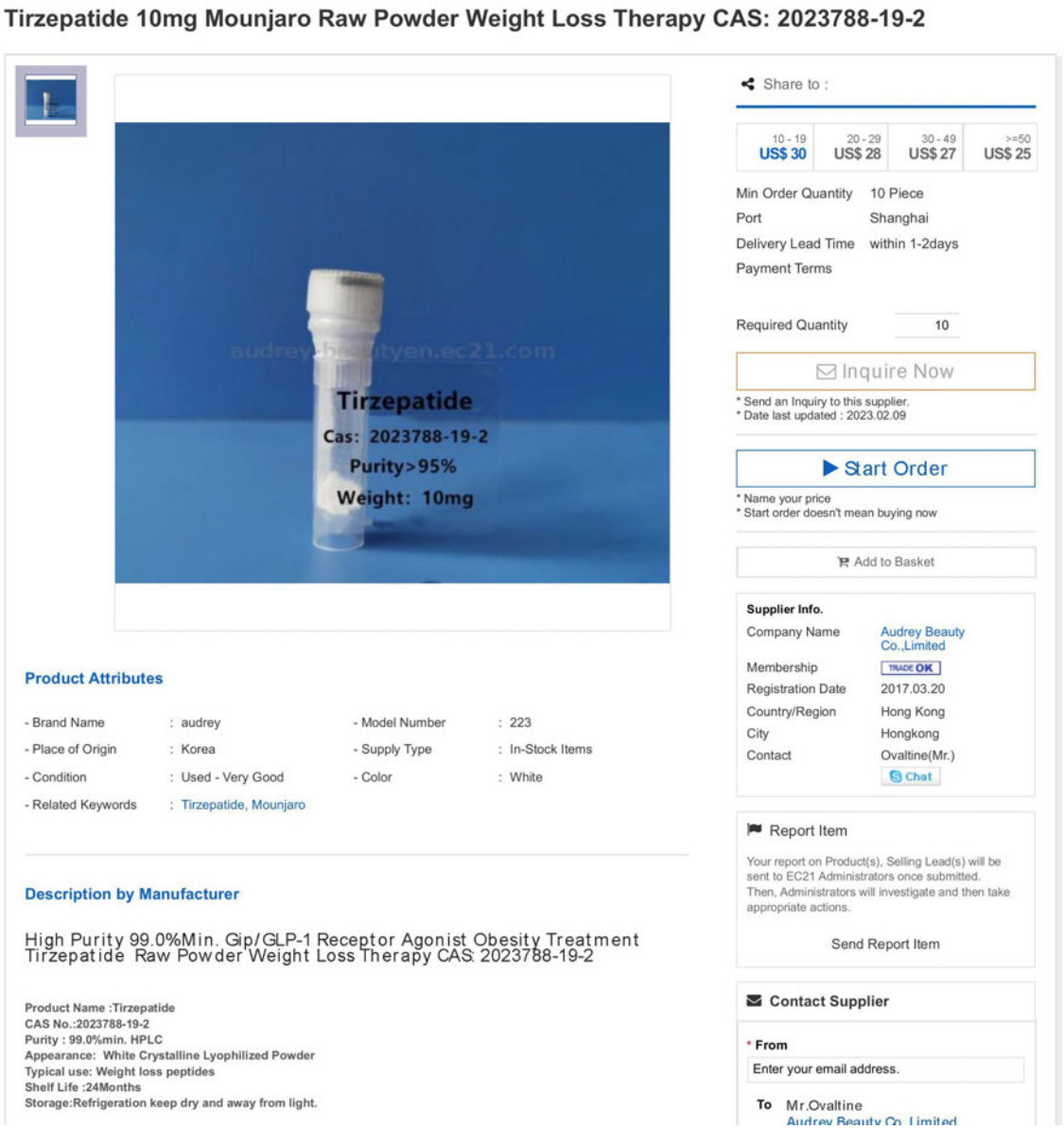
Lilly argues Audrey Beauty's "unauthorized use of 'Mounjaro' is likely to confuse consumers and cause them to mistakenly believe that the Unapproved Drug Products derive from the same source as and/or are affiliated with MOUNJARO®." Lilly Br. at 53–55. Staff argues "there is sufficient undisputed substantial, reliable, and probative evidence to find that Audrey Beauty's use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 44.

For the reasons discussed below, substantial, reliable, and probative evidence shows Audrey Beauty's use of Mounjaro in its advertised goods creates a likelihood of confusion. Thus, summary determination of trademark infringement is warranted with respect to Audrey Beauty.

##### a. DuPont Factor 1

DuPont Factor 1 concerns the "similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." *Swagway*, 934 F.3d at 1338–39. Audrey Beauty advertises a product on its website titled "Tirzepatide 10mg Mounjaro Raw Powder Weight Loss Therapy CAS: 2023788-19-2."

[22] Lilly does not separately address Mews Mews. Instead, Lilly argues Mews Mews imports accused products "on behalf of, and/or in conjunction with, Audrey Beauty." Lilly Br. at 53 (citing Ex. 16 (Audrey Beauty shipping label listing Mew Mews as the return address)). The undersigned agrees that the trademark infringement analysis applies equally to Audrey Beauty and Mew Mews. For simplicity, the two respondents are collectively referred to as Audrey Beauty in this section.




Ex. 28 at LILLY_ITC_0000903 (excerpt). The website also lists "Related Keywords" that include "Tirzepatide, Mounjaro." *Id*.

Lilly argues Audrey Beauty designation is "not just similar but actually ***identical*** to MOUNJARO® in appearance, sound, and connotation, cutting strongly in favor of a likelihood of confusion." Lilly Br. at 53–54 (emphasis in original). Staff agrees that Audrey Beauty's use of the "Mounjaro" mark to describe its product "strongly favors a likelihood of confusion." Staff Br. at 37–38.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 1 weighs in favor of a likelihood of confusion. Audrey Beauty's describes its tirzepatide product as "Mounjaro Raw Powder." Ex. 28 at LILLY_ITC_0000903. The evidence shows that the use of the term "Mounjaro," considered in context, indicates a likelihood of consumer confusion. *See Swagway*, 934 F.3d at 1338–39.

**b. DuPont Factor 2**

DuPont Factor 2 concerns the "similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Swagway*, 934 F.3d at 1338–39. Lilly registered Mounjaro in connection with pharmaceutical preparations—namely, pharmaceutical preparations for the treatment of diabetes—and uses the mark in for its tirzepatide product to treat type-2 diabetes. *See* Ex. 24 at Lilly_ITC_0000685–86. Audrey Beauty markets its tirzepatide product as a "Weight Loss Therapy" and "Obesity Treatment." Ex. 28 at LILLY_ITC_0000903. Based on the advertising image, Audrey Beauty's product is an unmarked vial containing a white powder. Ex. 28 at LILLY_ITC_0000903. In contrast, Lilly's Mounjaro product is an auto-injector pen with Mounjaro prominently on the label. Ex. 65.

In addition to noting that Audrey Beauty also markets a tirzepatide-containing product, Lilly argues that Audrey Beauty sells its product in a 10 mg dosage, which is an FDA-approved dosage of Mounjaro. Lilly Br. at 56–57; Ex. 90 at 2 (Mounjaro is available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg dosages.).

Staff argues "this factor is neutral, neither favoring nor disfavoring a likelihood of confusion, or at best weighs slightly in favor finding a likelihood of confusion." Staff Br. at 38.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 2 weighs, on balance, in favor of a likelihood of confusion. Both Lilly's and Audrew Beauty's products contain tirzepatide. Although Audrey Beauty focuses its advertising on weight loss, whereas Mounjaro is registered and used in connection with diabetes treatment, the similarity of the underlying goods and the fact they are both marketed for pharmaceutical-type applications weighs in favor of a likelihood of confusion.

**c. DuPont Factor 3**

DuPont Factor 3 concerns the "similarity or dissimilarity of established, likely-to-continue trade channels." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the undersigned finds that this factor weighs somewhat against a likelihood of confusion.

**d. DuPont Factor 4**

DuPont Factor 4 concerns the "conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." *Swagway*, 934 F.3d at 1338–39; *see also Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."). Lilly argues this DuPont factor is not applicable to the analysis. *See* Section IV.B.

Staff argues the higher price point of Mounjaro, Lilly's prominent use of the Mounjaro mark on the label for its products, and the lack of labelling by Audrey Beauty on its product weighs against a likelihood of confusion under DuPont Factor 4. Staff Br. at 39–40. Audrey Beauty's product is $36 for a 10 mg vial and provided in an unlabeled vial. Ex. 10; Ex. 28 at LILLY_ITC_0000903. Lilly sells Mounjaro in packaging displaying the Mounjaro Mark priced at $267.27 per dose. *See* Section IV.C.1.d n.13; Ex. 3 at LILLY_ITC_0000164.

The present evidence of record shows that DuPont Factor 4 weighs against a likelihood of confusion. The lack of branding on Audrey Beauty's product and packaging, as shown in Audrey Beauty's advertising, weighs against a likelihood of confusion among consumers. *See* Ex. 28; *Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."); Section IV.C.1.d *supra*. Moreover, Mounjaro is sold at a significantly higher price point. *See* Ex. 90 at 2; Ex. B ¶ 99. In addition, as noted above regarding DuPont Factor 3, the evidence shows that conditions under which sales are made (in terms of prescription requirements) differ.

**e. DuPont Factor 5**

DuPont Factor 5 concerns the "fame of the prior mark (sales, advertising, length of use)." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the evidence of record shows no genuine issue of material fact that the level of fame of the Mounjaro mark favors a likelihood of confusion.

**f. DuPont Factor 6**

DuPont Factor 6 concerns "[t]he number and nature of similar marks in use on similar goods." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark in connection with its tirzepatide-containing products, and related advertisements. *See* Lilly Br. at 50–52. Audrey Beauty uses the Mounjaro mark in connection with its tirzepatide-containing product. Ex. 28 at LILLY_ITC_0000903. Staff agrees that the use of Mounjaro by Lilly and Audrey Beauty for tirzepatide-based products favors a finding of likelihood of confusion. Staff Br. at 41.

There is no genuine issue of material fact that DuPont Factor 6 weighs in favor of a likelihood of confusion for the same reasons as set forth above for SHS.

### g. DuPont Factor 7

DuPont Factor 7 concerns "[t]he nature and extent of actual confusion." *Swagway*, 934 F.3d at 1338–39. Lilly does not present survey results for Audrey Beauty; however, Lilly seeks to extend Dr. Isaacson's opinions to apply to other Trademark Respondents. Lilly Br. at 55–56. Staff disagrees stating Lilly "has not submitted any evidence of actual confusion due to Audrey Beauty's advertising. Thus, this factor does not weigh in favor of a likelihood of confusion." Staff Br. at 41.

The evidence of record shows that this factor is neutral, as the survey evidence at issue relates to potential confusion (DuPont Factor 12) rather than actual confusion. *See Certain Casual Footwear*, at 22-31 (discussing "actual confusion" separately from survey results); MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32.184 (5th ed., 2024 update) ("Survey Results are Not Evidence of 'Actual Confusion'").

### h. DuPont Factor 8

DuPont Factor 8 concerns "[t]he length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 8, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

### i. DuPont Factor 9

DuPont Factor 9 concerns "[t]he variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Swagway*, 934 F.3d at 1338–39. Lilly uses the

Mounjaro mark for its tirzepatide product to treat diabetes and uses a separate mark—Zepbound—for its tirzepatide product related to weight loss. Lilly Br. at 4–6. Audrey Beauty markets its tirzepatide product as a "Weight Loss Therapy" and "Obesity Treatment." Ex. 28 at LILLY_ITC_0000903. Staff argues "Audrey Beauty's use of the Asserted Trademark, widely known as a diabetes medication, for the incorrect indication (weight loss) in addition to diabetes would tend to slightly favor a finding of a likelihood of confusion or be neutral at best." Staff Br. at 60.

The evidence of record shows that DuPont Factor 9 is neutral for the reasons set forth in Section IV.C.1.i.

**j. DuPont Factor 10**

DuPont Factor 10 concerns "[t]he market interface between applicant and the owner of a prior mark." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 10, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**k. DuPont Factor 11**

DuPont Factor 11 concerns "[t]he extent to which applicant has a right to exclude others from use of its mark on its goods." *Swagway*, 934 F.3d at 1338–39. The record evidence shows that DuPont Factor 11 is neutral as Audrey Beauty's product is sold in connection with weight loss, whereas Lilly's trademark registration relates to diabetes treatment. *See* Part I.C *supra*.

### l. DuPont Factor 12

DuPont Factor 12 concerns "[t]he extent of potential confusion, i.e., whether de minimis or substantial." *Swagway*, 934 F.3d at 1338–39. Lilly relies on the similarity of the marks and Dr. Isaacson's surveys to argue there is substantial confusion based on the survey results about SHS and TCP. Lilly Br. at 55–56; *see also* Section IV.B (Lilly citing supporting survey evidence of substantial confusion for DuPont Factor 12). Staff argues this DuPont factor only minimally favors a likelihood of confusion because even though Audrey Beauty uses the Mounjaro mark twice on its website, the image of the product sold is prominently displayed without a Mounjaro mark. Staff Br. at 42–43.

Based on the record evidence, there is no genuine issue of material fact that this factor weighs in favor of a likelihood of confusion. Audrey Beauty advertises its product on its website as "Mounjaro Raw Powder" suggesting to the consumer that it is a precursor or otherwise related to the Mounjaro product. Ex. 28 at LILLY_ITC_0000903.[23]

### m. DuPont Factor 13

DuPont Factor 13 concerns "[a]ny other established fact probative of the effect of use." *Swagway*, 934 F.3d at 1338–39. Common to all Trademark Respondents, Lilly argues use of the Mounjaro mark, marketing products as suitable for the same or similar purposes as Mounjaro, and selling products in the same dosages as Mounjaro are sufficient to infer intent to benefit from the reputation of the Mounjaro mark. Lilly Br. at 58–59.

For the reasons discussed above in Section IV.C.1.m, DuPont Factor 13 carries little weight in the analysis.

[23] Dr. Isaacson's survey results are not particularly persuasive given that Audrey Beauty's use of the "Mounjaro" mark appears less prominent than in the web pages of SHS and TCP.

#### n. Conclusion

As discussed above, there is substantial, reliable, and probative evidence of likelihood of confusion as to Audrey Beauty. In particular, Factors 1, 2, 5, 6, and 12 weigh in favor of a likelihood of confusion, Factors 7, 8, 9, 10, 11 and 13 are neutral or are not considered, and Factors 3 and 4 weigh against a likelihood of confusion. Based *inter alia* on the similarity of the marks and the lack of dispute, the evidence does not show a genuine issue of material fact as to the likelihood of confusion based on Audrey Beauty's use of the Mounjaro trademark and summary determination is warranted. *See Swagway*, 450 F.3d at 1340.

### 5. Triggered Brand

Triggered Brand advertises a tirzepatide product on its website as "Tirzepatide Vials – 5mg." Ex. 43 at LILLY_ITC_0000978–79. Under the "Properties" section for the product, the website states "Synonyms: Tirzepatide (LY3298176 2023788-19-2 Tirzepatide Mounjaro GTPL11429." *Id.*

Lilly argues Triggered Brand's "unauthorized use of "Mounjaro" is likely to confuse consumers and cause them to mistakenly believe that the Unapproved Drug Products derive from the same source as and/or are affiliated with MOUNJARO®." Lilly Br. at 53–55. Staff argues "there is sufficient undisputed substantial, reliable, and probative evidence to find that Triggered Brand's use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 68.

For the reasons discussed below, substantial, reliable, and probative evidence shows Triggered Brand's use of Mounjaro in its advertised goods creates a likelihood of confusion. Thus, summary determination of trademark infringement is warranted with respect to Triggered Brand.

### a. DuPont Factor 1

DuPont Factor 1 concerns the "similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." *Swagway*, 934 F.3d at 1338–39. Triggered Brand advertises a tirzepatide product on its website as "Tirzepatide Vials – 5mg":


Ex. 43 at LILLY_ITC_0000978–79. Under the "Properties" section for the product, the website states "Synonyms: Tirzepatide (LY3298176) 2023788-19-2 Tirzepatide Mounjaro GTPL11429." *Id*. The product's description includes claims of "Tirzepatide to lower blood glucose levels, increase insulin sensitivity, boost feelings of satiety, and accelerate weight loss. Tirzepatide was developed to fight type 2 diabetes, but has additionally been shown to protect the cardiovascular system and act as a potent weight loss agent." *Id*.

Lilly argues Triggered Brand's designation is "not just similar but actually ***identical*** to MOUNJARO® in appearance, sound, and connotation, cutting strongly in favor of a likelihood of confusion." Lilly Br. at 53–54 (emphasis in original). Lilly further argues Triggered Brand promotes its product as synonymous with Mounjaro. *Id*. at 56. Staff agrees that Triggered

Brand's use of the Mounjaro mark to describe its product "strongly favors a likelihood of confusion." Staff Br. at 37–38.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 1 weighs in favor of a likelihood of confusion. Triggered Brand describes its tirzepatide product as synonymous with "Mounjaro." Ex. 43 at LILLY_ITC_0000979. The evidence shows that the use of the term "Mounjaro," considered in context, indicates a likelihood of consumer confusion. *See Swagway*, 934 F.3d at 1338–39.

**b. DuPont Factor 2**

DuPont Factor 2 concerns the "similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Swagway*, 934 F.3d at 1338–39. Lilly registered Mounjaro in connection with pharmaceutical preparations—namely, pharmaceutical preparations for the treatment of diabetes—and uses the mark in for its tirzepatide product to treat type-2 diabetes. *See* Ex. 24 at Lilly_ITC_0000685–86; Lilly Br. at 13-14. Triggered Brand notes in its marketing material that tirzepatide "lower[s] blood glucose levels, increase[s] insulin sensitivity, boost[s] feelings of satiety, and accelerate[s] weight loss." Ex. 43 at LILLY_ITC_0000979.

In addition to noting that Triggered Brand also markets a tirzepatide-containing product, Lilly argues that Triggered Brand sells its product in a 5 mg dosage, which is an FDA-approved dosage of Mounjaro. Lilly Br. at 56–57; Ex. 90 at 2 (Mounjaro is available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg dosages.).

Staff argues Triggered Brand's use of the mark "in connection with the sales of a product for treatment of diabetes and for weight loss" favors a likelihood of confusion. Staff Br. at 63–64.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 2 weighs in favor of a likelihood of confusion. Both Lilly's and Triggered Brand's products contain tirzepatide, and Triggered Brand describes its product in connection to diabetes treatment. *See* Ex. 43 at LILLY_ITC_0000979.

**c. DuPont Factor 3**

DuPont Factor 3 concerns the "similarity or dissimilarity of established, likely-to-continue trade channels." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, this factor weighs somewhat against a likelihood of confusion.

**d. DuPont Factor 4**

DuPont Factor 4 concerns the "conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." *Swagway*, 934 F.3d at 1338–39; *see also Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."). Lilly argues this DuPont factor is not applicable to the analysis. *See* Section IV.B.

Staff argues the higher price point of Mounjaro, Lilly's prominent use of the Mounjaro mark on the label for its products, and Triggered Brand's use of its own label and mark weighs against a likelihood of confusion under DuPont Factor 4. Staff Br. at 64–65. Triggered Brand's product is $111.99 per 5 mg vial and provided in a vial labeled with a "TB" logo and "TRIGGERED" name. Ex. 43 at LILLY_ITC_0000978. Lilly sells Mounjaro in packaging displaying the Mounjaro Mark priced at $267.27 per dose. *See* Section IV.C.1.d n.13; Ex. 3 at LILLY_ITC_0000164.

The present evidence of record shows that DuPont Factor 4 weighs against a likelihood of confusion. Triggered Brand's use of its own branding for the product, as shown in its advertising,

weighs against the likelihood of confusion among consumers. *See* Ex. 43; *Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."); Section IV.C.1.d *supra*. Moreover, at least for certain customers utilizing a 2.5 or 5 mg dose, Mounjaro is sold at a significantly higher price point. *See* Ex. 90 at 2; Ex. B ¶ 99. In addition, as noted above regarding DuPont Factor 3, the evidence shows that the conditions under which sales are made (in terms of prescription requirements) differ.

**e. DuPont Factor 5**

DuPont Factor 5 concerns the "fame of the prior mark (sales, advertising, length of use)." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the evidence of record shows no genuine issue of material fact that the level of fame of the Mounjaro mark favors a likelihood of confusion.

**f. DuPont Factor 6**

DuPont Factor 6 concerns "[t]he number and nature of similar marks in use on similar goods." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark in connection with its tirzepatide-containing products, and related advertisements. *See* Lilly Br. at 50–52. Triggered Brand uses the Mounjaro mark in connection with its tirzepatide-containing product. Ex. 43 at LILLY_ITC_0000978–79. Staff agrees that the use of Mounjaro by Lilly and Triggered Brand for tirzepatide-based products favors a finding of likelihood of confusion. Staff Br. at 66.

There is no genuine issue of material fact that DuPont Factor 6 weighs in favor of a likelihood of confusion for the same reasons as set forth above for SHS.

**g. DuPont Factor 7**

DuPont Factor 7 concerns "[t]he nature and extent of actual confusion." *Swagway*, 934 F.3d at 1338–39. Lilly does not present survey results for Triggered Brand; however, Lilly seeks to extend Dr. Isaacson's opinions to apply to other Trademark Respondents. Lilly Br. at 55–56. Staff disagrees stating Lilly "has not submitted any evidence of actual confusion due to [Triggered Brand's] advertising. Thus, this factor does not weigh in favor of a likelihood of confusion." Staff Br. at 66.

The evidence of record shows that this factor is neutral, as the survey evidence at issue relates to potential confusion (DuPont Factor 12) rather than actual confusion. *See Certain Casual Footwear*, at 22-31 (discussing "actual confusion" separately from survey results); MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32.184 (5th ed., 2024 update) ("Survey Results are Not Evidence of 'Actual Confusion'").

**h. DuPont Factor 8**

DuPont Factor 8 concerns "[t]he length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning DuPont Factor 8, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**i. DuPont Factor 9**

DuPont Factor 9 concerns "[t]he variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Swagway*, 934 F.3d at 1338–39. Lilly uses the

Mounjaro mark for its tirzepatide product to treat diabetes and uses a separate mark—Zepbound—for its tirzepatide product related to weight loss. Lilly Br. at 4–6. Triggered Brand notes in its marketing material that tirzepatide "lower[s] blood glucose levels, increase[s] insulin sensitivity, boost[s] feelings of satiety, and accelerate[s] weight loss." Ex. 43 at LILLY_ITC_0000979.

Staff argues "Triggered Brand's use of the Asserted Trademark, widely known as a diabetes medication, for the incorrect indication (weight loss) in addition to diabetes would tend to slightly favor a finding of a likelihood of confusion or be neutral at best." Staff Br. at 66.

The evidence of record shows that DuPont Factor 9 is neutral for the reasons set forth in Section IV.C.1.i.

**j. DuPont Factor 10**

DuPont Factor 10 concerns "[t]he market interface between applicant and the owner of a prior mark." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 10, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**k. DuPont Factor 11**

DuPont Factor 11 concerns "[t]he extent to which applicant has a right to exclude others from use of its mark on its goods." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the record evidence shows that DuPont Factor 11 weighs in favor of a likelihood of confusion.

### l. DuPont Factor 12

DuPont Factor 12 concerns "[t]he extent of potential confusion, i.e., whether de minimis or substantial." *Swagway*, 934 F.3d at 1338–39. Lilly relies on the similarity of the marks and Dr. Isaacson's surveys to argue there is substantial confusion based on the survey results about SHS and TCP. Lilly Br. at 55–56; *see also* Section IV.B (Lilly citing supporting survey evidence of substantial confusion for DuPont Factor 12). Staff argues this DuPont factor only minimally favors a likelihood of confusion because Triggered Brand's product has its own label that does not display a Mounjaro mark. Staff Br. at 67.

Based on the record evidence, there is no genuine issue of material fact that this factor weighs in favor of a likelihood of confusion based on Triggered Brand's use of the Mounjaro mark as a "synonym" for its product. *See* discussion *supra*.[24]

### m. DuPont Factor 13

DuPont Factor 13 concerns "[a]ny other established fact probative of the effect of use." *Swagway*, 934 F.3d at 1338–39. Common to all Trademark Respondents, Lilly argues use of the Mounjaro mark, marketing products as suitable for the same or similar purposes as Mounjaro, and selling products in the same dosages as Mounjaro are sufficient to infer intent to benefit from the reputation of the Mounjaro mark. Lilly Br. at 58–59. Staff disagrees that such an inference is appropriate here, where the Trademark Respondents defaulted before providing and discovery. *See* Staff Br. at 67–68.

For the reasons discussed above in Section IV.C.1.m, DuPont Factor 13 carries little weight in the analysis.

[24] Dr. Isaacson's survey results are not particularly persuasive including because Triggered Brand's use of the "Mounjaro" mark appears less prominent than in the web pages of SHS and TCP.

#### n. Conclusion

As discussed above, there is substantial, reliable, and probative evidence of likelihood of confusion as to Triggered Brand. In particular, Factors 1, 2, 5, 6, 11, and 12 weigh in favor of a likelihood of confusion, Factors 7, 8, 9, 10, and 13 are neutral or are not considered, and Factors 3 and 4 weigh against a likelihood of confusion. Based *inter alia* on the similarity of the marks and the lack of dispute, the evidence does not show a genuine issue of material fact as to the likelihood of confusion based on Triggered Brand's use of the Mounjaro trademark and summary determination is warranted. *See Swagway*, 450 F.3d at 1340.

### 6. Paradigm Peptides[25]

Paradigm Peptides advertises a tirzepatide product on its website as "Tirzepatide (5mg)" decribed as "[f]or those seeking effective treatment from type 2 diabetes and obesity, tirzepatide (5mg) is a highly promising solution." Ex. 18 at LILLY_ITC_0002700. Under the "ADDITIONAL INFORMATION" section for the product, the website states "Synonyms: GTPL11429; P1206; Mounjaro; GIP/GLP-1 RA." *Id*. at LILLY_ITC_0002701–02.

Lilly argues Paradigm Peptides' "unauthorized use of "Mounjaro" is likely to confuse consumers and cause them to mistakenly believe that the Unapproved Drug Products derive from the same source as and/or are affiliated with MOUNJARO®." Lilly Br. at 53–55. Staff argues "there is sufficient undisputed substantial, reliable, and probative evidence to find that [Paradigm Peptides]'s use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 74.

For the reasons discussed below, substantial, reliable, and probative evidence shows Paradigm Peptide's use of Mounjaro in its advertised goods creates a likelihood of confusion.

[25] Although there is no violation as to Paradigm Peptides (*see* Section I.B.4), likelihood of confusion is assessed for purposes of the GEO analysis. *See* Section VIII.A *infra*.

### a. DuPont Factor 1

DuPont Factor 1 concerns the "similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." *Swagway*, 934 F.3d at 1338–39. Paradigm Peptides advertises a tirzepatide product on its website as "Tirzepatide (5mg)":


Ex. 18 at LILLY_ITC_0002700. The product is described as "[f]or those seeking effective treatment for type 2 diabetes and obesity, tirzepatide (5mg) is a highly promising solution." *Id.* Based on the product photo, the vials contain a label with the Paradigm Peptides logo and "Tirzepatide 5mg." *Id.* Under the "ADDITIONAL INFORMATION" section for the product, the website states "Synonyms: GTPL11429; P1206; Mounjaro; GIP/GLP-1 RA." *Id.* at LILLY_ITC_0002701–02.

Lilly argues Paradigm Peptides' designation is "not just similar but actually ***identical*** to MOUNJARO® in appearance, sound, and connotation, cutting strongly in favor of a likelihood of confusion." Lilly Br. at 53–54 (emphasis in original). Lilly further argues Paradigm Peptides

promotes its product as synonymous with Mounjaro. *Id.* at 56. Staff agrees that Paradigm Peptides' use of the Mounjaro mark to describe its product "strongly favors a likelihood of confusion." Staff Br. at 68–69.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 1 weighs in favor of a likelihood of confusion. Paradigm Peptides describes its tirzepatide product as synonymous with Mounjaro. Ex. 18 at LILLY_ITC_0002701–02. The evidence shows that the use of the term "Mounjaro," considered in context, indicates a likelihood of consumer confusion. *See Swagway*, 934 F.3d at 1338–39.

**b. DuPont Factor 2**

DuPont Factor 2 concerns the "similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Swagway*, 934 F.3d at 1338–39. Lilly registered Mounjaro in connection with pharmaceutical preparations—namely, pharmaceutical preparations for the treatment of diabetes—and uses the mark in for its tirzepatide product to treat type-2 diabetes. *See* Ex. 24 at Lilly_ITC_0000685–86.

Paradigm Peptides markets its product as "[f]or those seeking effective treatment for type 2 diabetes and obesity." Ex. 18 at LILLY_ITC_0002700. In addition to noting that Paradigm Peptides also markets a tirzepatide-containing product, Lilly argues that Paradigm Peptides sells its product in a 5 mg dosage, which is an FDA-approved dosage of Mounjaro. Lilly Br. at 56–57; Ex. 90 at 2 (Mounjaro is available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg dosages.).

Staff argues Paradigm Peptides' use of the mark "in connection with the sales of a product for treatment of diabetes and for weight loss" favors a likelihood of confusion. Staff Br. at 69–70.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 2 weighs in favor of a likelihood of confusion. Both Lilly's and Paradigm Peptide's products contain tirzepatide, and Paradigm Peptide describes its product as an "effective treatment for type 2 diabetes." *See* Ex. 18 at LILLY_ITC_0002700.

**c. DuPont Factor 3**

DuPont Factor 3 concerns the "similarity or dissimilarity of established, likely-to-continue trade channels." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, this factor weighs somewhat against a likelihood of confusion.

**d. DuPont Factor 4**

DuPont Factor 4 concerns the "conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." *Swagway*, 934 F.3d at 1338–39; *see also Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."). Lilly argues this DuPont factor is not applicable to the analysis. *See* Section IV.B.

Staff argues the higher price point of Mounjaro, Lilly's prominent use of the Mounjaro mark on the label for its products, and Paradigm Peptide's use of its own label and mark weighs against a likelihood of confusion under DuPont Factor 4. Staff Br. at 70–71. Paradigm Peptide's product is $120 per 5 mg vial and provided in a vial labeled with Paradigm Peptide's logo and name. Ex. 18 at LILLY_ITC_0002700; Ex. 37 at LILLY_ITC_0002833. Lilly sells Mounjaro in

packaging displaying the Mounjaro Mark priced at $267.27 per dose. *See* Section IV.C.1.d n.13; Ex. 3 at LILLY_ITC_0000164.

The present evidence of record shows that DuPont Factor 4 weighs against a likelihood of confusion. Paradigm Peptides' use of its own branding on its product, as shown in its advertising, weighs against a likelihood of confusion among consumers. *See* Ex. 18; *Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."); Section IV.C.1.d *supra*. Moreover, at least for certain customers utilizing a 2.5 or 5 mg dose, Mounjaro is sold at a significantly higher price point. *See* Ex. 90 at 2; Ex. B ¶ 99. In addition, as noted above regarding DuPont Factor 3, the evidence shows that conditions under which sales are made (in terms of prescription requirements) differ.

**e. DuPont Factor 5**

DuPont Factor 5 concerns the "fame of the prior mark (sales, advertising, length of use)." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the evidence of record shows no genuine issue of material fact that the level of fame of the Mounjaro mark favors a likelihood of confusion.

**f. DuPont Factor 6**

DuPont Factor 6 concerns "[t]he number and nature of similar marks in use on similar goods." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark in connection with its tirzepatide-containing products, and related advertisements. *See* Lilly Br. at 50–52. Paradigm Peptide uses the Mounjaro mark in connection with its tirzepatide-containing product. Ex. 18 at LILLY_ITC_0002700–03. Staff agrees that the use of Mounjaro by Lilly and Paradigm Peptide for tirzepatide-based products favors a finding of likelihood of confusion. Staff Br. at 72.

There is no genuine issue of material fact that DuPont Factor 6 weighs in favor of a likelihood of confusion for the same reasons as set forth above for SHS.

**g. DuPont Factor 7**

DuPont Factor 7 concerns "[t]he nature and extent of actual confusion." *Swagway*, 934 F.3d at 1338–39. Lilly does not present survey results for Paradigm Peptide; however, Lilly seeks to extend Dr. Isaacson's opinions to apply to other Trademark Respondents. Lilly Br. at 55–56. Staff disagrees stating Lilly "has not submitted any evidence of actual confusion due to Paradigm Peptide's advertising. Thus, this factor does not weigh in favor of a likelihood of confusion." Staff Br. at 72.

The evidence of record shows that this factor is neutral, as the survey evidence at issue relates to potential confusion (DuPont Factor 12) rather than actual confusion. *See Certain Casual Footwear*, at 22-31 (discussing "actual confusion" separately from survey results); MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32.184 (5th ed., 2024 update) ("Survey Results are Not Evidence of 'Actual Confusion'").

**h. DuPont Factor 8**

DuPont Factor 8 concerns "[t]he length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning DuPont Factor 8, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

#### i. DuPont Factor 9

DuPont Factor 9 concerns "[t]he variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark for its tirzepatide product to treat diabetes and uses a separate mark—Zepbound—for its tirzepatide product related to weight loss. Lilly Br. at 4–6. Paradigm Peptides markets its product as "[f]or those seeking effective treatment for type 2 diabetes and obesity." Ex. 18 at LILLY_ITC_0002700.

Staff argues "Paradigm Peptides' use of the Asserted Trademark, widely known as a diabetes medication, for the incorrect indication (weight loss) in addition to diabetes would tend to slightly favor a finding of a likelihood of confusion or be neutral at best." Staff Br. at 72.

The evidence of record shows that DuPont Factor 9 is neutral for the reasons set forth in Section IV.C.1.i.

#### j. DuPont Factor 10

DuPont Factor 10 concerns "[t]he market interface between applicant and the owner of a prior mark." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 10, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

#### k. DuPont Factor 11

DuPont Factor 11 concerns "[t]he extent to which applicant has a right to exclude others from use of its mark on its goods." *Swagway*, 934 F.3d at 1338–39. For the same reasons

discussed above in Section IV.C.1, the record evidence shows that DuPont Factor 11 weighs in favor of a likelihood of confusion.

**l. DuPont Factor 12**

DuPont Factor 12 concerns "[t]he extent of potential confusion, i.e., whether de minimis or substantial." *Swagway*, 934 F.3d at 1338–39. Lilly relies on the similarity of the marks and Dr. Isaacson's surveys to argue there is substantial confusion based on the survey results about SHS and TCP. Lilly Br. at 55–56; *see also* Section IV.B (Lilly citing supporting survey evidence of substantial confusion for DuPont Factor 12). Staff argues this DuPont factor only minimally favors a likelihood of confusion because Paradigm Peptides' product has its own label that does not display a Mounjaro mark. Staff Br. at 73.

Based on the record evidence, there is no genuine issue of material fact that this factor weighs in favor of a likelihood of confusion based on Triggered Brand's use of the Mounjaro mark as a "synonym" for its product. *See* discussion *supra*.[26]

**m. DuPont Factor 13**

DuPont Factor 13 concerns "[a]ny other established fact probative of the effect of use." *Swagway*, 934 F.3d at 1338–39. Common to all Trademark Respondents, Lilly argues use of the Mounjaro mark, marketing products as suitable for the same or similar purposes as Mounjaro, and selling products in the same dosages as Mounjaro are sufficient to infer intent to benefit from the reputation of the Mounjaro mark. Lilly Br. at 58–59. Staff disagrees that such an inference is appropriate here, where the Trademark Respondents defaulted before providing and discovery. *See* Staff Br. at 67–68.

[26] Dr. Isaacson's survey results are not particularly persuasive given that Paradigm Peptides' use of the "Mounjaro" mark appears less prominent than in the web pages of SHS and TCP.

For the reasons discussed above in Section IV.C.1.m, DuPont Factor 13 carries little weight in the analysis.

**n. Conclusion**

As discussed above, there is substantial, reliable, and probative evidence of likelihood of confusion as to Paradigm Peptides. In particular, Factors 1, 2, 5, 6, 11, and 12 weigh in favor of a likelihood of confusion, Factors 7, 8, 9, 10, and 13 are neutral or are not considered, and Factors 3 and 4 weigh against a likelihood of confusion. Based *inter alia* on the similarity of the marks and the lack of dispute, the evidence does not show a genuine issue of material fact as to the likelihood of confusion based on Paradigm Peptides' use of the Mounjaro trademark and summary determination is warranted. *See Swagway*, 450 F.3d at 1340.

**7. GenX Peptides**[27]

GenX Peptides advertises a tirzepatide product on its website as "Tirzepatide 5mg." Ex. 15 at LILLY_ITC_0002818. The description of the product includes "Tirzepatide is a compound that has been shown to help with weight loss by reducing food intake and increasing feelings of fullness" and "Tirzepatide can lead to significant weight loss in animal models when used in combination with a calorie-controlled diet and increased physical activity." *Id*. at LILLY_ITC_0002819. GenX Peptides includes Mounjaro as a synonym for its product: "Synonyms: LY3298176, GIP/GLP-1 RA, Mounjaro." *Id*. at LILLY_ITC_0002820.

Lilly argues GenX Peptides' "unauthorized use of "Mounjaro" is likely to confuse consumers and cause them to mistakenly believe that the Unapproved Drug Products derive from the same source as and/or are affiliated with MOUNJARO®." Lilly Br. at 53–55. Staff argues

[27] Although there is no violation as to GenX Peptides based on lack of sufficient importation evidence (*see* Section III.B.4), likelihood of confusion is assessed for purposes of the GEO analysis. *See* Section VIII.A *infra*.

"there is sufficient undisputed substantial, reliable, and probative evidence to find that GenX Peptides' use of the Asserted Trademark results in a likelihood of confusion." Staff Br. at 50.

For the reasons discussed below, there is substantial, reliable, and probative evidence showing that GenX Peptides' use of Mounjaro in its advertised goods creates a likelihood of confusion.

**a. DuPont Factor 1**

DuPont Factor 1 concerns the "similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression." *Swagway*, 934 F.3d at 1338–39. GenX Peptides advertises a tirzepatide product on its website as "Tirzepatide 5mg":


Ex. 15 at LILLY_ITC_0002818. Based on the product photo, the vials contain a label with the GenX Peptides logo and "Tirzepatide 5mg." *Id.* GenX Peptides describes the product as "Tirzepatide is a compound that has been shown to help with weight loss by reducing food intake and increasing feelings of fullness" and "Tirzepatide can lead to significant weight loss in animal models when used in combination with a calorie-controlled diet and increased physical activity." *Id*. at LILLY_ITC_0002819. Under a section heading "Synonyms," GenX Peptides includes Mounjaro: "Synonyms: LY3298176, GIP/GLP-1 RA, Mounjaro." *Id*. at LILLY_ITC_0002820.

Lilly argues GenX Peptides' designation is "not just similar but actually ***identical*** to MOUNJARO® in appearance, sound, and connotation, cutting strongly in favor of a likelihood

of confusion." Lilly Br. at 53–54 (emphasis in original). Lilly further argues GenX Peptides promotes its product as synonymous with Mounjaro. *Id*. at 56. Staff agrees that GenX Peptides' use of the Mounjaro mark as a synonym for the accused product "strongly favors a likelihood of confusion." Staff Br. at 44.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 1 weighs in favor of a likelihood of confusion. GenX Peptides describes its tirzepatide product as synonymous with Mounjaro. Ex. 15 at LILLY_ITC_0002820. The evidence shows that the use of the term "Mounjaro," considered in context, indicates a likelihood of consumer confusion. *See Swagway*, 934 F.3d at 1338–39.

**b. DuPont Factor 2**

DuPont Factor 2 concerns the "similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use." *Swagway*, 934 F.3d at 1338–39. Lilly registered Mounjaro in connection with pharmaceutical preparations—namely, pharmaceutical preparations for the treatment of diabetes—and uses the mark in for its tirzepatide product to treat type-2 diabetes. *See* Ex. 24 at Lilly_ITC_0000685–86; Lilly Br. at 13-14.

GenX Peptides markets tirzepatide as "a compound that has been shown to help with weight loss." Ex. 15 at LILLY_ITC_0002819. In addition to noting that GenX Peptides also markets a tirzepatide-containing product, Lilly argues that GenX Peptides sells its product in a 5 mg dosage, which is an FDA-approved dosage of Mounjaro. Lilly Br. at 56–57; Ex. 90 at 2 (Mounjaro is available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg dosages.).

Staff argues Lilly's trademark "does not reference tirzepatide or treatments for obesity," thus GenX Peptides' use of the mark makes DuPont Factor 2 "neutral, neither favoring nor

disfavoring a likelihood of confusion, or at best weighs slightly in favor finding a likelihood of confusion." Staff Br. at 45.

Based on the record evidence, there is no genuine issue of material fact that DuPont Factor 2 weighs, on balance, in favor of a likelihood of confusion. Both Lilly's and GenX Peptides' products contain tirzepatide. Although GenX Peptides' marketing focus appears to be on the weight loss benefits of its product, it also describes its "Mechanism of Action" as "tirzepatide helps to lower blood sugar levels and improve glycemic control in individuals with type 2 diabetes." *See* Ex. 15 at LILLY_ITC_0002819. The similarity of the underlying goods and the fact they are both marketed for pharmaceutical-type applications, including diabetes, weighs in favor of a likelihood of confusion.

**c. DuPont Factor 3**

DuPont Factor 3 concerns the "similarity or dissimilarity of established, likely-to-continue trade channels." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, this factor weighs somewhat against a likelihood of confusion.

**d. DuPont Factor 4**

DuPont Factor 4 concerns the "conditions under which and buyers to whom sales are made, i.e. 'impulse' vs. careful, sophisticated purchasing." *Swagway*, 934 F.3d at 1338–39; *see also Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."). Lilly argues this DuPont factor is not applicable to the analysis. *See* Section IV.B.

Staff argues the higher price point of Mounjaro, Lilly's prominent use of the Mounjaro mark on the label for its products, and GenX Peptide's use of its own label and mark weighs against a likelihood of confusion under DuPont Factor 4. Staff Br. at 46–47. GenX Peptides'

product is $91.50 per 5 mg vial[28] and provided in a vial labeled with GenX Peptide's logo and name. Ex. 15 at LILLY_ITC_0002818. Lilly sells Mounjaro in packaging displaying the Mounjaro Mark priced at $267.27 per dose. *See* Section IV.C.1.d n.13; Ex. 3 at LILLY_ITC_0000164.

The present evidence of record shows that DuPont Factor 4 weighs against a likelihood of confusion. GenX Peptides' use of its own branding on its product, as shown in its advertising, weighs against a likelihood of confusion among consumers. *See* Ex. 15; *Casual Footwear*, Comm'n Op. at 20 ("[T]his factor weighs against likelihood of confusion because the accused [products] have different tags and different price points than [complainant's product]."); Section IV.C.1.d *supra*. Moreover, at least for certain customers utilizing a 2.5 or 5 mg dose, Mounjaro is sold at a significantly higher price point. *See* Ex. 90 at 2; Ex. B ¶ 99. In addition, as noted above regarding DuPont Factor 3, the evidence shows that the conditions under which sales are made (in terms of prescription requirements) differ.

**e. DuPont Factor 5**

DuPont Factor 5 concerns the "fame of the prior mark (sales, advertising, length of use)." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the evidence of record shows no genuine issue of material fact that the level of fame of the Mounjaro mark favors a likelihood of confusion.

**f. DuPont Factor 6**

DuPont Factor 6 concerns "[t]he number and nature of similar marks in use on similar goods." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark in connection with its

[28] Six 5 mg vials ordered for a total of $549 leads to a price per vial of $91.50 ($549 / 6). *See* Ex. 34 at LILLY_ITC_0002826 (showing total order cost); Ex. 35 (photos of six vials received).

tirzepatide-containing products, and related advertisements. *See* Lilly Br. at 50–52. GenX Peptides uses the Mounjaro mark in connection with its tirzepatide-containing product. Ex. 15 at LILLY_ITC_0002818–21. Staff agrees that the use of Mounjaro by Lilly and GenX Peptides for tirzepatide-based products favors a finding of likelihood of confusion. Staff Br. at 48.

There is no genuine issue of material fact that DuPont Factor 6 weighs in favor of a likelihood of confusion for the same reasons as set forth above for SHS.

**g. DuPont Factor 7**

DuPont Factor 7 concerns "[t]he nature and extent of actual confusion." *Swagway*, 934 F.3d at 1338–39. Lilly does not present survey results for GenX Peptides; however, Lilly seeks to extend Dr. Isaacson's opinions to apply to other Trademark Respondents. Lilly Br. at 55–56. Staff disagrees stating Lilly "has not submitted any evidence of actual confusion due to GenX Peptides' advertising. Thus, this factor does not weigh in favor of a likelihood of confusion." Staff Br. at 48.

The evidence of record shows that this factor is neutral, as the survey evidence at issue relates to potential confusion (DuPont Factor 12) rather than actual confusion. *See Certain Casual Footwear*, at 22-31 (discussing "actual confusion" separately from survey results); MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32.184 (5th ed., 2024 update) ("Survey Results are Not Evidence of 'Actual Confusion'").

**h. DuPont Factor 8**

DuPont Factor 8 concerns "[t]he length of time during and conditions under which there has been concurrent use without evidence of actual confusion." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning DuPont Factor 8, this factor will not

be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

**i. DuPont Factor 9**

DuPont Factor 9 concerns "[t]he variety of goods on which a mark is or is not used (house mark, 'family' mark, product mark)." *Swagway*, 934 F.3d at 1338–39. Lilly uses the Mounjaro mark for its tirzepatide product to treat diabetes and uses a separate mark—Zepbound—for its tirzepatide product related to weight loss. Lilly Br. at 4–6. GenX Peptides markets tirzepatide as "a compound that has been shown to help with weight loss" and describes its "Mechanism of Action" as "tirzepatide helps to lower blood sugar levels and improve glycemic control in individuals with type 2 diabetes." *See* Ex. 15 at LILLY_ITC_0002819.

Staff argues "GenX Peptides' use of the Asserted Trademark, widely known as a diabetes medication, for the incorrect indication (weight loss) in addition to diabetes would tend to slightly favor a finding of a likelihood of confusion or be neutral at best." Staff Br. at 72.

The evidence of record shows that DuPont Factor 9 is neutral for the reasons set forth in Section IV.C.1.i.

**j. DuPont Factor 10**

DuPont Factor 10 concerns "[t]he market interface between applicant and the owner of a prior mark." *Swagway*, 934 F.3d at 1338–39. No party has argued that this factor is applicable to the analysis. *See* Section IV.B; Staff Br. at 34–36. Because no party has presented evidence concerning factor 10, this factor will not be considered in the analysis of the likelihood of confusion. *See Swagway*, 934 F.3d at 1339 ("The Commission need not consider every *DuPont* factor[,] . . . only those factors which are supported by evidence in the record.").

### k. DuPont Factor 11

DuPont Factor 11 concerns "[t]he extent to which applicant has a right to exclude others from use of its mark on its goods." *Swagway*, 934 F.3d at 1338–39. For the same reasons discussed above in Section IV.C.1, the record evidence shows that DuPont Factor 11 weighs in favor of a likelihood of confusion.

### l. DuPont Factor 12

DuPont Factor 12 concerns "[t]he extent of potential confusion, i.e., whether de minimis or substantial." *Swagway*, 934 F.3d at 1338–39. Lilly relies on the similarity of the marks and Dr. Isaacson's surveys to argue there is substantial confusion based on the survey results about SHS and TCP. Lilly Br. at 55–56; *see also* Section IV.B (Lilly citing supporting survey evidence of substantial confusion for DuPont Factor 12). Staff argues this DuPont factor only minimally favors a likelihood of confusion because GenX Peptides' product has its own label that does not display a Mounjaro mark. Staff Br. at 49.

Based on the record evidence, there is no genuine issue of material fact that this factor weighs in favor of a likelihood of confusion based on GenX Peptide's use of the Mounjaro mark as a "synonym" for its product. *See* discussion *supra*. [29]

### m. DuPont Factor 13

DuPont Factor 13 concerns "[a]ny other established fact probative of the effect of use." *Swagway*, 934 F.3d at 1338–39. Common to all Trademark Respondents, Lilly argues use of the Mounjaro mark, marketing products as suitable for the same or similar purposes as Mounjaro, and selling products in the same dosages as Mounjaro are sufficient to infer intent to benefit from

[29] Dr. Isaacson's survey results are not particularly persuasive given that GenX Peptide's use of the "Mounjaro" mark appears less prominent than in the web pages of SHS and TCP.

the reputation of the Mounjaro mark. Lilly Br. at 58–59. Staff disagrees that such an inference is appropriate here, where the Trademark Respondents defaulted before providing and discovery. *See* Staff Br. at 67–68.

For the reasons discussed above in Section IV.C.1.m, DuPont Factor 13 carries little weight in the analysis.

#### n. Conclusion

As discussed above, there is substantial, reliable, and probative evidence of likelihood of confusion as to GenX Peptides. In particular, Factors 1, 2, 5, 6, 11, and 12 weigh in favor of a likelihood of confusion, Factors 7, 8, 9, 10, and 13 are neutral or are not considered, and Factors 3 and 4 weigh against a likelihood of confusion. Based *inter alia* on the similarity of the marks and the lack of dispute, the evidence does not show a genuine issue of material fact as to the likelihood of confusion based on GenX Peptides' use of the Mounjaro trademark and summary determination is warranted. *See Swagway*, 450 F.3d at 1340.

## V. FALSE DESIGNATION OF ORIGIN

Lilly asserts Accused Products from Audrey Beauty, Mew Mews, SHS, Biolabshop, Triggered Brand, Strate Labs, Paradigm Peptides, and GenX Peptides (collectively, "False Designation Respondents") have used false and misleading designations of origin that are likely to confuse consumers regarding the origin, sponsorship, or approval of their goods. Lilly Br. at 61.[30] Lilly alleges these Respondents, in addition to using Lilly's Mounjaro mark, use additional names and marks owned by Lilly in connection with its own tirzepatide-based medicines and

[30] It is unclear whether Audrey Beauty and Mew Mews are identified by Lilly as False Designation Respondents. *Compare* Lilly Br. at 3 and 61. The same evidence showing trademark infringement as to these two Respondents also shows false designation of origin, and at the least supports Lilly's request for a GEO as to false designation of origin. *See* Section VIII.A *infra*.

research; cite to clinical trials and research articles related to such trials that tested Lilly's tirzepatide medicines; reference FDA approvals of Lilly tirzepatide medicines; and reference information related to FDA approval, safety warnings, and dosages of Lilly's tirzepatide medicines. *Id*. at 61–62. As further support for likelihood of confusion, Lilly argues these respondents reference Lilly's Surmount and Surpass clinical trials and claim the Accused Products treat the same illnesses or conditions in the same doses as Lilly's products. Lilly Br. at 64–66.

As discussed above, Lilly has shown a likelihood of confusion for SHS, Triggered Brand, Paradigm Peptides, and GenX Peptides in the context of trademark infringement, *see* Section IV.[31] The same evidence also supports a finding of false designation of origin for these Respondents based at least on the trademark use. *Ross Bicycles*, 765 F.2d at 1503–04 ("The factors relevant to establishing [false designation of origin] are identical to the factors relevant to establishing a likelihood of confusion with respect to trademark infringement under 15 U.S.C. § 1114."); *Casual Footwear*, Comm'n Op. at 34. Staff agrees. Staff Br. at 81. Thus, there is substantial, reliable, and probative evidence that SHS, Triggered Brand, Paradigm Peptides, and GenX Peptides used false and misleading designations of origin and the record fails to show a genuine issue of material fact precluding summary determination as to that issue. The reference by certain of these Respondents to Lilly's clinical trials, in combination with the Mounjaro mark, reinforces the likelihood of confusion as to origin.[32]

[31] However, summary determination of violation has not been shown as to Paradigm Peptides or GenX Peptides due to lack of proof of service (Paradigm Peptides) and insufficient proof of importation (GenX Peptides). This applies both to the trademark infringement and false designation of origin claims.

[32] Lilly relies on use of the Mounjaro mark in its allegations relating to false designation of origin. *See, e.g.*, Lilly Br. at 64 ("coupled with the False Designation Respondents' use of identical 'Mounjaro designations and additional deceptive suggestions of connection to Lilly, these factors are effectively

As discussed in more detail below, with respect to Biolabshop, there exists a genuine issue of material fact precluding summary determination. With respect to Strate Labs, the evidence supports summary determination of false designation of origin.

**A. Biolabshop**

Lilly argues that Biolabshop references the results of Lilly's Surpass and/or Surmount clinical studies; suggests use of its product for type 2 diabetes and weight loss; and offers its product in the same dosage as the Domestic Industry Products. Lilly Br. at 65–66. Lilly also argues these same facts manifest ill intent by Biolabshop, and that the evidence as a whole shows false designation of origin. *Id.* at 61-66. Staff disagrees, arguing that there is insufficient evidence to determine Biolabshop's manifest intent or to find a likelihood of confusion. Staff Br. at 81–87 (arguing that only DuPont factor 5, the fame of Lilly's mark, weighs in favor of finding a likelihood of confusion). *See also* Lilly Reply at 4-6; Staff Sur-Reply at 3-5.

The undersigned finds Lilly has not shown by substantial, reliable, and probative evidence that Biolabshop used false and misleading designations of origin that constitute a violation of the Lanham Act. In particular, the evidence shows that Biolabshop does not mention Mounjaro in its advertisement and has its own branding and logo on the bottle and packaging:

dispositive of likelihood of confusion"); *see also id.* at 68, 69 (relying on use of and evidence relating to "Mounjaro").


Ex. 59 at LILLY_ITC_0001117 (excerpt); Lilly Br. at 68 (acknowledging that Biolabshop does not describe their products as Mounjaro).

Biolabshop's website states "[t]irzepatide is used to treat type 2 diabetes in adults" and "[u]sed in the form of an injection – in a multicenter, randomized and double-blind clinical trial – it helped participants lose even more than 20 percent body weight." *Id*. at LILLY_ITC_0001117. Lilly asserts that these references "can only refer to Lilly's double-blind clinical trials, as there is no evidence of others." Lilly Reply at 5 (emphasis removed). However, the website does not refer by name to Lilly or Lilly's clinical trial names—Surpass and Surmount. Nor has Lilly provided evidence indicating that a reference to a clinical trial would be associated with Lilly in the minds of consumers. Similarly, that Biolabshop sells its tirzepatide product in a 5 mg vial, which matches one of the six available doses of Mounjaro, offers insufficient persuasive support for Lilly's position.[33] Lilly has not persuasively shown that any mark or Lilly signifier has been similarly used by Biolabshop. Accordingly, DuPont Factor 1 (mark similarity) weighs against a likelihood of confusion.

[33] Mounjaro is available in several dosages, including 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg. *See, e.g.*, Ex. 90 at 2.

Lilly's reliance on Dr. Isaacson's survey experiments also do not support Lilly's position. *See* Lilly Br. at 66–67. Dr. Isaacson found that the web pages for SHS and TCP "communicate[] to substantial percentages of survey respondents that the accused product sold on the web page has been shown to be effective, [and] has been tested in clinical trials, has been shown to be safe, is a medication for type 2 diabetes, is a medication for weight loss, is called Mounjaro, and is the same as Mounjaro." Ex. C ¶¶ 81–82. Dr. Isaacson's survey did not use the Biolabshop website, and his conclusions based on different products on different websites which include significantly different product information (*e.g.*, use of the word "Mounjaro") carry little weight as to the issue of whether consumers would associate Biolabshop's product with Lilly. *See id.* ¶ 121; *see also* Staff Br. at 85; Staff Sur-Reply at 5. Accordingly, DuPont Factor 12 does not weigh in favor of a likelihood of confusion.

Moreover, based on the same reasoning discussed regarding trademark infringement for certain other Respondents (*e.g.*, Strate Labs), DuPont Factors 3 and 4 weigh against a likelihood of confusion; DuPont Factor 2 weighs in favor of a likelihood of confusion; and DuPont Factors 7, 8, 9, 10, and 13 are neutral or not considered. In addition, DuPont Factors 5, 6, and 11 (relating to the strength of Lilly's marks) appear neutral here because Lilly has not persuasively pointed to any use of a Lilly mark or signifier (or close facsimile thereof) in connection with Biolabshop.[34]

Taken as a whole, and in view of Staff's arguments relating to Biolabshop, Lilly has not shown the absence of a genuine issue of material fact regarding its false designation of origin claim against Biolabshop. Accordingly, summary determination is not warranted.

[34] Nor has Lilly pointed to substantial, reliable, and probative evidence regarding the strength of references to clinical trials or 5 mg. doses as Lilly signifiers.

### B. Strate Labs

In support of its false designation of origin claim regarding Strate Labs, Lilly argues that Strate Labs markets its product as "Generic Mounjaro" and "provides a product description invoking the results of Lilly's 'SURMOUNT-1 clinical trial.' Lilly Br. at 64–65. Lilly argues that Strate Labs describes its product as "used to treat type 2 diabetes" and offers it in the same dosage as Lilly's Domestic Industry Products. *Id*. Lilly argues these same facts manifest bad intent by Strate Labs. Lilly contends that Dr. Isaacson's surveys indicate "a substantial percentage of consumers viewing the web pages he tested were confused about whether the products being sold . . . were tested in clinical trials," "were medications for type 2 diabetes and/or weight loss," or "were the subjects of these clinical trials and FDA approval." *Id.* at 66–67 (citing Isaacson Report ¶¶ 81–82).

Staff relies on the showing of a likelihood of confusion in the context of trademark infringement to also support a finding of false designation of origin. Staff Br. at 80–81.

As discussed *supra*, there exists at least a genuine issue of material fact as to whether Strate Labs has infringed Lilly's "Mounjaro" trademark. Lilly's false designation of origin claim, however, is broader and relies as well on the reference by Strate Labs on its webpage to Lilly's "SURMOUNT" clinical trial, as follows:

> Tirzepatide injection is used to treat type 2 diabetes. It is used together with diet and exercise to help control your blood sugar. Tirzapatide [sic] is a glucagon-like peptide-1 (GLP-1) receptor agonist. In the SURMOUNT-1 clinical trial, the average weight loss with tirzepatide after 72 weeks was 15% for the 5mg dose, 19.5% for the 10mg dose, and 20.9% for the 15mg dose.

Ex. 58 at LILLY_ITC_0001007. The evidence of record indicates that Lilly has a federal trademark registration in "SURMOUNT," on the principal register, which is *prima facie*

evidence of secondary meaning. *See* Potts Decl. ¶ 4; Lilly Br. at 63.[35] Secondary meaning "occurs when, in the minds of the public, the primary significance of a [mark] is to identify the source of the product rather than the product itself." *Converse, Inc. v. Int'l Trade Comm'n*, 909 F.3d 1110, 1116 (Fed. Cir. 2018). In this context, DuPont Factor 1 favors a likelihood of confusion. DuPont Factor 12 also favors a likelihood of confusion based on Strate Labs' use of the term SURMOUNT on its webpage.

With respect to the other DuPont Factors, Factors 2 and 11 weigh in favor of a likelihood of confusion[36]; Factors 3 and 4 weigh against a likelihood of confusion (for the same reasons set forth above regarding trademark infringement); and Factors 5, 6, 7, 8, 9, 10, and 13 are either neutral or not considered.[37]

Based on the evidence of record as a whole, and in particular Strate Labs' reference to and reliance on the "SURMOUNT" clinical trial on its website, Lilly has presented substantial, reliable, and probative evidence sufficient to show likelihood of confusion as to its false designation of origin claim against Strate Labs and thus summary determination is warranted.[38]

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[35] The undersigned takes judicial notice of the fact that Lilly has a trademark registration on the principal register, U.S. Reg. No. 6,747,106 (registration date March 31, 2022), for SURMOUNT, as a service mark for "Medical and scientific research in the field of diabetes and obesity." *See* Lilly Br. at 63 n.3; *In re Chippendales USA, Inc*., 622 F.3d 1346, 1356 (Fed. Cir. 2010) ("[T]his court may take judicial notice of the existence of the Playboy bunny trademarks[.]"). This is "prima facie evidence" of the mark's validity, "including that it has acquired secondary meaning." *Converse, Inc. v. Int'l Trade Comm'n*, 909 F.3d 1110, 1117 (Fed. Cir. 2018).

[36] Factor 2 (similarity of goods) favors a likelihood of confusion for the same reasons as discussed in Part IV for Strate Labs; Factor 11 (extent of right to exclude) favors likelihood of confusion based on SURMOUNT's status on the principal register.

[37] Factor 5 is neutral because there is little evidence regarding the level of fame of the SURMOUNT mark; Factor 6 is neutral based on lack of evidence regarding the issue of similar marks; Factors 7-10 and 13 are neutral or not considered for the same reasons discussed for Strate Labs in Part IV *supra*.

[38] With respect to the damage or injury requirement, *see* Part VII.C *infra*. *See generally Certain Food Processing Equipment and Packaging Materials Thereof*, Inv. No. 337-TA-1161, Order No. 14, 2020 WL 1504748, at *19 (injury to the domestic industry shows "likelihood of injury" for purposes of Lanham Act

## VI. FALSE ADVERTISING

Lilly asserts that advertising for the Accused Products from SHS, Total Compounding ("TCP"), and AustroPeptide (collectively designated the "False Advertising Respondents") "materially misrepresent the nature, characteristics, and qualities of their Unapproved Drug Products in violation of Section 43(a)(1)(B) of the Lanham Act." Lilly Br. at 71. Lilly alleges these Respondents "state that their products are the same as, or synonymous with, MOUNJARO®, are for the treatment of diabetes and/or weight loss, and have been the subject of clinical trials or FDA approval," claims which Lilly argues are literally false. *Id*. Furthermore, Lilly argues that AustroPeptide made literally false statements in its advertising because its tirzepatide product does not actually contain any tirzepatide. *Id*. In addition to the information on the False Advertising Respondents' websites themselves, Lilly relies on surveys conducted by Dr. Bruce Isaacson regarding advertisements on the SHS and TCP websites. Lilly Br. at 77–81; Ex. C, Appx. A ("Isaacson Report").

Lilly also argues that Arctic Peptides engages in false advertising (although Lilly does not include Arctic Peptides as one of the "False Advertising Respondents"). *See* Lilly Br. at 71, 88-91.

Lilly expressly does not seek a GEO based on its false advertising claims, but only seeks relief limited to the relevant Respondents (*i.e.*, an LEO and/or cease-and-desist order). Lilly Br. at 128 (arguing that substantial, reliable, and probative evidence supports its claims for trademark infringement and false designation of source but that "Complainant does not rely on the violation . . . based on false advertising to support entry of a GEO"); *see also* 148–49

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claim); Lilly Br. at 26. Similarly, the importation evidence shows use in commerce. See Part III.B supra; Lilly Br. at 26.

(requesting an LEO against the False Advertising Respondents); *id.* at 149 (seeking cease-and-desist orders directed to, *inter alia*, SHS, Total Compounding, and Arctic Peptides).

For the reasons discussed below, summary determination is warranted with respect to SHS, AustroPeptide, and Arctic Peptides with respect to Lilly's false advertising claim.

### A. Total Compounding

As discussed above, Total Compounding has not been found in default and no adequate proof of service was filed. Accordingly, no violation of section 337 has been shown as to Total Compounding with respect to any claim, including the false advertising claim, and thus it is unnecessary to address whether the specific elements of false advertising have been met.[39]

### B. SHS

Lilly alleges in the Complaint and in its summary determination briefing that SHS engages in false advertising regarding the products sold on its website. Second Am. Compl. ¶¶ 139–44; Lilly Br. at 71-76. In particular, Lilly alleges that SHS refers to "Mounjaro" in the product name and makes false statements on its website that indicate it is selling products that have been subjected to clinical trials and approved by the FDA. Second Am. Compl. ¶¶ 139–44; Lilly Br. at 73–74. Lilly argues that its survey evidence with respect to SHS supports the contention that SHS's website communicates misleading messages. *See* Lilly Br. at 79-81 (citing Isaacson Rpt.).

Staff agrees that SHS has engaged in false advertising in violation of the Lanham Act and does not challenge Lilly's allegations of false advertising by SHS. Staff Br. at 88-92.

[39] In addition, since Lilly does not seek a GEO as to the false advertising claim, there is no need to address Total Compounding as part of a potential "pattern of violation" for purposes of assessing a potential GEO.

Based on Lilly's unchallenged allegations and the additional supporting survey evidence, the undersigned finds that Lilly is entitled to a finding of violation for false advertising under 19 U.S.C. § 1337(g)(1) with respect to its requested remedies of a limited exclusion order and cease and desist order directed to SHS. *See* 19 U.S.C. § 1337(g)(1); *Laerdal Med. Corp. v. Int'l Trade Comm'n*, 910 F.3d 1207, 1212–13.

### C. AustroPeptide

Lilly alleges in the Complaint and its summary determination briefing that AustroPeptide markets its products as containing tirzepatide and that this representation constitutes false advertising. Second Am. Complaint ¶ 203; Lilly Br. at 75. The following excerpt from AustroPeptide's website states it is selling "Tirzepatide 10mg."


Ex. 29 at Lilly_ITC_0001040. AustroPeptide also describes its product with the chemical registry number for tirzepatide, "CAS: 2023788-19-2." *Id.*; Lilly Br. at 75; Second Am. Complaint ¶ 202. Lilly tested AustroPeptide's tirzepatide product and determined it did not contain any tirzepatide. Ex. 60 at Lilly_ITC_0001080 (testing report stating "[t]he suspect

tirzepatide sample does not contain tirzepatide . . . [and] are spectrally consistent with mannitol-based material."); Second Am. Complaint Ex. 45. Lilly further argues that AustroPeptide markets its product "through 'research' showing the effectiveness of tirzepatide in treating type 2 diabetes and weight management," and that these statements falsely imply that the AustroPeptide products "were the subject of those studies or FDA approvals." Lilly Br. at 74.

Staff agrees that AustroPeptide's statements that its product contains tirzepatide constitute false advertising. *See* Staff Br. at 96-101.[40] Upon consideration of the record, the undersigned finds that Lilly is entitled to a finding of violation under 19 U.S.C. § 1337(g)(1) with respect to its requested remedy of a limited exclusion order and cease and desist order directed to AustroPeptide. *See* 19 U.S.C. § 1337(g)(1); *Laerdal*, 910 F.3d at 1212–13.

### D. Arctic Peptides

According to the Complaint and summary determination briefing, Artic Peptides advertises its product as "Tirzepatide" available in 5 mg and 10 mg doses:

[40] Staff further states that "[g]iven the egregious nature of the false statements made by AustroPeptide regarding its Accused Product . . . there does not seem to be a need to reach Complainant's arguments about AustoPeptide's generic statements regarding tirzepatide research." Staff Br. at 99 n.27.


Tirzepatide

USD $74.39 – USD $130.19

Tirzepatide is a peptide that activates both GLP-1 and GIP receptors. It was developed to ght type 2 diabetes by lowering blood sugar levels, boosting insulin sensitivity, and reducing hunger. In addition to cardiovascular bene s, recent trials have demonstrated impressive results when used for weight loss.

Available dosages: 5mg and 10mg

Description

Important Notice:

- This product is sold for research purposes as a lyophilized (freeze-dried) powder.
- The dosage on the label refers to the total amount inside the vial.
- The following lab supplies are required for reconstitution: bacteriostatic water for mixing, and syringes to draw from the vials.
- If you have any questions regarding reconstitution or storage, please reach out to us by email or live chat.

Ex. 51 at LILLY_ITC_0001185–86 (excerpts).

Lilly contends that Arctic Peptides makes "literally and necessarily false statements" by claiming that "its Unapproved Drug Products" were "developed to fight type 2 diabetes by lowering blood sugar levels, boosting insulin sensitivity, and reducing hunger. In addition to cardiovascular benefits, recent trials have demonstrated impressive results when used for weight loss." Lilly Br. at 88–89. Lilly argues Arctic Peptides' claims are literally false because the product advertised is not FDA approved, not shown to be safe, not developed to have therapeutic effects, and has not been subject to any of the clinical trials mentioned on the website. *Id*. Lilly

also argues Artic Peptides' claim that the product is for "research purposes only" is false because the product is sold with syringes and bacteriostatic water explicitly for human use. *Id*.; *see generally* Second Am. Complaint ¶¶ 233-237.

Staff argues that the evidence fails to show that Artic Peptides' statements are literally false. Staff contends that the Arctic Peptides website contains "a general statement about the results of recent trials without identifying who conducted those trials. There is no reference to Lilly. There is also no reference to Mounjaro®, SURMOUNT® or SURPASS® trials." Staff at 102. Staff contends that these general statements are "literally true." *Id.* at 102–03 (citing Lilly's Complaint and press releases about clinical trials). Staff also argues there is no evidence to support Lilly's claim that Artic Peptides sells its products for human use and not research purposes as stated on the website. Staff contends that there is insufficient evidence of false or deceptive statements. *Id*.

As discussed *supra*, Lilly does not seek a general exclusion order with respect to Lilly's false advertising claim. Moreover, Staff states that "the facts alleged in the Complaint and 2nd Amended Complaint will be presumed to be true with respect to the defaulting respondents for the purposes of *limited* exclusion orders" but not with respect to "their request for a GEO." Staff Br. at 2 (emphasis in original). Because Lilly does not seek a GEO based on its false advertising allegations, a finding of violation is appropriate.[41]

[41] Staff appears to assume that Lilly seeks a GEO with respect to its false advertising claim but this is contradicted by Lilly's filings. *See* Lilly Br. at 128 ("Complainant does not rely on the violation of Section 337(a)(1)(A) based on false advertising to support entry of a GEO."); *see also id.* at 148 (seeking LEO against the False Advertising Respondents). Moreover, the record does not show non-cumulative new post-complaint evidence refuting the allegations in the complaint. *See* Second Am. Compl. ¶¶ 56-61.

## VII. DOMESTIC INDUSTRY

Lilly asserts claims trademark infringement under Section 337(a)(1)(C), Lilly Br. at 49–61, and false designation of origin and false advertising under Section 337(a)(1)(A), *id.* at 61–91. For purposes of Lilly's Section 337(a)(1)(C) claims, Lilly must show that it satisfies both the technical prong of the domestic industry requirement through use of the Asserted Trademark, and that Lilly has satisfied the economic prong through substantial investments under sub-prongs (A), (B), and/or (C). These issues are addressed below in sections VII.A and VII.B, respectively.

For purposes of Lilly's Section 337(a)(1)(A) claims, "a complainant must show that those unfair acts have substantially injured or threatened to injure the domestic industry." *Bone Cements*, Inv. No. 337-TA-1153, Comm'n Op. at 11; *Rubber Resins,* Inv. No. 337-TA-849, Comm'n Op. at 9. Evidence for such injury may include "the volume of imports and their degree of penetration, complainant's lost sales, underselling by respondents, reductions in complainants' declining production, profitability and sales, and harm to complainant's good will or reputation." *Rubber Resins*, Inv. No. 337-TA-849, Comm'n Op. at 60-61. Lilly's injury allegations are addressed in section VII.C.

For the reasons discussed below, summary determination that Lilly has satisfied the technical prong and economic prong for its claims of trademark infringement is warranted. Summary determination is also warranted as to Lilly's claims of injury to a domestic industry for its claims of false designation of source and false advertising.

### A. Technical Prong (Section 337(a)(1)(C) claims)

Lilly asserts that the domestic industry products plainly display the asserted trademark on both the products themselves and on the packaging for the domestic industry products. Lilly Br.

at 92–95. The Staff agrees. Staff Br. at 105–10. As the images below show, Lilly's tirzepatide auto-injector pens display the MOUNJARO mark:


Second Am. Compl. ¶ 329; *See also* Ex. 65 (product photos). Similarly, the packaging for the domestic industry products prominently displays the asserted trademark:

Ex. 25 at Lilly_ITC_0000769; *see also id.* at Lilly_ITC_0000770–74 (packaging for other doses).

Substantial, reliable, and probative evidence thus shows Lilly has satisfied the technical prong of the domestic industry requirement.

### B. Economic Prong (Section 337(a)(1)(C) claims)

To meet the economic prong of the domestic industry requirement, Lilly relies on investments in three facilities related to the manufacture of the domestic industry products and components thereof. Lilly Br. at 95–111. Lilly also asserts it has made "significant employment of labor and capital related to the research and development" of the domestic industry products. *Id*. at 111. In support of its position, Lilly submitted declarations of it expert, Thomas Vander Veen, Ex. B (Vander Veen Decl.), Lilly Senior Vice President and Chief Financial Officer of Global Manufacturing and Quality Jonathan Haug, Ex. D (Haug Decl.), Lilly Senior Vice President and Chief Financial Officer of Global Research and Development Todd Farnsworth, Ex. E[42] (Farnsworth Decl.), Senior Vice President and Chief Financial Officer at Lilly Diabetes & Obesity and Lilly USA Mark A. Stempel, Ex. F (Stempel Decl.).

Staff agrees there is substantial evidence that Lilly satisfies the domestic industry requirement based on investments in plant and equipment for the domestic industry products, and that the investments are "significant both qualitatively and quantitatively" in size and in the context of Lilly's "similar investments made globally." Staff Br. at 114–16. Additionally, Staff agrees that the evidence shows that Lilly has made significant investments in labor and capital, and that these investments are qualitatively and quantitatively significant. *Id*. at 116–18.

[42] After filing the present motion, Lilly submitted corrected versions of exhibits E and F. *See* EDIS Doc ID 826627. All references to these exhibits will be to the corrected versions.

However, Staff argues Lilly has presented insufficient evidence that its investments in research and development meets the economic prong under Section 337(a)(3)(C) because Lilly "does not explain how this investment is qualitatively and quantitative substantial." *Id*. at 119.

For the reasons set forth below, the evidence shows that the economic prong of the domestic industry requirement is met based on Lilly's investments in the domestic industry products under at least sub-prongs (A) and (B).

**1. Domestic Activities**

The evidence shows Lilly operates three facilities related to the production of Mounjaro in Indianapolis, Indiana. Lilly Br. at 95–96; Ex. D ¶ 3. Lilly's Indianapolis Device Assembly and Packaging ("IDAP") facility "[redacted]" Ex. D ¶ 5; Lilly Br. at 98–99. The Indianapolis Parenteral Manufacturing ("IPM") facility is where "[redacted]." Ex. D ¶ 8; Lilly Br. at 100. The Indianapolis Active Pharmaceutical Ingredient ("API") facility [redacted] "[redacted]," including tirzepatide. Ex. D ¶ 11; Lilly Br. at 101.

Lilly relies on its fiscal year 2023 investments and expenditures for the IDAP, IPM, and API facilities to establish the existence of a domestic industry under sub-prongs (A) and (B). Lilly Br. at 103. [redacted]. Ex. 69; Lilly Br. at 102–03. [redacted]y. Ex. 68 at LILLY_ITC_0002369.

### 2. Allocation Method

To allocate the expenses and the FTE of each facility to the domestic industry products, Lilly relies on the calculation of "[redacted] to capture "[redacted] Lilly Br. at 105; Ex. B ¶ 55; Ex. 4 at 164–65. The evidence shows that this "[redacted] calculation is used by Lilly in the ordinary course of business. *See* Lilly Br. at 105; Ex. B ¶ 55. Lilly describes the allocation method as follows:

[redacted]

Lilly Br. at 105; Ex. B ¶ 55.

Dr. Vander Veen used this [redacted] method to allocate Lilly's investments in his analysis. *Id.*; Ex. B ¶¶ 55–56. At the IDAP facility, [redacted]. Ex. B at Tab 3a; Lilly Br. at 108. However, [redacted]. Ex. B at Tab 3a. To provide an analysis specific to Mounjaro, Dr. Vander Veen [redacted]. Ex. B ¶ 56, Tab 3a; Lilly Br. at 108. Using these methods, Dr. Vander Veen determined the proportion of total expenses allocable to Mounjaro at each facility is: [redacted]. Ex. B ¶ 56. These percentages are consistent with statements by Jonathan Haug, Lilly's Chief Financial Officer of

Global Manufacturing and Quality. Ex. D ¶¶ 6, 9, 12 ( ).

Based on the evidence of record, the undersigned finds the method above is a reasonable and appropriate way to allocate Lilly's expenses to the domestic industry products.

### 3. Investments in Plant and Equipment

The evidence shows cognizable plant and equipment expenditures at Lilly's three facilities. Lilly tracks manufacturing expenses broken down into categories. Lilly Br. at 106–07; Ex. 69 (column headings). Dr. Vander Veen relied upon two of these categories—depreciation & amortization and maintenance & repairs—for plant and equipment expenses under sub-prong (A). Lilly Br. at 106–07; Ex. 69; Ex. B ¶ 53. Relying on Lilly's financial records, Dr. Vander Veen stated Lilly invested over for plant and equipment in the IDAP, IPM, and API facilities in 2023. Ex. B ¶ 54, Tab 5; Ex. 69. Applying the allocation percentages for each facility described above, Dr. Vander Veen attributed of the total investment as expenses specific to Mounjaro. Ex. B ¶ 57. Dr. Vander Veen's analysis and his allocation of expenses to each facility is summarized in the table below:

Ex. B ¶ 57, Tab 5 (showing 2023 investments); Lilly Br. at 108–09; Ex. 69.

Staff submits that Lilly's investments in plant and equipment for the domestic industry product support a finding that the domestic industry requirement has been met. Staff Br. at 114–16.

Based on the undisputed evidence of record, the undersigned finds that Lilly has reliably quantified its domestic industry expenditures in plant and equipment related to the domestic industry products.

#### 4. Investments in Labor or Capital

Lilly asserts that its investments in labor and capital expenditures are cognizable under sub-prong (B). Lilly Br. at 109–14. Lilly relies on the same three facilities for labor and capital as it did for the plant and equipment. *Id.* The evidence shows that Lilly maintains [redacted] full time equivalent employees ("FTE") at the IDAP facility, [redacted] FTE at the IPM facility, and [redacted] FTE at the API facility. Ex. D ¶ 6, 9, 12.

As discussed above, Lilly tracks its manufacturing expenses in several categories. *Id.* at 109–110; Ex. 69. Dr. Vander Veen employed what Lilly characterizes as a "conservative approach" by only including compensation and benefits expenditures in his employment of labor and capital calculations. *Id.*; Ex. B ¶ 58. Compensation and benefits expenditures for the three facilities in 2023 totaled [redacted] as detailed in the table below:

[redacted]

Ex. B ¶ 59, Tab 6a; Lilly Br. at 109–10. Applying the allocation percentages discussed above, Dr. Vander Veen allocated the compensation and benefits expenses at the three facilities:

| | Total Labor & Capital Expenses for Mfg. | MOUNJARO® [redacted] | MOUNJARO®-Specific Expenses for Mfg. |
|---|---|---|---|
| IDAP | [redacted] | | |
| IPM | | | |
| API | | | |

Lilly Br. at 110; Ex. B ¶ 60–61, Tab 6a. Summing these values, Dr. Vander Veen concluded that Lilly incurred Mounjaro-specific manufacturing expenses of [redacted] in 2023 related to labor and capital. Ex. B ¶ 60–61, Tab 6a.

In addition to its manufacturing facilities, the evidence shows that Lilly has labor costs related to research and development of its tirzepatide products at its research and development headquarters in Indianapolis, Indiana. Ex. E ¶ 2–6. Lilly categorizes its research and development investments by [redacted], dividing them into [redacted] costs and [redacted] cost. Ex. E ¶ 6–7. [redacted] costs reflect money Lilly [redacted] and are discussed in more detail in section VII.B.5 below. *Id.* Mr. Farnsworth describes Lilly's [redacted] costs as investments

[redacted], including "[redacted]" *Id.* For the [redacted] between 2018 and 2023, Lilly had [redacted] investments of [redacted]. *Id.* ¶ 4. For the purposes of the present analysis, Lilly has limited its [redacted] investments to [redacted] of [redacted] costs for 2023 related to the use of tirzepatide for [redacted], the FDA-approved indication for Mounjaro. Lilly Br. at 112; Ex. 73 at 1 ([redacted]). Based on Lilly's historical trends, Mr. Farnsworth estimates [redacted] of [redacted] costs are employee compensation and benefits. Ex. E ¶ 8.

Lilly tracks employee [redacted] on research and development of tirzepatide, both for employees in the United States and worldwide. *Id.* ¶ 9; Lilly Br. at 112; Ex. 73. This information permitted Dr. Vander Veen to calculate the U.S. FTE as a percentage of the worldwide total. Ex. B ¶ 64.[43] For 2023, [redacted] of the worldwide FTE related to [redacted] were in the United States. Ex. B, Tab 7c. Because the [redacted] presumably includes work related to [redacted], Dr. Vander Veen used the same allocation percentage discussed earlier [redacted] to account for the portion of the [redacted] attributable to Mounjaro. *See* Section VII.B.2; Ex. B ¶ 64 [redacted] Applying this adjustment,

[43] Dr. Vander Veen states Lilly estimates the compensation and benefits for [redacted] researchers is approximately [redacted] that of [redacted] researchers. Ex. B ¶ 64. He states he has "conservatively not adjusted for this [redacted] compensation," instead using the FTE based on [redacted] to form the allocation percentages. *Id.* This indicates the actual financial investment is larger than Dr. Vander Veen states. As concluded below, Lilly's evidence is sufficient to show a domestic industry even under this more conservative monetary calculation.

the U.S. percentage of worldwide FTE related to Mounjaro is approximately [redacted]. Ex. B ¶ 64, Tab 7c; Lilly Br. at 112–13. Dr. Vander Veen applied this percentage to Lilly's 2023 [redacted] costs related to the use of tirzepatide [redacted] and concluded the total U.S. [redacted] costs related to Mounjaro to be [redacted]. Ex. B ¶ 64, 68, Tab 7a.

Further reducing this U.S. apportionment to [redacted] (the proportion of [redacted] expenses that Mr. Farnsworth estimates represents employee compensation and benefits), Dr. Vander Veen concludes Lilly invested [redacted] in the employment of labor related to research and development of Mounjaro in the United States for 2023. Ex. B ¶¶ 64, 68, Tab 7a; Lilly Br. at 113–14.

In total, Dr. Vander Veen states Lilly's 2023 labor costs incurred for manufacturing [redacted] and for research and development [redacted] related to Mounjaro is [redacted]. Ex. B ¶ 65; Lilly Br. at 114. The Staff agrees with Lilly's conclusion. Staff Br. at 116–18.

Based on the evidence presented by Lilly and Dr. Vander Veen, the undersigned finds that Lilly has reliably quantified its domestic industry expenditures in labor or capital related to the domestic industry products.[44]

### 5. Investments in Research and Development

Lilly asserts that its investments in research and development expenditures are cognizable under sub-prong (C). Lilly Br. at 114–17. As noted above, Lilly categorizes its research and development investments by [redacted], dividing them into [redacted] costs and [redacted] costs. Ex.

[44] Replicating the monetary calculations using the percentages listed by Lilly in its brief results in slightly different investment amounts than those provided by Lilly. This is presumably caused by rounding issues. Regardless, the slight variations in the absolute dollar values are not material to the analysis and do not materially affect the result.

E ¶ 6–7. [redacted] costs reflect money Lilly invests [redacted] *Id.*; Lilly Br. at 114–15. For 2023, Lilly's [redacted] costs of tirzepatide [redacted]. Ex. 71 at 1 ([redacted]); Lilly Br. at 115. To limit this figure to U.S. investments, Dr. Vander Veen calculated that approximately [redacted] of patients enrolled in Lilly's diabetes-related tirzepatide clinical trials were in the United States in 2023. Ex. B ¶ 67, Tab 7b.[45] Using this percentage to apportion the [redacted] costs, Dr. Vander Veen calculates Lilly's [redacted] research and development costs in 2023 to be [redacted]. *Id*. As noted above, Dr. Vander Veen calculated Lilly's total [redacted] costs in this category to be [redacted]. Ex. B ¶ 68, Tab 7a. Combining the two, Dr. Vander Veen concludes that Lilly's 2023 investments in the domestic industry products is [redacted]. *Id*. ¶ 69. The Staff agrees with Lilly's evidence and Dr. Vander Veen's calculations. Staff Br. at 118–19.

Based on the evidence presented by Lilly and Dr. Vander Veen, the undersigned finds that Lilly has reliably quantified its domestic industry expenditures in research and development related to the domestic industry products.

**6. Significance**

The evidence shows that Lilly's domestic investments under at least sub-prongs (A) and (B) are qualitatively and quantitatively significant.

With respect to plant and equipment, Lilly is headquartered in Indianapolis, Indiana, and all three manufacturing facilities are located there. Ex. D ¶¶ 3–4. The API facility [redacted]; the IPM facility [redacted]; and the IDAP facility [redacted]. Ex.

[45] Dr. Vander Veen also provided calculations for the years 2018-2022. *See* Ex. B ¶ 69.

D ¶¶ 5, 8, 11; Lilly Br. at 118. Staff agrees "the activities of the API, IPM and IDAP facilities are crucial to make the product marked with the Asserted Trademark." Staff Br. at 114–15. Thus, the investments are qualitatively significant. The evidence also shows quantitative significance: [redacted] of Lilly's global plant and equipment investments related to Mounjaro are in the United States. Ex. B ¶ 78 [redacted] in the United States versus [redacted] in non-U.S. investments). *Cf. Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 29–30 (EDIS Doc. ID 649139) (June 20, 2018) (finding significance based in part of comparison of domestic investments in plant and equipment to total investments in plant and equipment for principal product); *Certain Movable Barrier Operator Systems and Components Thereof*, Inv. No. 337-TA-1118, Comm'n Op. at 20-26 (EDIS Doc. ID 730303) (Jan. 12, 2021).

Lilly's labor investments are also qualitatively and quantitatively significant. Lilly employs approximately [redacted] employees in the United States involved in production of Mounjaro. Ex. D ¶ 13. These production-related activities show qualitative significance as they are critical to making the DI product. The evidence also shows quantitative significance. In 2023, [redacted] of Lilly's employees working on tirzepatide were in the United States. Ex. B ¶ 81. Further, Lilly's domestic investment in labor represented [redacted] of its global manufacturing labor investments related to Mounjaro. Lilly Br. at 121; Ex. B ¶ 79 [redacted] in U.S. investments compared to [redacted] in non-U.S. investments for 2023). *Cf. Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 67-69 (EDIS Doc. ID 750094) (Aug. 23, 2021) (finding quantitative significance based on comparison of R&D labor hours in the United States to global R&D labor hours).

Staff agrees that Lilly's investments under sub-prong (A) and (B) are quantitatively and qualitatively significant. Staff Br. at 114–16, 118.[46]

For the reasons discussed above, the undersigned finds Lilly has satisfied the economic prong of the domestic industry requirement for its section 337(a)(1)(C) claims based on Lilly's significant, cognizable investments relating to the domestic industry products.

### C. Injury (Section 337(a)(1)(A) claims)[47]

With respect to its false designation of origin and false advertising claims, Lilly alleges that "the False Designation Respondents' use of confusingly similar designations of origin and Arctic Peptides and the False Advertising Respondents' false and misleading statements regarding the nature of the Unapproved Drug Products substantially injure or threaten substantial injury to Lilly's domestic industry." Lilly Br. at 123–126; 19 U.S.C. § 1337(a)(1)(A)(i). In particular, Lilly alleges injury to Lilly's reputation and goodwill, which Lilly contends are evidenced by patient complaints and the efforts Lilly has undertaken to warn the public of and combat non-Lilly tirzepatide products. Lilly Br. at 123–125. Lilly further argues that the Respondents' acts threaten future injury in the form of underselling and diverting sales from Lilly's domestic industry products. *Id.* at 125–26.

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[46] With respect to sub-prong (C), the evidence shows that [redacted] Lilly's research and development facilities are in the United States [redacted]. Ex. B ¶ 49; Lilly Br. at 122. As noted above, Lilly invested over [redacted] in research and development of Mounjaro in 2023. Lilly argues that this "represents a substantial investment" in the exploitation of the Asserted Trademark. Lilly Br. at 122. Lilly further notes its investments in Mounjaro were even higher in 2022 at [redacted], and total more than [redacted] in research and development from 2018 to 2023. *Id.* at 122–23; Ex. B ¶ 69. Staff does not dispute Lilly's calculations but does not believe qualitative and quantitative significance has been shown. *See* Staff Br. at 118–19. As discussed above, the record shows that Lilly's domestic investments under sub-prongs (A) and (B) are significant, and thus it is unnecessary to reach sub-prong (C).

[47] Lilly's Section 337(a)(1)(A) claims require a showing of injury to a domestic industry. The evidence showing the existence of a domestic industry is the same as that set forth above for the Section 337(a)(1)(C) claims.

Staff agrees that Respondents' and third-party "sales of tirzepatide products of unknown composition and quality pose a substantial threat of future harm to Complainant's Mounjaro® brand and diverted sales." Staff Br. at 123.

Lilly's specific allegations of injury are discussed below.

**1. Consumer Complaints about Other Tirzepatide Products**

Lilly presents evidence showing that some consumers have received products that were not the Mounjaro product they believed they would receive. Lilly relies on "Authentication Reports," "Complaint Record Reports," and a "Complaint Synopsis Report" to demonstrate that certain customers have received tirzepatide products that were not Mounjaro. Lilly Br. at 123–24; Exs. 75–80. One patient contacted Lilly reporting illness and hospitalization after taking tirzepatide. Ex. 76 (patient chat transcript); Ex. 77 ("Complaint Record Report"). Despite the patient contacting Lilly to inquire about the medication, Lilly confirmed that the medication was not Mounjaro. *Id*. According to another report, a different patient contacted Lilly about adverse reactions to an inauthentic Mounjaro received from a "med spa" in Florida. Ex. 78 at LILLY_ITC_0002606. Another Complaint Synopsis Report indicates a patient received a different compounded tirzepatide product and not Mounjaro as expected. Ex. 80 at LILLY_ITC_0002622-23. Testing of a tirzepatide product associated with a patient complaint to Lilly indicated the sample was not Mounjaro and contained three impurities not found in Mounjaro. Ex. 75 at LILLY_ITC_0002585; *see also* Ex. 79 (similar testing of another sample).

Lilly argues that Lilly and/or Mounjaro will likely suffer reputational harm if a consumer is harmed by one of the Respondents' products, and if consumers believe those products are Mounjaro or the same as Mounjaro. Lilly Br. at 124. Staff notes that Lilly did not cite evidence that the consumer complaints discussed above have substantially harmed Lilly, but Staff agrees

"it seems reasonable to conclude that as sales and the manufacture of inauthentic Mounjaro® increase, consumer complaints will rise as consumers inject themselves with products of unknown composition and/or quality," and that would pose a substantial threat of future harm to the Mounjaro brand. Staff Br. at 121–22.

**2. Lilly's Effort to Educate Customers**

To address its concerns over the sale of tirzepatide products that may be confused with Mounjaro, Lilly undertook efforts to educate consumers. Lilly Br. at 124–25. Lilly launched a website, tirzepatide.lilly.com, informing consumers of how to identify and distinguish Mounjaro from non-Mounjaro tirzepatide products. *Id.*; Ex. A ¶ 13; Ex. 81. Lilly also submitted evidence of published open letters to the public detailing potential risks of other tirzepatide preparations, such as contaminants, impurities, and different chemical compounds. Ex. A ¶ 14; Exs. 83, 84. The evidence also shows that Lilly trained its employees to identify [redacted]. Ex. A ¶ 15; Ex. 86. Finally, the evidence shows that Lilly [redacted] and conducted [redacted] research to "investigate the [redacted] and related consumer opinions." Ex. A ¶ 16; Ex. 87 ([redacted]).

Staff agrees that Respondents' actions created Lilly's need to undertake its public relations campaign, but notes that Lilly did not "quantify the costs of these public relations campaign in terms of employees diverted from profitable tasks." Staff Br. at 122. Staff contends that "there is insufficient evidence to conclude Complainant suffered substantial harm to its domestic industry as a result of it." *Id.*

### 3. Respondents' Ability to Undersell Lilly's Mounjaro Products

Lilly further alleges that Respondents' false designations of origin and false advertising, combined with the ability to exploit cheaper foreign production costs and lack of quality control expenses, permit Respondents to sell their tirzepatide products at a fraction of the cost of Mounjaro. Lilly Br. at 125–26; Ex. B ¶¶ 98–101. The evidence shows that a single dose of Mounjaro is approximately $267.27.[48] The evidence shows that multiple Respondents have marketed their products at lower prices than Mounjaro, at least at the 5 mg and 10 mg dosage levels:[49]

| Respondent | Price |
|---|---|
| Audrey Beauty/Mew Mews | $36 per 10 mg tube (Ex. 10) |
| AustroPeptide | $41 per 10 mg vial (sold as $410 per ten 10 mg vials) (Ex. 29 at LILLY_ITC_0001040) |
| Biolabshop | €99.99 per 5 mg vial (Ex. 32 at LILLY_ITC_0001127)[50] |
| GenX Peptides | $91.50 per 5 mg vial (Ex. 34 at LILLY_ITC_0002826; Ex. 35)[51] |
| Paradigm Peptides | $120 per 5 mg vial (Ex. 37 at LILLY_ITC_0002833) |
| Strate Labs | $224.95 per 10 mg vial (Ex. 58 at LILLY_ITC_0001007) |
| SHS | $129 per 5 mg vial (Ex. 41 at LILLY_ITC_0000866) |
| Triggered Brand | $111.99 per 5 mg vial (Ex. 43 at LILLY_ITC_0000978) |
| TCP | $250 per 15 mg vial (Ex. 47 at LILLY_ITC_0002638–39) |
| Arctic Peptides | $130.19 per 10 mg vial (Ex. 51 at LILLY_ITC_0001185–86) |

[48] The list price of Mounjaro is $1,069.08 "per fill" which contains four weekly injections. Ex. B ¶ 99; Ex. 90 at 1–2. This results in a list price for a single dose of $267.27 ($1,069.08 / 4). The price of Mounjaro does not appear to vary with the dosage, *i.e.*, a 5 mg and 15 mg dose are the same price. Ex. B ¶ 99; Ex. 90 at 1–2 (only noting insurance, eligibility for the Mounjaro Savings Program, and pharmacy charges as affecting the price a patient pays); Staff Br. at 128 n.36.

[49] As discussed *supra*, a violation has not been found as to GenX Peptides, TCP, Paradigm Peptides, Strate Labs, or Biolabshop.

[50] This amount is approximately $110. *See* Staff Sur-Reply at 5 n.4 (citing https://www.forbes.com/advisor/money-transfer/currency-converter/eurusd/?amount=99 , last accessed Aug. 18, 2024.).

[51] Six 5 mg vials ordered for a total of $549 leads to a price per vial of $91.50 ($549 /6).

*See* Staff Br. at 122-123 (same); *see also* Ex. B ¶ 100.

Dr. Vander Veen opines that Respondents will continue to be able to undersell Mounjaro because they are able to take advantage of lower foreign production costs and are unlikely to expend the cost to comply "current Good Manufacturing Practices." Ex. B ¶¶ 91-93. Dr. Vander Veen further opines that Respondents can price their products lower than Mounjaro because they "have not made the same significant and substantial investments in developing and commercializing an FDA-approved tirzepatide treatment." *Id*. ¶ 100. Lilly contends that this means Respondents are "likely to divert future sales from Lilly and thereby injure Lilly's domestic industry." Lilly Br. at 126. Staff agrees that Respondents can undersell the list price of Mounjaro but notes that Lilly provides no evidence of diverted sales. Staff Br. at 122–23. Considering that 2023 sales of Mounjaro were $4.83 billion, Staff states that it is "of the view that there is insufficient evidence to show that Complainant has suffered substantial harm due to sales of the Accused Product." *Id*. at 123. However, Staff considers the number of third-parties currently selling tirzepatide products to create a threat of future injury to Lilly in the form of diverted sales. *Id*. (citing Ex. B ¶¶ 94–97 (discussing the threat of further U.S. market penetration).

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Based on the evidence set forth above, there is substantial, reliable, and probative evidence that the Accused Products pose a substantial threat of future harm through damage to the reputation of the Mounjaro brand and the threat of underselling Mounjaro as a result of the false designation of origin by certain Respondents shown in Sections V and VI above, and the record fails to show a genuine issue of material fact precluding summary determination. In

addition, the allegations and evidence show a substantial threat of injury based on false advertising by SHS, AustroPeptide, and Arctic Peptides.[52]

## VIII. PRELIMINARY RECOMMENDED DETERMINATION ON REMEDY AND BOND[53]

The Commission has broad discretion to select the form, scope, and extent of the remedy imposed for a violation of section 337. *See, e.g.*, *Hyundai Elecs. Indus. Co. v. Int'l Trade Comm'n*, 899 F.2d 1204, 1208-09 (Fed. Cir. 1990). Section 337(d) provides in pertinent part that if the Commission determines that there is a violation, "it shall direct that the articles concerned . . . be excluded from entry into the United States." 19 U.S.C. § 1337(d)(1). The Commission may enter either a limited or a general exclusion order. 19 U.S.C. § 1337(d)(2). The Commission may issue a cease and desist order ("CDO") in addition to, or instead of, an exclusion order. 19 U.S.C. § 1337(f)(1). During the 60-day Presidential review period under 19 U.S.C. § 1337(j) "articles directed to be excluded from entry under subsection (d) . . . shall . . . be entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3).

### A. General Exclusion Order

In an investigation where no respondent appears to contest the complainant's allegations, a violation of section 337 must be established by "substantial, reliable, and probative" evidence before the Commission can issue a general exclusion order. 19 U.S.C. § 1337 (d)(2), (g)(2). Section 337(g)(2) provides:

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[52] *See* 19 U.S.C. § 1337(g)(1); *Laerdal*, 910 F.3d at 1212–13. As noted *supra*, there is no violation as to TCP based on lack of service.

[53] The recommendations in this section apply based on the findings of violation appropriate upon summary determination. To the extent further proceedings are held before the undersigned on issues where summary determination was not granted, these recommended determinations could potentially be updated.

> In addition to the authority of the Commission to issue a general exclusion from entry of articles when a respondent appears to contest an investigation concerning a violation of the provisions of this section, a general exclusion from entry of articles, regardless of the source or importer of the articles, may be issued if—
>
> > (A) no person appears to contest an investigation concerning a violation of the provisions of this section,
> >
> > (B) such a violation is established by substantial, reliable, and probative evidence, and
> >
> > (C) the requirements of subsection (d)(2) are met.

*Id*. Section 337(d)(2) provides:

> The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that—
>
> > (A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or
> >
> > (B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.

19 U.S.C. § 1337(d)(2); *see also Ground Fault Circuit Interrupters and Prods. Containing Same*, Inv. No. 337-TA-615, Comm'n Op. at 25 (EDIS Doc. ID 321819) (Mar. 26, 2009). "Satisfaction of either of the requirements in subsection (d)(2) will suffice to support issuance of a GEO." *Certain LED Lightning Devices and Components Thereof*, Inv. No. 337-TA-1107, Comm'n Op. at 6 (EDIS Doc. ID687961) (Sept. 11, 2019).

Lilly and Staff both submit that a GEO directed to imports of tirzepatide that infringe the Asserted Trademark and/or violate the prohibition against false designation of origin under 15 U.S.C. § 1125(a)(1)(A) is appropriate in this investigation. Lilly Br. at 128–29; Staff Br at 124. Lilly does not rely on its claims of false advertising to support an entry of a GEO. [54] Lilly

[54] Staff argues a GEO is also appropriate for violations of false advertising. *See* Staff Br. at 124. Because Lilly does not seek a GEO in connection to its claims of false advertising, a GEO is not recommended.

Br. at 128. The undersigned recommends that, should the Commission find a violation, the Commission should issue a general exclusion order as to imports of tirzepatide in connection with infringement of the Asserted Trademark or false designation of origin.

Lilly has shown by reliable, probative, and substantial evidence that a violation of section 337 has occurred with respect to both trademark infringement and false designation of origin under 15 U.S.C. § 1125(a)(1)(A) by Respondents Audrey Beauty, Mew Mews, SHS, and Triggered Brand and with respect to false designation of origin by Strate Labs. *See* Sections IV, V. Each of these respondents was also found in default. *See* Order Nos. 13, 23. The remaining analysis below concerns satisfaction of the requirements of section 337(d)(2).

**1. Circumvention of a Limited Exclusion Order**

Lilly submits that there is significant evidence establishing that a GEO is necessary to prevent infringing respondents from circumventing a LEO. Lilly Br. at 129. Specifically, Lilly asserts respondents in this investigation "chose not to participate in this investigation, and many of which have hidden their true identities and channels of supply." *Id*.

Staff agrees and contends that the sellers of the Accused Products are underselling Lilly and conduct their operations anonymously using online web stores. Staff Br. at 128–31. Staff further argues the limited or incorrect contact information for several respondents, and the presence of numerous other entities that sell products similar to the Accused Products online supports entry of a GEO. *Id*. at 131–32.

"In determining whether conditions are ripe for circumvention, the Commission has considered whether it is difficult to identify sellers or manufacturers, whether previous attempts to address infringement have been unsuccessful, and whether infringing operations could be easily replicated." *Certain Toner Cartridges, Components Thereof, & Sys. Containing Same*, Inv.

No. 337-TA-1174, Comm'n Op., EDIS Doc. ID 728235, at 16 (Dec. 17, 2020); *see also Certain Pumping Bras*, Inv. No. 337-TA-988, Comm'n Op., EDIS Doc. ID 607842, at 11 (Apr. 7, 2017) ("*Pumping Bras*") (noting that sales made via the Internet make it difficult to identify and locate manufacturers and sellers); *Certain Toner Cartridges and Components Thereof*, Inv. No. 337-TA-918, Comm'n Op., EDIS Doc. ID 566475, at 6 (Oct. 1, 2015) (finding various practices such as facilitating circumvention through Internet operations, masking of identities and product sources, and use of unmarked, generic, and/or reseller-branded packaging show a high likelihood of circumvention of a LEO). Relevant market conditions also include strong demand for the products and high profits. *See Certain Elec. Skin Care Devices, Brushes & Chargers Therefore, & Kits Containing the Same*, Inv. No. 337-TA-959, Comm'n Op. at 15–16 (EDIS Doc ID 603444) (Feb. 13, 2017) (finding high profits and strong demand for infringing products support a likelihood of circumvention of a limited exclusion order); *Certain Vaporizer Cartridges and Components Thereof*, Inv. No. 337-TA-1211, Comm'n Op. at 9–10 (EDIS Doc ID 764256) (Mar. 1, 2022) (noting "a significant [profit] margin in which infringers can undercut [Complainant] on price, but still make substantial profits" supports entry of a GEO).

The undersigned finds that such conditions are present here. In addition, the presence of defaulting respondents that failed to participate in the investigation favors issuance of a GEO. *Certain Fish-Handling Pliers & Packaging Thereof*, Inv. No. 337- TA-1169, Comm'n Op. at 12–13, 2020 WL 5942003, at *8 (Sept. 29, 2020) ("[The named respondents] failed to respond to the complaint and notice of investigation and failed to participate in this investigation, suggesting they are unlikely to abide by a Commission remedy limited to [the named respondents]".)

### a. Online sales and non-descript packaging

Certain of the Respondents for which a violation has been found as to trademark infringement and/or false designation of origin make their sales online through web-based storefronts. *See* Exs. 28 (Audrey Beauty/Mew Mews), 41 (SHS), 43 (Triggered Brand), 58 (Strate Labs). Certain of the Accused Products from these Respondents are shipped in generic packaging. *See* Exs. 20 (unlabeled vials lacking company name return address from SHS), 16 (unlabeled vials from Audrey Beauty or Mew Mews). The Commission has previously recognized that sales conducted through websites can support the issuance of a GEO because "even if the exclusion order listed the website(s) through which the respondents were known to conduct their operations, it would be simple for those respondents to set up new website(s) and continue their operations." *Certain Toner Cartridges, and Components Thereof*, Inv. No. 337-TA-918, Comm'n Op. at 7–8 (Oct. 1, 2015) (EDIS Doc. ID 566475). The online sales and/or non-descript packaging used by these Respondents increases the likelihood an LEO would be circumvented.

### b. Incentive to sell infringing products because of high demand and profitability

There is also substantial, reliable, and probative evidence that high demand and opportunity for larger profit margins provide an incentive for entities to continue selling Accused Products. Mounjaro generated approximately $4.7 billion in revenue worldwide in 2023. Ex. A ¶ 9. This revenue included "higher realized prices due to . . . increased demand." Ex. B ¶ 120 (citing Eli Lilly and Company 2023 Annual Report on Form 10-K).

The evidence shows that SHS, Audrey Beauty/Mew Mews, Strate Labs, and Triggered Brand undersell Lilly's Mounjaro product, at least at the 5 mg level (for SHS and Triggered Brand) and/or the 10 mg level (for Audrey Beauty/Mew Mews and Strate Labs). *See* Section

VII.C.3 (summarizing the pricing of Accused Products). As set forth by Dr. VanderVeen, these Respondents did not need to invest in research to develop tirzepatide, did not incur costs associated with FDA approval or clinical trials, and as discussed above often have minimal packaging and marketing. *See* Ex. B ¶¶ 88–93 (discussing foreign cost advantages). The ability to realize a large profit margin on a product that also has high demand heightens the risk that these Respondents will ignore an LEO.

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Based on the evidence discussed above, a GEO is appropriate as to Lilly's trademark infringement and false designation of origin claims based on the need to prevent circumvention of an LEO.

**2. Pattern of Violation and Difficulty Identifying Source**

Lilly also argues that a GEO is warranted because there is a pattern of violation, and it is difficult to identify the source of the accused products. Lilly Br. at 143–48; Lilly Reply at 9–10. Staff's view is Lilly has submitted "insufficient evidence to establish the need for a GEO under Section 337(d)(2)(B)." Staff Br. at 132–33. According to Staff, Lilly has evidence of a large number of entities selling tirzepatide for weight loss but has not offered much evidence showing those third parties are infringing the Asserted Trademark or violating the prohibition of false designation of origin. *Id*.

"[I]n determining whether a GEO is warranted, the Commission looks not only to the activities of active respondents, but also to those of respondents that have been terminated from an investigation as well as non-respondents." *Certain Toner Cartridges, and Components Thereof*, Inv. No. 337-TA-918, Comm'n Op., EDIS Doc. ID 566475, at 9 (Oct. 1, 2015); *Certain Luxury Vinyl Tile and Components Thereof*, Inv. No. 337-TA-1155, Comm'n. Op., EDIS Doc.

ID 721148, at 11-12 (Oct. 5, 2020). For the reasons set forth below, the evidence indicates that a GEO is warranted under Section 337(d)(2)(B).

**a. Pattern of Violation**

The evidence of record shows a pattern of trademark infringement and false designation of origin. In particular, as shown in Sections IV and V above, there is substantial, reliable and probative evidence of trademark infringement and/or false designation of origin by Respondents SHS, TCP, Audrey Beauty, Mew Mews, Triggered Brand, Paradigm Peptides, Strate Labs, and GenX Peptides.[55] Lilly also provided evidence of trademark infringement and/or false designation of origin by Terminated Respondents Unewlife, Supopeptide, and Steroide Kaufen. *See* Section I.B.3 *supra*; Vander Veen Rpt. ¶ 145-147 (Ex. B); Second Am. Compl. ¶¶ 24-25, 117-125, 289-290 and Exs. 12-17 (Unewlife) (selling Tirzepatide Raw Powder and providing product categories "manjaro," "mounjaro coupon," and "eli lilly tirzepatide"); *id.* ¶¶ 157-162, 296-297 and Ex. 26 (Steroide Kaufen) (listing product as "Tirzepatide (Mounujaro) Without Prescription); *id.* ¶¶ 209-211, 306-308 and Ex. 46 (Supopeptide) (stating that Tirzepatide "is being developed by Eli Lilly and Company"). Lilly also provided evidence of trademark infringement and false designation of origin by proposed respondent Swiss Chems. *See* Section I.A; Mot. No. 1377-005, Exs. 81 (Swiss Chems listing Mounjaro as a synonym for its tirzepatide

[55] Although a section 337 violation was not found as to GenX Peptides (based on lack of sufficient importation evidence) and as to TCP and Paradigm Peptides (based on lack of service), the "pattern of violation" analysis may take into account evidence relating to non-respondents or terminated respondents whose activities appear to infringe the relevant intellectual property. *See Certain Toner Cartridges and Components Thereof*, Inv. No. 337-TA-918, Comm'n Op., EDIS Doc. ID 566475, at 9 (Oct. 1, 2015). This logic also supports consideration of activities by respondents whose activities appear to infringe the intellectual property at issue but for which a violation finding was not made based on difficulties with service or obtaining information relating to a defaulting party sufficient to meet the "substantial, reliable, and probative" evidence standard for importation. *Cf. Certain Mobile Device Holders and Components Thereof*, Inv. No. 337-TA-1028, 2018 WL 4042764, at *11 (March 22, 2018) (finding GEO warranted under section 337(d)(2)(B) because, *inter alia*, "both the Commission and [Complainant] had difficulty serving some respondents in this investigation").

product), 88. In addition, Lilly has provided evidence indicating an internet offer for sale of another "Mounjaro" product by an entity in China. *See* Lilly Br. at 143-145; Ex. 106 (selling "Highest Quality Tirzepatide Mounjaro 5mg 10mg 15mg Tirzepatide"). This evidence is sufficient to show a pattern of violation. *See Certain Battery-Powered Ride-On Toy Vehicles and Components Thereof*, Inv. No. 337-TA-314, Comm'n Op. at 6-7, 10 (Apr. 9, 1991) (EDIS Doc. ID 235431). (finding a "widespread pattern of unauthorized use" based on evidence relating to six foreign manufacturers of accused products with respect to one asserted design patent and three manufacturers of accused products with respect to another asserted design patent); *Certain Loom Kits for Creating Linked Articles*, Inv. No. 337-TA-923, Comm'n Op., at 13-14 (June 26, 2015) (EDIS Doc. ID 559662) (finding a pattern of violation based on evidence that "ten different respondents imported infringing products from China into the United States or sold such products inside the United States in violation of section 337").[56]

Lilly also cites to several websites of third-party entities purporting to sell tirzepatide, but without mentioning "Mounjaro." Lilly has not shown that selling tirzepatide alone constitutes trademark infringement or false designation of origin. Lilly describes two of the third-party websites as advertising tirzepatide "in connection with buzzwords like 'weight loss,' 'weight management,' and 'glucose control,' which falsely suggest the product is FDA-approved for the treatment of type 2 diabetes or for chronic weight management." Lilly Br. at 144–45 (citing

[56]Additional third party websites, notably those shown in Exs. 101, 103, and 105 appear to be selling "Mounjaro" in injector pens that appear identical to Lilly's and it is unclear whether they could potentially be "gray market" or similar goods. *See generally Bourdeau Bros., Inc. v. Int'l Trade Comm'n*, 444 F.3d 1317, 1321-23 (Fed. Cir. 2006). Such goods infringe a trademark if, *inter alia*, there are "material differences" between the imported goods and those authorized for sale in the United States. *Id.* Lilly did not provide any descriptive detail for these Exhibits (or any declaration relating thereto) and, in response to Staff's criticism on this point, stated only that the "evidence speaks for itself." Lilly Reply at 9; Staff Br. at 133. Without further explanation, the undersigned provides minimal weight to this evidence as supporting a pattern of violation.

exhibits 99 and 102). Lilly also has not shown that any mention of clinical studies necessarily constitutes trademark infringement or false designation of origin.[57] Thus, the evidence relating to these websites is not credited for purposes of assessing whether a GEO is warranted.

Considered in full, the evidence of record indicates a pattern of violation with respect to trademark infringement and false designation of origin.

**b. Difficulty Identifying Source**

The record evidence also shows difficulty in identifying the source of many of the infringing and potentially infringing products. As discussed above, the evidence shows that sellers operate online stores and often have limited information on the products themselves to identify the source. *See* Section VIII.A.1; *see also* Lilly Br. at 130–33, 136–42; Staff Br. at 130–32. In addition, the evidence shows that Lilly had difficulty serving certain Respondents. *See* Lilly Br. at 146-48; *Certain Mobile Device Holders and Components Thereof*, Inv. No. 337-TA-1028, 2018 WL 4042764, at *11 (March 22, 2018) (finding GEO warranted under section 337(d)(2)(B) because, *inter alia*, "both the Commission and [Complainant] had difficulty serving some respondents in this investigation"). The undersigned finds that such evidence supports the issuance of a GEO. *See Certain Pillows and Seat Cushions, Components Thereof, and Packaging Thereof*, Inv. No. 337-TA-1328, Comm'n Op., EDIS Doc. ID 808365, at 9 (Nov. 13, 2023) ("The Commission further finds that it is difficult to identify sources of infringing products because the products at issue are sold through online marketplaces and delivered with generic packaging.").

[57] Lilly's reply brief also argues certain statements on the third-party websites are "literally false and therefore violate[] the Lanham Act's prohibition on false advertising." Lilly Reply at 9. However, Lilly has represented that it is not seeking a GEO based on false advertising. *See* Lilly Br. at 128. ("Complainant does not rely on the violation of Section 337(a)(1)(A) based on false advertising to support entry of a GEO.").

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For these reasons, a GEO is also warranted as to Lilly's trademark infringement and false designation of origin claims based on a pattern of violation and difficulty in identifying the source of infringing products.

**3. Conclusion**

For the reasons above, the undersigned finds that the evidence establishes that a GEO is necessary to prevent circumvention of an exclusion order limited to products of the Defaulting Respondents; and that there is a pattern of violation of section 337, and it is difficult to identify the source of products infringing and potentially infringing the Asserted Trademark. *See* 19 U.S.C. § 1337(d)(2)(A), (B). Accordingly, the undersigned recommends that, in the event the Commission finds a violation of section 337, the appropriate remedy is a GEO prohibiting imports in connection with which there is infringement of the Asserted Trademark and/or violation of the prohibition against false designation of origin under 15 U.S.C. § 1125(a)(1)(A).

**B. Limited Exclusion Orders**

A limited exclusion order directed to respondents' infringing products is among the remedies that the Commission may impose. *See* 19 U.S.C. § 1337(d).

Lilly submits that in the alternative to a GEO on the trademark infringement and false designation of origin claims, Lilly requests "a LEO against the Defaulting Respondents and any affiliates, subsidiaries, and assigns." Lilly Br. at 148-49. Lilly also seeks "a LEO against False Advertising Respondents AustroPeptide, Total Compounding, and SHS and their affiliates and assigns." *Id.* Staff agrees that a LEO directed to the named respondents that have defaulted is an appropriate remedy. Staff Br. at 133–34.

Should the Commission find a violation but not issue a GEO, the undersigned recommends that limited exclusion orders be issued directed to products of the Respondents for which a violation is found as to trademark infringement and false designation of origin. Further, the undersigned recommends a limited exclusion order as to SHS and AustroPeptide[58] of products falsely advertised in the United States.

### C. Cease and Desist Orders

Lilly asserts that cease and desist orders are appropriate for domestic defaulting respondents.[59] Lilly Br. at 149–50. Staff agrees that if a violation is found, issuance of a cease-and-desist order to the domestic respondents would be appropriate.

Under section 337(f)(1), the Commission may issue a cease-and-desist order ("CDO") in addition to, or instead of, an exclusion order. 19 U.S.C. § 1337(f)(1). "Cease and desist orders are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order." *Certain Arrowheads with Deploying Blades & Components Thereof & Packaging Therefor*, Inv. No. 337-TA-977, Comm'n Op. at 16-17, 2017 WL 11261373, at *10, (EDIS Doc. ID 610060) (Public Version Apr. 28, 2017); *see also Certain Electric Skin Care Devices, Brushes & Chargers Therefor, & Kits Containing Same*, Inv. No. 337-TA-959, Comm'n Op. at 26, 2017 WL 8683854, at *15,

[58] Complainant does not appear to seek an LEO based on false advertising as to Arctic Peptides. *See* Lilly Br. at 148 ("Complainant also requests a LEO against False Advertising Respondents AustroPeptide, Total Compounding, and SHS and their affiliates and assigns."); *see also id.* at 71, 88 (Arctic Peptides not defined as one of the "False Advertising Respondents" despite allegations of false advertising).

[59] While directing its request for cease and desist orders to only "domestic Defaulting Respondents," Lilly names all defaulting respondents, even those that are foreign companies. Lilly Br. at 149–50. Staff limits domestic respondents to: (i) Arctic Peptides LLC, (ii) GenX Peptides, (iii) Paradigm Peptides, (iv) Strate Labs LLC, and (v) Triggered Brand. Staff Br. at 136.

EDIS Doc. ID 603444 (Public Version Feb. 13, 2017) (same). "In the case of named respondents in the United States who have been found in default or who have not participated in the investigation, the Commission has inferred commercially significant domestic inventories or significant domestic operations with respect to the infringing articles." *Certain Toner Supply Containers and Components Thereof (II)* ("*Toner Supply II*"), Inv. No. 337-TA-1260, Comm'n Op., EDIS Doc. ID 777011, at 18 (Aug. 3, 2022).

Because three named Respondents in the United States have been found to violate section 337, the undersigned finds that it is appropriate under the circumstances to infer commercially significant U.S. inventories and/or significant domestic operations with respect to Arctic Peptides, Triggered Brand, and Strate Labs. *See* Second Am. Compl. ¶¶ 34 (Triggered Brand in Florida), 36 (Strate Labs in Texas), 44 (Arctic Peptides in Iowa); Order No. 13. Therefore, in the event the Commission finds a violation of section 337, the undersigned recommends that CDOs issue directed to these Respondents.[60] The record evidence does not indicate that the foreign respondents maintain commercially significant inventories or have significant domestic operations in the United States. Therefore, the undersigned does not recommend issuance of CDOs against the foreign respondents.

### D. Bond

Lilly submits that the bond rate should be set at 100 percent of the entered value of the Accused Products. Lilly Br. at 150–53. Lilly argues that "[b]ecause the price differential is more than 100 percent for many of the Respondents, the bound should be set at 100%." *Id*. at 152.

[60] As detailed in Section III.B.4, a violation of section 337 is inappropriate for GenX Peptides because Lilly failed to show substantial, reliable, and probative evidence of importation. If the Commission finds importation and violation of section 337, then the undersigned recommends that a CDO also issue directed to GenX Peptides.

Staff contends that it is impossible to establish a bond based on price differentials or royalty information because the Defaulting Respondents have not provided any discovery in this investigation and there is no established royalty rate. Staff Br. at 136–37. Staff therefore agrees with Lilly's request for a bond in the amount of 100 percent of entered value during the 60-day Presidential review period. *Id*. at 137.

During the 60-day period of Presidential review, imported articles subject to an exclusion order are entitled to conditional entry under bond. 19 U.S.C. § 1337(j)(3). The amount of the bond must be an amount sufficient to protect the complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. § 210.50(a)(3). "The Commission typically sets the bond based on the price differentials between a respondent's and a complainant's products or based on a reasonable royalty rate." *Certain Oil-Vaping Cartridges, Components Thereof, and Prods. Containing the Same*, Inv. No. 337-TA-1286, Comm'n Op., EDIS Doc. ID 801339, at 23 (Aug. 1, 2023); *see also Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276, Comm'n Op., at 119 (EDIS Doc. ID 808521) (Nov. 14, 2023) (Commission uses reasonable royalty rates to set bond); *Certain Non-Volatile Memory Devices and Prods. Containing the Same*, Inv. No. 337-TA-1046, Comm'n Op., at 67 (EDIS Doc. ID (659979) (Oct. 26, 2018). 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 (June 2, 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 minimis* and without adequate support in the record), order rescinded by Certain Flash Memory Circuits and Prods. Containing Same, Inv. No. 337-TA-382, 1999 WL 600027 (Sep. 18, 1997).

Based on the limited pricing information evidence in the record, the undersigned agrees with Lilly and Staff that the Commission should set the bond value at 100 percent. Mounjaro is approximately $267.27 per dose. *See* Section VII.C.3 n.48. As shown in the table below, at least at the 5 mg or 10 mg dose level, the Defaulting Respondents sell their products at significantly lower prices.

| Respondent | Price |
|---|---|
| Audrey Beauty / Mew Mews | $36 per 10 mg tube (Ex. 10) |
| AustroPeptide | $41 per 10 mg vial (sold as $410 per ten 10 mg vials) (Ex. 29 at LILLY_ITC_0001040) |
| Biolabshop | €99.99 per 5 mg vial (Ex. 32 at LILLY_ITC_0001127) |
| GenX Peptides | $91.50 per 5 mg vial (sold as six vials for $549) (Ex. 34 at LILLY_ITC_0002826; Ex. 35) |
| Strate Labs | $224.95 per 10 mg vial (Ex. 58 at LILLY_ITC_0001007) |
| SHS | $129 per 5 mg vial (Ex. 41 at LILLY_ITC_0000866) |
| Triggered Brand | $111.99 per 5 mg vial (Ex. 43 at LILLY_ITC_0000978) |
| Arctic Peptides | $130.19 per 10 mg vial (Ex. 51 at LILLY_ITC_0001185–86) |

*See also* Ex. B ¶ 100 (showing similar pricing information gathered by Dr. Vander Veen); Lilly Br. at 151–52. As Lilly notes, many of the price differentials exceed 100% of the price for the Defaulting Respondents' products. Lilly Br. at 152. The Commission has imposed a 100% bond when the evidence "demonstrates a wide range of prices charged by the Respondents, generally well below the retail price charged for [Complainant's] product." *In the Matter of Certain Tadalafil or Any Salt or Solvate Thereof & Prod. Containing Same*, Inv. No. 337-TA-539, Initial Determination, 2005 WL 3498446, at *4–5 (Dec. 6, 2005), *aff'd in relevant part*, Comm'n Op., 2008 WL 2109706 (May 1, 2008). Here, the range of Defaulting Respondents' prices supports a 100% bond.

Accordingly, the undersigned recommends that the Commission set a bond of 100% during the Presidential review period if a violation is found.

## IX. CONCLUSION

For the foregoing reasons, Lilly's summary determination motion (1377-016) is GRANTED-IN-PART.

It is the Initial Determination of the undersigned that Lilly is entitled to summary determination on violation, based on trademark infringement, by Respondents Audrey Beauty, Mew Mews, SHS, and Triggered Brand.[61] Summary determination of violation of section 337 is also warranted with respect to false designation of origin by Respondents Audrey Beauty, Mew Mews, SHS, Triggered Brand, and Strate Labs.[62] Summary determination of violation of section 337 is warranted with respect to false advertising by Respondents SHS, AustroPeptide, and Arctic Peptides.

For its trademark infringement claims under section 337(a)(1)(C), Lilly is entitled to summary determination that it has satisfied the technical and economic prongs of the domestic industry requirement. For its false designation of origin and false advertising claims under section 337(a)(1)(A), Lilly is entitled to summary determination that it has satisfied the injury requirement.

Pursuant to Commission Rule 210.42(h), this initial determination shall become the determination of the Commission unless a party files a petition for review of the initial determination pursuant to Commission Rule 210.43(a), or the Commission, pursuant to

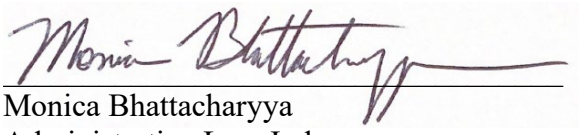
[61] A violation of section 337 based on trademark infringement was not found as to Respondent GenX Peptides (based on lack of sufficient evidence of importation); by Respondent TCP and Paradigm Peptides (based on lack of service); or by Strate Labs (based on insufficient evidence of likelihood of confusion, at least on summary determination).

[62] A violation based on false designation of origin was not found as to Respondent GenX Peptides (based on lack of sufficient evidence of importation); by Respondent TCP and Paradigm Peptides (based on lack of service); or by Respondent Biolabshop (based on insufficient evidence of likelihood of confusion, at least on summary determination).

Commission Rule 210.44, orders, on its own motion, a review of the initial determination or certain issues contained herein. 19 C.F.R. § 210.42(d).

This order has been issued with a confidential designation. Within seven days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this final initial determination with any proposed redactions consistent with the manner specified by Ground Rule 1.9.[63] To the extent possible, the proposed redacting should be made electronically, in a PDF of the issued order, using the "Redact Tool" within Adobe Acrobat, wherein the proposed redactions are submitted as "marked" but not yet "applied." The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

**SO ORDERED.**



Monica Bhattacharyya
Administrative Law Judge

[63] Redactions should be limited to avoid obscuring the reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, explaining why each proposed redaction meets the definition for confidential business information in 19 C.F.R. § 201.6(a).

**CERTAIN PRODUCTS CONTAINING TIRZEPATIDE AND PRODUCTS PURPORTING TO CONTAIN TIRZEPATIDE** **Inv. No. 337-TA-1377**

## 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, **Yoncha Kundupoglu, Esq.,** and the following parties as indicated, on **December 19, 2024**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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☐ Via First Class Mail
☒ Other: Email Notification