

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN PRODUCTS CONTAINING
TIRZEPATIDE AND PRODUCTS
PURPORTING TO CONTAIN
TIRZEPATIDE**

Investigation No. 337-TA-1377

**NOTICE OF A COMMISSION DETERMINATION NOT TO REVIEW
AN INITIAL DETERMINATION FINDING RESPONDENTS IN VIOLATION OF
SECTION 337; REQUEST FOR WRITTEN SUBMISSIONS ON REMEDY, THE
PUBLIC INTEREST, AND BONDING**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined not to review an initial determination (“ID”) (Order No. 26) of the presiding administrative law judge (“ALJ”), partially granting a motion for summary determination on violation of section 337. The Commission requests written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 27, 2023, based upon a complaint filed on behalf of Eli Lilly and Company of Indianapolis, Indiana (“Lilly”). 88 FR 82914, 82914-15 (Nov. 27, 2023). The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain products containing tirzepatide or purporting to contain tirzepatide by reason of false designation of source and false and misleading advertising, the threat or effect of which is to destroy or substantially injure an industry in the United States, and by reason of infringement of U.S.

Trademark No. 6,809,369. *Id.* The complaint also alleges that a domestic industry exists pursuant to subsection (a)(2) of section 337. *Id.* The Commission’s notice of investigation named as respondents: (1) Arctic Peptides LLC of Akeny, Iowa (“Arctic Peptides”); (2) Audrey Beauty Co. of Hong Kong, China (“Audrey Beauty”); (3) Biolabshop Limited of Lancaster, United Kingdom (“Biolabshop”); (4) Mew Mews Company Limited of Hong Kong, China (“Mew Mews”); (5) Strate Labs LLC of Spring, Texas (“Strate Labs”); (6) Steroide Kaufen of Bialystok, Poland (“Steroide Kaufen”); (7) Super Human Store of Barcelona, Spain (“SHS”); (8) Supopeptide of Cedar Grove, New Jersey (“Supopeptide”); (9) Triggered Supplements LLC (d/b/a The Triggered Brand) of Clearwater, Florida (“Triggered Brand”); (10) Unewlife of Cedar Grove, New Jersey (“Unewlife”); and (11) Xiamen Austronext Trading Co., Ltd. (d/b/a AustroPeptide) of Fujian, China (“AustroPeptide”). *Id.* at 82915. The Office of Unfair Import Investigations (“OUII”) is also named as a party in this investigation. *Id.*

On March 21, 2024, the investigation terminated in part, based on withdrawal of the related allegations in the complaint, as to respondents Unewlife, Supopeptide, and Steroide Kaufen. Order No. 8 (Mar. 7, 2024), *unreviewed by* Comm’n Notice (Mar. 21, 2024).

On May 15, 2024, the Commission found Arctic Peptides, Audrey Beauty, Biolabshop, Mew Mews, Strate Labs, SHS, Triggered Brand, and AustroPeptide in default. Order No. 13 (Apr. 22, 2024), *unreviewed by* Comm’n Notice (May 15, 2024).

On May 21, 2024, the complaint was amended to add as respondents Fibonacci Sequence LLC (d/b/a GenX Peptides) of Houston, Texas (“GenX Peptides”); and Paradigm Peptides of Michigan City, Indiana (“Paradigm Peptides”). Order No. 12 (Apr. 22, 2024), *unreviewed by* Comm’n Notice (May 21, 2024), available at 89 FR 46159, 46159-60 (May 28, 2024).

On June 13, 2024, the complaint was further amended to add as a respondent Total Compounding Pharmaceuticals of Australia (“Total Compounding”). Order No. 16 (May 8, 2024), *unreviewed by* Comm’n Notice (June 13, 2024), available at 89 FR 5149, 51549-50 (June 18, 2024).

On October 16, 2024, the Commission found GenX Peptides in default. Order No. 23 (Aug. 27, 2024), *unreviewed by* Comm’n Notice (Oct. 16, 2024).

On July 12, 2024, Lilly moved for summary determination on violation based on allegations of trademark infringement, false designation of origin, and/or false advertising against (1) Arctic Peptides, (2) Audrey Beauty, (3) Biolabshop, (4) Mew Mews, (5) Strate Labs, (6) SHS, (7) Triggered Brand, (8) AustroPeptide, (9) GenX Peptides, (10) Paradigm Peptides, and (11) Total Compounding. On December 6, 2024, the ALJ issued the subject ID, which partially granted the motion. Order No. 26 (Dec. 6, 2024). The ID granted Lilly’s motion regarding trademark infringement as to respondents Audrey Beauty, Mew Mews, SHS, and Triggered Brand, but denied the motion as to GenX Peptides, Total Compounding, Paradigm Peptides, and Strate Labs. *E.g.*, ID at 134 (including n.61). The ID granted Lilly’s motion regarding false designation of origin as to respondents Audrey Beauty, Mew Mews, SHS,

Triggered Brand, and Strate Labs, but denied the motion as to GenX Peptides, Total Compounding, Paradigm Peptides, and Biolabshop. *E.g., id.* (including n. 62). And the ID granted Lilly's motion as to false advertising as to respondents SHS, AustroPeptide, and Arctic Peptides. *E.g., id.* The ID additionally found that Lilly is entitled to summary determination as to the domestic industry requirement. *E.g., id.* No petitions for review of the ID were filed.

The subject ID included the ALJ's Preliminary Recommended Determination on Remedy and Bond ("RD"), should a violation be found. The RD recommended: (1) a general exclusion order directed to certain products containing tirzepatide and products purporting to contain tirzepatide imported, sold for importation, and/or sold after importation for the asserted trademark infringement and false designation of origin allegations; (2) in the alternative to a general exclusion order for the asserted trademark infringement and false designation of origin allegations, limited exclusion orders directed to Audrey Beauty, Mew Mews, SHS, Triggered Brand, Strate Labs, and AustroPeptide; (3) limited exclusion orders directed to SHS and AustroPeptide for the false advertising allegations; and (4) in addition to either a general exclusion order or limited exclusion orders, cease and desist orders directed to Arctic Peptides, Triggered Brand, and Strate Labs. The Commission notes that only the portions of Order No. 26 that correspond to a grant of a summary determination of violation for a particular respondent and claim are ripe for review at this time.

Having reviewed the record of the investigation, including the ID and the parties' submissions to the ALJ, the Commission has determined not to review the ID.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is further to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on February 5, 2025. Reply submissions must be filed no later than the close of business on February 12, 2025. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1377) in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and

Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on January 22, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton", enclosed in a thin black rectangular border.

Lisa R. Barton
Secretary to the Commission

Issued: January 22, 2025