INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1145]

Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same Commission Decision To Review in Part a Final Initial Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination (''FID'') of the presiding administrative law judge (''ALJ'') finding a violation of section 337 of the Tariff Act of 1930, as amended. The Commission also requests written submissions, under the schedule set forth below, on remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. 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.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.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: On March 6, 2019, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by Medytox Inc. of Seoul, South Korea; Allergan plc of Dublin, Ireland; and Allergan, Inc. of Irvine, California (collectively, ''Complainants''). *See* 84 FR 8112–13 (Mar. 6, 2019). The complaint, as supplemented, alleges a violation 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 botulinum toxin products, processes for manufacturing or relating to same and certain products containing same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States. *See id.* The notice of investigation names as respondents Daewoong Pharmaceuticals Co., Ltd. (''Daewoong'') of Seoul, South Korea and Evolus, Inc. (''Evolus'') of Irvine, California (collectively, ''Respondents''). *See id.* The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation. *See id.*

On July 6, 2020, the ALJ issued the FID finding a violation of section 337 based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain botulinum neurotoxin products by reason of the misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States. *See* FID at 273.

The FID also includes a recommended determination (''RD'') recommending that, if a violation is found, the Commission issue: (1) A limited exclusion order barring entry of certain botulinum toxin products that are imported, sold for importation, and/or sold after importation by respondents Daewoong and Evolus; and (2) a cease and desist order against Evolus. The RD also recommends that the Commission impose a bond based on price differential during the period of Presidential review.

On July 20, 2020, Respondents filed a petition for Commission review of the FID. On July 28, 2020, Complainants and OUII filed responses to Respondents' petition. On September 18, 2020, Respondents filed a motion for leave to file a notice of new factual development. The Commission has determined to accept Respondents' filing.

The Commission has determined to review the FID in part. Specifically, the Commission has determined to review the FID's findings with respect to subject matter jurisdiction, standing, trade secret existence and misappropriation, and domestic industry, including the existence of such domestic industry as well as any actual or threatened injury thereto. The Commission has determined not to review the remainder of the FID. The Commission has also determined to allow Complainants to respond to Respondents' notice of new factual development in their written submissions to the Commission pursuant to the present notice.

In connection with its review, the Commission requests that the parties brief their positions with reference to the applicable law and the evidentiary record regarding the following questions:

1. Describe the differences between the Medytox strain and other Hall A-hyper strains and explain the relevance of those differences to Complainants' trade secrets misappropriation claim.

2. Discuss the availability in the marketplace of Hall A-hyper strains since Dr. Hall's discovery in the 1920s and the U.S. Army's development in the 1940s (*i.e.,* not just during the 2009–2010 timeframe and thereafter).

3. For the alleged domestic industry costs regarding activities related to regulatory approvals and compliance (including costs for activities such as relevant research and development or testing): (A) Which of those regulatory activities are of a nature that can only be performed in the United States (for either legal or practical reasons), and which could have been carried out in another country; and (B) does the record permit allocation of costs between those two categories?

4. What is the federal legal standard for determining what constitutes a misappropriation of trade secrets sufficient to establish an ''unfair method of competition'' under Section 337?

5. Is injury to the complainant an element of a federal trade secret misappropriation cause of action that is necessary to establish an ''unfair method of competition'' under Section 337(a)(1)(A) (distinct from the ''threat or effect'' requirements of Section 337(a)(1)(A)(i)–(iii))?

6. Please explain whether, consistent with the federal common law, the injury requirement discussed in the FID (*see* FID at 45 (''(4) that the respondent has used or disclosed the trade secret *causing injury to the complainant.*'') (emphasis added)) refers to injury within the meaning of section 337(a)(1)(A)(i)–(iii) (*i.e.,* ''threat or effect'' subsections) and not a separate ''injury'' requirement for establishing trade secret misappropriation.

In seeking briefing on these issues, the Commission has not determined to excuse any party's noncompliance with Commission rules and the ALJ's procedural requirements, including requirements to present issues in submissions to the ALJ and in petitions for Commission review. The Commission may, for example, decline to disturb certain findings in the FID upon finding that issue was not presented in a timely manner to the ALJ or to the Commission.

In addition, in connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent(s) 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 (Dec. 1994) (Comm'n Op.).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or 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: The parties to the investigation are requested to file written submissions on the questions identified in this notice. 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 also address the recommended determination by the ALJ on remedy and bonding. Complainants and the Commission Investigative Attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainants are further requested to provide the HTSUS numbers under which the accused products are imported, and to supply the names of known importers of the products at issue in this investigation.

Written submissions and proposed remedial orders must be filed no later than close of business on October 9, 2020. Reply submissions must be filed no later than the close of business on October 16, 2020. Initial written submissions may not exceed 60 pages in length, exclusive of any exhibits, while reply submissions may not exceed 30 pages in length, exclusive of any exhibits. 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 (March 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1145'') 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. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. 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,[1] solely for cybersecurity purposes. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The Commission's vote on this determination took place on September 21, 2020.

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.

Issued: September 21, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–21158 Filed 9–24–20; 8:45 am]

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DEPARTMENT OF JUSTICE

[OMB Number 1140–0080]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change of a Currently Approved Collection; Notification of Change of Mailing or Premise Address

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection (IC) is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until November 24, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact:

[1] All contract personnel will sign appropriate nondisclosure agreements.