UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN BOTULINUM TOXIN PRODUCTS, PROCESSES FOR MANUFACTURING OR RELATING TO SAME AND CERTAIN PRODUCTS CONTAINING SAME**	**Investigation No. 337-TA-1145 (Rescission)**

NOTICE OF COMMISSION DECISION TO INSTITUTE A RESCISSION PROCEEDING AND RESCIND THE REMEDIAL ORDERS, TO GRANT THE MOTION TO LIMIT SERVICE OF THE SETTLEMENT AGREEMENT, TO DENY AS MOOT THE MOTION TO TERMINATE, AND TO INDICATE RULING ON MOTION TO VACATE; TERMINATION OF THE RESCISSION PROCEEDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to institute a rescission proceeding and rescind the remedial orders issued in the underlying investigation, to grant the motion to limit service of the settlement agreement, and to deny as moot the motion to terminate the investigation. The Commission has further determined that if the Federal Circuit dismisses the pending appeals as moot, the Commission will vacate its final determination. The rescission proceeding is terminated.

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 ("Medytox"); Allergan plc of Dublin, Ireland; and Allergan, Inc. of Irvine, California (collectively, "Allergan") (all 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") was also a party to the investigation. *See id.*

On July 6, 2020, the Administrative Law Judge issued a final initial determination ("FID") finding a violation of section 337 based on the misappropriation of Complainants' asserted trade secrets (including the Medytox bacterial strain and Medytox manufacturing processes), the threat or effect of which is to destroy or substantially injure an industry in the United States. On September 21, 2020, the Commission issued a notice determining to review the FID in part. *See* 85 FR 60489-90 (Sept. 25, 2020).

On December 16, 2020, the Commission found a violation of section 337 based on the misappropriation of Complainants' trade secrets (including the Medytox manufacturing processes but not the Medytox bacterial strain). *See* 85 FR 83610-11 (Dec. 22, 2020). The Commission issued a limited exclusion order ("LEO") against certain botulinum neurotoxin products that are imported and/or sold by Respondents Daewoong and Evolus and a cease and desist order ("CDO") against Evolus. *Id.* The Commission also set a bond during the period of Presidential review in an amount of $441 per 100U vial of Respondents' accused products. *Id*

On February 12, 2021, Complainants filed an appeal from the Commission's final determination with the Federal Circuit. On the same day, Respondents also filed an appeal from the Commission's final determination of a violation of section 337. On February 18, 2021, Complainants and Evolus (collectively, "the Settling Parties") announced that they had reached a settlement agreement to resolve all pending issues between them.

On March 3, 2021, the Settling Parties filed a joint petition to rescind the LEO and CDO (collectively, "the remedial orders") based on the settlement agreement. On the same day, the Settling Parties also filed a joint motion to limit service of the settlement agreement. On March 16, 2021, Daewoong filed a notice of non-opposition to the joint motion to limit service. On April 1, 2021, the Settling Parties further filed a joint motion to terminate the investigation without prejudice pursuant to 19 CFR 210.21(b). On April 5, 2021, Daewoong filed a response to the Settling Parties' petition to rescind the remedial orders stating that it does not oppose the Settling Parties' petition for recission. Daewoong's response also included a motion for vacatur of the Commission's final determination. On April 8, 2021, OUII filed a response in support of the Settling Parties' petition to rescind and their joint motion to limit service. On April 12, 2021, Daewoong filed a response to the Settling Parties' motion to terminate the investigation, arguing that the motion to terminate should be denied as moot and opposing termination without prejudice. On April 15, 2021, Medytox filed a response in opposition to Daewoong's motion to vacate the final determination. On April 23, 2021, Daewoong filed a motion for leave to file a reply in support of its motion to vacate and on April 29, 2021, Medytox filed a response in

opposition to the motion for leave to file a reply; the Commission accepts both of these filings and Daewoong's motion for leave to file a reply is granted.

Having reviewed the parties' submissions relating to (and in response to) the Settling Parties' petition to rescind, their joint motion to limit service, their joint motion to terminate, and Daewoong's motion to vacate, and for the reasons discussed in the Commission Opinion issued concurrently herewith, the Commission has determined to grant the joint petition to rescind the remedial orders and the joint motion to limit service, and to deny as moot the joint motion to terminate the investigation. The Commission has further determined that, if the Federal Circuit dismisses the pending appeals as moot, the Commission will vacate its final determination. Commissioner Karpel concurs in the determination to grant the Settling Parties' motion to rescind the remedial orders and their motion to limit service; and to deny as moot their motion to terminate the investigation. However, Commissioner Karpel would deny Daewoong's motion to vacate the Commission's final determination as procedurally improper. She would also deny Daewoong's motion for leave to file a reply. Further, Commissioner Karpel would decline to issue an indicative ruling as to whether Daewoong has established equitable entitlement to the extraordinary remedy of vacatur on the basis of the record before the Commission.

The rescission proceeding is terminated.

The Commission's vote on this determination took place on May 3, 2021.

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.

Lisa R. Barton
Secretary to the Commission

Issued: May 3, 2021