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 (Remand)**

NOTICE OF COMMISSION DECISION TO VACATE ITS FINAL DETERMINATION ON REMAND

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has vacated its final determination following dismissal of the appeals to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") challenging various aspects of that determination.

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*. 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 and the sale in the United States 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 an 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 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 against certain botulinum neurotoxin ("BTX") products that are imported and/or sold by Respondents Daewoong and Evolus and a cease and desist order against Evolus (collectively, "the remedial orders"). *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 (Appeal No. 21-1653). On the same day, Respondents also filed an appeal from the Commission's final determination of a violation of section 337 (Appeal No. 21-1654). On February 18, 2021, Complainants and Evolus (collectively, "the Settling Parties") announced that they had reached a settlement to resolve all pending issues between them.

On March 3, 2021, the Settling Parties filed a joint petition to rescind the remedial orders based on settlement agreements and other confidential agreements between and among several of the Settling Parties. On April 5, 2021, Daewoong filed a response to the Settling Parties' petition not opposing recission of the remedial orders and also including a motion for vacatur of the Commission's final determination. On April 8, 2021, OUII filed a response in support of the joint petition to rescind. On April 15, 2021, Medytox filed a response in opposition to Daewoong's motion to vacate the final determination.

On May 3, 2021, the Commission determined to rescind the remedial orders. *See* 86 FR 24665-66 (May 7, 2021). The Commission also issued an indicative ruling that, if the Federal Circuit dismisses the pending appeals as moot, the Commission will vacate its final determination. *See id.* The Commission explained that "if the Federal Circuit finds that the . . . appeals are moot" and "[i]f appellate review for Daewoong is prevented, it would be plainly through happenstance, and vacatur would be warranted to prevent any preclusive effect of the final determination against Daewoong." *See* Comm'n Op. at 8 (May 3, 2021).

On June 21, 2021, Medytox also reached a settlement agreement with AEON Biopharma ("AEON"). AEON is Daewoong's exclusive licensee in the United States for therapeutic applications of BTX products, while Evolus is the exclusive licensee for aesthetic applications. Consequently, as Medytox stated before the Federal Circuit, "the result of the two settlements is that Medytox has now resolved its disputes with and granted licenses to the two companies that hold the exclusive rights to distribute Daewoong's BTX products in the United States." *See* ECF 69, Medytox Statement of Non-Opposition at 2 (Fed. Cir. Docket No. 21-1653); ECF 68, Medytox Letter at 1 (Fed. Cir. Docket No. 21-1653). Thus, Medytox did not oppose the Commission's and Daewoong's motions to dismiss the appeals as moot and no longer opposes vacatur of the Commission's final determination upon remand. On July 26, 2021, the Federal Circuit issued an order dismissing the appeals "to the extent that the appeals are deemed moot" and remanding "the matter . . . for the Commission to address vacatur of its final determination." *Medytox v. ITC*, No. 21-1653, Order at 2 (Fed. Cir. July 26, 2021).

In accordance with the Commission's May 3, 2021 indicative ruling of vacatur and the Commission's reasoning related thereto, and in view of the Federal Circuit's dismissal of the related appeals as moot, the Commission hereby vacates on remand its final determination. Commissioner Karpel does not join the Commission's decision to vacate. As she has previously stated, the Commission's decision to exercise its discretion to grant the extraordinary remedy of vacatur requires an analysis, based on a complete record and after having heard from all parties on the issue, that includes a careful balancing of the equities, including with respect to the public interest. *See* Comm'n Op. at 9-10 n.15 (May 3, 2021). Commissioner Karpel does not consider that such an analysis was done when the Commission issued its indicative ruling regarding vacatur, *see id.,* or on remand.

The Commission's vote on this determination took place on October 28, 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: October 28, 2021