PUBLIC VERSION

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**	**Inv. No. 337-TA-1145**

COMMISSION OPINION

The Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"), based on misappropriation of trade secrets, on review of the final initial determination ("FID") of the presiding administrative law judge ("ALJ"). This opinion sets forth the Commission's reasoning in support of its determination. The Commission affirms all findings in the FID that are not inconsistent with this opinion.

I. BACKGROUND

A. Procedural Background

On March 6, 2019, the Commission instituted this investigation under section 337 based on a complaint filed by Medytox Inc. of Seoul, South Korea ("Medytox"); and Allergan plc[1] of Dublin, Ireland and Allergan, Inc. of Irvine, California (collectively, "Allergan").[2] *See* 84 Fed. Reg. 8112-13 (Mar. 6, 2019). The complaint, as supplemented, alleges a violation of section

[1] On July 1, 2020, the ALJ issued an initial determination granting an unopposed motion to amend the complaint and notice of investigation to reflect a corporate name change from Allergan plc to Allergan Limited. *See* Order No. 43 (July 1, 2020), *unreviewed*, Comm'n Notice (July 20, 2020).

[2] "Complainants" refers to Medytox and Allergan, collectively.

337 based upon the importation and 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 Complainants' trade secrets. *See id.* The notice of investigation names Daewoong Pharmaceuticals Co., Ltd. of Seoul, South Korea ("Daewoong") and Evolus, Inc. of Irvine, California ("Evolus") (collectively, "Respondents") as respondents in this investigation. *See id.* The Office of Unfair Import Investigations ("OUII") is also a party to the investigation. *See id.*

The presiding Administrative Law Judge ("ALJ") conducted an evidentiary hearing on February 4-7, 2020. On July 6, 2020, the ALJ issued a final initial determination ("FID") finding a violation of section 337 based on the misappropriation of Complainants' 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 ALJ's recommended determination ("RD") recommends that, should the Commission find a violation of section 337, that the Commission issue: (1) a limited exclusion order ("LEO") barring entry, for a duration of ten (10) years, of certain botulinum toxin products that are imported or sold in the United States by Respondents Daewoong and Evolus; and (2) a cease and desist order ("CDO") against Evolus. *See* RD at 258, 264. The RD also recommends that the Commission impose a bond in the amount of $441 per 100U vial based on price differential during the period of Presidential review. *See id.* at 271.

On July 28, 2020, the Commission issued a notice requesting statements on the public interest. *See* 85 Fed. Reg. 46711 (Aug. 3, 2020) ("the PI Notice"). On August 5, 2020, the parties filed statements on the public interest pursuant to Commission Rule 210.50, 19 C.F.R. §

210.50. On August 17-18, 2020, several non-parties filed written submissions in response to the PI Notice.[3]

On September 21, 2020, the Commission issued a notice determining to review the FID in part. *See* 85 Fed. Reg. 60489-90 (Sept. 25, 2020) ("the WTR/Remedy Notice"). Specifically, the Commission 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. *See id.* The Commission determined not to review the remainder of the FID. *See id.* The notice invited written submissions from the parties on issues under review, and from the parties, interested government agencies, and any other interested parties on issues of remedy, the public interest, and bonding. *See id.* The Commission requested 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

[3] Submissions were filed by AEON Biopharma, Inc., Kingsmen Digital Ventures, Merz North America, Inc., the R Street Institute, Dr. Frank Agullo, Dr. Bonnie Baldwin, Dr. Louis Bucky, Dr. M. Bradley Calobrace, Susan Coker, Dr. Richard D'Amico, Michael Farah, Dr. Shubha Ghosh, Jennifer Gowdy, Dr. Vladimir Grigoryants, Gary Clyde Hufbauer, Dr. Lorrie Klein, Jacki Kment, Mark Koepsell, Dr. Karen Kohatsu, Dr. Mary Lupo, Dr. Manolis Manolakakis, Roger Milgrim, Dr. Todd Mirzai, Dr. Bradley Musser, Justine Politz, Kimmi Ragone, Drs. Morgan and Lesley Rebach, Susie Reese, Dr. James Stern, Dr. Adrienne Stewart, Dawn Stringini, and Dr. Eduardo Weiss.

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.

On October 9, 2020, the parties, including the IA, filed written submissions in response to the WTR/Remedy Notice,[4] and on October 16, 2020, the parties filed responses to each other's

[4] *See* Complainants' Initial Submission on the Issues under Review in the Final Initial Determination Finding a Violation of Section 337 and on Remedy, the Public Interest, and Bonding (Oct. 9, 2020) (hereinafter, "Complainants' Resp. Br."); Respondents' Response to the Commission on Issues under Review, Remedy, Bond and Public Interest and Request for Oral Argument (Oct. 9, 2020) (hereinafter, "Respondents' Resp. Br."); Opening Submission of the Office of Unfair Import Investigations in Response to the Commission's September 21, 2020 Notice (Oct. 9, 2020) (hereinafter, "IA's Resp. Br.").

submissions.[5] Respondents also filed a notice of a new factual development on September 30, 2020, indicating that Daewoong was able to obtain a *C. botulinum* strain from another source.

On October 5-9, 2020, certain non-parties filed written submissions concerning the public interest, including: AEON Biopharma, Inc.; the American Antitrust Institute; Dr. William Adams; Dr. Thomas Bender III; Dr. Arkady Kagan; and Dr. Alexander Rivkin.

B. Overview of the Technology

BTX[6] products have therapeutic as well as aesthetic applications, including, "the treatment of chronic migraine headaches, cervical dystonia, hyperhidrosis, spasticity, [] urinary incontinence, . . . the temporary improvement to the appearance of glabellar lines (sometimes called frown lines), lateral canthal lines (sometimes called crow's feet), and forehead lines." *See* FID at 9 (citing Joint Technology Stipulation at 2 (July 26, 2019)). For example, the BTX product can "operate[] as a neuromuscular blocking agent, which functions by temporarily interfering with nerve signals and temporarily relaxing targeted muscles through localized injections." *See id.* at 10 (citing CX-16C (Neervannan WS[7]) at Q/A 9).

BTX products are made from the bacterium *Clostridium botulinum*, commonly referred to as *C. botulinum*. *See id.* As explained in the FID, the *C. botulinum* bacteria, when cultured

---

[5] *See* Complainants' Reply Submission on the Issues under Review in the Final Initial Determination Finding a Violation of Section 337 and on Remedy, the Public Interest, and Bonding (Oct. 16, 2020) (hereinafter, "Complainants' Reply Br."); Respondents' Reply Brief on the Commission's Questions on Review and on Remedy, the Public Interest, and Bonding (Oct. 16, 2020) (hereinafter, "Respondents' Reply Br."); Reply Submission of the Office of Unfair Import Investigations in Response to the Commission's September 21, 2020 Notice (Oct. 16, 2020) (hereinafter, "IA's Reply Br.").

[6] BTX refers to botulinum toxin and is used interchangeably with BoNT, *i.e.*, botulinum neurotoxin.

[7] "Neervannan WS" refers to the Witness Statement ("WS") of Dr. Seshadri Neervannan, Allergan's Senior Vice President of Pharmaceutical Development.

(*i.e.*, grown), produce a neurotoxin complex which includes a neurotoxin protein molecule along with several other neurotoxin associated proteins. *See id.* (citing CX-10C (Pickett[8] WS) at Q/A 187). Producing BTX products "involves culturing the *C. botulinum* bacteria, and then separating, isolating, and purifying the neurotoxin complex" produced from that bacteria. *See id.* The BTX products of Complainants Medytox and Allergan, as well as respondent Daewoong[9] use the neurotoxin complex, with a molecular weight of 900 kDa.[10] *See id.*

The FID also noted that "[d]ifferent strains of *C. botulinum* produce different serotypes [or variants] of neurotoxin." *See id.* (citing CX-10C (Pickett WS) at Q/A 67). There are seven serotypes (A to G) and several subtypes within each serotype (*e.g.*, A1, A2, etc.). *See id.* Not every strain, however, produces commercially viable BTX products. *See id.* The properties of the strain as well as the manufacturing process are essential in determining whether and how a strain can be used to produce a commercially viable BTX product. *See id.* (citing CX-10C (Pickett WS) at Q/A 70). For example, the Hall A-hyper strain, a strain of *C. botulinum*, which was developed by U.S. army researchers in the 1940s, "makes the separation and purification process easier and the manufacturing process safer" and "only sporulates[11] poorly and does not form spores during the manufacturing process, which streamlines downstream processing and

---

[8] Dr. Andrew Pickett is Complainants' technical expert in this investigation.

[9] Daewoong manufactures and Evolus sells their BTX products under the brand name Jeuveau® in the United States. *See* FID at 9 (citations omitted).

[10] The molecular masses of proteins, nucleic acids, and other large polymers are often expressed with the units kilodaltons (kDa).

[11] "Sporulate" means forming spores. As explained in the FID, "[c]ertain bacterial cells may convert into dormant spores, which are robust bodies that can withstand extreme conditions." *See* FID at 12 n.5 (citing RX-3164C (Witness Statement of Respondents' technical expert, Dr. Dr. Brenda Anne Wilson) at Q/A 179).

helps manufacturers meet the high standards required for making botulinum toxin." *See id.* at 11-12 (citing CX-10C (Pickett WS) at Q/A 71-83; CX-13C (Jung[12] WS) at Q/A 37).

C. The Asserted Trade Secrets

As noted in the FID, Complainants allege that Daewoong misappropriated: (i) Medytox's *Clostridium botulinum* bacterial strain used to manufacture its BTX products; and (ii) certain Medytox's manufacturing processes for BTX products.[13] *See* FID at 19-21; *id.* at 19 (citing Compl. at ¶ 52); *see also id.* at 20 ("Medytox also alleges that Daewoong misappropriated Medytox's secret manufacturing processes and related testing information for its 900 kDa botulinum toxin products, including Meditoxin, Innotox, and MT10109L."); *id.* at 112-13 (citing CX-2572C (Complainant Medytox's Disclosure Pursuant to Order No. 17) at 2-3; CX-10 (Pickett WS) at Q/As 194-203). Specifically, the FID explains that "Medytox uses a strain of *C. botulinum* that originate[s] from a subculture of the Hall A-hyper strain," but "is genetically distinct from other 'Hall A-hyper' strains." *See id.*

In particular, Complainants allege that "Daewoong obtained Medytox's strain through former Medytox employee Dr. Byung Kook Lee (also referred to as 'BK Lee')." *See* FID at 20. Complainants further allege that "Daewoong misappropriated Medytox's secret manufacturing processes and related testing information for its 900 kDa botulinum toxin products, including Meditoxin, Innotox, and MT10109L." *See id.*

---

[12] Dr. Hyun Ho Jung is the founder and Chief Executive Officer of Medytox.

[13] While the FID at times refers to the Meditoxin manufacturing process, *see*, *e.g.*, FID at 19, the FID also makes clear that the trade secrets include but are not limited to the Meditoxin process. *See* FID at 112-13; *see also id.* at 129 (stating that "Medytox used the Meditoxin manufacturing process as the starting point for extensive experimentation to further improve its manufacturing process, which resulted in several innovations" and that "Medytox's innovations were recorded in documents such as the EBR, the PQP, and the attachments to the PQP."); *see also* CX-2063C (Experimental Batch Record ("EBR")); CX-2064C (Project and Quality Plan ("PQP")).

Complainants allege that Daewoong uses the misappropriated Medytox strain of *C. botulinum* to produce DWP-450, Daewoong's BTX product, which is accused in this investigation. *See id.*

D. Complainants' Domestic Industry Products

The FID considers Allergan's BOTOX® Cosmetic, BOTOX® therapeutic, and MT10109L[14] as domestic industry products. *See* FID at 160. The FID finds that Allergan's manufacture, R&D, and sale of BOTOX® products qualify as a domestic industry, even though they do not practice the misappropriated trade secrets, because the BOTOX® products directly compete with the accused products. *See id.* at 158 (citing *TianRui Grp. Co. v. ITC*, 661 F.3d 1322, 1335-37 (Fed. Cir. 2011)). The FID also finds that the importation and sale of Respondents' unfair imports have the threat and effect of causing substantial injury to the domestic industry relating to Allergan's BOTOX® products. *See id.* at 208, 220.

The FID further finds that Allegan established a domestic industry with respect to MT10109L, which is a BTX product that Medytox licensed to Allergan for commercialization in the United States and is produced using Medytox's bacterial strain and manufacturing processes that allegedly constitute trade secrets; but MT10109L has not yet been approved by the FDA for sale in the United States. *Id.* at 189-90. The FID finds, however, that complainants have not provided sufficient evidence that importation of Respondents' products have a direct effect or

[14] MT10109L is a liquid-form, animal-protein-free alternative BTX product. *See* FID at 6-7. BOTOX® and the accused products, on the other hand, contain animal proteins.

likely effect of threatening substantial injury to Allergan's industry related to MT10109L. *Id.* at 225.[15]

E. Respondents' Accused Products

The notice of investigation defines the scope of the investigation and the accused products as follows:

> [B]otulinum neurotoxin products manufactured by [Daewoong], specifically: (1) DWP-450 (prabotulinumtoxinA), variously marketed under the brand names Nabota®, Jeuveau™ and other brand names; (2) products containing or derived from DWP-450; and (3) products containing or derived from the BTX strain assigned the high-risk pathogen control number 4-029-CBB-IS-001 by the Korean Centers for Disease Control and Prevention or the manufacturing process used to manufacture DWP-450.

See 84 Fed. Reg. 8112. As noted in the FID, "DWP-450-derived products are sold in South Korea under the brand name Nabota, in the United States under the brand name Jeuveau®, and in Canada and Europe under the brand name Nuceiva." *See* FID at 8. As noted above, Daewoong manufactures the accused products in South Korea and Evolus sells them in the United States. *See id.* at 9 (citing RX-3162C (Moatazedi[16] WS) at Q/A 75; Hr'g Tr. at 899 (Moatazedi)).

[15] No party petitioned for review of the FID's finding of no injury as to MT10109L. Therefore, the Commission has determined that Complainants have abandoned seeking relief as to MT10109L by failing to file a petition for review of the no injury finding of the FID. Accordingly, on review, the Commission terminates Complainants' claim of a Section 337 violation based on MT10109L and the FID's findings on domestic industry as to MT10109L are therefore moot.

[16] David Moatazedi is the President and Chief Executive Officer of Evolus.

II. LEGAL STANDARDS

A. Standard of Review

On review, Commission Rule 210.45(c) provides that "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge" and that "[t]he Commission also may make any findings or conclusions that in its judgment are proper based on the record in the proceeding." *See* 19 C.F.R. § 210.45(c). In addition, as explained in *Certain Polyethylene Terephthalate Yarn and Products Containing Same*, "[o]nce the Commission determines to review an initial determination, the Commission reviews the determination under a *de novo* standard." Inv. No. 337-TA-457, Comm'n Op., 2002 WL 1349938, *5 (June 18, 2002) (citations omitted). This is "consistent with the Administrative Procedure Act which provides that once an initial agency decision is taken up for review, 'the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule.'" *Id.* (citing 5 U.S.C. § 557(b)).

B. Existence and Misappropriation of Trade Secrets

The existence of a trade secret is a prerequisite to any finding of misappropriation of trade secrets. The Uniform Trade Secrets Act ("UTSA") defines a "trade secret" as information that "(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." UTSA § 1(4). The Commission considers six factors in determining whether a trade secret exists:

> (1) the extent to which the information is known outside of complainant's business;

> (2) the extent to which it is known by employees and others involved in complainant's business;
>
> (3) the extent of measures taken by complainant to guard the secrecy of the information;
>
> (4) the value of the information to complainant and to his competitors;
>
> (5) the amount of effort or money expended by complainant in developing the information; and
>
> (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

See Certain Processes for the Manufacture of Skinless Sausage Casings & Resulting Prod., Inv. No. 337-TA-148/169, Initial Determination, 1984 WL 273789, *94 (July 31, 1984) ("*Sausage Casings*"), *unreviewed*, Comm'n Op., 1984 WL 273970, at *2 (Jan. 1, 1984) (citing Restatement of Torts § 757, comment b). These factors are not individually dispositive. Rather, they are "instructive guidelines for ascertaining whether a trade secret exists." *See Learning Curve Toys, Inc. v. PlayWood Toys, Inc.*, 342 F.3d 714, 722 (7th Cir. 2003).

As to misappropriation, the Federal Circuit in *TianRui* held that "a single federal standard, rather than the law of a particular state, should determine what constitutes a misappropriation of trade secrets sufficient to establish an 'unfair method of competition' under section 337." *TianRui*, 661 F.3d at 1327. Sources of applicable law include the UTSA, the Restatement (Third) of Unfair Competition, the Restatement of Torts, the Defend Trade Secrets Act of 2016 (18 U.S.C. §§ 1831-39) ("DTSA"),[17] and federal common law. Complainants bear the burden to establish a *prima facie* case of misappropriation but once they make that showing,

[17] The DTSA provides that "district courts of the United States shall have original jurisdiction of civil actions brought under this section." 18 U.S.C. § 1836(c).

the burden shifts to Respondents to show independent development. *See Sausage Casings*, 1984 WL 273789, *95 ("When respondent asserts that his use of the secret process is the product of independent development, respondent bears a heavy burden of persuasion to show that independent development."); *see also Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1241 (8th Cir. 1994) ("[O]nce [plaintiff] produced convincing evidence of misappropriation, [defendant] was obligated to provide persuasive evidence of lawful derivation.").

The Commission noted that "the UTSA defines misappropriation as:

> (i) acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or
>
> (ii) disclosure or use of a trade secret of another without express or implied consent by a person who
>
> (A) used improper means to acquire knowledge of the trade secret; or
>
> (B) at the time of disclosure or use, knew or had reason to know that his knowledge of the trade secret was (I) derived from or through a person who had utilized improper means to acquire it; (II) acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or (III) derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or
>
> (C) before a material change of his [or her] position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake."

See Certain Crawler Cranes & Components Thereof, Inv. No. 337-TA-887, Comm'n Op., 2015 WL 13817116, *22, *33 (May 6, 2015) (citing UTSA § 1(2)). The Commission also held that the elements of the unfair act of misappropriation of trade secrets are:

(1) a protectable trade secret exists;

(2) the complainant is the owner of the trade secret;

(3) the complainant disclosed the trade secret to respondent while in a confidential relationship or the respondent wrongfully took the trade secret by unfair means; and

(4) the respondent has used or disclosed the trade secret causing injury to the complainant.

See id. (citing UTSA, § 1(4)). The Commission noted that the UTSA does not define the term "use" (element four) but that the Restatement provides that "use" includes "the marketing of goods that embody a trade secret, [where] the trade secret is employed in manufacturing or production, or is relied on to assist or accelerate research or development." *See id.* at *33 (citing Restatement (Third) of Unfair Competition § 40, Comment c).

Element four of misappropriation, as stated above, also requires injury to the Complainant. Such injury stems from the language of section 337(a)(1)(A) which requires a showing of injury as an element of a trade secret misappropriation claim, *e.g.*, actual or threatened injury to a domestic industry under section 337(a)(1)(A)(i). The substantive unfair act or unfair method of competition relating to misappropriation of trade secrets does not require a separate injury showing under the UTSA or the Restatement. *See* UTSA § 1(2); Restatement (Third) of Unfair Competition § 40; Restatement of Torts § 757; *see also TianRui*, 661 F.3d at 1327 ("[A] single federal standard, rather than the law of a particular state, should determine what constitutes a misappropriation of trade secrets."); *accord* Complainants' Resp. Br. at 33-40; *but see* IA's Resp. Br. at 18-19 ("[T]he trade secret injury requirement is separate from the (a)(1)(A) injury requirement and that the trade secret injury requirement is satisfied when the

trade secret is used or disclosed.") (citing Milgrim on Trade Secrets § 7.07[1] (1968)).[18] Respondents argue that "[t]he common law . . . includes a clear requirement that there be 'injury to the complainant' or, as some of the common law authorities phrase it, 'detriment to the plaintiff.' . . . This common-law injury requirement is separate and distinct from the injury showing that is required under Section 337(A)(1)(a)." *See* Respondents' Resp. Br. at 14 (citing Milgrim on Trade Secrets, § 15.01[1][d] (2018)). While federal district courts may require a distinct type of injury to establish standing or damages, such injury is not required to establish the substantive unfair act of misappropriation of trade secrets before the Commission. Respondents conflate the injury for standing or damages with a substantive injury requirement to establish the tort of trade secret misappropriation. *See* Respondents' Resp. Br. at 14-25.

C. Domestic Industry

Under section 337(a)(1)(A), a complainant must prove the existence and injury, or threat of injury, to a domestic industry or to trade and commerce in the United States. *See* 19 U.S.C. § 1337(a)(1)(A).

1. Existence of a Domestic Industry

Trade secret misappropriation investigations at the Commission are governed by 19 U.S.C. § 1337(a)(1)(A), which declares unlawful—

> Unfair methods of competition and unfair acts in the importation of articles . . ., 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

[18] In effect, the IA states that injury is not a separate requirement because it is subsumed in the use or disclosure element. *See* IA's Resp. Br. at 18-19; IA's Reply Br. at 8; *accord* Complainants' Reply Br. at 11.

(iii) to restrain or monopolize trade and commerce in the United States.

19 U.S.C. § 1337(a)(1)(A). Complainants alleged injury under section 337(a)(1)(A)(i) (*see* Compl. at ¶ 148) and therefore, they must show that they have an "industry in the United States," and that the industry has suffered "actual substantial injury, or threat of substantial injury." *See, e.g., Certain Rubber Resins & Processes for Mfg. Same,* Inv. No. 337-TA-849, Comm'n Op., 2014 WL 7497801, *5 (Feb. 26, 2014) ("*Rubber Resins*") ("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.").

In addressing whether an "industry . . . in the United States" exists under section 337(a)(1)(A), the Commission has historically considered the "nature and significance" of the complainant's activities that allegedly form the domestic industry. *See Certain Miniature, Battery-Operated, All Terrain, Wheeled Vehicles* ("*Toy Vehicles*"), Inv. No. 337- TA-122, USITC Pub. No. 1300, Comm'n Op. at 6 (Oct. 1982) ("The threshold question of the existence of an 'industry . . . in the United States' . . . requires an inquiry into the nature and significance of complainants' business activities in the United States which relate to the STOMPER toy vehicles."), *aff'd by Schaper Mfg. Co. v. ITC*, 717 F.2d 1368 (Fed. Cir. 1983); *Certain Modular Structural Systems*, Inv. No. 337-TA-164, USITC Pub. No. 1668, Comm'n Op. at 13 (June 1984) (necessary to determine "the nature and significance" of complainant's activities in the United States with respect to the relevant product to determine "whether there is an industry 'in the United States' within the meaning of section 337"); *Certain Cube Puzzles*, Inv. No. 337-TA-112, USITC Pub. 1334, Comm'n Op. at 30 (Jan. 1983) ("We find that Ideal's domestic activities are of the appropriate nature and are significant enough to conclude that their domestic business

activities constitute an 'industry . . . in the United States.'").[19] Indeed, Commission decisions under section 337(a)(1)(A) after the amendments to Section 337 in the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, have continued to rely upon pre-1988 section 337 precedent. *See Certain Ink Markers & Packaging Thereof*, Inv. No. 337-TA-522, Order No. 30 at 57-58, (July 25, 2005) ("*Ink Markers*") ("The administrative law judge finds that investigations prior to the Omnibus Trade & Competitiveness Act of 1988 (1988 Act) and when injury to a domestic industry had to be established for all unfair acts, including statutory intellectual property based cases, are helpful in determining how to define the industry for the acts relating to the trade dress in issue.") (*unreviewed, see* USITC Pub. No. 3971); *see also Certain Cast Steel Railway Wheels, Certain Processes for Manufacturing or Relating to Same & Certain Prods. Containing Same*, Inv. No. 337-TA-655, ID at 78-79 n. 38 (Oct. 20, 2009), *unreviewed by* Notice (Dec. 17, 2009) ("*Cast Steel Railway Wheels*") (same). In light of Congress's decision to retain the term "industry" and the fact that Congress was aware of the Commission's pre-1988 precedent, the pre-1988 precedent continues to provide guidance for investigations instituted under the current version of section 337(a)(1)(A). *See* S. REP. NO 100-71 at 129; *see also* 2B SUTHERLAND STATUTORY CONSTRUCTION § 49:9 (7th ed.) ("[L]egislative action by amendment or appropriation of some parts of a law which has received a contemporaneous and practical construction may indicate approval of interpretations relating to the unchanged and unaffected parts."); *Lindahl v. Office of Pers. Mgmt*., 470 U.S. 768, 782-83 (1985) ("Moreover, the fact that Congress amended [the relevant statutory section] in 1980 without explicitly repealing the established [legal] doctrine itself gives rise to a presumption that

[19] In affirming the Commission's determination in *Toy Vehicles*, the Federal Circuit found that the "nature and extent" of complainant's activities were "insufficient" to constitute an "industry in the United States." *Schaper Mfg.*, 717 F.2d at 1372.

Congress intended to embody [that doctrine] in the amended version of [that statutory section].”). Specifically, the Commission looks at what activities are performed by the complainant in the United States and determines whether they are the types of activities that Congress sought to protect from unfairly traded imports or whether they are the types of activities that a “mere importer” would perform. *See, e.g., Certain Apparatus for the Continuous Production of Copper Rod* (“*Copper Rod*”), Inv. No. 337-TA-52, USITC Pub. 1017, Comm’n Op. at 53-55 (Nov. 1979) (finding a domestic industry in the development, licensing of patents and trade secret know-how, engineering, start-up operations and other technical assistance for SCR systems as well as subcontracted component manufacture).

The Commission considers “the realities of the marketplace,” when determining the domestic industry in a trade secrets investigation or other investigation based on unfair acts other than the infringement of statutory intellectual property rights (such as patents). The Federal Circuit has upheld the Commission’s pragmatic approach to the determination of whether a complainant can obtain protection under Section 337 for its domestic industry. For example, in *TianRui*, the Federal Circuit affirmed the Commission’s definition of the complainant’s domestic industry as the investments and activities relating to “wheels domestically produced by the trade secret owner” which compete with appellants’ imported wheels, even though these wheels did not use the complainant’s trade secrets. *See TianRui*, 661 F.3d at 1335-37, *affirming Cast Steel Railway Wheels*, Inv. No. 337-TA-655, ID at 80 (Oct. 16, 2009) (domestic industry is defined as a United States industry that is “the target of the unfair acts and practices.”), *unreviewed by* Comm’n Notice (Dec. 17, 2009); *see also* 19 C.F.R. § 210.12(a)(6)(ii) (requiring the complaint to “include a detailed statement as to whether an alleged domestic industry exists or is in the process of being established (*i.e.*, for the latter, facts showing that there is a significant likelihood

that an industry will be established in the future), and include a detailed description of the domestic industry affected, including the relevant operations of any licensees" for claims under section 337(a)(1)(A)(i) or (ii)). The *TianRui* Court further rejected the contention that "investigations involving intellectual property under the unfair practices provision [(*i.e.*, section 337(a)(1)(A))] require the existence of a domestic industry that relates to the asserted intellectual property in the same manner that is required for statutory intellectual property [(*i.e.*, section 337(a)(1)(B)-(E))]." *See TianRui*, 661 F.3d at 1335-37.

2. Injury to the Domestic Industry

Under section 337(a)(1)(A)(i), "the complainant [must also] demonstrate . . . that there [is] actual substantial injury or the threat of substantial injury to a domestic industry." *See Rubber Resins*, Comm'n Op., 2014 WL 7497801, *5; *see also* 19 C.F.R. § 210.12(a)(8) (requiring the complaint to "state a specific theory and provide corroborating data to support the allegation(s) in the complaint concerning the existence of a threat or effect to destroy or substantially injure a domestic industry, to prevent the establishment of a domestic industry, or to restrain or monopolize trade and commerce in the United States" for claims under section 337(a)(1)(A)).

In addition, "[w]hen the complainant alleges actual injury, there must be a causal nexus between the unfair acts of the respondents and the injury." *Rubber Resins*, Comm'n Op., 2014 WL 7497801, at *30. Similarly, when the complainant alleges a threatened injury, such "injury must [] be 'substantive and clearly foreseen,' with a causal connection between the action of the respondents and the threatened injury." *Id.* at *32 (citations omitted).

III. DISCUSSION

The Commission 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. *See* 85 Fed. Reg. at 60489-90. For the reasons set forth below, the Commission has determined to affirm the FID in part and reverse in part. Specifically, the Commission has determined to affirm with modification the FID's findings with respect to subject matter jurisdiction, standing, domestic industry, and trade secret existence and misappropriation as it relates to Medytox's manufacturing processes. The Commission has also determined to reverse the FID's finding that a protectable trade secret exists with respect to Medytox's bacterial strain. Accordingly, the Commission finds a violation of section 337 with respect to Respondents' importation and sale in the United States of Respondents' unfair imports.

A. Subject Matter Jurisdiction

The FID finds "subject matter jurisdiction based on the alleged (and in this case proven) importation of products made by misappropriated trade secrets, which has resulted in harm to the domestic industry." *See* FID at 27-28 (citing *Rubber Resins*, ID at 16-18, 2013 WL 4495127 (June 17, 2013), *unreviewed in relevant part*, Comm'n Op. (Jan. 15, 2014)). The FID dismisses Respondents' "extraterritoriality argument," finding that such argument "was rejected by the Federal Circuit in *TianRui*." *See id.* at 26 (citing *TianRui*, 661 F.3d at 1329). The FID reasons that "*TianRui* did not turn on whether the trade secrets at issue had been developed and practiced in the United States" but on whether the "goods at issue were imported and injured, or could injure, a domestic industry." *See id.* at 26-27 (citing *TianRui*, 661 F.3d at 1332). The Commission affirms the FID's findings as to subject matter jurisdiction as explained below.

Respondents argue that the FID's "interpretation of the scope of Section 337 is contrary to the statute and its legislative history, which confirms that Section 337's enforcement powers exist to protect and remedy violations of U.S. intellectual property rights." *See* Respondents'

Pet. at 14-15. Respondents rely on 19 U.S.C. § 1337(a)(1)(B)-(C), the legislative history relating to the 1988 amendments (*e.g.*, H.R. REP. NO. 100-40, pt. 1, at 155 (1987), and precedent relating to the statutory intellectual property rights (*Interdigital Commc'ns v. ITC*, 707 F.3d 1295 (Fed. Cir. 2013) (*en banc*)). Complainants respond that these arguments relate to the statutory intellectual property provisions rather than trade secret misappropriation under section 337(a)(1)(A). *See* Complainants' Pet. Resp. at 15-16.

Respondents further argue that jurisdiction over this investigation is not supported by precedent, specifically stating that "in *Tianrui* [and *Rubber Resins*], the trade secrets at issue were developed and owned by a U.S. company." Respondents' Pet. at 19-20 (citing *TianRui*, 661 F.3d at 1324; *Rubber Resins*, ID, 2013 WL 4495127, at *22-27). Respondents contend that the Commission has no jurisdiction to adjudicate claims of infringement of non-U.S. intellectual property ("IP") rights.

Contrary to Respondents' assertions, the Commission finds that subject matter jurisdiction exists in this investigation. As the Federal Circuit recognized in *TianRui*, the "focus" of section 337 is "on the act of importation and the resulting domestic injury" and therefore, the Commission "does not purport to regulate purely foreign conduct." *TianRui*, 661 F.3d at 1329 (citing *Morrison v. Nat'l Austl. Bank Ltd.*, 130 S. Ct. 2869, 2884 (2010)). The Supreme Court has held that "[i]f the conduct relevant to the statute's focus occur[s] in the United States, then the case involves a permissible domestic application even if other conduct occurred abroad." *RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2101 (2016); *see also Akzo N.V. v. USITC*, 808 F.2d 1471, 1488 (Fed. Cir. 1986) ("Properly viewed, § 337 and its predecessor provisions represent a valid delegation of this broad Congressional power for the public purpose of providing an adequate remedy for domestic industries against unfair practices

beginning abroad and culminating in importation."). Here, both importation and injury involve conduct occurring in the United States; importation involves the entry of goods into the United States and injury relates to "an industry in the United States" under section 337(a)(1)(A)(i). *See* FID at 22; *infra* section III(D)(2).

Respondents' contention that this is a foreign dispute between foreign companies involving no U.S. IP rights is also incorrect. *See* Respondents' Pet. at 20 (*TianRui*, 661 F.3d at 1324); *see also TianRui*, 661 F.3d at 1324 ("We conclude that the Commission has authority to investigate and grant relief based in part on extraterritorial conduct insofar as it is necessary to protect domestic industries from injuries arising out of unfair competition in the domestic marketplace."). While *TianRui* is not factually identical to the present case (because in *TianRui*, the trade secrets owner was located in the United States), *TianRui* is not so limited and does not negate jurisdiction in this case. *Accord* IA's Pet. Resp. at 5; Complainants' Pet. Resp. at 18; 19 U.S.C. § 1337(a)(1)(A). Rather, as discussed above, *TianRui* found that the Commission "does not purport to regulate purely foreign conduct" and *TianRui* made such finding "[i]n light of the statute's focus on the act of importation and the resulting domestic injury." *See TianRui*, 661 F.3d at 1329 (citing *Morrison v. Nat'l Austl. Bank Ltd.*, 130 S. Ct. 2869, 2884 (2010)). Nor does any of Respondents' cited precedent impose a geographical restriction as to the locus of development or ownership of the trade secrets asserted in a Section 337 investigation as Respondents contend.

In any event, Respondents' arguments ignore the FID's findings that (a) Medytox licensed its [ ] to [

] to co-complainant Allergan, *see* FID at 31-32 ("The license includes [

].") (quoting JX-50C.20); and (b) the misappropriation of the trade secrets injures and threatens a domestic industry relating to Allegan's BOTOX® products. *See* FID at 208, 220. *Accord* Complainants' Pet. Resp. at 11; *infra* section III(D)(1).

Furthermore, Respondents incorrectly suggest that the trade secrets must be developed or practiced in the United States. *See* Respondents' Pet. at 20. Although Section 337(a)(1)(B)-(E), protects domestic industries that exploit U.S. IP rights as defined by the IP statutes specified in these provisions, there is no requirement that these statutory intellectual property rights are restricted to IP that was created or developed in the United States. For example, U.S. patent rights do not require development or invention in the United States. *See*, *e.g.*, 35 U.S.C. § 119. Similarly, there is no requirement in Section 337(a)(1)(A) that trade secrets be developed, created, or practiced in the United States. The Federal Circuit in *TianRui* distinguished unfair acts based on statutory IP rights (*i.e.*, under section 337(a)(1)(B)-(E)) and expressly rejected a requirement that the domestic industry practice the asserted trade secrets under section 337(a)(1)(A). *See TianRui*, 661 F.3d at 1335-37.

Thus, the Commission has determined to affirm the FID with the supplemental analysis discussed above.

B. Standing

The FID finds that both Medytox (as the owner) and Allergan (as the licensee) have standing to assert trade secret misappropriation in this investigation. *See* FID at 28-38. Specifically, the FID finds that "Medytox has established ownership of its trade secret strain and

manufacturing process." *See id.* at 29. In addition, as to Allergan, the FID notes that "Allergan has an exclusive license as to MT10109L and [

]." *See id.* at 36 (citing JX-50C.14). The FID further finds that "[t]he plain language of the license agreement states that Allergan is the exclusive licensee [

] which includes the asserted trade secrets in this investigation." *See id.* (citing JX-50C.15). The FID also finds that "significant aspects of the asserted trade secrets are incorporated in the manufacturing of MT10109L, and it uses the misappropriated BTX strain." *See id.* The FID concludes that "Allergan is the exclusive licensee of these trade secrets in the U.S. with regard to MT10109L, and therefore has independent standing." *See id.* at 36-37 (citing CX-11C (Rhee[20] WS) at Q/As 52, 55, 57, 120; CX-12C (Kim[21] WS) at Q/A 90; CX-17C (Chang[22] WS) at Q/A 70); *accord* Complainants' Pet. Resp. at 28; IA's Pet. Resp. at 7.

Respondents erroneously assert that "standing is a constitutional requirement before the Commission just as in Article III courts." *See* Respondents' Pet. at 22 (citing *Certain Wireless Devices, Including Mobile Phones & Tablets II*, Inv. No. 337-TA-905, Order No. 12 at 7 (May 1, 2014) ("*Certain Wireless Devices*")).[23]

[20] Dr. Chang Hoon Rhee is Head of the Biopharmaceutical Development Department at Medytox.

[21] Dr. Hack Woo Kim is a Director at Medytox.

[22] Dr. Seong Hun Chang is Head of Quality System Management at Medytox.

[23] In *Certain Wireless Devices*, respondents alleged that the asserted patents were not properly assigned to the sole complainant. *Certain Wireless Devices*, Inv. No. 337-TA-905, Order No. 12 at 2.

While the Commission requires by rule[24] that at least one complainant is the owner or exclusive licensee of the subject intellectual property, *see* Commission Rule 210.12(a)(7), standing before administrative agencies is distinct from constitutional standing before Article III federal courts. *See Envirocare of Utah, Inc. v. Nuclear Regulatory Comm'n*, 194 F.3d 72, 74 (DC Cir. 1999) ("Agencies . . . are not constrained by Article III of the Constitution; nor are they governed by judicially-created standing doctrines restricting access to the federal courts.") (citation omitted); *Ecee, Inc. v. Fed. Energy Regulatory Comm'n*, 645 F.2d 339, 349 (5th Cir. 1981) ("Administrative adjudications, however, are not an [A]rticle III proceeding to which either the 'case or controversy' or prudential standing requirements apply; within their legislative mandates, agencies are free to hear actions brought by parties who might be without standing if the same issues happened to be before a federal court.") (citations omitted); *accord* Complainants' Pet. Resp. at 25.[25]

Respondents do, however, correctly assert that Allergan is not an exclusive licensee of the asserted trade secrets. Respondents explain that "Medytox is free [

[24] The Commission may impose certain standing requirements by rule or through adjudication. *See*, *e.g.*, *SiRF Tech., Inc. v. ITC*, 601 F.3d 1319, 1326 n.4 (Fed. Cir. 2010) (affirming violation finding in patent infringement investigation; noting that the "Commission 'strictly reads the federal [patent] standing precedent' into its rules"); *Certain Carbon & Alloy Steel Prods.*, Inv. No. 337-TA-1002, Comm'n Op., 2018 WL 7572059, *15-16 (Mar. 19, 2018) (requiring complainants to sufficiently plead antitrust injury standing when asserting certain antitrust claims before the Commission).

[25] On appeal before a federal court, however, a party seeking review of an agency's final action in a federal court must "supply the requisite proof of an injury in fact" to establish standing. *See Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1171-72 (Fed. Cir. 2017) (citing *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007); *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014)).

]. *See* Respondents' Pet. at 27 (citing JX-50C at §§ 1.51. 1.60, 2.4(a)). Thus, Respondents conclude, "Allergan has [

]. *See id.* at 28 (citing *WiAv Solutions LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265-67 (Fed. Cir. 2010) ("[A]n exclusive licensee lacks standing to sue a party who has the ability to obtain . . . a license from another party with the right to grant it."); *see also* Complainants' Pet. Resp. at 31 ("The license is exclusive as to MT10109L and [

]") (citing JX-50C.14).

WiAv Solutions, however, applies to standing in federal courts and, as discussed above, the Commission Rule requires only that "at least one complainant"–not every complainant–be the owner or exclusive licensee of the subject intellectual property. *See* 19 C.F.R. § 210.12(a)(7); *see also Certain Diltiazem Hydrochloride & Diltiazem Preparations*, Inv. No. 337-TA-349, Order No. 35, 1994 WL 930265, *2 (Sept. 2, 1994) (finding that a purchaser, manufacturer, and seller of pharmaceutical products had "sufficient commercial and legal interest" to appear as a joint complainant with the patent owner); *accord* Complainants' Pet. Resp. at 23.

Thus, the Commission has determined to affirm the FID with the modified analysis discussed above.

C. Trade Secret Misappropriation

1. The Medytox Strain

(i) Existence of a Trade Secret

The FID finds that "the Medytox BTX strain . . . is genetically unique from other strains, distinguishable from other Hall A-hyper strains, and is commercially valuable." *See* FID at 64. The FID analyzes the six *Sausage Casings* factors (*see supra* section II(B)) and concludes that

the Medytox strain is a protectable trade secret. *See id.* at 65-87. Specifically, which respect to factors 1 and 2, the FID finds that, while the DNA sequence of Hall A-hyper strains may be known, it is the embodiment of the DNA in the bacteria, *i.e.*, "the viable bacterial cell capable of reproduction" that gives the Medytox strain its value. *See id.* at 67-68. As to factor 3, the FID finds (and Respondents do not dispute) that "Medytox took adequate precautions to protect its Hall A-hyper strain from disclosure." *See id.* at 69-70.

With respect to factor 4, the FID finds that "Medytox's strain is commercially valuable" and that "[t]he strain is an essential element of Medytox's manufacturing process for BTX." *See* FID at 73-74 (citing CX-11C (Rhee WS) at Q/A 10; CX-13C (Jung WS) at Q/A 37). The FID also discusses the "qualities that make [Medytox's strain] particularly valuable for commercial manufacture" but finds that such qualities appear to result from the fact that "[t]he Medytox strain is derived from the Hall A-hyper strain," rather than any improvement by Medytox itself. *See id.* at 74-76 (citing CX-13C (Jung WS) at Q/As 21, 35; CX-15C (Keim[26] WS) at Q/A 4).

As to factor 5, the FID states that "there is no requirement that a trade secret be the product of any particular amount of investment." *See id.* at 80 (citing *Learning Curve*, 342 F.3d at 728). The FID further finds that while "[t]he strain passed without monetary compensation (at least at the time of transfer) between people connected by close relationships, . . . [t]he value of a gift is not . . . diminished by the fact that it is given without monetary payment." *See id.* at 81 (citing Hr'g Tr. (Jung) at 332-333; *Liautaud v. Liautaud*, 221 F.3d 981, 986 (7th Cir. 2000)).

Lastly, as to factor 6, the FID finds "no evidence that Medytox ever made its strain available for sale or available to others outside of Medytox for any purpose." *See id.* at 87.

[26] Dr. Paul S. Keim was retained as a technical expert for Complainants.

The FID does not address whether A-hyper strains were previously available but finds that "Daewoong's internal contemporaneous records further reflect that [

]." *See id.* at 86 (citing CX-2180C.9-11 (2009 BTA Memo)). The FID thus concludes that "the Medytox strain is protectable as a trade secret, because: (a) the strain has economic value, (b) it is not generally known or readily ascertainable, and (c) Medytox has taken reasonable precautions to maintain its secrecy." *See id.* at 87 (citing *Rubber Resins*, Comm'n Op. at 10, 2014 WL 7497801, at *5).

Respondents argue that "[t]he unprotected sharing of the strain extinguished any claim to trade secret protection for it." *See* Respondents Pet. at 52 (citing 1 Milgrim on Trade Secrets §1.05[1] at 1-316 ("Since secrecy is a requisite element of a trade secret, it follows that unprotected disclosure of the secret will terminate that element and, at least prospectively, forfeit the trade secret status.")). Respondents further contend that "from the time Dr. Ivan Hall found the strain in soil in the 1920s until government restrictions on transfer of dangerous bacteria heightened in 2001, the Hall-A Hyper strain passed between and through an innumerable array of academic, government, and private entities—without consideration or documentation, and without any effort to impose confidentiality obligations, including restrictions on further disclosure and use, on those who were granted access to the strain." *See id.*

Respondents further argue that "trade secret eligibility is applied to information—it does not apply to a material object or living organism." *See id.* at 53-54. Respondents contend that "the Medytox botulinum strain does not embody any information that is secret" but that "[t]he strain is a copy of the so-called Hall-A Hyper strain—a well-known cell line that traces back to Dr. Ivan Hall's study of the organism almost a century ago." *See id.* at 56. In particular,

Respondents explain, "the Medytox strain only differs from the Hall-A Hyper sequence published on GenBank by six nucleotides or 'SNPs'[27] out of 3.6 million" and "these infinitesimally small differences do not imbue the Medytox strain with any distinguishing or superior characteristics as compared to any other Hall-A Hyper strain." *See id.* (citing CX-15C.15, 29 (Keim WS) at Q/As 48-49, 112); *see also* CX-15C (Keim WS) at Q/A 118 (testifying that SNPs are caused by mutations that develop as a strain is grown and replicated).

Still further, Respondents argue that "Medytox fails the competitive advantage requirement [for trade secrets]" because "Medytox is far from alone in using the Hall-A Hyper strain to produce commercial botulinum toxin," and "the majority of competitors in the botulinum market (past, present, and in the foreseeable future) use exactly the same strain." *See id.* at 58. Lastly, Respondents contend that "Medytox's copy of the Hall-A strain also cannot be a trade secret because the strain is available for purchase on the open market for relatively inexpensive prices." *See id.* at 62.

Complainants rebut Respondents' contention that trade secret protection cannot apply to a live organism. Complainants explain that "the valuable characteristics of Medytox's strain are the product of . . . 'genetic messages'—that is, information that is encoded in the strain's genetic makeup." *See* Complainants' Pet. Resp. at 45-46 (citing FID at 62; CX-10C (Pickett WS) at Q/A 113; *Certain Coamoxiclav Prods. Potassium Clavulanate Prods., & Other Prods. Derived From Clavulanic Acid*, Inv. No. 337-TA-479, ID, 2003 WL 1793272, at *7 (Mar. 6, 2003) (finding that the "reason that the [bacterial] strain has an 'independent significant commercial value' is that it allegedly contains a highly valuable trade secret, *i.e.*, its genetic information."); *Pioneer Hi-Bred*, 35 F.3d at 1235-41 (affirming the district court's finding that the genetic

[27] "SNP" refers to a single nucleotide polymorphism. *See* FID at 100.

messages of Pioneer's hybrid seed corn were trade secrets)); *see also Salsbury Labs., Inc. v. Merieux Labs., Inc.*, 735 F. Supp. 1555, 1569 (1989) (finding the use of a particular strain of a virus to constitute trade secret information); *accord* IA's Pet. Resp. at 19-20.

Complainants contend that "the Medytox strain is unique . . . and different from all other strains, including those published on GenBank." *See* Complainants' Pet. Resp. at 52 (citing FID at 64, 67-68); *see also* IA's Pet. Resp. at 21 ("Daewoong did not create a commercially viable strain from the Hall A-hyper strain CP000727.1 that was available on GenBank, was unable to find a company from which to license a commercially viable strain and then resorted to misappropriating Medytox's BTX strain."); *see also* Complainants' Resp. Br. at 18 (agreeing that "the genetic sequence of the Hall A-hyper strain held at the Fort Detrick Army base has been published" but arguing that "[c]reation of bacterial strains such as *C. botulinum* using a published DNA sequence simply is not possible") (citing FID at 67-68). Complainants further argue that "[t]here is no evidence that at the time Daewoong sought a strain for commercial BTX production, it could have obtained Medytox's strain or any other version of the Hall A-hyper [strain]." *See* Complainants' Pet. Resp. at 47-48 (citing CX-10C (Pickett WS) at Q/As 89, 99).

The Commission finds that Complainants fail to satisfy their burden to show that the Medytox strain is a protectable trade secret. In particular, Complainants' expert failed to demonstrate that the Medytox strain is distinct from its parent Hall A-hyper strain that Medytox was freely gifted with no restrictions, including no obligations of confidentiality. *See* FID at 90-91; CX-10C (Pickett WS) at Q/As 110-113; CX-13C (Jung WS) at Q/A 22; CX-14C (Yang WS) at Q/As 7-8. The record shows that the Medytox strain stems from a Hall A-hyper strain that was given to Medytox by Dr. Kyu Hwan Yang with no restrictions as to use or confidentiality. *Id*. Dr. Yang had acquired the Hall A-hyper strain that he gifted to Medytox from the

University of Wisconsin in 1979, again free of any restrictions. The record also shows that the Hall A-hyper strain held by the University of Wisconsin was freely circulated to other entities as well. Under these circumstances, where the strain was circulated without restrictions, and because as explained below there is no evidence in the record that the Medytox strain is distinct from the parent strain given to Medytox, the Commission finds that it does not qualify as a trade secret.

Complainants appear to focus on the 2009-2010 timeframe when Daewoong sought a Hall A-hyper strain. However, they fail to address Respondents' argument that the strain was widely and freely available before the anthrax attacks of 2001, which caused governments to tighten regulations on the transfer of dangerous bacteria. *See* Respondents' Pet. at 51-52; *see also* CX-10C (Pickett WS) at Q/As 70-109. Complainants also focus on the period after the 1980s when "commercial applications for botulinum neurotoxin were discovered" and "the limited number of companies and institutions that held the Hall A-hyper strain took steps to secure their strains." *See* Complainants' Resp. Br. at 23-24 (citing RX-3506.4 (Pickett); CX-10C (Pickett WS) at Q/A 61, 67-85; CX-16C (Neervannan WS) at Q/As 7, 10, 15); *accord* IA's Resp. Br. at 10-14.

The fact that the strains became valuable after the discovery of commercial applications or the tightening of government regulations does not salvage the loss of trade secret status of the strains before the 1980s. Indeed, as Respondents correctly note, "once trade secret status is lost it cannot be regained." *See* Respondents' Pet. at 61 (citing 1 Milgrim on Trade Secrets § 1.03 at 1-299). Complainants respond that, unlike the present case, "trade secret protection was lost [in the cases cited by Respondents] because the trade secret holder itself disclosed it to third parties without appropriate confidentiality provisions." *See* Complainants' Pet. Resp. at 55.

Here, there is no dispute that the University of Wisconsin was a proper owner when Dr. Yang freely and unrestrictedly took samples of the university's *C. botulinum* strain to the Korea Advanced Institute of Science and Technology in 1978.[28] *See* Respondents' Pet. at 60 (citing Compl. ¶ 42; CX-5.2-5 (Smith Decl.); CX-14C.12 (Yang WS) at Q/A 10; RX-3166C.20 (Sullivan WS) at Q/A 111); *see also* Respondents' Resp. Br. at 6-7 (citing RX-3024C (Yang Dep.) at 23:7-25 (reproduced below), 24:14-25:2, 25:16-26:4, 31:16-33:2); *see also* CX-14C (Yang WS) at Q/As 9-11. As Dr. Yang testified:

> Back [in the 1970s], when it came to the botulinum strains, each graduate student doing research, or it could be a post-doctorate student as well, they will do – they will conduct their research using the strains in the lab, or if they need it, they would request and acquire strains from a different university, and they would take the strains and they would consider it theirs in conducting their research, whether it went – whether such research went on for five years or seven to eight years. They would be conducting their own research using their own strains, and these strains could have been kept in the freezer in the lab, or they could take it and bring it home and keep it in their own freezer, and they would use their strains to conduct experiments or tests. That was the system that was in place at that time at the lab.

RX-3024C (Yang Dep.) at 23:7-25.

The IA states that "the Hall A-hyper strain was not readily available," *see* IA's Resp. Br. at 3 n.2, but the IA fails to address the evidence of record and Dr. Yang's own experience and testimony in obtaining a *C. botulinum* strain from the University of Wisconsin. Similarly, Complainants do not adequately rebut Respondents' argument that the strain lost its trade secret status by being freely circulated with no confidentiality restrictions. For example, Complainants admit to "a limited number of transfers decades ago among academics studying the Hall A-hyper

[28] The Medytox strain is derived from a parent strain which Dr. Yang obtained from the University of Wisconsin and which he subsequently gifted to Medytox. *See* FID at 81, 90.

strain" but argue that such transfers "are not 'sales' or evidence that the strain is available 'for purchase.'" *See* Complainants' Reply Br. at 6-7. There is no requirement, however, that the strain be commercially available or the subject of a sale for the strain to lose any trade secret status. *See FMC Corp. v. Taiwan Tainan Giant Indus. Co.*, 730 F.2d 61, 63 (2d Cir. 1984) ("A trade secret once lost is, of course, lost forever.").

Thus, the Commission finds that Complainants failed to satisfy their burden to establish that a trade secret exists and is not lost at least with respect to the strain from the University of Wisconsin, which is the parent of Medytox's strain. In particular, Complainants provide no evidence that the Medytox strain is distinct from that of the University of Wisconsin. *See* Respondents' Pet. at 66-67 ("Dr. Keim reached his 'unique SNPs' opinion without analyzing any other strains from the [University of Wisconsin] line.") (citing Hearing Tr. 156:10-25 (Keim)). Accordingly, there is no evidence in the record to support a claim that the Medytox strain gained trade secret status after it was acquired from Dr. Yang and from the University of Wisconsin. As to the SNPs which allegedly distinguish the Medytox strain from other Hall A-hyper strains, there is no evidence that they confer "independent economic value, actual or potential, from not being generally known" onto the Medytox strain. *See* UTSA § 1(4). Rather, the SNPs appear to be trivial differences that are caused by random mutations that develop as a strain is grown and replicated and are not the result of Medytox's research and development. *See* CX-15C (Keim WS) at Q/A 118. Nor is there any evidence that the SNPs contribute to the unique advantages of Medytox's bacterial strain. *See* UTSA § 1(4) (defining a trade secret as information that "derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use"). Instead, the advantages the FID

identifies (*i.e.*, that the strain is exceptionally productive and stable, that it makes the separation and purification process easier, and that it sporulates poorly) do not relate to Medytox's strain specifically but to Hall A-hyper strains generally. *See* FID at 11-12. Further, as discussed above, Complainants' expert, Dr. Keim, did not analyze other strains originating from the University of Wisconsin and did not determine whether the SNPs are unique to Medytox's strain or whether they are present in other University of Wisconsin strains.

Complainants also argue that "the relevant assessment regarding public accessibility of the Medytox strain should focus on the status of the Medytox strain at the time Daewoong stole it." *See* Complainants' Resp. Br. at 19, 27 (citing *Telex Corp. v. IBM Corp.*, 367 F. Supp. 258, 357-58 (N.D. Okla. 1973), *aff'd in part, rev'd in part*, 510 F.2d 894 (10th Cir. 1975) ("That subsequent to the invasion of IBM's trade secrets a portion of the information in the course of marketing of IBM products became available to the public, including Telex, did not excuse Telex's conduct in the first instance nor insulate it from liability to both monetary and equitable relief."). *Telex*, however, is inapposite because, at the time of the misappropriation, the information at issue in that case had not lost trade secret status. In contrast, in the present case, the Medytox strain did not qualify as a trade secret at the time of the alleged misappropriation, and there can be no misappropriation in the absence of evidence that the Medytox strain had or acquired such trade secret status at that time.[29]

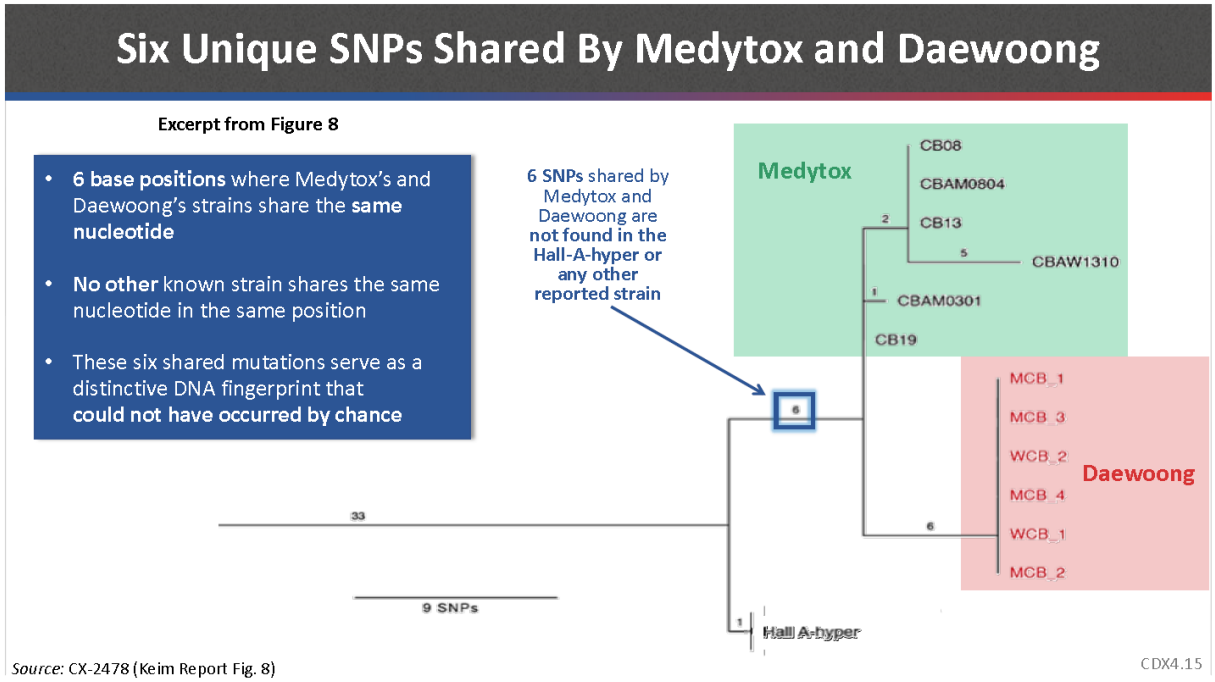
Thus, for the reasons explained above, the Commission finds that Complainants failed to satisfy their burden to establish that the Medytox strain or its genetic makeup qualify as a trade

[29] Notably, Complainants here did not assert claims of conversion or theft (*see* Compl. ¶¶ 36-133) which, unlike misappropriation, do not require establishing the existence of a trade secret. *See*, *e.g.*, *Mattel, Inc. v. MGA Entertainment, Inc.*, 782 F. Supp. 2d 911, 997 (C.D. Cal. 2011); *Bijan Designer for Men, Inc. v. Katzman*, No. 96-CV-7345, 1997 WL 65717, *8 (S.D.N.Y. Feb. 7, 1997).

secret. Accordingly, the Commission has determined to reverse the FID's finding that the Medytox strain qualifies as a trade secret.

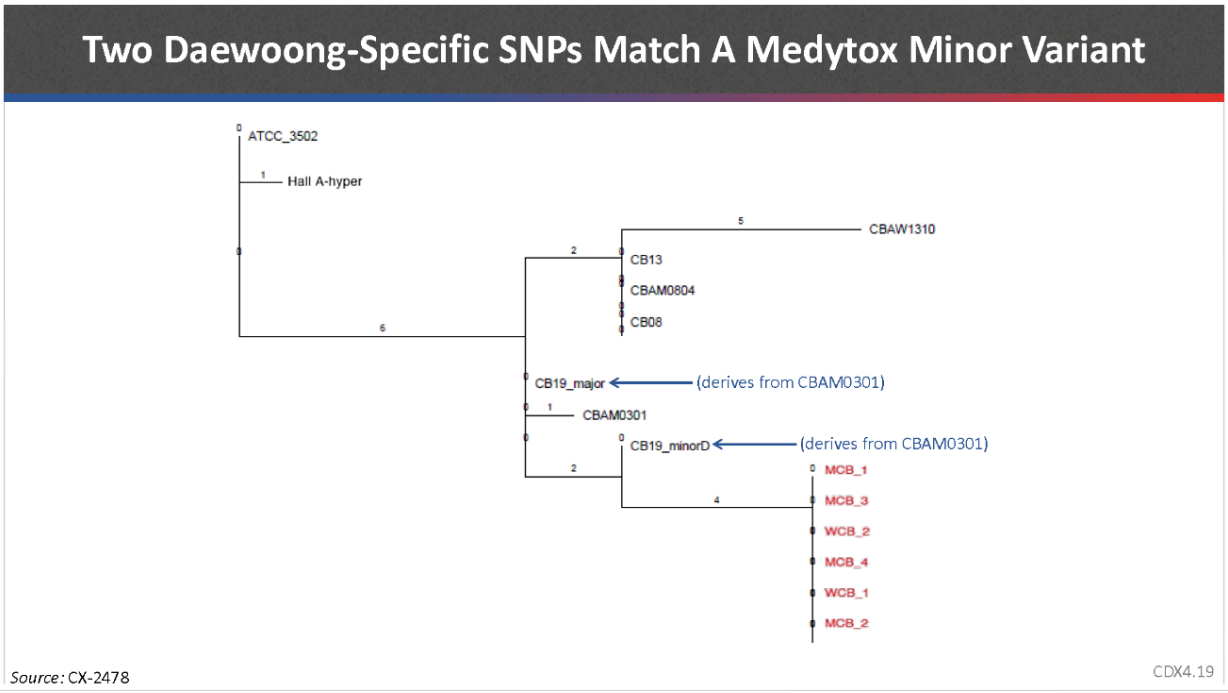
(ii) Misappropriation by Daewoong

The FID finds that Respondents misappropriated the Medytox bacterial strain. *See* FID at 92-110. Specifically, the FID notes that Dr. Byung Kook Lee (also referred to as "BK Lee"), a former employee, had access to Medytox's strain. *See id.* at 93. The FID finds that "it has not been established that Dr. BK Lee took the strain from Medytox and, for consideration or otherwise, gave it to Daewoong." *Id.* In addition, the FID finds that "no evidence was presented to show when and how a specific quantity of Medytox's strain went missing." *See id.* at 94. The FID does find, however, that "misappropriation has been shown through the genetic evidence." *See id.* at 94. Specifically, the FID finds that "the Medytox and Daewoong strains share distinctive DNA fingerprints, six SNPs, that confirm they are a match." *See id.* at 99 (citing CX-15C (Keim WS) at Q/A 16, 50, 117-18; CX-2603.1 (Keim WS errata)); *see also* CDX-4C.15 (reproduced below). The FID further finds that "[t]he possibility of two unrelated strains sharing the same six identical SNPs at the exact same nucleotide positions along a DNA sequence of nearly 3.7 million nucleotides is effectively impossible. *See id.* (citing CX-15C (Keim WS) at Q/A 117).



CDX-4C.15.

The FID further finds that "[i]n addition to the six shared SNPs found in both the Medytox and Daewoong strains, Dr. Keim also found shared SNPs between two Medytox 'minor variants' and the six SNPs that otherwise distinguish the Daewoong strain from the Medytox strain." *See id.* at 107. When considering these minor variants, Dr. Keim's phylogenetic tree shows "an even shorter branch between the Medytox and Daewoong strains." *See id.* at 109 (citing CDX-4C.19, reproduced below).



CDX-4C.19.

Indeed, the FID explains, "two of the six SNPs that separate the Daewoong sample from CB19 . . . are actually the same two SNPs that separate the minor and major variants in CB19," *i.e.*, one of Medytox's strains. *See id.* In other words, "[t]he CB19 minor variant clearly became 'fixed' in the Daewoong cell banks as a major variant." *See id.* (citing CX-15C (Keim WS) at Q/A 134). Because, "CB19 was created in 2019 . . . via [ ] from CBAM0301 [(a Medytox strain)], and therefore would reflect the major and minor variants contained in that vial of the CBAM0301 cell bank . . . [t]he most logical conclusion is that the Daewoong strain was obtained from a sample of CBAM0301 or one of the several other Medytox cell banks that were created from CBAM0301." *See id.* at 109-110 (citing CX-15C (Keim WS) at Q/A 135).

The FID rejects "Daewoong's claim that it found its strain in the soil, especially in view of the fact that the Medytox strain and the Hall A-hyper strain were both developed in the

laboratory." *See id.* at 103 (citing Hr'g Tr. (Keim) at 203-204, 307). The FID concludes that "Daewoong got its strain from . . . Medytox." *See id.* at 110.

Respondents no longer assert the defense of independent development, *i.e.*, that Daewoong found its strain in the soil, but they argue that the FID "improperly shift[s] the burden to Respondents to prove that Daewoong legitimately obtained its strain." *See* Respondents' Pet. at 70. Respondents contend that the "'close relationship' [between the Medytox and Daewoong strains] is not *prima facie* proof of misappropriation, as such a relationship could be explained by the strains' common ancestry or parallel evolution." *See id.* at 72.

Respondents further argue that "substantial evidence at the hearing demonstrated that the Daewoong strain is significantly different and did not come from the Medytox strain." *See id.* For example, Respondents argue that "[a]t trial, Dr. Keim admitted that if the Allergan strain or another [University of Wisconsin] strain had the same SNPs[] he assumed without evidence were 'unique' to Medytox and Daewoong, then 'it would be impossible for me to distinguish which one it came from, without considering those [ ].'" *See id.* at 67 (citing Hr'g Tr. (Keim) at 159:12-14). Respondents also fault the ALJ for failing to compel Allergan to produce samples of its strain and argue that Dr. Keim should have tested that strain which also descended from the University of Wisconsin. *See id.* at 68. Respondents contend that "[t]he ALJ's discovery ruling precluding discovery into Allergan's strain and process on the basis of insufficient relevance guts his misappropriation finding." *See id.* at 69 (citing Order No. 24 (Sept. 12, 2019)).

The Commission agrees with the FID's analysis. The genetic evidence establishes by more than a preponderance of the evidence (indeed by near certainty) that Daewoong derived its strain from Medytox. Furthermore, Respondents mischaracterize the record. On cross-

examination, they asked Dr. Keim to discount the minor alleles theory and to assume that other strains from the University of Wisconsin share the same six SNPs as the Medytox and Daewoong strains. *See* Respondents' Pet. at 67 (citing Hr'g Tr. (Keim) at 159:12-14). Based on such an assumption, Dr. Keim testified that he would not be able to conclude whether the Daewoong strain was derived from Medytox or another University of Wisconsin strain. *See id.*

The problem for Respondents is that there is no support in the record for their assumption and they fail to account for additional evidence presented by Dr. Keim (*e.g.*, the minor variants evidence). In addition, before the ALJ, Respondents relied on the unpersuasive theory that they found their strain in the soil not from some other source relating to the University of Wisconsin. *See* FID at 51-53.

Thus, the Commission finds that the FID correctly rejects Respondents' theory and correctly credits Dr. Keim's testimony. *See id.* at 103; *accord* Complainants' Pet. Resp. at 65; IA's Pet. Resp. at 27-29. Furthermore, contrary to Respondents' assertion, the differences between the Medytox and Daewoong strains (in the 16S region) do not negate that Daewoong's strain derives from Medytox. *See* Respondents' Pet. at 72 ("Both Dr. Keim and Complainants' expert Dr. David Sherman testified that multiple SNPs were found in the highly-conserved and slow-to-evolve 16S rRNA region of the two strains.") (citing CX-15C.50 (Keim WS) at Q/As 207-210; CX-1964C (Ex. E to Keim Review of Sherman Analysis); Hr'g Tr. (Sherman) 826:15-827:18). As Dr. Keim testified, however, "[t]hat the Daewoong strain has experienced mutations after being separated from the Medtyox strain does not change the fact that it was derived from the Medytox strain." *See* CX-15C (Keim WS) at Q/A 215; *accord* Complainants' Pet. Resp. at 69. Nor does the FID improperly shift the burden to Respondents. Rather, Complainants presented a solid *prima facie* case that Respondents acquired Medytox's strain by

improper means. On the other hand, Respondents' independent development theory is not credible. As the IA explains:

> Daewoong's "independent development" argument requires one to accept that a man [
>
>]. It is logically and scientifically implausible, if not impossible, and the Final ID was correct in not accepting Daewoong's poultry feces story.

IA's Pet. Resp. at 29.

Lastly, Respondents mischaracterize Order No. 24. Respondents did not request a sample of Allergan's bacterial strain but "[d]ocuments and information indicating whether Allergan's Hall-A hyper strain produces spores, together with documents laying out the results of any such spore testing." *See* Order No. 24, at 2. The ALJ properly determined that "discovery into the current and historical Allergan process should not be compelled, due to excessive burden in view of little or no relevancy to this investigation." *See id.* at 8. Indeed, "Complainants do not allege that any trade secret asserted in this investigation was misappropriated from Allergan" but from Medytox. *See id.* at 6. In addition, Respondents appear to tie their non-existent request for a sample of Allergan's strain to Dr. Keim's (Complainants' expert) alleged failure to analyze whether that strain (which also originates from the University of Wisconsin) includes the six SNPs shared by Medytox and Daewoong's strains. *See* Respondents' Pet. at 68-69. Respondents' argument is not only unsupported by the record but is also nonsensical. *Accord* Complainants' Pet. Resp. at 63-64.

Thus, the Commission finds that the evidence supports the FID's findings that Daewoong acquired the Medytox strain by improper means. However, because the Commission finds that the Medytox strain does not qualify as a protectable trade secret, Complainants cannot establish the unfair act of trade secret misappropriation by Daewoong as to the Medytox strain.

2. The Medytox Manufacturing Processes

Complainants assert 13 trade secrets in connection with Medytox's manufacturing processes, namely:

Trade Secrets 1 and 2: The use of [

] of the manufacturing process.

Trade Secret 3: The [

] of the manufacturing process.

Trade Secret 4: The use of [

].

Trade Secret 5: [

]

Trade Secret 6: The use of [

].

Trade Secret 7: The use of [

].

Trade Secret 8: The use of a [

].

Trade Secret 9: The [
].

Trade Secret 10: The use of [

].

Trade Secret 11: The use of [

].

Trade Secret 12: The use of a second [

].

Trade Secret 13: [ ].

See FID at 112-13 (citing CX-2572C (Complainant Medytox's Disclosure Pursuant to Order No. 17) at 2-3; CX-10C (Pickett WS) at Q/As 194-203).

The FID finds that Daewoong misappropriated Medytox's trade secrets in its manufacturing processes. *See* FID at 132-52. The FID finds that "[t]he evidence establishes that Dr. BK Lee had access to, and knowledge of, numerous details of Medytox's manufacturing process, and also worked with Daewoong when it was trying to develop its own process." *See id.* at 132. The FID finds that "an abundance of evidence establishes that the Daewoong process is derived from, and in many ways identical to, Medytox's trade secret process." *See id.* Specifically, the FID finds, "three factors demonstrate that Daewoong misappropriated the manufacturing process from Medytox: (1) the similarity of Daewoong's process to Medytox's; (2) the lack of evidence of Daewoong's independent development; and (3) the implausibly fast timeline by which Daewoong achieved BTX production at commercial scale." *See id.*

The FID further finds that Daewoong's manufacturing process substantially overlaps with Medytox's manufacturing process. *See id.* at 134-136 (citing CDX-10C.2 (reproduced below); CX-10C (Pickett WS) at Q/As 243-54).

[

]

In particular, the FID discusses "three key similarities" between the Daewoong and Medytox processes. *See id.* at 136. First, the FID finds, "[

]." *See id.* (citing CX-2068C.9 (Medytox Batch Record Version No. 5); JX-22.19 (Daewoong 450DC-010 Batch Record)). The FID notes that [

] and that [

] *See id.* at 136-37. Second, the FID continues, [

] *See id.* at 137 (citing CX-2064C.10 (BK Lee Email Attach., 11/02/07); JX-22.64-67 (450DS-010 Batch Record); CX-10C (Pickett WS) at Q/As 251, 253, 257). The FID finds that [

] *See id.*

The FID further notes [

,[30]

] *See id.* at 138 (citing CX-1727.12 (Daewoong U.S. Patent 9,512,418); JX-7C.6 (BLA Submission Section 3.2.S.2.6)). Third, the FID notes that [

] *See id.* at 139-40 (citing JX-7C.6 (Daewoong FDA Submission section 3.2.S.2.6)).

The FID finds that "Daewoong has not provided sufficient evidence demonstrating its own independent development of its manufacturing process." *See id.* at 143. The FID also finds "a lack of any contemporaneous documentation of citations to the disparate published scientific literature dating back to as early as the 1940s on which Daewoong purportedly relied to piece together the steps of the manufacturing process for the DWP-450 drug substance." *See id.* at 142. The FID further notes that [

] *See id.* at 148 (citing JX-26C-JX-29C; CX-2598C, JX-17C). The FID finds that "it is not credible to reach the milestone of a commercial scale batch in such a short period of time." *See id.* (citing CX-10C (Pickett WS) at Q/As 303-16). Rather, the FID credits Dr. Pickett's testimony that "it would take at least three months for an inexperienced team seeking to develop a manufacturing process from scratch to review the academic literature and an additional 18 months to conduct small scale process research experimentation before proceeding to a commercial-scale batch." *See id.* (citing CX-10C (Pickett WS) at Q/As 320-25).

[30] [
]

The Commission has determined to affirm the FID's findings regarding the existence and misappropriation of Medytox's trade secrets relating to its manufacturing processes.

D. Domestic Industry

1. Existence of "an Industry in the United States"

During the investigation, Complainants asserted the existence of "an industry in the United States" under section 337(a)(1)(A)(i) in connection with: (1) Medytox's MT10109L (which is an animal-protein-free BTX product that Medytox licensed to Allergan for commercialization in the United States); and (2) Allergan's BOTOX® products (which are non-animal-protein free BTX products that were developed and commercialized solely by Allergan and are not encompassed by Medytox's license to Allergan). The FID finds that an industry exists in the United States with respect to both MT10109L and BOTOX®. *See* FID at 158-90. However, the FID finds that injury or threat of injury to such industries is established with respect to BOTOX® but not MT10109L. No party petitioned for review of the FID's finding of no injury as to MT10109L. Therefore, the Commission has determined that Complainants have abandoned seeking relief as to MT10109L by failing to file a petition for review of the no injury finding of the FID. Accordingly, on review, the Commission terminates Complainants' claim of a Section 337 violation based on MT10109L and the FID's findings on domestic industry as to MT10109L are therefore moot.

As to BOTOX®, the FID finds that "[u]nder Commission precedent, a complainant may rely upon investments by unrelated licensees [(*e.g.*, not related corporate entities)] to prove the existence of a domestic industry requirement." *See* FID at 158 (citing *Certain Electronic Imaging Devices*, Inv. No. 337-TA-726, Order No. 18, 2011 WL 826919 (Feb. 7, 2011) ("*Electronic Imaging*"), *unreviewed*, Comm'n Notice (Mar. 8, 2011)).

The FID finds that Allergan has invested billions of dollars in the United States in domestic manufacturing, R&D, FDA clinical trials and other FDA-related activities, physician education, and sales and marketing activities essential for the commercialization of BOTOX® and the expansion of the indications for which it may be prescribed.[31, 32] *See* FID at 162. Respondents do not challenge the qualifying nature or amounts of Allergan's domestic investments related to BOTOX®.[33] Rather, Respondents argue that "[t]he record evidence shows that Allergan's domestic investments are insubstantial when compared to its investments abroad." *See* Respondents' Pet. at 87.

The FID finds that "Allergan has made significant domestic investments in research and development related to BOTOX (constituting BOTOX® Cosmetic and BOTOX® therapeutic

---

[31] The Commission notes that the FID does not consider which of these investments, such as those for sales and marketing, might be more akin to activities of a mere importer, and thus possibly meriting less or no weight in the Commission's analysis.

[32] Commissioner Schmidtlein does not join footnote 31. She observes that the "mere importer" test was developed to assess the existence of any cognizable domestic industry in situations where complainant's domestic industry products are made overseas and imported into the United States. *See Schaper,* 717 F.2d at 1373 ("Congress did not mean to protect American importers (like Schaper) who cause the imported item to be produced for them abroad and engage in relatively small nonpromotional and non-financing activities in this country."). That scenario, which gave rise to the "mere importer" test, is not present in the current investigation. For example, Allergan manufactures the active pharmaceutical ingredient, the most valuable part of BOTOX®, in the United States. In such a situation, she does not concur with the premise that the Commission is required to inquire whether each individual domestic activity performed by a complainant is that of a "mere importer."

[33] Respondents' Petition for Review contains one sentence that purports to challenge the FID's findings as to the nature and amount of the domestic industry investments relating to BOTOX®. Respondents' Pet. at 88 ("After excising mere importer activities, such as R&D and FDA trials, and sales and marketing, what remains of Allergan's proffered investments is Botox API manufacture at its facility [ ]."). This single sentence in the petition provides no factual or legal analysis and therefore does not meet the requirements of Commission Rule 210.43(b)(2). 19 C.F.R. § 210.43(b)(2) ("The petition for review must set forth a concise statement of the facts material to the consideration of the stated issues, and must present a concise argument providing the reasons that review by the Commission is necessary or appropriate to resolve an important issue of fact, law, or policy.").

collectively) and in BOTOX® Cosmetic individually." *See* FID at 167-180. The FID also finds that Allergan's investments in Ireland are [ ] less substantial than its investments in the United States. *See* FID at 184-85. The FID explains that "[t]he [active pharmaceutical ingredient ("API")] is the most valuable and most important component to the BOTOX® product." *See id.* at 163 (citing CX-18C at Q/A 54; CX-16C at Q/A 22). Specifically, the FID finds that "Dr. Neervannan estimated the value of the API constitutes at least [ ]." *See id.* (citing CX-16C at Q/A 22). The FID finds that "[o]nce the BOTOX® API has been manufactured [in the United States], it is delivered to Allergan's 'finish and fill' facility in Westport, Ireland, which [ ]." *See id.* (citing CX-16C at Q/A 20; CX-8C at Q/A 73; CX-18C at Q/A 53). The FID concludes that "[i]n view of the differing nature of the activities performed in Ireland and the United States, and the large differential in the investments made by Allergan in those two countries, . . . Allergan's operations in Ireland do not diminish Allergan's significant and substantial investments in the domestic industry." *See id.* at 167; *accord* Complainants' Pet. Resp. at 88-90; IA's Pet. Resp. at 35-36.

As explained above, in addressing whether an "industry in the United States" exists under section 337(a)(1)(A), the Commission has historically considered the "nature and significance" of the complainant's activities that allegedly form the domestic industry. The Commission considers the Complainants' qualifying expenditures as the initial step of the analysis. The

Commission finds that Complainants have qualifying expenditures in manufacturing and R&D.[34, 35]

Allergan's BOTOX®-related manufacturing investments include [ ] in Allergan's [ ] facility where Allergan manufactures the API for BOTOX®. *See* FID at 169 n.23. As the FID notes:

> Because of the highly potent and potentially lethal nature of the *C. botulinum* bacterium from which BOTOX®'s toxin is cultivated, [ ] has to comply with regulations and oversight by various government entities, including the Centers for Disease Control ("CDC"), FDA, FBI and Department of Homeland Security. [CX-16C] at Q/A 25, 26; CX-0018C at Q/A 57–59. Accordingly, Allergan has to ensure that [ ] has specialized equipment, operating systems, and security systems in order to comply with stringent security, safety, and health regulations when [ ], including the FDA's Good Manufacturing Processes "GMP" regulations.

See FID at 170. Allegan's investments in specialized equipment used [ ] for BOTOX®-related activities total [ ]. *Id.* at 169-70. Allergan employs [ ] full-time employees in manufacturing positions such as API manufacturing, quality control, and other technical support work for the manufacturing of BOTOX®. The work of these employees is exclusively with

[34] The FID's findings appear to consider expenditures for sales and marketing expenses in its analysis of domestic industry investments. *See* FID at 174-75. Given the magnitude of Allergan's manufacturing and R&D investments discussed herein, the Commission does not consider these sales and marketing expenditures in its domestic industry analysis.

[35] Commissioner Schmidtlein does not join footnote 34. She finds that sales and marketing investments, when combined with other qualifying domestic investments or activities, can be credited in determining whether a domestic industry exists. She observes that the legislative history indicates that marketing and sales in the United States "alone" cannot establish the existence of a domestic industry. H.R. Rep. No. 100-40, Pt. 1, at 157 (1987) ("Marketing and sales in the United States ***alone*** would not, however, be enough to meet this test."). (emphasis added). Allergan does not have a sales and marketing domestic industry "alone." Therefore, Commissioner Schmidtlein sees no issue with counting Allergan's domestic sales and marketing investments as qualifying investments in this case.

BOTOX®, and their total aggregated annual compensation (including salary, bonus, and benefits) is [ ]. *Id.* at 174.

R&D, testing, and clinical operations relating to BOTOX® products take place in other Allergan facilities in [ ]. *Id.* at 171-72. The chart below identifies these facilities and shows the activities at each of these facilities:

Facility Name	**Address**	**Sq. Footage**	**Principal Use**
[ ]	[ ]	[ ]	R&D, drafting of protocols, monitoring and statistical analysis, and overseeing clinical trials for BOTOX®
[ ]	[ ]	[ ]	R&D, and testing, including clinical studies for additional indications for BOTOX®
[ ]	[ ]	[ ]	Toxin research relating to BOTOX®, development, and testing
[ ]	[ ]	[ ]	Clinical operations and quality control testing. [ ].

FID at 171. Allergan has invested [ ] in R&D in the United States from 1992 through Q1 2019. *Id.* at 179. This includes R&D related to improving Allergan's manufacturing process, expanding the number of cosmetic and therapeutic indications approved by the FDA, and complying with FDA regulatory requirements, including clinical testing required by the FDA. *Id.* Allergan employs [ ] full-time employees in research and development and their total annual aggregated compensation is [ ]. *Id.* at 174. These figures do not take into

account the additional the number of R&D personnel who recorded a portion of their time to BOTOX®-related R&D projects: [ ] employees in 2014, [ ] employees in 2015, [ ] employees in 2016, [ ] employees in 2017, and [ ] employees in 2018. *Id.* at 175. Accordingly, the Commission supplements the FID with respect to Complainants' qualifying expenditures in manufacturing and R&D relating to BOTOX® products.

In considering the significance of the Complainants' domestic investments, a comparison of domestic investments to foreign investments is one appropriate mode of contextual analysis, but not the only permissible one.[36] For example, in *Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op., 2019 WL 5622443 (Oct. 28, 2019) ("*Carburetors*"), which was a patent case examining domestic industry under section 337(a)(3), the Commission held that "comparing complainant's domestic expenditures to its foreign expenditures is *one of the possible factors* that the Commission could but . . . *is not required to consider*." *Carburetors*, 2019 WL 5622443, at *6 (emphasis added). The Commission has in addition, or alternatively, "considered, among other things, the value added to the article in the United States by the domestic activities. *Id.* at *13; *see also Schaper*, 717 F.2d at 1373 ("There

[36] As discussed above at page 15, the Commission's "nature and significance" standard developed in its case law, and affirmed by the Federal Circuit, continues to be applied subsequent to the legislative amendments in 1988 to trade secret misappropriation and other unfair acts claims arising under Section 337(a)(1)(A)(i).

is simply not enough significant value added domestically to the toy vehicles by [the complainant's] activities in this country . . . .").[37]

[37] Commissioner Schmidtlein agrees that there is no requirement that a complainant must establish its domestic investments are significant relative to its foreign investments. She also observes that the threshold question of the existence of an "industry in the United States" under section 337(a)(1)(A) does not even *require* a complainant to show its domestic investments are significant or substantial. Rather, it calls for an inquiry into the "nature and extent" of complainant's investments or activities in the United States. *See Schaper*, 717 F.2d at 1372 (explaining that the "nature and the extent of Schaper's domestic activities" were insufficient to constitute an "industry in the United States"). This standard has also been expressed in Commission opinions as considering the "nature and significance" of the complainant's domestic activities. *See supra*.

In Commissioner Schmidtlein's view, considering the nature and extent of a complainant's domestic activities fundamentally differs from *requiring* a complainant to show its domestic activities are significant or substantial. Congress expressly chose to define domestic industries for statutory IP cases (*e.g.*, patent, registered trademark, and copyright) by *requiring* that there be certain prescribed activities in the United States that are either "significant" or "substantial." *See* 19 U.S.C. § 1337(a)(3)(A)-(C) ("significant investment in plant and equipment," "significant employment of labor or capital," or "substantial investment" in the exploitation of the IP right). Congress did not use this language to define the domestic industry requirement for general unfair trade practices under section 337(a)(1)(A). *See* 19 U.S.C. § 1337(a)(1)(A). This textual distinction is strong evidence that Congress did not intend to limit the definition of "an industry in the United States" under section 337(a)(1)(A)(i) in the same way as it did in section 337(a)(3). In fact, the Commission in *Certain Hand Dryers* held that "an industry in the United States" under section 337(a)(1)(A)(i) "is not limited to the domestic industry definition for statutory IP rights under" section 337(a)(3). *Certain Hand Dryers and Housing for Hand Dryers*, Inv. No. 337-TA-1015, Comm'n Op. at 4 (Oct. 30, 2017) (citing *Tianrui Group Co. Ltd. v. Int'l Trade Comm 'n*, 661 F.3d 1322, 1335-37 (Fed. Cir. 2011)). For these reasons, Commissioner Schmidtlein does not hold the view that domestic activities asserted to show an "industry in the United States" under section 337(a)(1)(A)(i) need to be "significant" or "substantial."

Similarly, Commissioner Schmidtlein does not hold the view that caselaw interpreting the meaning of "significant" or "substantial" under section 337(a)(3) necessarily constrains or limits the bounds of what an "industry in the United States" is under section 337(a)(1)(A)(i). Rather, she believes that the threshold under section 337(a)(1)(A)(i) simply calls for an inquiry into the "nature and extent" of complainant's business activities in the United States, *see Schaper*, 717 F.2d at 1372, and that this threshold may be satisfied even if the investments or activities may not qualify as significant or substantial under a section 337(a)(3) standard.

The Commission agrees with the FID that, based on the record evidence that the API constitutes at least [ ] of the overall value of BOTOX® and that Allergan manufactures the API in the United States, Allergan's expenditures are significant.[38] This conclusion is further supported by the fact that from 2014 to 2018, [ ] of Allergan's R&D investments related to BOTOX® were in the United States (the U.S. share was [ ] out of a worldwide total of [ ]).[39, 40] FID at 179.

[38] Commissioner Schmidtlein finds that the billions of dollars identified by the FID as invested by Allergan in the United States related to BOTOX® for manufacturing, R&D, FDA clinical trials and other FDA-related activities, physician education, and sales and marketing activities are sufficient to establish the existence of "an industry in the United States." *See* FID at 162-180. She declines to join the majority in comparing domestic investments to foreign expenditures in making the determination that the domestic investments are sufficient to establish the existence of "an industry in the United States."

[39] These R&D investments include expenses related to clinical operations and quality control testing; [ ]; R&D and testing including clinical studies for additional indications for BOTOX®; R&D, drafting of protocols, monitoring and statistical analyses and overseeing clinical trials for BOTOX®; and toxin research relating to BOTOX®, development and testing. FID at 171. These activities are not the sort of activities that a "mere importer" would conduct in the United States, and Respondents did not argue otherwise in their petition for review.

Chair Kearns notes that Complainants and Respondents agree that there was no requirement that Allergan's activities relating to regulatory approvals and compliance take place in the United States. *See* Complainants' Resp. Br. at 28-29; Respondents' Resp. Br. at 13. In his view, the fact that there was no such requirement, and that Allergan chose to conduct them in the United States rather than abroad, supports the conclusion that these are not the activities of a "mere importer."

[40] Commissioner Schmidtlein does not join footnote 39. While she agrees that the itemized activities identified in that footnote should be included in assessing the existence of a domestic industry, as explained above in footnote 32 she does not agree with the premise that the Commission needs to examine whether each domestic activity performed by Allergan is akin to the sort of activity a "mere importer" would conduct. Further, she would not agree with the premise that in determining whether domestic activities may be counted, the Commission must first determine whether the activities must be performed in the United States.

Respondents also argue that the FID "erred by considering Allergan's alleged domestic industry in Botox" because "Allergan does not have standing under settled Commission and Article III precedent." *See* Respondents' Pet. at 87. As discussed *supra* section III(B), however, the Commission finds that Allergan has standing to join this investigation and, as such, the Commission finds that Complainants can rely on Allergan's investments to satisfy the domestic industry requirement. *See* FID at 37-38; *accord* IA's Pet. Resp. at 33. Regardless of Respondents' standing objection, Medytox is permitted to rely on the investments of non-exclusive licensees to satisfy the domestic industry requirement. *Cf. Electronic Imaging*, 2011 WL 826919, at *3.

While a patentee must establish, under section 337(a)(2), that the domestic industry of its licensees relates to articles that are protected by the patent, there is no such requirement for trade secret misappropriation claims under section 337(a)(1)(A). Indeed, unlike the requirement that a domestic industry practice or exploit statutory IP rights under Section 337(a)(2)-(3), *TianRui* makes clear that section 337(a)(1)(A) does not require that the domestic industry products practice the asserted trade secrets. *See TianRui*, 661 F.3d at 1335-37. Rather, the Court explained that where the unfair imports "directly compete" with the domestically-produced products, such competition is "sufficiently related to the investigation to constitute an injury to an 'industry' within the meaning of section 337(a)(1)(A)." *Id*. at 1337.

Contrary to Respondents' suggestion, there is no basis for interpreting section 337(a)(1)(A) or *TianRui* as imposing a requirement that Allergan's BOTOX® practice the trade secret (or be licensed to do so). The language of section 337(a)(1)(A) is broad and allows the Commission to find a violation in connection with, *inter alia*, "unfair acts in the importation of

articles" the "threat or effect of which is—(i) to destroy or substantially injure *an industry* in the United States." 19 USC § 1337(a)(1)(A) (emphasis added).

In 1988, when Congress added the requirement for statutory intellectual property rights that the industry be "with respect to the articles protected by the patent, copyright," and other statutory IP rights, Congress specifically did not extend that requirement to non-statutory unfair acts under section 337(a)(1)(A). Indeed, section 337(a)(1)(A) can cover "dumping or countervailing duties, or even unfair trade practices such as false advertising or other business torts"—none of which involve proprietary rights.[41] H.R. REP. NO. 100-40 Part I, at 156 (1987). Instead, the statute requires only that the unfair act cause substantial injury, or the threat of injury, to a domestic industry. *See* 19 U.S.C. § 1337(a)(1)(A)(i).

TianRui also distinguished unfair acts based on statutory IP rights (*i.e.*, under section 337(a)(1)(B)-(E)) and expressly rejected a requirement that "an industry in the United States" practice the asserted non-statutory IP under section 337(a)(1)(A). *See TianRui*, 661 F.3d at 1335-37. What matters here is that one complainant (Medytox) asserts that its trade secrets have been misappropriated by Respondents and another complainant (Allergan), who is a non-exclusive licensee of Medytox, asserts that the importation and sale of Daewoong's products that

[41] Under section 337(b)(3), "[i]f the Commission has reason to believe that the matter before it (A) is based solely on alleged acts and effects which are within the purview of section 1671 [(Countervailing duties imposed)] or 1673 [(Antidumping duties imposed)] of this title, or (B) relates to an alleged copyright infringement with respect to which action is prohibited by section 1008 of title 17, the Commission shall terminate, or not institute, any investigation into the matter." 19 C.F.R. § 1337(b)(3). In addition, "[i]f the Commission has reason to believe the matter before it is based in part on alleged acts and effects which are within the purview of section 1671 or 1673 of this title, and in part on alleged acts and effects which may, independently from or in conjunction with those within the purview of such section, establish a basis for relief under this section, then it may institute or continue an investigation into the matter." *Id.*

use misappropriated trade secrets has caused injury to its competing industry in the United States.

Respondents argue that the FID erred by failing to "consider fully the only investigation with facts even remotely similar to those presented here" citing the ID in the consolidated *Sausage Casings* investigation, Inv. No. 337-TA-148/169. Respondents' Pet. at 44. Respondents argue that the trade secret owner Union Carbide sought to establish a domestic industry based in part of the operations of its licensee Teepak, but the ALJ rejected the licensee's investments where "nothing on the record [] indicate[s] that any other domestic company is making use of the trade secrets at issue." *Id.* at 44-45 (citing *Sausage Casings*, Inv. No. 337-TA-148/169, 1984 WL 273789, at *133). Read carefully, however, the ID cites *Schaper Mfg. Co. v. USITC*, 717 F.2d 1368, 1371 (Fed. Cir. 1983), for this proposition, which in turn cites to patent-related provisions, including two patent decisions, then-Commission Rule 210.20 (now codified as 19 C.F.R. § 210.12), and the 1974 legislative history. The cited legislative history states that "[i]n cases involving the claims of U.S. patents, the patent must be exploited by production in the United States, and the industry in the United States generally consists of the domestic operations of the patent owner, his assignees and licensees devoted to such exploitation of the patent." H.R. REP. NO. 93-571, at 78 (1973). The Commission's rule at the time (as now) required the complaint to plead the domestic industry practicing the patent and was not a pleading requirement for non-patent cases. The cases cited in *Schaper* also involve patents. Thus, the ID's statement in *Sausage Casings* improperly extended the definition of domestic industry in patent cases to other unfair act claims in section 337 practice generally. Moreover, to the extent that *Sausage Casings* restricted the domestic industry in a trade secret

misappropriation claim to the domestic operations that exploit the asserted trade secret, it has been overruled by *TianRui*, which held to the contrary.

Thus, the Commission agrees with the FID's conclusion that there is "an industry in the United States" with respect to BOTOX®, with the modified analysis above. In particular, the Commission finds that Allergan's expenditures are significant based on the API's contribution to the overall value of BOTOX® and the share of overall R&D performed in the United States. The facts that Allergan is a non-exclusive licensee and that it does not practice the trade secrets found to be protectable does not change our findings. As discussed above, consistent with Federal Circuit precedent, an industry in the United States may be found to exist based on qualifying investments in domestic products that "directly compete" with the accused products– in this instance BOTOX®. *See TianRui*, 661 F.3d at 1337.

2. Injury to the "Industry in the United States"

Having found that a domestic industry exists, under section 337(a)(1)(A)(i), "the complainant [must also] demonstrate . . . that there [is] actual substantial injury or the threat of substantial injury to a domestic industry." *See Rubber Resins*, Comm'n Op., 2014 WL 7497801, *5. In addition, "[w]hen the complainant alleges actual injury, there must be a causal nexus between the unfair acts of the respondents and the injury." *Id.* at *30. Similarly, when the complainant alleges a threatened injury, such "injury must [] be 'substantive and clearly foreseen,' with a causal connection between the action of the respondents and the threatened injury." *Id*. at *32 (citations omitted).

As discussed above, the FID finds no injury or threat of injury to an industry concerning MT10109L, and no party petitioned for review of that finding. *See* FID at 220-25. The Commission, therefore, has determined that the Complainants have abandoned seeking relief as

to MT10109L by failing to file a petition for review of that no injury finding of the FID. Accordingly, on review, the Commission terminates Complainants' claim of a Section 337 violation based on MT10109L and the FID's findings on domestic industry as to MT10109L are therefore moot.

As to BOTOX®, the FID finds that Complainants have lost sales and profits and "have suffered an actual injury to the BOTOX® domestic industry." *See id.* at 198. For example, the FID explains, the evidence demonstrates that the 2.61 percent market share for Respondents' Jeuveau® product "came entirely at the expense of BOTOX® Cosmetic." *See id.* (citing CX-18C at Q/As 112-17; CX-2433C). The FID also finds evidence of price erosion, explaining that "Allergan's internal models indicate [

]." *See id.* at 208 (citing CX-18C (Malackowski[42] WS) at Q/A 181). The FID further finds a threat of future injury to BOTOX®. *See id.* at 211-220. Specifically, the FID finds that: (1) "Daewoong has more than sufficient foreign manufacturing capacity to supply the domestic demand for Jeuveau® (and indeed the entire U.S. BTX cosmetic market)"; (2) "Evolus has already entered the market with Jeuveau® with the specific intent of targeting Allergan"; (3) "[R]espondents have the ability to undersell BOTOX®"; and (4) "Allergan also faces potential long-term price erosion due to Jeuveau®." *See id.* The Commission affirms these findings that Respondents' importation and sale have caused and threaten to cause substantial injury to the domestic industry found to exist.

Respondents repeat their argument that "any purported injury to Botox is not cognizable in this investigation" because Allergan lacks standing. *See* Respondents' Pet. at 88. As

[42] James E. Malackowski was retained by Complainants as a domestic industry expert.

discussed *supra* section III(B), the Commission disagrees that Allergan lacks standing and therefore the premise of Respondents' argument fails.

Respondents also argue that the FID fails to find a causal nexus between Respondents' unfair acts and any injury to the domestic industry. *See id.* at 93. Respondents' assertions are unsupported. In the context of the existence of a domestic industry, the FID finds that "it was appropriate to consider an industry in domestically produced products that 'directly compete' with the imported products." *See* FID at 158 (citing *TianRui*, 661 F.3d at 1337; *Rubber Resins*, ID at 648-51, 2013 WL 4495127, at *239). In the present case, there is ample evidence of a causal relationship or nexus between Respondents' unfair acts and the injury to the domestic industry. Respondents' accused product, which exists solely due to Respondents' misappropriation of Medytox's trade secrets, competes directly with BOTOX®, and the court in *TianRui* agreed that such direct "type of competition, is sufficiently related to the investigation to constitute an injury to an 'industry' within the meaning of section 337(a)(1)(A)." *See TianRui*, 661 F.3d at 1337. Respondents' importation and sales have captured 2.61% of U.S. market share entirely at the expense of Allergan's BOTOX® Cosmetic. *See* FID at 198. Each percentage point of lost market share represents more than [ ] in lost profit per year for Allergan. *Id.* The FID thus finds that Respondents' unfair imports have caused over [ ] in annualized lost profits for Allergan. *Id.* at 198-99. The evidence shows that Respondent's market share gains are projected to continue to [ ] market share directly at the expense of BOTOX® Cosmetic representing an annual loss of more than [ ] in profit. *Id.* at 200-01.

Moreover, the FID found that Respondents' aggressive pricing has adversely impacted Allegan's prices. The FID found that Evolus aggressively prices Jeuveau® to physicians at a [

] such that [

]. *Id.* at 205. While Evolus has flexibility in pricing Jeuveau®. Allergan is constrained in its ability to discount BOTOX® products due to the Centers for Medicare & Medicaid Services' ("CMS") regulations. *Id.* at 206. Thus, the FID found that Evolus's aggressive pricing of Jeuveau® will erode Allergan's profitability for both BOTOX® Cosmetic and BOTOX® therapeutic. "Inasmuch as Evolus [

]." FID at 208. These findings amply support the FID's conclusion that Respondents' unfair imports have cause substantial injury to the domestic industry.

Similarly, the FID's findings as to the threat of future injury are well-supported. The evidence shows that Daewoong has more than sufficient foreign manufacturing capacity to supply the domestic demand for Jeuveau® (and the entire U.S. BTX cosmetic market) and that it has targeted Allergan's sales specifically. *See* FID at 211, 214. Moreover, the evidence shows Respondents are able to undersell, and will continue to be able to undersell, BOTOX® products and that Allergan will face long-term price erosion as a result, affecting both BOTOX® Cosmetic and BOTOX® therapeutic. *Id.* at 214-15, 220. Evolus' market share projections show that Respondents are confident that they can attain "the number two U.S. market position within 24 months of launch," which "will result in over [ ] in yearly lost profits to Allergan." *Id.* at 219-20. These findings provide a clear assessment of the market in the

presence of the Respondents' imports demonstrating "relevant conditions or circumstances from which probable future injury can be inferred." *Railway Wheels*, Unreviewed ID at 81–82.

Respondents further argue that the FID "neglected to consider the entire picture, ignoring the rising sales and profits of Botox, and erring in concluding how much market share Jeuveau took, or threatens to take, from Botox Cosmetic." *See* Respondents' Pet. at 90. Respondents essentially argue that injury or threat thereof can never be proven where complainants' sales or profits have increased. Not only is Respondents' theory legally unfounded, but also it fails to account for the FID's finding, supported by record evidence, that Respondents' unfair imports, that have benefitted from stolen trade secrets, have driven down prices for Allergan's BOTOX® Cosmetic BOTOX® products, captured market share directly at the expense of Allergan, have caused Allergan to lose over [ ] in annualized lost profits and threaten future annual losses of more than [ ] in profit, and threaten long-term price erosion.

Respondents contend that "[e]ven assuming Allergan is correct that Jeuveau will cut into Botox's market share and sales, that is not enough to establish injury to domestic investments, which is the operative test at the ITC." *See id.* at 89. Contrary to Respondents' contention, the evidence of record discussed above as to lost market share, lost profits, and underselling amply support the inference that Allergan's domestic investments in manufacturing and R&D have been, and its ongoing production and R&D efforts have been and will continue to be, adversely impacted by Respondents' unfair imports.

Respondents further argue the FID incorrectly finds "actual substantial injury to Botox Therapeutic" where "Jeuveau is only approved for cosmetic indications." *See id.* at 92. The Commission agrees with the FID that the relationship in pricing between BOTOX® Cosmetic and BOTOX® therapeutic results in Jeuveau® causing injury to BOTOX® therapeutic. *See*

FID at 206-07. Respondents have shown no error in the FID's findings as to this pricing relationship.

As discussed above, the FID correctly finds actual and threatened injury to the industry related to BOTOX®. As noted by Complainants, "Commission precedent confirms that financial harms, such as lost sales and price erosion, are indeed sufficient to support a finding of actual substantial injury." *See* Complainants' Pet. Resp. at 92-93 (citing *Rubber Resins*, Comm'n Op. at 63, 2014 WL 7497801, at *32; *Certain Light-Emitting Diode Prods.*, Inv. No. 337-TA-947, Initial Determination at 482-83 (July 29, 2016)); *accord* IA's Pet. Resp. at 37-38.

Thus, the Commission has determined to affirm the FID's finding of injury with respect to the domestic industry related to BOTOX®. In particular, the Commission finds that there is a causal nexus between the unfair act asserted (*i.e.*, importation of articles that impinge upon the asserted trade secrets) and injury and threat of injury to the domestic industry as found in the FID.

For the foregoing reasons, the Commission finds a violation of section 337 with respect to the importation and sale of Respondents' botulinum neurotoxin products.

IV. REMEDY, PUBLIC INTEREST, AND BONDING

The RD recommends that the Commission issue an LEO barring entry of botulinum neurotoxin products that are imported or sold by Respondents Daewoong and Evolus and a CDO against Evolus. The RD also recommends that the Commission set a bond based on price differential during the period of Presidential review.

As discussed below, the Commission has determined to adopt the RD with respect to remedy and bonding except that the Commission limits the duration of the LEO and CDO to 21 months and sets the bond during the period of Presidential review in an amount of $441 per

100U vial (based on price differential). The Commission further finds that the public interest will not be adversely affected by the issuance of the remedial orders.

A. Remedy

The Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan, S.A. v. USITC*, 787 F.2d 544, 548 (Fed. Cir. 1986).

1. Limited Exclusion Order

Section 337 requires the Commission to issue LEOs against named respondents that have imported or sold unfairly traded articles:

> If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States . . . .

See 19 U.S.C. § 1337(d)(l). *See also Spansion, Inc. v. ITC*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) ("[T]he Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise.").

The RD recommends that the Commission issue an LEO excluding botulinum neurotoxin products that are imported or sold by Respondents Daewoong and Evolus. *See* RD at 257-58. The RD further states that "[t]he duration of an order in a trade secret misappropriation case is set as the time it would have taken to independently develop the trade secrets." *See id.* at 257 (citing *Rubber Resins*, Comm'n Op., 2014 WL 7497801, at *43). The RD recommends that the LEO have a ten-year duration if the Commission finds both Medytox's strain and Medytox's manufacturing process to be trade secrets. *See* RD at 257-58.

The RD further states that "[i]f the misappropriation of the Medytox manufacturing process is considered independently, . . . the duration of the [LEO] . . . should be for a period of

at least 21 months from the time of issuance of the exclusion order." *See id.* (citing CX-18C (Malackowski WS) at Q/A 205; CX-10C (Pickett WS) at Q/A 320-25); *accord* Complainants' Resp. Br. at 53; IA's Resp. Br. at 23.

Because the Commission finds that Complainants failed to establish that Medytox's strain is a trade secret, the Commission finds that the record supports issuing an LEO for a duration of 21 months as recommended in the RD. *See* RD at 258 (citing CX-18C (Malackowski WS) at Q/A 205; CX-10C (Pickett WS) at Q/A 320-25); *accord* Complainants' Resp. Br. at 53; IA's Resp. Br. at 23.

Accordingly, the Commission has determined to issue an LEO with a 21-month duration. The Commission declines to limit the LEO to aesthetic applications. Both aesthetic and therapeutic versions of BOTOX® have been considered in the domestic industry analysis and while Respondents' products may be currently sold for aesthetic applications only, the scope of the investigation (botulinum neurotoxin products) is not so limited. *See* 84 Fed. Reg. at 8112.

Furthermore, under the specific facts of this case involving trade secret misappropriation, and where it is not readily apparent by inspection at the border whether an imported product is manufactured using the misappropriated trade secrets, the Commission has determined to require Respondents to obtain a ruling (via an advisory opinion or a modification proceeding) from the Commission prior to the importation of any accused products. *See Canadian Tarpoly Co. v. USITC*, 640 F.2d 1322, 1326 (C.C.P.A. 1981) (affirming the Commission's authority to require an advisory opinion); *see also* 19 C.F.R. § 210.79 (advisory opinions); 19 C.F.R. § 210.76 (modification proceedings).

Thus, the Commission has determined to: (1) issue an LEO covering certain botulinum toxin products that are imported or sold in the United States by Respondents Daewoong and

Evolus; and (2) require Respondents to obtain a ruling from the Commission under Commission Rules 210.76 or 210.79 (19 C.F.R. §§ 210.76, 210.79) prior to the importation of any articles at issue.

2. Cease and Desist Order

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a CDO as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs 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.[43] *See, e.g.*, *Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof* ("*Table Saws*"), Inv. No. 337-TA-965, Comm'n Op. at 4-6 (Feb. 1, 2017); *Certain Protective Cases & Components Thereof*, Inv. No. 337-TA-780, USITC Pub. No. 4405, Comm'n Op. at 28 (Nov. 19, 2012) (citing *Certain Laser Bar Code Scanners & Scan Engines, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-551, Comm'n Op. at 22 (June 24, 2007)). Complainants bear the burden on this issue. "A complainant seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order." *Table Saws*, Comm'n Op. at 5 (citing *Certain Integrated Repeaters, Switches,*

[43] When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidtlein does not adopt the view that the inventory or domestic operations needs to be "commercially significant" in order to issue the CDO. *See, e.g.*, *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 65, n.24 (Mar. 25, 2019); *Table Saws*, Comm'n Op. at 6-7, n.2 (Feb. 1, 2017). In Commissioner Schmidtlein's view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO. *Id.* Commissioner Schmidtlein supports issuance of the CDO against Evolus due to its maintenance of domestic inventory of Jeuveau.

Transceivers, & Prods. Containing Same, Inv. No. 337-TA-435, USITC Pub. No. 3547 (Oct. 2002), Comm'n Op. at 27 (Aug. 16, 2002); *see also* H.R. REP. No. 100-40, at 160 (1987)).

The RD recommends that the Commission issue a CDO against Evolus. *See* RD at 264. The RD finds that "Evolus, as of year-end 2019, maintained a domestic inventory of [ ] vials of 100U of Jeuveau® having an imported value of [ ]." *See id.* (citing JX-139C (Stipulation of Material Facts Relating to Importation and Inventory) at ¶ 6). The RD concludes that Evolus maintains "a commercially significant domestic inventory." *See id.* As to Daewoong, however, the RD finds that "[C]omplainants did not provide admissible evidence of the existence of a domestic inventory of any accused product held by Daewoong or its agents." *See id.* Complainants no longer appear to seek a CDO against Daewoong. *See* Complainants' Br. at 49; *accord* IA's Resp. Br. at 25-26.

Respondents argue that "the value of the domestic inventory of Jeuveau®, discounting sales of Xeomin and Dysport, comprises at most [ ] of the value of the domestic market for cosmetic neurotoxin products." *See* Respondents' Br. at 43. Respondents, however, do not provide any evidence to contradict Complainants' assertion that the inventory is commercially significant relative to Jeuveau®'s market share. *See* Complainants' Reply Br. at 26 ("Evolus's inventory is commercially significant in the context of its imports and sales over time.") (citing CX-18C (Malackowski WS) at Q/As 208-11).

Thus, the Commission finds that a CDO is warranted as to Evolus. As noted, Complainants are no longer seeking a CDO with respect to Daewoong. Accordingly, the Commission has determined to issue a CDO against Evolus with the same 21-month duration as the LEO discussed *supra* section IV(A)(1).

B. The Public Interest

Section 337 requires the Commission, upon finding a violation of section 337, to issue an LEO "unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(l). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest. *See, e.g.*, *Certain Fluidized Supporting Apparatus & Components Thereof*, Inv. Nos. 337-TA-182/188, USITC Pub. 1667, Comm'n Op. at 1–2, 23–25 (Oct. 1984) (finding that the public interest warranted denying complainant's requested relief). Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief in light of the statutory public interest factors. For example, the Commission has allowed continued importation for ongoing medical research, exempted service parts, grandfathered certain infringing products, and delayed the imposition of remedies to allow affected third party consumers to transition to non-infringing products. *E.g.*, *Certain Microfluidic Devices*, Inv. No. 337-TA-1068 Comm'n Op. at 1, 22–48, 53–54 (analyzing the public interest, discussing applicable precedent, and ultimately issuing a tailored LEO and a tailored CDO); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067, Comm'n Op. at 32–33 (July 18, 2019) (exempting service parts); *Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets*, 337-TA-543, USITC Pub. No. 4258, Comm'n Op. at 150–51 (Oct. 2011) (grandfathering certain products); *Certain*

Personal Data & Mobile Comm'n Devices & Related Software, 337-TA-710, USITC Pub. No. 4331, Comm'n Op., at 72–73, 80–81 (June 2012) (delaying imposition of remedy).

The statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. 19 U.S.C. § 1337(d)(l), (f)(l). Thus, the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in the proceeding. 19 U.S.C. § 1337(d)(l) & (f)(l).

With respect to the first public interest factor (public health and welfare), the Commission finds that excluding the accused products would not adversely affect the public health and welfare. Respondents assert that an exclusion order would threaten the development of new treatments, to the detriment of public health. *See* Respondents' Resp. Br. at 56. Respondents contend that "Daewoong and its commercial collaborator Aeon Biopharma, Inc., are currently working to bring new treatments for [ ] to market based upon Daewoong's botulinum products." *See id.*; *see also* AEON Biopharma, Inc.'s Public Interest Submission at 4 (Oct. 9, 2020) ("AEON PI Br.").

As Complainants explain, however, the clinical trials have yet to begin [ ] and AEON admits that substitution is possible (even if it involves more time and cost). *See* Complainants' Reply Br. at 25; AEON PI Br. at 2; *see also* IA's Resp. Br. at 31. AEON also admits that BOTOX® shares the same 900 kDa molecular weight as ABP-450 and "potentially exhibits clinically similar behavior and effect upon injection." *See* AEON PI Br. at 5. Furthermore, as noted by Complainants, "[t]o the extent Daewoong and Aeon Biopharma are working to bring a BTX product to the market for any new treatments, there is no

requirement that any aspect of drug development, testing, or clinical trials take place in the United States." *See* Complainants' Reply Br. at 29.

Nor does the record evidence suggest any adverse effect on the second (competitive conditions in the U.S. economy), third (production of like or directly competitive articles), and fourth (United States consumers) public interest factors. Respondents allege that an exclusion order would harm U.S. consumers and competitive conditions in the U.S. economy by eliminating a needed constraint on the BOTOX® monopoly. *See* Respondents' Resp. Br. at 48-52. Respondents assert that "as of early 2019, [] Botox held 70% of the U.S. cosmetic market" and "[i]n the therapeutic market, Botox's share is even higher: more than 90%." *See id.* (citing Compl. ¶ 4; RX-1632.3-4). Respondents further contend that Allergan entered into a distribution agreement with Medytox to prevent Medytox from entering the U.S. market. *See id.* at 54-55. Respondents argue that excluding other competitors would extend Allergan's monopoly and would be against the public interest. *See id.* at 55.

As Complainants argue, however, "there are other companies that market BTX products for treating adult glabellar lines (among other indications), including Dysport . . . and Xeomin." *See* Complainants' Resp. Br. at 57; *see also* IA's Resp. Br. at 32; Merz North America, Inc.'s Statement on the Public Interest (Aug. 18, 2020). In addition, Complainants continue, "Allergan alone could meet the US demand for all BTX products needed for treating adult glabellar lines (the only use for which Jeuveau is approved by the FDA)." *See* Complainants' Resp. Br. at 57. Complainants conclude that with "with at least three sources of FDA-approved BTX products, . . . there will be no shortfall in supply . . . , [and] there are no public health, safety, or welfare considerations that caution against issuance of the recommended remedial orders." *See id.* at 57-58.

Complainants further explain that [

] *See id.* at 59. According to Complainants, [

] *See id.* (citing Hr'g Tr. (Moatazedi) at 913-14); *see also* Complainants' Reply Br. at 27-28. Furthermore, as Complainants note, even if "some retailers and consumers may have to pay a higher price," it "does not justify a determination that the public interest in protecting intellectual property rights is in any way outweighed." *See id.* at 28 (citing *Certain Lens-Fitted Film Packages*, Inv. No. 337-TA-406, Comm'n Op. at 18, 1999 WL 436531, at *13 (Jun. 28, 1999)).

Based on the record evidence, the Commission finds that the remedial orders would cause little to no harm to the public health and welfare, the competitive conditions in the United States economy, the production of like or directly competitive products in the United States, and United States consumers. Thus, the Commission has determined that the public interest factors do not preclude the issuance of remedial orders in this investigation.

C. Bonding

If the Commission enters an exclusion order or a cease and desist order, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same,*

& Prods. Containing Same, Including Self-stick Repositionable Notes, Inv. No. 337-TA-366, USITC Pub. No. 2949, Comm'n Op. at 24 (Jan. 16, 1996). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., Certain Audio Digital-to-Analog Converters & Prods. Containing Same*, Inv. No. 337-TA-499, Comm'n Op. at 25 (Mar. 3, 2005). Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a 100 percent bond. *See, e.g., Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods Using the Same*, Inv. No. 337-TA-634, Comm'n Op. at 6-7 (Nov. 24, 2009). The complainant, however, bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-533, USITC Pub. No. 3975, Comm'n Op. at 40 (July 21, 2006).

The RD recommends that the Commission set a bond based on price differential during the period of Presidential review. *See* RD at 270-71. Specifically, the RD recommends that the Commission set a bond in the amount of $441 per 100U vial of Jeuveau® (which reflects the difference in the average sales price of [ ] for BOTOX® Cosmetic and the imputed imported value of a 100U vial of Jeuveau® of nearly [ ]). *See id.* at 270 (citing See CX-2331C (Allergan Financial Projections for 2019); JX-139C (Stipulation of Material Facts Relating to Importation and Inventory) at ¶ 6); *accord* Complainants' Resp. Br. at 56-57; IA's Resp. Br. at 27-28. The imputed import value is the unit value of Evolus's U.S. inventories, which is in line with the [ ] price per 100U vial that Evolus agreed to pay Daewoong under their license and supply agreement. *See* IA's Resp. Br. at 27. The RD finds that a bond calculated based on "the

difference in average sales price between Jeuveau® and BOTOX® Cosmetic is not sufficient to protect Allergan from further injury." *See id.* at 271.

Respondents argue that "the RD calculated a bond rate that is higher than the rate requested by Complainants." *See* Respondents' Resp. Br. at 45. Respondents argue that the Commission should impose a zero bond because "the Botox Cosmetic list price is $601 per 100U vial, whereas the list price for the same 100U vial of Jeuveau is $610 per vial." *See id.* at 44 (citing RD at 271; RX-3158C.61 (Mulhern[44] WS) at Q/A 357; CX-1705C.31 (Moatazedi Dep. at 125:6-17). Alternatively, Respondents argue that "the experts for both sides . . . concluded that a bond based upon a reasonable royalty would be [ ], which is the rate set forth in the Medytox-Allergan License Agreement." *See id.* at 45 (citing CX-18C.74 (Malackowski WS) at Q/A 216; RX-3158.60-62 (Mulhern WS) at Q/A 352, 360-64; JX-50C.38 (Allergan-Medytox Agreement)).

The Commission supports imposing the bond amount recommended by the ALJ, which is $441 per 100U vial of Jeuveau®. This bond amount was requested by both Complainants and OUII in their briefing to the Commission, and was proposed by OUII in the proceeding before the ALJ. *See* Complainants' Br. at 56-57; IA's Br. at 26-28. Bonding is governed by section 337(j)(3), which states that the bond amount is "determined by the Commission to be sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3). The statutory language referring to protection from "any" injury is broad, and allows the parties to put forward different theories to establish an appropriate bond amount for importation and sale of unfair imports during the period of Presidential review. Common theories asserted by parties, and accepted by the Commission in previous investigations depending on the facts, include bond amounts based

[44] Carla S. Mulhern served as an expert for Respondents.

on the difference in sales prices between the domestic industry products and the unfair imports and bonds based on a reasonable royalty rate. However, those are not the only ways of establishing a bond amount sufficient to protect the complainant from any injury under the broad language of the statute. *See, e.g., Certain Two-Way Radio Equipment and Systems, Related Software and Components* Thereof, Inv. No. 337-TA-1053, Comm'n Op. at 45-46 (Dec. 18, 2018) (using lost profits as a basis of a bond amount). Further, the Commission is not required to impose a bond amount based on the difference in sales prices between the domestic industry and the infringing products if that amount is shown to be insufficient to protect the complainant from injury.

Respondents have a high profit margin in the sale of Jeuveau® since the record shows the imputed imported value of about [ ] per 100U vial while the list price is $610 per 100U vial. The ultimate sale price to physicians can vary depending on the various discounts Evolus offers. RD at 270-271. The record shows Jeuveau® has an average sales price, when the discounts are taken into consideration, of about [ ] per vial. CX-18C (Malackowski WS) at Q/A 217. The $441 per 100U vial bond recommended by the ALJ reflects the difference in the average sales price of [ ] for BOTOX® Cosmetic versus the [ ] imputed imported value of a 100U vial of Jeuveau®. RD at 270. Complainants and OUII argue that calculating bond in this manner is appropriate because it removes the gross profit from the sale of Jeuveau® and also mitigates Evolus's ability to [

] Complainants' Br. at 57; IA's Br. at 27-28. Complainants' expert testified that a lower bond amount calculated based on the difference between the average sale prices of BOTOX® and Jeuveau® will not adequately protect Complainants from injury because they will still

experience lost profits and lost market share with a bond at that level. *See* CX-18C (Malackowski WS) at Q/A 215-217. The Commission finds that Complainants are entitled to protection under section 337(j) from the injuries identified and that the record supports a finding that the bond amount of $441 per 100U vial is "sufficient to protect complainant" from those injuries. The Commission therefore finds that Complainants and OUII have shown that a bond amount of $441 per 100U vial of Jeuveau® is warranted on this factual record.

V. CONCLUSION

For the foregoing reasons, the Commission determines that Complainants have established a violation of section 337 by Respondents based on the misappropriation of trade secrets relating to Medytox's manufacturing processes. The Commission also determines that: (1) the appropriate remedy is an LEO directed against Respondents' unfair imported products and a CDO directed against Evolus for a duration of 21 months; (2) the public interest does not preclude this remedy; and (3) the bond during the period of Presidential review is set in an amount of $441 per 100U vial of accused product.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 13, 2021

CERTAIN BOTULINUM TOXIN PRODUCTS, PROCESSES FOR MANUFACTURING OR RELATING TO SAME AND CERTAIN PRODUCTS CONTAINING SAME **Inv. No. 337-TA-1145**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER, COMMISSION** has been served via EDIS upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on **January 13, 2021.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Allergan Limited and Allergan, Inc.:

Brian M. Buroker, Esq.
GIBSON, DINN & CRUTCHER LLP
1050 Connecticut Avenue NW
Washington, DC 20036-5841
Email: bburoker@gibsondunn.com

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

On Behalf of Complainant Medytox Inc.,

Nowell D. Bamberger, Esq.
CLEARY GOTTLIEB STEEN & HAMILTON LLP
2112 Pennsylvania Avenue NW
Washington, DC 20037
Email: nbamberger@cgsh.com

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

On Behalf of Respondent Daewoong Pharmaceuticals Co., Ltd.:

David F. Nickel, Esq.
FOSTER, MURPHY, ALTMAN & NICKEL, PC
1150 18th Street, NW, Suite 775
Washington, DC 20036
Email: dnickel@fostermurphy.com

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

On Behalf of Respondent Evolus, Inc. :

Nicholas Groombridge, Esq.
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
Email: ngroombridge@paulweiss.com

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download