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

VERIFIED COMPLAINT OF MEDYTOX AND ALLERGAN UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

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D	Confidential	Medytox Orientation Material for New Hires – Introduction to Our Security System
E	Confidential	Medytox PC Security Management Rules
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G	Confidential	Isolation and Characterization of Daewoong *Clostridium botulinum* Type A Hall strain
H	Confidential	Daewoong Submission to Director of Korea Centers for Disease Control and Prevention, Re: Notification of the high-risk pathogen isolation, July 19, 2010
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Q	Public	Daewoong Pharmaceuticals Presentation, "The Current State of Biological Pharmaceutical Product Research and Development Using Botulinum Toxin," Sept. 7, 2012
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I. INTRODUCTION

1. This case concerns unfair acts in the importation into the United States of DWP-450, soon to be marketed under the brand name Jeuveau™, a botulinum neurotoxin ("BTX") product manufactured by Daewoong Pharmaceuticals Co., Ltd. ("Daewoong") of South Korea based on misappropriated trade secrets of Medytox.

2. Complainants Medytox Inc. ("Medytox") and Allergan plc and Allergan, Inc. (together with their subsidiaries, "Allergan") (collectively, "Complainants") respectfully request that the United States International Trade Commission (the "Commission") institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Complainants seek a limited exclusion order to remedy the unlawful and unauthorized importation into the United States of Respondents' botulinum neurotoxin products manufactured using Medytox's misappropriated trade secrets currently known as DWP-450 and planned to be marketed under the name Jeuveau™ ("Accused Products"). Complainants also request cease and desist orders preventing Respondents from engaging in and profiting from their unfair trade practices through the importation, sale, or sale for importation of the Accused Products.

3. BTX products are biologics that may have both therapeutic and aesthetic applications. These include treatment of chronic migraine headaches, cervical dystonia, hyperhidrosis, spasticity, urinary incontinence, as well as temporary improvement to the appearance of glabellar lines, crow's feet, and forehead lines.

4. The leading BTX products sold in the United States are BOTOX® (onabotulinumtoxinA) and BOTOX® Cosmetic (onabotulinumtoxinA) (collectively "BOTOX®"), which are manufactured, marketed, and sold by Allergan. BOTOX® has been approved for sale in the United States since 1989. The U.S. market for BTX products is valued

at approximately $3.5 billion, and Allergan's BOTOX® comprises in excess of 70% of that market.

5. As discussed at greater length below, Allergan developed the U.S. market for BTX products through substantial and sustained investment in research and development in the United States, clinical testing in the United States, and sales and marketing in the United States. Allergan currently maintains substantial operations in California and elsewhere in the United States related to the development and sale of BOTOX® in the U.S. market. Over nearly 30 years, Allergan has invested more than [redacted] in the development of the BTX market, including the U.S. domestic market for BOTOX®.

6. Medytox is a Korean manufacturer of BTX products, including the market-leading BTX products Meditoxin® and Innotox®. Through an exclusive licensing agreement, Medytox and Allergan have partnered to introduce MT10109L, a derivative of Medytox's Innotox®, to the established U.S. domestic BTX products market. Both Allergan and Medytox have made substantial investments to bring MT10109L to the U.S. market, including more than $100 million in investments by Medytox and more than $75 million in investments by Allergan. MT10109L has commenced the initial steps of Phase III clinical trials as part of the process to obtain FDA approval for its sale in the United States.

7. Allergan's 30-year investment in the domestic BTX products market, including its partnership with Medytox, will be substantially injured by the unfair acts of Respondents. Respondents are importing DWP-450, which was created using trade secrets stolen from Medytox. DWP-450 will directly compete with BOTOX® and undercut BOTOX® significantly on price, leading to lower revenue, lower profits, a reduced return on investment

and, as a result, cause significant injury to the industry that Allergan has invested significantly to develop in the United States.

8. In September 2013, Daewoong entered into a licensing agreement (the "Daewoong Agreement") with Respondent Evolus, Inc. ("Evolus") to import DWP-450 into the United States. Evolus is a medical aesthetic company that was formed in November 2012, whose sole focus has been on bringing DWP-450 to the U.S. market. Pursuant to the Daewoong Agreement, Daewoong agreed to manufacture and supply DWP-450 to Evolus, and Evolus has an exclusive license to import, distribute, and commercialize DWP-450 in the United States and other markets. The Daewoong Agreement was reportedly valued to be approximately $250 million.[1]

9. During its short history, Evolus has hired a number of former Allergan employees and formed a management team around them, including its President and Chief Executive Officer, David Moatazedi, who was Allergan's Senior Vice President of U.S. Medical Aesthetics.

10. Since early 2014, Evolus has been engaged in the process of obtaining U.S. Food and Drug Administration ("FDA") approval to market DWP-450 in the United States, which has involved the importation of DWP-450 into the United States for clinical testing. Evolus has announced plans for the commercial launch of DWP-450 in Spring 2019, and contemplates using products that will be manufactured in South Korea and imported to the United States.

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[1] Heejin Kim, *Hedge Fund Manager Who Bet on Botox Turns to Rival*, Bloomberg (Nov. 30, 2017), https://www.bloomberg.com/news/articles/2017-11-30/hedge-fund-manager-who-backed-allergan-bets-on-botox-alternative.

11. The sole source of DWP-450 in the world is Daewoong's manufacturing facility in South Korea. All DWP-450 sold worldwide, including any used or sold in the United States, must be imported from that facility. Evolus has confirmed that its sole source of DWP-450 to date has been the Daewoong manufacturing facility in South Korea.

12. To date, Evolus has imported DWP-450 to the United States as part of its clinical testing program, which began in 2014 and was completed as part of its application for FDA approval of DWP-450. As discussed at greater length below, those clinical tests, which were conducted in California, Florida, and Nebraska, required the importation of DWP-450. In addition, Evolus has stated publicly that it expects to begin selling DWP-450 in the United States under the brand name Jeuveau™ shortly after FDA approval, which is currently expected in February 2019. To do so, Evolus must have already imported and stockpiled significant volumes of DWP-450, or must have plans to do so imminently.

13. Daewoong and Evolus's importation of DWP-450 threatens substantial injury to the well-established domestic BTX product market. *See infra* Section VII. In particular, DWP-450 is being, and will be, marketed to physicians and others as a direct competitor of BOTOX®, with the objective of undercutting the domestic market in BTX products and quickly obtaining substantial market share. For example, Evolus has stated in securities filings and investor presentations that:

a. DWP-450 "will offer the U.S. market the first known 900 kDa neurotoxin alternative to BOTOX,"[2]

[2] *See* Exhibit A, which is true and correct excerpt of Evolus' 10K dated Mar. 29, 2018, at 4.

b. Due to comparable characteristics, "DWP-450 may be easily integrated into existing aesthetic physician practices,"[3] and

c. Evolus's plan is to substantially undercut the market for BOTOX® by pricing DWP-450 20% to 25% lower than the current price of BOTOX®.[4]

14. Market analysts predict that Evolus could undercut the price of BOTOX® by as much as 30%. In addition, experts and analysts note that DWP-450 has a similar efficacy and safety profile to BOTOX®, meaning that their interchangeability will lead to direct competition between the two BTX products.[5]

15. Importation of DWP-450 to compete with BOTOX® and other BTX products, including MT10109L, in the United States constitutes unfair acts, the threat or effect of which is to substantially injure an industry in the United States in violation of 19 U.S.C. § 1337(a)(1)(A), because DWP-450 was developed on the basis of misappropriated trade secrets stolen from Medytox by its former employee, Byung Kook ("BK") Lee, and provided to Daewoong. Specifically, BK Lee took from Medytox confidential documents describing in detail the company's most secret, most protected manufacturing processes, as well as a sample of Medytox's BTX strain, and went to work for Daewoong. BK Lee's theft of Medytox's trade secrets is well documented by Medytox's computer security system, as described below. Moreover, the circumstances of BK Lee's departure from Medytox and employment at Daewoong, and Daewoong's purported discovery and exploitation of its own BTX strain – an

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[3] *Id.*

[4] *See* Exhibit S, which is a true and accurate copy of the slide deck and transcript of the October 1, 2018 Evolus Investor Presentation at Cantor Fitzgerald Global Healthcare Conference, at 22.

[5] GlobalData Healthcare, *Evolus's 'frown line' treatment Jeuveau could threaten Botox revenues*, Pharmaceutical Technology (Jan. 11, 2019), https://www.pharmaceutical-technology.com/comment/botox-competitor-jeuveau/.

occurrence the company's lead researcher has himself described as "miraculous" – confirm that, in fact, DWP-450 was developed on the basis of Medytox's stolen trade secrets.

16. Daewoong and Evolus are able to introduce DWP-450 into the U.S. market at a price that they have touted will be substantially lower than the price of BOTOX®, and to thereby undercut the market for BOTOX®, because they were not required to make the massive research and development investments that Allergan and Medytox have incurred and continue to incur to develop their products. Importing DWP-450 to compete against BOTOX®, MT10109L, and other BTX products in the U.S. market would accordingly constitute an unfair method of competition and unfair act in violation of 19 U.S.C. § 1337.

17. Allergan and Medytox accordingly seek (a) institution of an investigation pursuant to 19 U.S.C. § 1337 with respect to Respondents' violation of that section, (b) a hearing on permanent relief pursuant to 19 U.S.C. § 1337(c), (c) a limited exclusion order with respect to forbidding entry into the United States of Respondents' BTX products, including DWP-450, (d) cease and desist orders pursuant to 19 U.S.C. § 1337(f) prohibiting Respondents and their related companies from engaging in the importation, sale for importation, marketing, distribution, offering for sale, the sale after importation of, or otherwise transferring within the United States Respondents' BTX products, including DWP-450, that were developed, made, and imported using Medytox's trade secrets, (e) requirement of a bond during the Presidential review period pursuant to 19 U.S.C. § 1337(j)(3), (f) an order compelling the return of Medytox's trade secrets, and (g) such other and further relief as the Commission deems just and proper.

II. COMPLAINANTS AND THEIR BUSINESS

a. Medytox Inc.

18. Complainant Medytox is a limited liability corporation established under the laws of the Republic of Korea ("Korea") with its principal place of business located at 626 Tehran Road, Gangnam, Seoul, Korea. Medytox maintains offices in the United States at 20271 Goldenrod Lane, Suite 2080/2082, Germantown, Maryland 20876. Its shares trade on the KOSDAQ under the code "086900." Medytox is the owner of the trade secrets at issue in this case.

19. Medytox was founded in 2000 for the purpose of researching, developing, and manufacturing BTX products. In 2006, Medytox obtained approval from the Korean Ministry of Food and Drug Safety to sell the first domestically-developed BTX product in Korea, Meditoxin®. Like BOTOX®, Meditoxin® has a range of therapeutic and aesthetic uses. Meditoxin® has also been approved for sale in other countries, including countries in Asia, Eastern Europe, and Latin America, under various brand names.[6]

20. Since developing Meditoxin®, Medytox has continued its research and development activities related to BTX products. For example, in addition to Meditoxin®, Medytox has also developed a liquid-form, animal-protein-free alternative BTX product called Innotox®. Innotox® is currently being sold in Korea. In September 2013, pursuant to a supply and licensing agreement, Medytox licensed a formulation of Innotox® to Allergan for commercialization in the United States. This formulation is known as MT10109L. The initial steps of Phase III clinical trials for MT10109L began in the United States in Fall 2018.

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[6] These brand names include Neuronox®, Siax®, Botulift®, Cunox®, Tonytox®, and Meditoxin®.

b. Allergan plc and Allergan, Inc.

21. Complainant Allergan plc is a public limited company established under the laws of the Republic of Ireland with its principal executive offices at Clonshaugh Business and Technology Park, Coolock, County Dublin, Ireland. Allergan plc operates in the United States through its subsidiaries, including Allergan, Inc., a corporation organized under the laws of the State of Delaware with its principal place of business at 5 Giralda Farms, Madison, NJ 07940. Its shares trade on the New York Stock Exchange under the ticker symbol "AGN."

22. Allergan is a global pharmaceutical company focused on the development, manufacturing, and commercialization of branded pharmaceutical, device, biologic, surgical, and regenerative medicine products for distribution around the world. It is known for its portfolio of products for medical aesthetics, the central nervous system, eye care, gastroenterology, women's health, urology, and anti-infective therapeutic categories.

23. Among Allergan's products is BOTOX®, which is a product derived from the botulinum neurotoxin type A, which, in turn, is produced by processing the bacterium *Clostridium botulinum* ("*C. botulinum*"). BOTOX® is used to treat a range of muscular conditions and for aesthetic purposes, such as treating glabellar lines, crow's feet, and forehead lines. Allergan was the first company to launch a BTX product in the United States, achieving approval from the FDA for BOTOX® for therapeutic uses in 1989 and for aesthetic uses in 2002.

24. BOTOX® is the leading product in the domestic industry at issue in this case, that is, the domestic industry in BTX products. Importation of DWP-450 by Evolus threatens to cause substantial injury to that domestic industry.

III. RESPONDENTS AND THEIR BUSINESS

a. Daewoong Pharmaceuticals Co., Ltd.

25. Respondent Daewoong Pharmaceuticals Co., Ltd. is a limited liability company established under the laws of Korea with its principal place of business located at Bongeunsaro 114-gil 12, Gangnam, Seoul, South Korea. Its shares trade on the KOSPI under the code "069620."

26. Daewoong's business includes the manufacture and sale of pharmaceutical products and medical devices. It manufactures DWP-450, a BTX product. It currently sells a formulation of DWP-450 in Korea under the brand name Nabota®.[7]

27. As discussed below, Daewoong is commercializing DWP-450 in the United States through a licensing and supply agreement with Evolus.

28. Daewoong and Evolus have imported DWP-450 into the United States for use in clinical trials that commenced in 2014. Daewoong and Evolus also have or intend to import DWP-450 for commercial use following anticipated FDA approval in February 2019.

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[7] *See* Exhibit A. In public statements to its investors Evolus alternatively treats DWP-450 and Nabota® as identical products, or at most, as immaterially "slightly different." Compare Exhibit A at 20 ("Daewoong currently markets DWP 450 in South Korea under its own brand name, Nabota."), with Exhibit A at 9 (explaining slight differences). The slight difference between Nabota® and DWP-450 involves the packaging of the drug substance into the final product, including the use of a different human serum albumin as a stabilizing agent in this final stage. *See* Exhibit A at 9, 17. The drug substance is not altered by the packaging process. *See infra* Section V.a.ii. The immateriality of this difference is evidenced by Evolus's reliance upon Nabota® test results to demonstrate the efficacy of DWP-450 to its investors. *See* Exhibit A at 8-9. This Complaint refers to Daewoong's BTX product as DWP-450, unless referring exclusively to the final product currently being sold in Korea under the brand name Nabota®, in which case "Nabota®" is used. This is consistent with Daewoong's business documents, which refer to the development of "DWP-450." *See* Exhibit B, which is a true and accurate copy of Daewoong's Business Report dated June 29, 2010, at 16.

b. Evolus, Inc.

29. Evolus is a public corporation organized under the laws of Delaware with its principal place of business located at 17901 Von Karman Avenue, Suite 150, Irvine, California 92614. Its shares trade on the NASDAQ under the ticker symbol "EOLS."

30. Evolus is a medical aesthetics company focused on delivering advanced aesthetic procedures and treatments to physicians and consumers. Currently, Evolus has only one product candidate: DWP-450, developed through an exclusive licensing agreement with Daewoong.

IV. PRODUCTS AT ISSUE

31. Pursuant to 19 C.F.R. § 210.12(a)(12), Complainants state that the Accused Products are botulinum neurotoxin products manufactured by Daewoong Pharmaceuticals Co., Ltd., specifically DWP-450 (prabotulinumtoxinA), variously marketed under the brand names Nabota®, Jeuveau™ and other brand names, products containing or derived therefrom, and products containing or derived from the BTX strain or manufacturing process used to manufacture the same.

32. DWP-450 is currently marketed by Daewoong in Korea and elsewhere under the Brand name Nabota®, and in November 2018 the U.S. FDA granted conditional approval for use of the brand name Jeuveau™ if it is approved to be sold in the United States. DWP-450 is indicated as a temporary treatment to improve the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults.[8]

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[8] U.S. Nat'l Library of Med., *Safety Study of DWP-450 (Botulinum Toxin, Type a) to Treat Glabellar Lines – EV-006 (EV-006)*, https://www.clinicaltrials.gov/ct2/show/NCT02428608?term=DWP-450&rank=1 (last visited Dec. 20, 2018).

33. Evolus licensed DWP-450 from Daewoong pursuant to a license and supply agreement entered into on September 30, 2013 (the "Daewoong Agreement"). Under the Daewoong Agreement, Evolus has an exclusive license from Daewoong to distribute DWP-450 in the United States, among other countries.

34. Evolus has applied to the FDA for approval to sell DWP-450 in the United States, listing "Daewoong Pharmaceutical Co." in South Korea as its manufacturing facility. In September 2014, the FDA accepted Evolus's Investigational New Drug application to conduct clinical trials on DWP-450.[9] Clinical trials of DWP-450 in the United States, for which Daewoong imported sufficient supplies of DWP-450, began shortly thereafter. In July 2017, Evolus announced that the FDA had accepted its Biologics License Application ("BLA") for DWP-450.[10] The BLA identified Daewoong as the exclusive manufacturer of DWP-450 and stated that Daewoong's manufacturing would be in Korea. Thus, all DWP-450 sold by Evolus must be imported into the United States. On or around September 2018, Evolus received a Prescription Drug User Fee Act ("PDUFA") action date of February 2, 2019, at which time the

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[9] ALPHAEON Corp., *FDA Accepts Investigational New Drug Application For ALPHAEON's Neurotoxin EVOSYAL*, CISION PR Newswire (Sept. 04, 2014) https://www.prnewswire.com/news-releases/fda-accepts-investigational-new-drug-application-for-alphaeons-neurotoxin-evosyal-273952531.html.

[10] Medytox submitted a citizen petition to the FDA on December 5, 2017 requesting that the FDA determine the identity and source of the DWP-450 BTX Strain and require Evolus to include the whole genome sequence of the BTX Strain in its submission. Medytox also submitted a supplemental citizen petition on May 4, 2018 requesting that the FDA require Evolus to include a single nucleotide polymorphism ("SNP") analysis of the whole genome sequence of the DWP-450 BTX Strain. Medytox received a response from the FDA on June 1, 2018 stating that the petitions were under evaluation.

FDA is likely to rule on Evolus' application for approval.[11] Evolus expects to commercially introduce DWP-450 in the United States by Spring 2019.[12]

35. If approved, DWP-450 will be the first (and only) BTX product sold in the United States based on a 900 kDa complex molecule since BOTOX® was first approved in 1989. The BTX products from Allergan and Medytox (BOTOX®, Meditoxin® and MT10109L) are each composed of the active botulinum neurotoxin coupled with complementary nontoxic accessory proteins to produce a 900 kDa complex. While there are other BTX products in the U.S. market, none of them have a 900 kDa complex. DWP-450, which as discussed below was developed using Medytox's trade secrets, is the only other product that has a 900 kDa complex. DWP-450 will therefore be a direct competitor of BOTOX®, and of MT10109L when it is approved for sale in the United States.

V. UNLAWFUL AND UNFAIR ACTS OF RESPONDENTS

36. Pursuant to 19 C.F.R. § 210.12(a)(2), Complainants state that DWP-450 is the product of unfair methods of competition and unfair acts, specifically the misappropriation of trade secrets belonging to Medytox. A former employee of Medytox, BK Lee, stole Medytox's trade secrets and BTX strain and transferred them to Daewoong, which then misappropriated them by using them to develop and manufacture DWP-450. In exchange for providing Daewoong with Medytox's trade secrets and BTX strain, which were necessary to the

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[11] *Evolus Received Conditional FDA Acceptance of Jeuveau™ Brand Name*, Evolus (Nov. 19, 2018), https://investors.evolus.com/news-releases/news-release-details/evolus-receives-conditional-fda-acceptance-jeuveautm-brand-name.

[12] *See* Exhibit V, which is a true and accurate excerpt of Evolus' 10-Q, dated Nov. 5, 2018, at 28; *see also Evolus Receives Acceptance of FDA BLA Resubmission for DWP-450*, GlobeNewswire (August 29, 2018), https://globenewswire.com/news-release/2018/08/29/1558232/0/en/Evolus-Receives-Acceptance-of-FDA-BLA-Resubmission-for-DWP-450.html.

development of DWP-450, Daewoong provided BK Lee with monetary compensation and facilitated his placement in a post-doctoral fellowship program at Purdue University in Indiana.

a. BTX Products and Their Manufacture

37. DWP-450 is a finished product manufactured from botulinum neurotoxins produced by a strain of *C. Botulinum* (a "BTX Strain"), a highly-toxic biologic substance. DWP-450 is manufactured from a particular type of BTX Strain – a Hall-A strain – which cannot be isolated from nature. On information and belief, DWP-450 is manufactured using a particular Hall-A strain referred to variously as the Hall-A Hyper Strain, which has unique characteristics making it especially useful in the manufacture of BTX products. The Hall-A Hyper Strain also cannot be isolated from nature. Manufacture of finished BTX products like DWP-450 requires possession of a BTX Strain, suitable manufacturing facilities and equipment, and knowledge of a proprietary manufacturing process.

i. The BTX Strain: *C. botulinum*

38. *C. botulinum* is a strictly anaerobic bacterium meaning it can only survive in zero-oxygen environments. Generally, it is an endospore-forming bacterium, which means that when it is exposed to adverse environments (*e.g.*, too much oxygen) or deprived of needed nutrients (*e.g.*, proteins and carbohydrates), it does not simply die, but rather retreats into a dormant form, which is called an endospore. An endospore is the equivalent of a plant seed, only highly resistant to environmental conditions. As discussed below, however, *see infra* ¶ 37, the strain of *C. botulinum* at issue in this case – the Hall-A Hyper Strain – has never been known to form an endospore. Instead, it is known to die when exposed to air or deprived of needed

nutrients. *See* Exhibit X, which is a true and accurate copy of the Declaration of Theresa Smith, at ¶ 2.

39. *C. botulinum* produces seven known toxin types (A–G) and over 40 toxin subtypes. Different strains of *C. botulinum*, of which there are thousands, are classified according to the type of toxin the bacterium produces. Of these, botulinum toxin type-A are the most commonly used in the development of BTX products because this is the botulinum toxin type with the highest potency (needing the smallest amount to achieve efficacy) and the longest duration of action. *See* Exhibit X at ¶ 3.

40. An American researcher, Dr. Ivan C. Hall, discovered thousands of *C. botulinum* strains in the United States between 1920 and 1942. Dr. Hall named each strain he discovered by using a similar nomenclature: "Hall" followed by a unique numerical identifier. These strains are commonly referred to collectively as "Hall strains." *See* Exhibit X at ¶ 2.

41. In 1943, Dr. Elizabeth McCoy and William Sarles reportedly discovered that one particular Hall type-A strain had the ability to produce more toxin per unit of culture than any other strain tested. This Hall strain quickly became the bacterium of choice for researchers. At some point during its transfer between laboratories, the unique identifier assigned to this particular Hall strain was lost. The strain has since become known variously as "*the* Hall strain" and the "Hall-A Hyper Strain." This strain is hereinafter referred to as the Hall-A Hyper Strain. *See* Exhibit X at ¶ 3. Medytox and Allergan both use the Hall-A Hyper Strain to manufacture their respective BTX products. *See, e.g.*, Confidential Exhibit Y, which is a true and accurate copy of the Declaration of Dr. Chang Hoon Rhee, at ¶ 22.

42. After being identified as a high-yield strain, a subculture of the Hall-A Hyper Strain was forwarded to the U.S. Army laboratory at Fort Detrick, Maryland, now known

as the U.S. Army Medical Research Institute of Infectious Diseases ("USAMRIID"). Subcultures were further transferred to the Food Research Institute ("FRI") at the University of Wisconsin-Madison. From there, the strain was provided to many laboratories around the world. All currently used subcultures of this strain likely originated from either USAMRIID or the University of Wisconsin-Madison. *See* Exhibit X at ¶ 4.

43. As early as 1957, researchers also identified a second unique feature of the Hall-A Hyper Strain: it did not form endospores when faced with an adverse environment or deprived of nutrients (*i.e.*, it did not "sporulate"); it died instead. *See* Exhibit X at ¶ 6.

44. The combination of being especially productive and non-sporulating makes the Hall-A Hyper Strain ideal for manufacturing BTX products. First, its productivity allows more toxin (and therefore BTX product) to be made from the same amount of bacterium. *See* Exhibit X at ¶ 3. Second, endospores risk contaminating equipment, which makes a non-sporulating BTX Strain more predictable and preferable for BTX product manufacturing.

45. Because the toxins produced by the bacterium are among the most dangerous in the world, the availability and transportation of BTX Strains and the toxins they produce have been strictly controlled by national authorities like the Centers for Disease Control and Prevention ("CDC") since at least the 1990s. In response to the September 11, 2001 terror attacks and the anthrax mailings in 2001, the USA PATRIOT Act, 18 U.S.C. § 175b, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 restrict the transfer and possession of dangerous biological agents or toxins known as "select agents." 42 U.S.C. § 262a. Due to the threat it poses to human health, botulinum toxin has always been classified as a select agent. 42 C.F.R. § 73.3.

46. The U.S. Department of Health and Human Services classifies BTX Strains as "Tier 1 Select Agents" because of their "potential to pose a severe threat to public health and safety." 42 C.F.R. § 73.3. Records are generally kept of legal movement of BTX Strains within the United States and importation of BTX products into the United States is regulated by the FDA.

ii. Development of BTX Products

47. Manufacturing BTX products requires separation and purification of the botulinum toxin produced during the cultivation of the *C. botulinum* bacterium by using a tailored manufacturing process that requires deep biopharmaceutical and microbiology expertise and advanced technologies. This multi-step process involves (1) cultivation of the strain stock to commercially viable quantities (*i.e.*, turning a small amount of the strain into a larger amount of the strain), (2) separation and purification of the botulinum toxin from the culture medium, and then (3) formulation of the toxin into a stable drug product for distribution.

48. **Microbial culturing**. Microbial culturing of the strain stock requires creating a "medium" that contains essential nutrients for the bacterium to use, which allows the bacterium to replicate. A certain quantity of bacterium is necessary to produce commercial amounts of toxin. The "medium" consists of a liquid broth composed of ingredients that are carefully chosen and precisely measured. The bacterium is added to the medium in a temperature- and acidity-controlled environment for a defined period of time. During this time, the bacterium exponentially replicates and eventually undergoes a process called "lysis." During lysis, the walls of the bacterium disintegrate and release the desired toxin.

49. **Separation and Purification**. Once the botulinum toxin has been released into the culturing medium, the toxin must be separated from other undesirable

substances, including other proteins and remaining bacteria. This involves several stages of sophisticated biochemical processes to remove unwanted materials. Each of these steps is chosen and carried out in a manner designed to achieve optimal productivity and purity. At the end of this phase, the resulting product is the final purified toxin, also referred to as the drug substance ("Drug Substance").

50. **Formulation Into A Drug Product**. The final purified toxin is combined with stabilizing agents before being packaged and distributed for use.

51. This process of turning a BTX Strain into a usable BTX product differs among BTX product manufacturers, reflecting years of research and development and considerable investment, and each company zealously guards its process as a trade secret.

b. Medytox's BTX Strain and Manufacturing Process Comprise Protectable Trade Secrets.

52. The trade secrets in this case are Medytox's manufacturing process for Meditoxin® and its BTX strain, which were misappropriated by Daewoong and used to develop DWP-450. For the reasons set out below, these comprise economically valuable, protectable, trade secrets that are not generally available and upon which Medytox has founded its business.

53. Meditoxin® is a BTX product manufactured by Medytox in Korea. It is not currently for sale in the United States but is currently registered for sale in over 30 countries (under various brand names), including Korea.

54. MT10109L is a BTX product also manufactured by Medytox in Korea. MT10109L is a variation of Innotox® (nivobolinumtoxinA), a BTX product also manufactured and sold by Medytox in Korea. MT10109L and Innotox® are liquid-form, animal-protein-free variations of Meditoxin®, which is sold in powder form and uses animal proteins during the manufacturing process. As noted, Medytox and Allergan have entered into an exclusive

licensing agreement pursuant to which Allergan will distribute MT10109L in the United States. Allergan began the initial steps of Phase III clinical trials of MT10109L in Fall 2018.[13]

55. Meditoxin® and MT10109L are manufactured using the Hall-A Hyper Strain. Medytox's acquisition of the Hall-A Hyper Strain is set out in further detail in Confidential Exhibit Z, which is a true and accurate copy of the Declaration of Dr. Hyun Ho Jung, at ¶ 10.

56. Dr. Hyun Ho Jung founded Medytox in 2000 to continue his research and development efforts related to the Hall-A Hyper Strain. *See* Confidential Exhibit Z at ¶ 2.

i. Medytox Invested Substantial Resources To Develop the Meditoxin® Drug Substance.

57. Since 2000 Medytox continued its research and development efforts, working to optimize the manufacturing process for a BTX product. This required a substantial investment by Medytox. Specifically, Medytox spent approximately [redacted] in funding from outside investors and significant human capital on research and development to cultivate its Hall-A Hyper Strain, eventually perfecting a manufacturing process designed to produce the Drug Substance and the final product Meditoxin®. Between the founding of the company in 2000 and the completion of Meditoxin clinical trials in 2006, Medytox had grown from having two employees to a team of 60 employees. *See* Confidential Exhibit Z at ¶ 14.

58. While academic literature describes in general terms how type A botulinum toxin could be produced for research purposes, the botulinum toxin separation and purification processes described in the academic literature are different from the processes

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[13] U.S. Nat'l Library of Med., *MT10109L in the Treatment of Glabellar Lines With or Without Concurrent Treatment of Lateral Canthal Lines*, https://clinicaltrials.gov/ct2/show/NCT03721016 (last visited Dec. 27, 2018).

employed in commercial botulinum toxin production process. Accordingly, the literature does not provide the technical know-how and processes required to commercialize a BTX product. When Medytox was founded, Allergan and Ipsen were the only two companies in the world to have successfully manufactured a BTX product from a BTX Strain and their manufacturing processes were not publicly known. Even now, companies zealously guard the secrecy of their BTX product manufacturing processes. *See* Confidential Exhibit Z at ¶ 23.

59. Medytox's process is the product of meticulous, time-consuming, and expensive research that generated substantial know-how for Medytox in the form of confidential and proprietary intellectual property – *i.e.*, trade secrets – relating to the manufacturing of its BTX product, Meditoxin®. Medytox documented the processes that it developed through its extensive research and development in a document referred to as the Batch Record ("Batch Record"). *See* Confidential Exhibit Z at ¶ 15. The Batch Record is the most sensitive and closely-guarded document any BTX manufacturer would have, and was so for Medytox.

60. The Batch Record explains in detail the entire step-by-step manufacturing process for the Meditoxin® Drug Substance. It is Medytox's ultimate blueprint for making botulinum toxin. For each step of the manufacturing process, the Batch Record explains: (1) the raw materials that are needed and in what quantities; (2) the equipment that is needed, including the proper calibration and use in the process; (3) step-by-step instructions on what to do with the raw materials and equipment; and (4) other special instructions and safety precautions. These are items not found in the publically-accessible literature. Moreover, the Batch Record is an integrated sequential process, whereby the output of one step is the input for the next step. The details of this process are unique to each manufacturer and highly valuable. *See* Confidential Exhibit Y at ¶ 26.

61. The information contained in Medytox's Batch Record is not and never has been publicly available. To the contrary, Medytox guards it as one of its most important trade secrets. *See* Confidential Exhibit Y at ¶ 26.

62. In addition to the Batch Report, Medytox also prepared what is called a Characterization Report for the Botulinum Toxin Type A (the "Characterization Report"). Every Drug Substance has certain characteristics. These characteristics include physiochemical properties, structural characterization and conformation, biological activities, immunological properties, and purity, among others. Because approval from a regulator such as the FDA to manufacture and sell a BTX product requires a manufacturer to describe in considerable detail these characteristics of the Drug Substance, identifying the specific characteristics of a Drug Substance product is critical. This is a time consuming, challenging, and costly task, requiring the analysis of many batches of the Drug Substance using sophisticated technology.

63. Accordingly, Medytox devoted substantial resources to identifying and testing the characteristics of the Meditoxin® Drug Substance. Medytox memorialized the characteristics of the Meditoxin® Drug Substance, *i.e.*, the comprehensive testing procedures used to assess the Meditoxin® Drug Substance's characteristics and the result of those testing procedures, in a Characterization Report for the Botulinum Toxin Type A.

64. The Characterization Report also details the specific tests that Medytox conducted to determine each individual characteristic of the Meditoxin® Drug Substance – its physiochemical properties, structural characterization and conformation, biological activities, immunological properties, and purity – and the results of each test. Supporting the Characterization Report are separate documents that provide additional detail about each test

Medytox ran to determine the characteristics of the Meditoxin® Drug Substance and the results of those tests.

65. The information contained in Medytox's Characterization Report is not now and never has been publicly available. To the contrary, Medytox guards it as one of its most important trade secrets. *See* Confidential Exhibit Y at ¶ 26.

66. The Batch Record and the Characterization Report contain nearly all the information needed to develop a BTX product. As discussed below, BK Lee printed 17 copies of the entire Batch Record and 2 copies of the Characterization Report, among other things. And the evidence indicates that BK Lee subsequently provided those documents to Daewoong.

ii. Medytox Made A Substantial Investment to Develop its Manufacturing Facility.

67. An integral part of developing a process to produce a BTX product is having a facility capable of manufacturing BTX products. Because of the exceptional potency of the toxin produced by BTX Strains, among other reasons, a BTX product manufacturing facility must be carefully designed and constructed.

68. Details of Medytox's current manufacturing facility are outlined in its Project and Quality Plan for Construction of the Botulinum Toxin Type A Complex Facility ("Project and Quality Plan"), including four of its attachments entitled List of Materials and Containers, Process Flow Diagram, Process Block Diagram, and Process Parameters and In-Process Control Limits.

69. As Medytox was developing Meditoxin®, it was also accumulating substantial knowledge about how to optimize a manufacturing facility, including the specific equipment and calibrations needed to manufacture a Drug Substance that was safe and commercially viable.

iii. Medytox's Investment in Meditoxin® Supported Korean Government Approval for Meditoxin® As The First Korean BTX Product.

70. [redacted] *See* Confidential Exhibit Z at ¶ 17.

71. [redacted] As Korean regulations at the time did not require non-clinical trial data for the approval of clinical trials, both clinical and non-clinical trials ran concurrently. *See* Confidential Exhibit Z at ¶ 17.

72. [redacted] in March 16, 2006, Medytox obtained product approval for Meditoxin® from the Korean Ministry of Food and Drug Safety. Medytox then began manufacturing and selling Meditoxin® in Korea.

73. In total, it took Medytox approximately [redacted] and cost approximately [redacted] to develop Meditoxin® and bring it to market in Korea.

74. The regulatory approval process in Korea at the time Medytox was developing Meditoxin® was substantially different from the process in place when Daewoong was developing and working toward regulatory approval for its BTX product. Operating under the regulatory process in place when Daewoong was working to win regulatory approval for its BTX product would likely cost much more and take longer as compared to the process in place when Medytox developed and obtained regulatory approval for Meditoxin®. *See* Confidential Exhibit Z at ¶ 20.

75. Since the launch of Meditoxin® in 2006, Medytox has expanded to become prominent in the Korean and worldwide biopharmaceutical market. Rigorous randomized controlled experiments have recognized the safety and efficacy of Meditoxin®. As of 2009, Medytox's market share in the Korean BTX product market was 34%. By 2015, Medytox's market share grew to nearly 40% and further growth is expected.[14]

iv. Medytox's Trade Secrets Have Supported Further Development Of An Innovative New Product –Innotox®.

76. Beginning in 2006, Medytox began researching and developing another BTX product that does not use animal-based proteins in the manufacturing process in order to expedite the regulatory approval process which contains more stringent requirements for products using animal-based proteins. *See* Confidential Exhibit Z at ¶ 25.

77. Medytox was able to take advantage of the years of research and development it had already invested in developing Meditoxin® to develop a BTX product that uses only non-animal proteins during the manufacturing process. Medytox brought the resulting BTX product, Innotox®, to market in Korea in June 2014. *See* Confidential Exhibit Z at ¶ 27. Innotox® is also in liquid form, in contrast to Meditoxin® which is in powder form. Unlike powder-form BTX products, which require reconstitution before use, Innotox® is sold pre-packaged for immediate use.

78. Medytox's experience developing Meditoxin® was directly relevant and helpful to its development of Innotox®. The process for developing Meditoxin® provided the foundational backbone for the manufacturing process for the Innotox® Drug Substance. [redacted]

[14] Medytox, *Medytox Home Page*, http://www.medytox.com/page/company_en?site_id=en (last visited Dec. 6, 2018).

[redacted] *See* Confidential Exhibit Y at ¶ 22.

79. On September 25, 2013, Medytox executed a supply and license agreement with Allergan for the distribution of MT10109L, a variation of Innotox®, in the United States (the "Medytox Agreement"). Under the terms of the Medytox Agreement, which in total is worth up to $362 million, Allergan paid Medytox an upfront payment of $65 million in exchange for exclusive rights worldwide, outside of Korea, to develop and commercialize MT10109L and other toxin products in development. Allergan also agreed to make milestone payments up to an aggregate of $116.5 million for certain development milestones and up to an aggregate of $180.5 million for certain commercialization milestones and sales royalties.[15]

80. On August 27, 2018, Allergan and Medytox submitted an Investigational New Drug application to the FDA and the initial steps of Phase III clinical trials for MT10109L in the United States began in Fall 2018. Both MT10109L and DWP-450 were developed for the same indication: the treatment of glabellar lines.

c. Medytox Took Extensive Steps To Protect Its Trade Secrets.

81. While developing Meditoxin®, Medytox obtained and created an enormous amount of valuable confidential and proprietary information. Medytox engaged in years of research and development to find the optimal manufacturing process for the optimal drug substance that it could manufacture in the optimal factory. As discussed, the results of these efforts were recorded in the Batch Record, Characterization Report, and the Project and Quality Plan, among other documents. In addition, Medytox's Hall-A Hyper Strain is itself very

[15] *Allergan, Inc. and Medytox, Inc. to Enter into Licensing Agreement*, Bus. Wire (September 25, 2013), https://www.businesswire.com/news/home/20130925006570/en/Allergan-Medytox-Enter-Licensing-Agreement.

valuable and was acquired by Medytox in exchange for valuable consideration as described in Confidential Exhibit Z at ¶ 10. Medytox's years of research reflected in the Batch Record, Characterization Report, the Project and Quality Plan, and other documents, and its ownership of the Hall-A Hyper Strain, therefore, were Medytox's commercial advantage over its competitors or its would-be competitors, and these items are of exceptional value to Medytox.

82. With access to Medytox's trade secrets, described above, and with a suitable BTX Strain such as Medytox's Hall-A Hyper Strain, a competitor would have everything necessary to create its own BTX product that competes with Medytox's BTX products. Not only would the competitor be able to enter the market with a competing product, but it would be able to do so without having invested even a fraction of the resources or time in research and development that Medytox and other companies such as Allergan had to invest to get to the same point. The competitor would not only be able to compete with Medytox, but it would have an enormous cost advantage over Medytox.

83. Given the importance of these items to Medytox's commercial advantage and success, Medytox guarded them carefully.

84. *First*, Medytox had in place physical and technological safeguards to ensure the security of its computer systems, which contained its trade secrets. All of Medytox's computers, tablets, and smart phones were password protected, had security firewalls, and employed encryption technology. *See* Confidential Exhibit AA, which is a true and accurate copy of the Declaration of Woo Han Kim, at ¶ 6; Confidential Exhibit D, which is a true and accurate copy of Medytox's Orientation Material for New Hires – Introduction to Our Security System, at 19-24; Confidential Exhibit E, which is a true and accurate copy of Medytox's PC Security Management Rules, at 5-6.

85. All incoming employees were also given training on Medytox's confidentiality and information security policies. Employees were instructed, for example, that sending data or information, especially decrypted information, through a personal email account is prohibited. Employees were also instructed that no printouts of Medytox documents should be taken outside of the company offices. *See* Confidential Exhibit D at 26. In October 2007, BK Lee was in charge of ensuring that all of the employees of the laboratory in which he worked signed a revised confidentiality agreement incorporating these requirements. *See* Confidential Exhibit AA at ¶ 7; *see also* Declaration of Woo Han Kim, Confidential Exhibit 2.

86. In addition, employee access to Medytox's trade secrets was on a need-to-know basis. Not all employees had access to all of Medytox's data. Employees were only given access to trade secrets and other proprietary information if they needed to access it in order to perform their job. *See* Confidential Exhibit AA at ¶ 15.

87. In August 2007, Medytox further upgraded its security systems, including blocking physical and web source storage, using Cautus-CM, an internal security server, to monitor company email and personal email sent from company servers; using Secuprint to track printing of company documents; and auto-encrypting all files. *See* Confidential Exhibit F, which is a true and accurate copy of Medytox Information Security System Establishment Project, at 5; *see also* Confidential Exhibit D at 20, 23; Confidential Exhibit E at 8; Confidential Exhibit AA at ¶ 6.

88. These safeguards were intended to prevent the improper misuse, theft, or disclosure of electronically-stored proprietary information or trade secrets related to Medytox's research and development efforts.

89. *Second*, Medytox had safeguards in place to protect its Hall-A Hyper Strain from misappropriation. At all relevant times, Medytox stored its Hall-A Hyper Strain in a high-security storage facility equipped with a security system to restrict access. Access to the facility was restricted by sensor technology to a select group of employees. BK Lee's supervisor had access to Medytox's Hall-A Hyper Strain and BK Lee could ask his supervisor for access to the Hall-A Hyper Strain to conduct certain tests. Any access to the Hall-A Hyper Strain was (and still is) strictly monitored, controlled, and permitted only on a need-to-use basis. *See* Confidential Exhibit AA at ¶ 10.

90. *Finally*, all of Medytox's employees were required to sign confidentiality agreements governing, among other things, the use of Medytox's proprietary information and trade secrets. The agreement BK Lee signed expressly stated that the confidentiality obligations described remain in effect after termination of employment. In signing the agreement, employees agreed, among other things, to:

a. Only use information obtained from Medytox in connection with his or her employment at Medytox;
b. Not disclose any of Medytox's confidential information to unauthorized third parties;
c. Protect Medytox's "information assets such as trade secrets;"
d. Comply with the Company's policies related to the use of email, including to only transmit or receive information related to Medytox's business through his or her Medytox email account; and
e. Return Medytox's confidential information to Medytox upon termination of employment.

See Declaration of Woo Han Kim, Confidential Exhibit 1.

d. DWP-450 Was Developed Through The Misappropriation of Medytox's Trade Secrets.

91. The evidence supports the conclusion that DWP-450 was developed through the misappropriation of Medytox's trade secrets stolen from Medytox by BK Lee. Specifically, and as discussed at further length below:

a. Medytox's electronic records clearly demonstrate that BK Lee stole its confidential manufacturing information, and there is strong circumstantial evidence that he also stole a physical sample of its BTX strain itself.

b. After leaving Medytox in August 2008, BK Lee began consulting for Daewoong from at least 2010 to 2011, the same time Daewoong was developing DWP-450.

c. Daewoong made payments to BK Lee under circumstances that do not appear to correspond to the consulting services that he purportedly provided to Daewoong.

d. The timeline of Daewoong's development of DWP-450 was implausibly short: Without any staff experienced in the development of BTX products, Daewoong claimed to identify its own BTX strain in a matter of weeks from roughly 200 soil samples and then applied to begin clinical trials on its own BTX product less than two years later.

e. The origin story Daewoong has told (that it discovered a non-sporulating, Hall-A BTX strain in the soil) is scientifically impossible.

f. Daewoong has repeatedly resisted any testing of its BTX strain or disclosure of gene sequencing information that would resolve whether the strain from which DWP-450 is developed is the same as Medytox's strain.

92. This evidence, and the evidence that Medytox expects to illicit from Daewoong, Evolus and others if an Investigation is instituted, will conclusively establish that DWP-450 is the product of misappropriation of Medytox's trade secrets in contravention of 19 U.S.C. § 1337(a)(1)(A).

i. BK Lee had access to and stole documents reflecting Medytox's most closely guarded trade secrets regarding its manufacturing processes.

93. BK Lee graduated from Hanyang University in 2004 with a master's degree in chemical engineering. His degree in chemical engineering has little relevance to the manufacture of BTX products. He joined Medytox and worked in its Research and Development group from 2004 to 2008 in lieu of serving in the military under Korea's Substitutional Military Service Program pursuant to the Military Service Act. BK Lee resigned in August 2008, promptly after fulfilling his service requirement. A true and accurate copy of BK Lee's letter of resignation is attached as Confidential Exhibit I.

94. BK Lee was a researcher at Medytox and was involved with projects such as strain cultivation and analysis of the properties of the Hall-A Hyper Strain. At times, his responsibilities included tasks concerning the manufacturing process of BTX products and developing a new working cell bank. When a BTX Strain is to be used over multiple manufacturing cycles and for many years (*i.e.*, a company intends to cultivate it many times for different batches of a Drug Substance), a company maintains both a "master cell bank" and a "working cell bank." The master cell bank maintains the original BTX Strain. The working cell bank is produced from the master cell bank and contains the BTX Strains used for testing and manufacturing. BK Lee had access to Medytox's Hall-A Hyper Strain. BK Lee's job responsibilities also required that he have access to the Batch Record, along with other proprietary information related to Medytox's BTX product manufacturing process, including specific information pertaining to Meditoxin® and Innotox®.

95. In August 2007, BK Lee became involved with Medytox's construction of a new manufacturing facility that was intended to manufacture a new BTX product. Although this project was shortly abandoned by Medytox, BK Lee provided design assistance for the new

manufacturing facility, which included overseeing equipment purchases and drafting documents that outlined the manufacturing process and the specialized equipment and tools needed to carry out that process.

96. Like all Medytox employees, BK Lee was required to protect Medytox's trade secrets. He signed a confidentiality agreement when he first joined Medytox in 2004 and then again in 2007. These confidentiality obligations required BK Lee to, among other things, only use Medytox's proprietary information in connection with his employment, protect that information as trade secrets, and not disclose any of Medytox's confidential information to unauthorized third parties. These obligations continue even after BK Lee left Medytox's employ. *See* Confidential Exhibit AA at ¶ 6; *see also* Declaration of Woo Han Kim, Confidential Exhibit 1. BK Lee violated his confidentiality obligations and stole Medytox's trade secrets by emailing himself and printing key documents that he would later pass on to Daewoong.

97. Medytox maintained information technology security records which tracked how its employees engaged with its systems. These included systems that allow for the tracking and review of employee emails and logging of all documents printed on Medytox computers.

98. On November 2, 2007, BK Lee emailed to his personal email address (under the deceptively-innocuous subject line "BK Lee Documents") the Project and Quality Plan and four of its attachments, which included details such as (a) an overview for manufacturing BTX products, (b) the hardware equipment that constituted Medytox's

manufacturing line, (c) blueprints for key components, (d) equipment specifications, and (e) diagrams for the manufacturing process.[16]

99. In the same November 2, 2007 email to himself, BK Lee also included the "Experimental Batch Record," which Medytox used to record experiments conducted on the Innotox® Drug Substance as it was being developed. *See* Confidential Exhibit AA at ¶ 19; *see* Declaration of Woo Han Kim, Confidential Exhibit 3; *see* Declaration of Woo Han Kim, Confidential Exhibit 4.

100. Then, on February 20, 2008, BK Lee printed at least 17 copies of the entire Batch Record. *See* Confidential Exhibit AA at ¶ 20; *see* Declaration of Woo Han Kim, Confidential Exhibit 5.

101. Thereafter, between February 2008 and July 2008, BK Lee also printed at least two copies of the Characterization Report (on February 20, 2008 – the same day he printed the 17 copies of the Batch Record – and March 3, 2008) and several copies of various documents detailing the various tests, test results, and analyses that underlie the Characterization Report. As previously discussed, the Batch Record and Characterization Report contained valuable trade secrets that resulted from years of research and development. With these documents, a competitor would have the necessary know-how to create the Meditoxin® Drug Substance or any other BTX Drug Substance. *See* Confidential Exhibit AA at ¶ 20; *see* Declaration of Woo Han Kim, Confidential Exhibit 5.

102. BK Lee had no legitimate reason or business justification for emailing to himself and printing Medytox's most sensitive documents. (According to Medytox's records,

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[16] A true and correct copy of a December 26, 2007 email from BK Lee to Bevis Lee with the subject: "Here is the draft specification," is attached as Confidential Exhibit J (showing BK Lee's personal email address was "[redacted]")

BK Lee never printed the Batch Record again. *See* Declaration of Woo Han Kim, Confidential Exhibit 5.) Though he had access to the Batch Record as part of his job responsibilities as a researcher working on strain cultivation and undiluted solution development, he had no business purpose for printing the entire Batch Record once, let alone 17 times on the same day. Rather, doing so was contrary to his confidentiality agreement and the professional obligations that he owed to Medytox as his employer.

103. BK Lee's theft of Medytox's trade secrets also coincided with his search for a new job. In June 2008, BK Lee informed his supervisor, Dr. Chang Hoon Rhee, a Vice President and head of the Biopharmaceutical Department, that he intended to leave Medytox in the near future. *See* Confidential Exhibit Y at ¶ 32. By July 2008, BK Lee had secured a new paid teaching position at Hanyang University. (As noted, he left Medytox in August 2008.) *See* Confidential Exhibit I; Confidential Exhibit K (July 22, 2008 email with subject line "This is Byung Kook Lee who will be joining as of July 28, 2008"), which is a true and accurate copy of Medytox's record of emails sent by BK Lee on July 24, 2008. The only possible inference is that BK Lee perceived that the documents he stole from Medytox would have some value to him once he left Medytox.

ii. <u>BK Lee also had access to Medytox's BTX Strain, and the evidence is consistent with him having stolen a sample of it.</u>

104. BK Lee also had the opportunity to steal Medytox's Hall-A Hyper Strain itself, and the evidence indicates he did. According to BK Lee's research notes, he accessed the Hall-A Hyper Strain in May 2008 to conduct experiments. *See* Declaration of Dr. Chang Hoon Rhee, Confidential Exhibit 1. After conducting the experiment, BK Lee could have stored the remaining samples of the Hall-A Hyper Strain in vials used in Medytox's laboratory, and likely did. BK Lee could then have taken those vials and taken them out of Medytox's premises in a

pocket or briefcase, and likely did. The vials containing the Hall-A Hyper Strain could then have been stored in any commercially available freezer, and likely were, and the strain would have remained viable until they were transferred to Daewoong.

iii. After leaving Medytox, BK Lee provided the strain and Medytox's manufacturing know-how to Daewoong.

105. BK Lee has admitted in court filings that after leaving Medytox (taking with him reams of Medytox's most confidential information and likely its Hall-A Hyper Strain), he went to work as a biosafety consultant at Daewoong. *See* Exhibit L, which is a true and accurate copy of the Declaration of Byung Kook Lee in Support of Specially Appearing Byung Kook Lee's Notice of Motion and Motion to Quash Service of Summons for Lack of Personal Jurisdiction and Joinder in Daewoong Defendants' Motion to Dismiss for *Forum Non Conveniens*, at 5. This is striking because BK Lee had no prior experience, either through his education or on the job experience, related to biosafety.

106. The timing of BK Lee's departure from Medytox, armed with its most critical business secrets, coincided almost exactly with Daewoong's need to obtain a replacement for BOTOX®, which it distributed under a 1995 licensing agreement with Allergan (the "Allergan Agreement").

107. In February 2006, Allergan gave Daewoong notice that it would be terminating the licensing agreement, touching off a frantic search by Daewoong for a replacement product. *See* Confidential Exhibit C, which is a true and accurate copy of the Letter from Allergan Asia Ltd. to Daewoong, "Re: Termination of Distributorship Agreement," dated Feb. 1, 2006.

108. In December 2008, Allergan and Daewoong terminated the Allergan Agreement pursuant to which Daewoong had been distributing BOTOX® in Korea. [redacted]

[redacted]

109. After the termination of the Allergan Agreement, Daewoong was under considerable economic pressure to find a replacement BTX product to distribute in Korea. Daewoong's distribution agreement with Allergan had provided approximately [redacted] in yearly revenue at the time it was terminated. Daewoong even engaged in failed negotiations with Medytox from May 2009 to January 2010 in an unsuccessful attempt to license another BTX product manufactured by Medytox, Coretox®, to distribute in Korea. *See* Confidential Exhibit Z at ¶ 33. Daewoong also approached Ipsen (which manufactures Dysport®) to see if Daewoong could negotiate a licensing agreement with them. These efforts proved to be unsuccessful. *See* Confidential Exhibit BB, which is a true and accurate copy of the Declaration of KwangJun Ryu, at ¶¶ 9-10.

110. BK Lee has admitted under oath that he worked as a biosafety consultant to Daewoong between at least 2010 and 2011, a concession that was necessary in order to explain the substantial compensation provided to him by Daewoong. *See supra* ¶ 104. In fact, however, Medytox believes that BK Lee began providing assistance to Daewoong either before or shortly after departing from Medytox in 2008.

111. In fact, Daewoong's head of development, Chang Woo Suh, told a former Daewoong employee, KwangJun Ryu, that he was given the strain. KwangJun Ryu is currently a

Medytox employee, but previously worked at Daewoong from February 2004 to March 2014. While KwangJun Ryu was employed at Daewoong, Chang Woo Suh told him that Chang Woo Suh had obtained the BTX strain and other materials for their BOTOX® replacement from a university friend. *See* Confidential Exhibit BB at ¶ 12. This "friend" must be BK Lee. Both Chang Woo Suh and BK Lee studied under the same professor at Hanyang University, worked in the same lab, and collaborated on a study with that same professor. *See* Confidential Exhibit BB at ¶ 13; Declaration of KwangJun Ryu, Exhibit 1. Chang Woo Suh even thanked BK Lee in the acknowledgment section of his Ph.D. dissertation. *See* Declaration of KwangJun Ryu, Exhibit 2.

112. Obtaining Medytox's trade secrets from BK Lee thus solved an existential problem for Daewoong, permitting it through minimal research and development to bring to market a highly-competitive BTX product just when it desperately required a replacement for the revenue it previously obtained from distributing BOTOX®.

iv. Daewoong's statements regarding the origin of its BTX strain are highly improbable

113. The explanation Daewoong has told the market, the Korean Ministry of Food and Drug Safety, and others about the acquisition of its BTX Strain is highly improbable.

114. Daewoong has claimed that it found a Hall-A strain in soil in the Yongin, Gyeonggi-do. *See* Confidential Exhibit G, which is a true and accurate copy of the Isolation and Characterization of Daewoong *Clostridium botulinum* Type A Hall strain, at 2; *see* Confidential Exhibit H, which is a true and accurate copy of the Daewoong Submission to Director of Korea Centers for Disease Control and Prevention, Re: Notification of the high-risk pathogen isolation, dated July 19, 2010; *see* Confidential Exhibit M, which is a true and accurate excerpt of Daewoong's Answer to Medytox's Korean Civil Complaint, at 11. Daewoong has repeatedly confirmed that its strain is both a Hall strain and a Hall-A strain.

115. In an October 2014 submission to GenBank, a public genetic sequence database, Daewoong identified the strain used in DWP-450 as a Hall-A strain.[17] Daewoong only submitted the portion of its DWP-450 strain that would be the same for all type A strains, when Daewoong could have submitted the entire genetic sequence so as to permit the resolution of the question about the origins of Daewoong's strain.

116. At a 2015 conference in Dubai, key opinion leaders for DWP-450 who were tasked with presenting on it, stated that the BTX Strain used in DWP-450 was a "Hall strain." *See* Confidential Exhibit Z at ¶ 34.

117. In a U.S. patent application filed on June 22, 2015, Daewoong identified the strain it used to produce DWP-450 as "Wild-type hall" "type A," referring to the same Hall strain used to produce BOTOX®. A true and accurate copy of Daewoong's U.S. Patent No. 9,512,418 B2 is attached as Exhibit N. BOTOX® uses the Hall-A Hyper Strain.[18]

118. Daewoong has never explained how it located a Hall-A strain (*i.e.*, a strain isolated in the United States by Dr. Hall) in the soil in Korea in 2010. As a preliminary matter, Daewoong could not have identified any "Hall" strain in soil. Hall strains are those that were identified by Dr. Hall, and any Hall strain must have a provenance relating back to one of the strains identified by Dr. Hall. At the very least, if Daewoong's claim that it isolated its BTX Strain from soil in Korea were to be believed, it has misidentified the strain it is using by calling it a "Hall" strain.

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[17] *Clostridium botulinum strain Hall neurotoxin type A gene, complete cds*, Nat'l Ctr. For Biotechnology Info, https://www.ncbi.nlm.nih.gov/nuccore/KJ997761.1 (last visited Oct. 31, 2018).

[18] Marco Pirazzini et al., *Botulinum Neurotoxins: Biology, Pharmacology, and Toxicology*, 69 Pharmacology Rev. 200, 235 (2017).

119. Furthermore, as mentioned above, the Hall-A Hyper Strain has been found to be a non-sporulating strain. A non-sporulating strain would not be able to survive in an aerobic environment, such as a soil sample. Therefore, if Daewoong's strain is a non-sporulating strain, it could not have been isolated from a soil sample. But, according to documents received from Health Canada pursuant to the Canadian Access to Information Act, Daewoong "claimed within their submission that their C botulinum strain was non-spore forming" in its submission for approval to sell DWP-450 in Canada. Assuming that Daewoong was truthful in its submission to Health Canada and its strain indeed is non-spore forming, Daewoong's claim that it located its BTX Strain in Korean soil must be false. A true and accurate copy of the letter from Health Canada to Counsel for Medytox is attached as Exhibit O.

120. More than that, however, Daewoong must be misrepresenting its origin story for its BTX Strain. It is highly implausible that the DWP-450 project leader, Cheong Se Kim, who had been hired in June 2010, isolated a *C. botulinum* strain from random soil samples and identified all of its characteristics by June 24, 2010, as he claimed to Medytox's CEO.

[redacted] But, according to Daewoong's website, Cheong Se Kim only joined Daewoong in June 2010. *See* Exhibit P, which is a true and accurate copy of a Daewoong press release, ""Nabota" successfully exported to US, Europe, South America,

[19] Cheong Se Kim contradicted himself in the Korean criminal investigation and denied that he personally isolated the BTX Strain. *See* Confidential Exhibit Z at ¶ 35.

Argentina and Iran! Daewoong people contribute to the global advancement," at 1. He could not possibly have tested all of the approximately 200 soil samples for a viable *C. botulinum* bacteria in the same month he joined the company.

121. *C. botulinum* is a microorganism and isolating it from soil samples requires a particularized and unique skill set and laboratory. As a strictly anaerobic organism, only a skilled microbiologist with experience handling anaerobic organisms, working with toxin producing strains, and finding bacteria in nature could have performed the work. This is especially the case given the timeline Daewoong has presented. As importantly, the microbiologist would have needed access to specialized laboratory facilities and equipment that is capable of maintaining the zero-oxygen environment that would be necessary to do the requisite testing.

122. This process would have taken substantial know-how that Daewoong did not have. Cheong Se Kim had little to no experience working with *C. botulinum*. He studied farming at Seoul National University and proteins at New York Polytechnical University. He had no prior research on the separation and identification of microorganisms, including *C. botulinum*. Indeed, at a 2016 conference also in Dubai, Medytox's CEO Dr. Hyun Ho Jung spoke with Cheong Se Kim about how he purportedly was able to isolate the BTX Strain for Daewoong. During the course of the conversation, it became clear to Dr. Hyun Ho Jung that Cheong Se Kim did not have the necessary knowledge or experience to have isolated the BTX Strain himself.

123. Nor was Cheong Se Kim supported by a team with the requisite experience. His team consisted of Chang Woo Suh, Kyung Min Min, and Nam Hui Kim, none of whom had expertise with *C. botulinum*. Chang Woo Suh, for example, is a graduate of the

Department of Chemical Engineering at Hanyang University and has no prior research on microorganisms like *C. botulinum*. Moreover, Chang Woo Suh had been demoted from a research position to an administrative position. It was around 2010 or 2011 (at the same time that Daewoong purportedly began development of DWP-450) that Chang Woo Suh regained his position as a researcher. *See* Confidential Exhibit BB at ¶ 14. Therefore Chang Woo Suh had every incentive to make sure that the DWP-450 team was successful so that he could continue in his role as a researcher. Chang Woo Suh had strong personal motivations to help Daewoong misappropriate Medytox's trade secrets and its BTX Strain from BK Lee.

v. The timing and other circumstances of Daewoong's purported development of DWP-450 are implausible.

124. Even assuming Daewoong had legitimately obtained the Hall-A Hyper Strain, which it did not, the speed with which Daewoong was able to bring a BTX product to market is so implausible as to leave no inference other than that Daewoong had the benefit of receiving Medytox's manufacturing trade secrets.

125. Despite having an inexperienced research team, Daewoong purports to have been able to submit a strain manufacturing report and a toxin manufacturing report for DWP-450 on October 29, 2010. *See* Exhibit Q, which is a true and accurate copy of the Daewoong Pharmaceuticals Presentation, "The Current State of Biological Pharmaceutical Product Research and Development Using Botulinum Toxin," dated Sept. 7, 2012, at 13. That is, barely four months after finding a Hall-A Hyper Strain in a random soil sample (in a country where a Hall-A Hyper Strain has never before been found) and without the necessary approvals for a containment BSL2 facility, Daewoong (a company that had never before produced a BTX product) was able to describe the characteristics of its strain and represent to the Korean government the amount of toxins it sought permission to handle each year.

126. Complainants estimate that Daewoong began non-clinical studies on DWP-450 by June 2011, which involves laboratory tests and animal studies of the BTX product to test its safety and efficacy prior to administering the BTX product to humans in clinical trials. This would mean that it was able to develop a manufacturing process for the toxin product, standardize the product, and build a manufacturing facility, all within only 12 months. This is an implausibly short amount of time, particularly given the personnel, equipment, and facilities limitations discussed above.

127. In total, it took Daewoong a little over three years to develop DWP-450 and bring it to market in Korea, even though it did so purportedly from a BTX Strain isolated in nature and without any experience or apparently qualified staff involved in the process. Even according to Chang Woo Suh, bringing Nabota to market in such a short time frame was "miracle-like." Exhibit P at 2. In contrast, Medytox's development of Meditoxin® took [redacted], even with the relevant expertise and a laboratory-grade BTX Strain that was already isolated.

128. The speed of this BTX product development can only be explained if Daewoong leveraged Medytox's trade secrets (developed over nearly a decade) about how to produce a BTX product in its own manufacturing process and used Medytox's Hall-A Hyper Strain.

vi. Daewoong rewarded BK Lee for his theft.

129. BK Lee admitted in a California state court filing that he worked as a consultant for Daewoong from at least 2010 to 2011. *See* Exhibit L at 5. Daewoong admitted in a Korean court filing that it had paid BK Lee 120 million KRW (approximately $110,000) over two years for expert consulting services relating to biosafety and general management. *See* Confidential Exhibit M at 25. Upon information and belief, Medytox believes this consulting

arrangement lasted through 2013 when Daewoong received approval to sell Nabota® in Korea. Medytox also believes Daewoong indirectly paid BK Lee an additional approximately $140,000 through intermediaries. *See* Confidential Exhibit AA at ¶ 21.

130. It is improbable that Daewoong had a legitimate consulting arrangement with BK Lee because BK Lee was not qualified to provide biosafety consulting services on BTX Strains. Biosafety involves preventing leakages, managing disposal, and maintenance. In order to be a biosafety consultant, a license and relevant education and experience is required. In 2008, when BK Lee left Medytox, the biosafety regulations in Korea had not yet been established, and therefore he did not become an expert on biosafety regulations during his time at Medytox. Moreover, he did not receive his Ph.D. until August 2012, and his dissertation focused on the "Fabrication of biosensors and cell arrays by inkjet printing of polymers and biomolecules." A true and accurate excerpt of the BK Lee's doctoral dissertation is attached as Exhibit R.

131. In addition to the consulting arrangement, Medytox believes Daewoong arranged an advantageous placement in a post-doctoral position at Purdue University for BK Lee. In 2011, BK Lee moved to Indiana to work as a visiting scholar at Purdue University. While there, BK Lee worked with a professor who is closely affiliated with Daewoong, Professor Ki Nam Park. Professor Park is an acquaintance of the former CEO of Daewoong, Jong-Wook Lee, who was CEO at the time of BK Lee's placement at Purdue University. Professor Park and Jong Wook Lee are both alumni of the pharmacy school of Seoul National University. In 2014,

Professor Park was the recipient of the "KASBP-Daewoong Achievement Award," which was created by Jong Wook Lee.[20]

vii. Daewoong's manufacturing process was derived from Medytox's.

132. Upon information and belief, Daewoong is using the process described in a U.S. patent that it has obtained in its manufacture of Nabota®, and this manufacturing process was derived from Medytox's manufacturing process for Meditoxin® as outlined in the stolen trade secrets. [redacted]

[20] Korean American Society in Biotech and Pharmaceuticals, *2014 KASBP Fall Symposium* (November 2014), http://www.kasbp.org/Resources/Documents/2014%20KASBP%20Fall%20Symposium%20Program%20Final.pdf.

133. Thus, not only is the speed with which Daewoong developed Nabota® improbable, but, in addition, the similarities in the actual manufacturing process suggests that Daewoong misappropriated Medytox's trade secrets.

VI. DOMESTIC INDUSTRY

134. Pursuant to 19 C.F.R. § 210.12(a)(7), Complainants state that the relevant domestic industry under 19 U.S.C. § 1337(a)(1) is the domestic U.S. market for sale of BTX products, a mature, well-developed market in which the predominant products are Allergan's BOTOX® (onabotulinumtoxinA) and BOTOX® Cosmetic (onabotulinumtoxinA).

135. Before Allergan introduced BOTOX® in 1989, there was no market for BOTOX® or BTX products in the United States. Over the course of 30 years, Allergan has invested over [redacted] researching, developing, and expanding the BTX product domestic market in which BOTOX® is sold. Today, the size of the BTX product domestic market is approximately $3.5 billion annually and BOTOX®'s share of that market is approximately $2.5 billion annually.

136. Allergan has created a domestic industry that includes significant investments in research and development facilities, manufacturing and testing plants and equipment, employment of significant labor forces, and substantial investment in the exploitation of BOTOX® in the United States.

137. Allergan has engaged in, and is continuing to engage in, a wide range of qualifying domestic industry activities in the United States that center around BOTOX® and the forthcoming sale of Medytox's BTX product MT10109L pursuant to an Exclusive License Agreement between Medytox and Allergan.

138. BOTOX® is currently approved by the FDA and is commercially available in the United States for eight therapeutic and three cosmetic indications.[21] Allergan continues to conduct research and development on additional uses and indications, with different dosages, all of which are designed to exploit and expand the domestic industry that Allergan created.

139. Pursuant to an Exclusive License Agreement, Allergan is working together with Medytox to research, develop, test, and obtain FDA approval of MT10109L, which is a formulation of Medytox's liquid BTX product, Innotox® (nivobolinumtoxinA).

140. Allergan has made and continues to make significant investments in plants and equipment with respect to the Domestic Industry Products. In Irvine, California, Allergan owns and maintains five separate buildings and has built more than [redacted] of commercial space for the research, development, testing, manufacturing, and clinical operations of the Domestic Industry Products. In Campbell, California, Allergan owns more than [redacted] for the commercial manufacturing of Domestic Industry Products. In each location, Allergan owns and maintains specialized equipment purchased and designed for the research, development, testing, manufacturing, and clinical operations of the Domestic Industry Products. Allergan has made a capital investment of more than [redacted] in acquiring and building these facilities, and it spends (on average) [redacted] annually to maintain and operate them.

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[21] BOTOX® has been approved for nine therapeutic indications, but FDA has since combined the approvals for the treatment of adult upper limb spasticity and adult lower limb spasticity into a single indication on the BOTOX® label ("Treatment of spasticity in adult patients"). Thus, there are currently a total of eight therapeutic indications in the BOTOX® label.

141. Allergan has significant employment of labor and capital with respect to the Domestic Industry Products. Allergan has approximately [redacted] in the United States engaged in the research, development, formulation, manufacturing, support, clinical and non-clinical testing, sales, delivery and physician education of and for the Domestic Industry Products. On average, Allergan spends approximately [redacted] annually on each employee for salary, benefits, and overhead or approximately [redacted] annually for the labor force responsible for the Domestic Industry Products.

142. By partnering with Medytox on the research, development, and regulatory approval of MT10109L in the United States, Allergan continues to make significant and substantial investments in Domestic Industry Products. To date, Allergan has invested more than [redacted] on this project alone. Medytox has invested more than [redacted] to bring MT10109L to market in the United States pursuant to its partnership with Allergan. This includes research and development, building additional manufacturing facilities and buying additional equipment, and operations costs, including salaries.

143. Currently, Allergan is sponsoring two parallel Phase III clinical trials for MT10109L in the United States for two different medical indications. Clinical trials for the treatment of glabellar lines and clinical trials for the treatment of lateral canthal lines began in Fall 2018.

144. In 2017, Allergan's net revenues from all products was approximately $15.9 billion of which BOTOX® was the largest product segment accounting for approximately $3.2 billion, or 20% of net product revenues. This is the result of [redacted] of sustained and significant investments [redacted] made by Allergan in BOTOX® projects and activities.

145. Allergan's investment activities are important to the Domestic Industry Products and represent significant added value, particularly given that BOTOX®, a substantial portion of the Domestic Industry Products, is substantially designed and developed in the United States. Moreover, Allergan's investments and activities are significant and substantial in the context of comparable products, the company's overall investments, and the relevant marketplace.

146. Allergan spends the majority of its product-related investment in the United States. On average, Allergan spends approximately 88% of its total research and development budget on activities in the United States.

147. The activities and investments described above are explained in detail in the Declaration of Charles Schultes III, a true and accurate copy of which is attached as Confidential Exhibit CC, and the Declaration of Dr. Mitchell Brin, a true and accurate copy of which is attached as Confidential Exhibit DD.

VII. SUBSTANTIAL INJURY, THREAT OF SUBSTANTIAL INJURY, AND TENDENCY TO SUBSTANTIALLY INJURE

148. Pursuant to 19 C.F.R. § 210.12(a)(8), Complainants state that Respondents' acts of unfair competition has given Respondents an unfair and significant competitive advantage that will substantially and irreparably injure Complainants' domestic industry pursuant to 19 U.S.C. § 337(a)(l)(A)(i) in at least the following ways:

a. Creating a new competitor (Evolus) in the market for Domestic Industry Products that did not exist beforehand. Since its formation in November 2012, Evolus has focused on only one product to bring to market in the United States – DWP-450. But for DWP-450, Evolus has no product that will compete with the Domestic Industry Products. Evolus exclusively

licensed DWP-450 from Daewoong in 2013, which was developed from the trade secrets stolen from Medytox. Daewoong, acting alone and in concert with Evolus, could not have developed a BTX product, supplied such product to Evolus for clinical trials and filed for FDA approval to launch such product in the U.S. market in the timeframe alleged herein but for Respondents' theft and misuse of Medytox's trade secrets. The loss of valuable and confidential technical information to a new competitor, including the necessary design and development information to make and have approved a substantially similar BTX product without dedicating the time and resources otherwise required will substantially and irreparably injure Complainants' domestic industry;

b. Allowing Evolus to unlawfully and unfairly compete with Allergan and the Domestic Industry Products in a way and manner that would not have existed without the theft of Medytox's trade secrets. Through the misuse of Medytox's trade secrets, Respondents have produced and are seeking FDA approval to launch a BTX product (DWP-450) that is the exact same molecular weight as the Domestic Industry Products (900 kDa). By launching a product with the same molecular weight, Respondents intend to make a "High-Impact, Disruptive Launch" or attack on the Domestic Industry Products. *See* Exhibit S, at 3, 14, 20; *see also* Exhibit EE, which is a true and accurate copy of the Evolus, Inc., 8-K, dated Jan. 4, 2019, at 3.

c. No other U.S. competitor has such a BTX product. As a result, Complainants are forced to compete against a company that is using Medytox's trade

secrets, interfering with the rights Allergan obtained under its Exclusive License Agreement with Medytox;

d. Destroying the secrecy and confidentiality of Medytox's trade secrets has diminished and substantially impaired the value of such trade secrets directly to Medytox and to Allergan under the terms of its Exclusive License Agreement with Medytox, *see supra* Section VII;

e. Causing on-going and systematic damage to the competitive position that Complainants have established and the ability to successfully launch and introduce new products, including MT10109L, and new applications into the relevant marketplace; and

f. Reducing the goodwill that Allergan has built with physicians, distributors and the public by being a market leader and innovator in the BTX product marketplace.

149. Respondents are specifically targeting the domestic industry that Allergan has spent substantial funds and time to develop as described above.

150. In July 2017, Evolus filed a Biologics License Application (BLA) with the FDA seeking approval of DWP-450 for the treatment of glabellar lines (commonly known as "frown lines").[22] This is the exact same indication that Allergan obtained for BOTOX® in 2002, and it was the very first aesthetic indication that FDA ever approved for a BTX product. All of the clinical trials that Evolus has conducted and overseen in the United States have been focused on the treatment of glabellar lines; they have been conducted for no other purpose or indication.

[22] *See* Exhibit U, which is a true and accurate copy of Evolus' S-1 executed July 16, 2018, at 1.

151. On August 29, 2018, Evolus reported that FDA has set February 2, 2019 as the action date for approval on its BLA (commonly known as the Prescription Drug User Fee Act (PDUFA) date). If approved, Evolus has stated that it intends to launch DWP-450 commercially in the U.S. in Spring 2019.

152. In November 2018, Daewoong announced that it has unveiled a second production facility to meet global demand for Nabota®/DWP-450. Daewoong estimates that the new facility will be able to manufacture five million vials of product each year and has the potential to manufacture up to nine million vials per year.[23]

153. Evolus anticipates capturing 15% of the U.S. market within two years of commercialization of DWP-450. *See* Exhibit T, which is a true and accurate copy of the Transcript of Evolus Earnings Call, dated Nov. 5, 2018, at 5.

154. Nearly all of Evolus's management team consists of former Allergan employees, who had access to confidential and trade secret information belonging to Allergan during their employment. Chief among them is Evolus's President and Chief Executive Officer, David Moatazedi, who was employed at Allergan for more than 13 years and who served most recently as Allergan's Senior Vice President of U.S. Medical Aesthetics.

155. Evolus has stated clearly and unapologetically that DWP-450 has been designed, developed, and will be sold with the intention of targeting Allergan and the domestic industry that Allergan created. As David Moatazedi recently explained to Evolus's investors, "we believe that the combination of Allergan's investment and Evolus entering as a new player

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[23] *See* Exhibit W, which is a true and accurate copy of Daewoong's press release, "Daewoong Pharmaceutical built 2nd plant for Nabota with annual capacity of 4.5 million vials for international expansion," dated Oct. 10, 2017 at 1.

in the [BOTOX® market] will enable us to continue to accelerate what we believe to be a high-growth market for the foreseeable future." Exhibit T at 6.

156. Evolus has repeatedly declared that DWP-450 will be "a frictionless alternative to the market leader [BOTOX®]," which it expects to cause a "High-Impact, Disruptive Launch." Exhibit S at 3, 14, 20; Exhibit EE at 3; Exhibit T at 5.

157. Given that DWP-450 will be the first (and only) 900 kDa BTX product in the U.S. since BOTOX® was first approved, and given that Evolus is seeking approval for the exact same indication, there can be no question that Respondents intend to substantially injure Allergan's position in the domestic industry, and Evolus and Daewoong's importation of Accused Products to date for purposes of clinical trials in the United States has already begun to harm Allergan's position. As Evolus explains in its most recent Annual Report, "We believe aesthetic physicians' familiarity with the 900kDa toxin complex's handling, preparation and dosing [*i.e.*, BOTOX®] will more easily facilitate incorporation of DWP-450 into their practices."[24]

158. With the former Allergan team in-charge, Evolus is pursuing customers through "high-touch pre-launch activities" and has also convinced over 250 key physician opinion leaders to invest in Evolus and its singular DWP-450 product for the sole purpose of "creating financial alignment" between the Domestic Industry and Evolus's success.[25]

159. The damage caused by Respondents' actions is expected to cause an immediate loss of market share along with price suppression and erosion if FDA approval of DWP-450 is received. Further, Respondents' actions will cause damage to Complainants'

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[24] *See* Exhibit A at 4.

[25] *See* Exhibit A at 4; Exhibit EE at 3; Exhibit S at 3, 14.

reputation, including the loss of first mover advantage for Domestic Industry Products under development, including MT10109L. And, there is likely to be other damage that will become clear when DWP-450 is approved and launched based on the confidential and valuable trade secret information unlawfully obtained.

160. Evolus has announced that it intends to and will price its DWP-450 product lower than those of the Domestic Industry Products, specifically 20 to 25% lower than the price of BOTOX®, so as to capture significant portions of the BTX product market. Market analysts predict that Evolus could undercut the price of BOTOX® by as much as 30%.[26] With knowledge of Allergan's confidential pricing and marketing strategies, Evolus's President and CEO has stated that Evolus will have an advantage by offering "pricing flexibility unconstrained by reimbursement." Exhibit S at 16.

161. On information and belief, Complainants allege that the Respondents' costs of producing DWP-450 are significantly lower than the costs of producing BOTOX®, because, among other reasons, Respondents have not invested in the research and development and infrastructure necessary to bring a BTX product to market without the unlawful misappropriation of Medytox's trade secrets. Further, Daewoong manufactures DWP-450 in Korea, while Allergan manufactures its BOTOX® products in the United States, where labor, regulatory, environmental, and production costs are reasonably higher than those in Korea.

162. In addition, Daewoong used Medytox's trade secrets to unfairly and improperly usurp Medytox's efforts to enter the U.S. market through a partnership with Evolus.

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[26] GlobalData Healthcare, *Evolus's 'frown line' treatment Jeuveau could threaten Botox revenues*, Pharmaceutical Technology (Jan. 11, 2019), https://www.pharmaceutical-technology.com/comment/botox-competitor-jeuveau.

163. After its success in selling Meditoxin® in Korea, Medytox began exploring selling Meditoxin® in other countries. In January 2013, Medytox and Evolus began discussions regarding a supply and license agreement whereby Medytox would sell and supply Meditoxin® to Evolus for distribution in the United States. Medytox and Evolus exchanged a term sheet and proceeded to negotiate the terms and conditions of the anticipated agreement.

164. After the initial meeting between the CEOs of Medytox and Evolus in Korea on March 19, 2013, the CEO of Medytox visited Evolus in California for a follow-up meeting on May 7, 2013. *See* Confidential Exhibit Z at ¶¶ 39, 40.

165. Approximately four months later, on or about September 30, 2013, Evolus and Daewoong signed the Daewoong Agreement whereby Daewoong granted Evolus the exclusive license to import, distribute, promote, market, develop, offer for sale, and otherwise commercialize DWP-450 in the United States, among other countries.[27] Daewoong's use of Medytox's trade secrets to usurp Medytox's negotiations regarding the importation of Meditoxin® constitute unfair trade practices in the importation of DWP-450 causing injury to Medytox.

166. Pursuant to 19 C.F.R. § 210.12(a)(8), Complainants further submit the following additional materials in support of their allegations concerning the existence of a threat and effect to destroy or substantially injure their domestic industry:

a. Declaration of Charles Schultes III, attached as Confidential Exhibit CC; and

b. Declaration of Dr. Mitchell Brin, attached as Confidential Exhibit DD.

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[27] *See* Exhibit A at 3.

VIII. IMPORTATION INTO, SALE FOR IMPORTATION INTO, AND SALE AFTER IMPORTATION INTO THE UNITED STATES

167. Pursuant to 19 C.F.R. § 210.12(a)(3), Complainants state that Respondents import, and will sell within the United States after importation, DWP-450, a BTX product. The specific instances of importation of DWP-450 set forth below are illustrative and non-exhaustive.

168. DWP-450 is exclusively manufactured by Daewoong in a single facility in South Korea. DWP-450 is then imported into the United States by Evolus. Evolus has stated in securities filings that it relies exclusively on Daewoong's manufacturing facilities in South Korea as its source of DWP-450, and accordingly the DWP-450 used in the U.S.-based clinical trials described below necessarily must have been imported to the United States from South Korea.[28]

169. In September 2014, the FDA accepted Evolus' Investigational New Drug application. On May 16, 2017, Evolus submitted a BLA for DWP-450 seeking approval for the treatment of adult patients with glabellar lines.[29]

170. To seek FDA approval for DWP-450, Evolus imported significant quantities of DWP-450 into the United States to conduct four separate clinical trials in the United States involving over 1,500 individuals beginning in 2014.

a. The first clinical trial for DWP-450 in the United States began in August 2014 in Santa Monica, California at ATS Clinical Research and was a Phase II long-term safety study. The study was designated as EV-004 by Evolus and NCT02184988 in the clinicaltrials.gov database. It involved 353 participants. Each participant in this clinical trial received up to four treatments of

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[28] *See* Exhibit U at 3, 23-24.

[29] ALPHAEON Corp., *ALPHAEON Submits Biologics License Application for DWP-450 Neuromodulator*, CISION PR Newswire (May 16, 2017) https://www.prnewswire.com/news-releases/alphaeon-submits-biologics-license-application-for-dwp-450-neuromodulator-300458255.html.

DWP-450, in a total of five intra-muscular sites, and the study concluded in December 2015.[30]

b. The second clinical trial began in January 2015 in Boca Raton, Florida at the office of Dr. Steven Fagien and was a pivotal Phase III safety and efficacy study. The study was designated as EV-001 by Evolus and NCT02334423 in the clinicaltrials.gov database. It involved 324 participants. Participants were randomly assigned 3:1 to receive DWP-450 or a placebo, and the study concluded in December 2015.[31]

c. The third clinical trial began in January 2015 in Beverly Hills, California at the Clinical Testing Center of Beverly Hills and was a pivotal Phase III safety and efficacy study. The study was designated as EV-002 by Evolus and NCT02334436 in the clinicaltrials.gov database. It involved 330 participants. Participants were randomly assigned 3:1 to receive DWP-450 or a placebo, and the study concluded in December 2015. This study was identical in format to study EV-001 since the US FDA requires that two identical, pivotal Phase III studies be carried out on botulinum toxin products for registration purposes.[32]

d. The fourth clinical trial for DWP-540 began in May 2015 in Omaha, Nebraska at the Advanced Skin Research Center and was a Phase II safety study. The study was designated as EV-006 by Evolus and NCT02428608 in the clinicaltrials.gov database. It involved 570 participants. Each participant in this clinical trial received up to 4 DWP-450 treatments. This study was completed on November 2016.[33]

171. Each of the foregoing studies were conducted under the direction of Evolus's Chief Medical Officer, Rui Avelar, M.D., who joined Evolus in 2014 after serving as the Chief Medical Officer for Allergan.[34]

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30 *Safety Study of DWP-450 (Botulinum Purified Neurotoxin, Type A) Injection to Treat Glabellar Lines (EV-004)*, U.S. Nat'l Library of Med. (last visited Dec. 6, 2018), https://clinicaltrials.gov/ct2/show/NCT02184988.

31 *A Phase III Study to Demonstrate the Safety and Efficacy of DWP-450 to Treat Glabellar Lines - EV001*, U.S. Nat'l Library of Med. (last visited Dec. 6, 2018), https://clinicaltrials.gov/ct2/show/NCT02334423?term=NCT02334423&rank=1.

32 *Id.*

33 *Id.*

34 *Company Officers*, Evolus, https://investors.evolus.com/corporate-governance/management (last visited Dec. 6, 2018).

172. Under the terms of the Daewoong Agreement, Daewoong will manufacture DWP-450 for commercial sale at Daewoong's facility in South Korea, and will supply Evolus with DWP-450 at an agreed-upon, transfer price. The initial term of the contract is from September 30, 2013 to the later of (i) the fifth anniversary of approval from the relevant governmental authority necessary to market and sell DWP-450 or (ii) September 30, 2023. Evolus made an upfront payment to Daewoong of $2.5 million and agreed to make milestone payments upon the completion of certain development and commercial milestones including FDA and European Medicines Agency approval for DWP-450, of up to an aggregate of $13.5 million. Evolus will be the sole owner of any marketing authorization and clinical trial results it pursues in a territory covered by the license.[35]

173. On May 15, 2018, FDA issued an Establishment Inspection Report to Daewoong Pharmaceutical confirming the favorable completion of its pre-approval inspection of Daewoong's manufacturing facility in South Korea which was purposefully built for production of DWP-450. As Evolus has reported, "The DWP-450 manufacturing facility is fully validated by Daewoong under current good manufacturing practice ("cGMP") requirements and has capacity expected to meet anticipated product demand. Evolus plans to utilize the Daewoong facility to support commercial production following the anticipated approval of DWP-450."[36]

174. In addition to the DWP-450 that has already been imported, Evolus and Daewoong have either already stockpiled DWP-450 product for commercial sale in the United

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[35] *See* Exhibit A at 20.

[36] *Evolus Announces Progress with DWP-450 Regulatory Submissions*, Evolus (May 16, 2018), https://investors.evolus.com/news-releases/news-release-details/evolus-announces-progress-dwp-450-regulatory-submissions.

States or have plans imminently to do so, and that product will also be imported from South Korea.

175. On August 2, 2018, Evolus re-submitted its BLA to the FDA.[37] On or around August 2018, Evolus received a PDUFA action date of February 2, 2019 on which the FDA is expected to complete its review process. Evolus has reported that it expects to bring DWP-450 to market by the Spring 2019.[38]

176. Evolus has publicly committed a budget of more than $100 million to commercializing DWP-450 as soon as it receives FDA approval. *See* Exhibit S, at 18; Exhibit T, which is a true and accurate copy of the transcript of the November 5, 2018 Evolus earnings call, at 2. Evolus's PDUFA action date is February 2, 2019, and Evolus expects to launch DWP-450 in the United States in Spring 2019. Evolus expects that DWP-450 will occupy the second largest market share for BTX products in the U.S. aesthetic space. *See* Exhibit S at 18.

177. Complainants believe that DWP-450 falls under one or more of the following classifications of the Harmonized Tariff Schedule ("HTS") of the United States: Heading No. 3002.90.5150. These HTS identifications are illustrative and not exhaustive. The identifications are not intended to limit the scope of the Investigation, nor are they intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

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[37] *Evolus Announces Early Resubmission to the FDA of its Biologics License Application for DWP-450*, Evolus (Aug. 2, 2018), https://investors.evolus.com/news-releases/news-release-details/evolus-announces-early-resubmission-fda-its-biologics-license.

[38] *Evolus Receives Acceptance of FDA BLA Resubmission for DWP-450*, GlobeNewswire (Aug. 29, 2018), https://globenewswire.com/news-release/2018/08/29/1558232/0/en/Evolus-Receives-Acceptance-of-FDA-BLA-Resubmission-for-DWP-450.html.

IX. RELATED LITIGATION

178. Pursuant to 19 C.F.R. § 210.12(a)(5), Complainants state that the following litigation is currently pending relating to the issues described herein.

a. Korean Actions

179. On October 30, 2017, Medytox filed an action in the Seoul Central District Court (Case No. 2017Ga-Hap574026), in Korea (the "Korean Action") alleging that Daewoong misappropriated trade secrets stolen from it by BK Lee to develop and market Nabota®.

180. The Korean court has been conducting regular hearings, the most recent of which was held on January 15, 2019. The focus of recent hearings has been determining testing procedures to confirm Medytox's allegations that Daewoong misappropriated its BTX Strain.

181. The Korean court has ordered that each party select experts to perform genetic sequencing and sporulation tests. Daewoong has selected Dr. Michel-Robert Popoff, a French botulinum toxin scientist at the Institut Pasteur, and Medytox submitted Dr. Ju Hong Park, a professor at the Seoul National University. The testing procedures have not yet been agreed upon, but each party's expert will independently perform the tests that are ultimately identified. One test will attempt to determine whether the parties have submitted for testing the BTX Strain used in their commercial manufacturing. The second will attempt to test whether the submitted strains form spores.

182. The Korean court has told the parties it will resolve any conflicts regarding proposed testing procedures by February 2019.

183. BK Lee and Daewoong are also the subject of an ongoing criminal investigation in Korea arising out of BK Lee's theft and Daewoong's purchase of Medytox's trade secrets. (Korean Criminal Case No. 2017-000236).

b. California Action

184. On June 6, 2017, Medytox filed suit against Daewoong, BK Lee, and Evolus in California (*Medytox Inc. v. Daewoong Pharmaceuticals Co., Ltd.*, Case No. 30-2017-00924912-CU-IP-CJC (Cal. Super. Ct., Orange Cty. 2017) (the "California Action")). The California Action alleged that Daewoong usurped Medytox's economic opportunity with Evolus to distribute a BTX product in the United States and sought to enjoin the distribution of DWP-450 in the United States.

185. On August 30, 2017, Daewoong moved to dismiss or stay the case on the basis of *forum non conveniens* and BK Lee moved to quash service of the summons and complaint based on a lack of personal jurisdiction, while separately joining Daewoong's Motion to Dismiss or Stay for *forum non conveniens*.

186. On October 12, 2017, the California court dismissed BK Lee for lack of personal jurisdiction and subsequently dismissed Daewoong based on *forum non conveniens*, recommending that Medytox instead seek a remedy against Daewoong in Korea.

187. The case against Evolus remains and is stayed pending the outcome of the Korean Action.

c. Indiana State Court[39]

188. On May 4, 2018, Medytox filed suit against BK Lee in Indiana Commercial Court in Marion County (*Medytox Inc. v. Byung Kook Lee*, Case No. 49D01-1805-PL-017584 (Ind. Super. Ct., Marion Cty. 2018) (the "Indiana Action")). The Indiana Action

[39] On July 13, 2018, Medytox filed an application pursuant to 28 U.S.C. § 1782 in the United States District Court for the Southern District of Indiana seeking leave to obtain discovery for use in a foreign proceeding.

asserts narrow claims solely concerning BK Lee's personal liability for his theft of Medytox's trade secrets.

189. On June 8, 2018, BK Lee filed a Motion to Dismiss or Stay based on *forum non conveniens* asserting that the proper forum for a suit against BK Lee is Korea.

190. On October 4, 2018, the Indiana Court dismissed the claims against BK Lee related to conduct that occurred in Korea for *forum non conveniens*, but left standing the claims against BK Lee related to conduct in Indiana. The remaining claims are, however, stayed pending the outcome of the Korea Action.

X. REQUEST FOR RELIEF

WHEREFORE, by reason of the foregoing, Complainants respectfully request that the United States International Trade Commission:

a. institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to the Respondents' violations of that section based on the importation into the United States, sale for importation, and/or the sale within the United States after importation of Respondents' BTX products, including DWP-450, that were developed, made, and imported using Medytox's trade secrets;

b. schedule and conduct a hearing on permanent relief pursuant to 19 U.S.C. § 1337(c) for the purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and following the hearing, to determine that there has been a violation of Section 337;

c. issue a limited exclusion order, pursuant to 19 U.S.C. § 1337(d) forbidding entry into the United States of Respondents' BTX products, including

DWP-450, that were developed, made, and imported using Medytox's trade secrets;

d. issue cease and desist orders, pursuant to 19 U.S.C. § 1337(f), prohibiting Respondents and their related companies from engaging in the importation, sale for importation, marketing, distribution, offering for sale, the sale after importation of, or otherwise transferring within the United States Respondents' BTX products, including DWP-450, that were developed, made, and imported using Medytox's trade secrets;

e. require a bond during the Presidential review period pursuant to 19 U.S.C. § 1337(j)(3);

f. order the return of Medytox's trade secrets and other confidential information whether maintained electronically or by hard copy, and the destruction of all copies of such trade secrets and other confidential information in Respondents' possession, including without limitation the stolen Hall-A Hyper Strain; and

g. issue such other and further relief as the Commission deems just and proper under the law, based upon the facts determined by the investigation and the authority of the Commission.

Dated: January 25, 2019

Respectfully submitted,

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VERIFICATION OF COMPLAINT

I, Dr. Mitchell Brin, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), the following:

1. I am the Senior Vice President Global Drug Development and Chief Scientific Officer, BOTOX® at Complainant Allergan plc, and am duly authorized to sign this complaint on behalf of Complainants Allergan plc and Allergan, Inc.;

2. I have read the complaint and am aware of its contents;

3. To the best of my knowledge, information and belief founded upon reasonable inquiry under the circumstances, the complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceedings;

4. To the best of my knowledge, information and belief founded upon reasonable inquiry under the circumstances, the claims and legal contentions of this complaint are warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law;

5. To the best of my knowledge, information and belief founded upon reasonable inquiry under the circumstances, the allegations and other factual contentions in the complaint regarding Allergan plc and Allergan Inc. have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 4, 2019 in Irvine, California

Dr. Mitchell Brin
Senior Vice President Global Drug Development
Chief Scientific Officer, BOTOX®
Allergan plc

VERIFICATION OF COMPLAINT

I, KwangJun Ryu, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.l2(a), the following:

1. I am the Vice President of Global Business Development of Medytox Inc. ("Medytox"), and am duly authorized to sign this complaint on behalf of Complainant Medytox;

2. I have read the complaint and am aware of its contents;

3. To the best of my knowledge, information and belief founded upon reasonable inquiry under the circumstances, the complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceedings;

4. To the best of my knowledge, information and belief founded upon reasonable inquiry under the circumstances, the claims and legal contentions of this complaint are warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law;

5. To the best of my knowledge, information and belief founded upon reasonable inquiry under the circumstances, the allegations and other factual contentions in the complaint regarding Medytox have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on December 27, 2018 in Seoul, Korea

KwangJun Ryu
Vice President of Global Business Development
Medytox Inc.