quinn emanuel trial lawyers | san francisco
50 California Street, 22nd Floor, San Francisco, California 94111-4788 | TEL (415) 875-6600 FAX (415) 875-6700

WRITER'S DIRECT DIAL NO.
(415) 875-6432

WRITER'S INTERNET ADDRESS
davidbilsker@quinnemanuel.com

March 30, 2022

FILED VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W., Room 112A
Washington, D.C. 20436

Re: *Certain* Botulinum *Toxin Products and Processes for Manufacturing or Relating to Same*

Dear Secretary Barton:

Enclosed for filing, please find documents in support of a request by Medytox Inc. ("Complainant") that the U.S. International Trade Commission institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, concerning certain *botulinum* toxin products and processes for manufacturing or relating to same. We have included a separate letter requesting confidential treatment for the unredacted confidential version of the Verified Complaint and three confidential exhibits included with this filing.

On March 16, 2020, the Commission provided "notice that it is temporarily waiving and amending certain of the Commission's rules that required the filing of paper copies, CD-ROMS, and other physical media in section 337 investigations to address concerns about COVID-19." International Trade Commission, Temporary Changes to Filing Procedures, Federal Register Vol. 85, No. 54 (March 19, 2020). Specifically, the Commission approved the temporary amendment of various rules "to permit parties to file section 337 complaints, exhibits, attachments, and appendices, electronically." *Id*. The International Trade Commission reiterated its policy on the "USITC Response to COVID-19" site updated on June 1, 2021. Accordingly, Complainant's filing only contains electronic documents.

Complainant's submission via EDIS includes the following:

1. One (1) electronic copy of Complainant's public Verified Complaint, pursuant to Commission Rule 210.8(a)(1)(i).

2. One (1) electronic copy of Complainant's confidential Verified Complaint, pursuant to Commission Rule 210.8(a)(1)(ii).

3. One (1) electronic copy of the public exhibits to the Verified Complaint pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9).

4. One (1) electronic copy of the confidential exhibits to the Verified Complaint, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii).

5. A letter and certification requesting confidential treatment for the information contained in confidential exhibits 56, 57, and 59 to the Verified Complaint, pursuant to Commission Rules 201.6(b) and 210.5(d).

6. A Statement on the Public Interest regarding the remedial orders sought by Complainant in the Verified Complaint, pursuant to Commission Rule 210.8(b).

Complainant confirms that it will serve copies of the non-confidential versions of the Complaint and all associated exhibits and appendices upon the institution of this investigation on the proposed Respondents and all other appropriate entities consistent with 19 C.F.R. part 201 (including 19 C.F.R. § 201.16) and the Temporary Procedures.

Please contact me with any questions regarding this filing.

Respectfully submitted,

/s/ David Bilsker

David Bilsker
Counsel for Complainant Medytox Inc.

quinn emanuel trial lawyers | san francisco
50 California Street, 22nd Floor, San Francisco, California 94111-4788 | TEL (415) 875-6600 FAX (415) 875-6700

WRITER'S DIRECT DIAL NO.
(415) 875-6432

WRITER'S INTERNET ADDRESS
davidbilsker@quinnemanuel.com

REQUEST FOR CONFIDENTIAL TREATMENT

March 30, 2022

FILED VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W., Room 112A
Washington, D.C. 20436

Re: ***Certain* Botulinum *Toxin Products and Processes for Manufacturing or Relating to Same***

Dear Secretary Barton:

Pursuant to Commission Rule 201.6, Complainant Medytox Inc. respectfully requests confidential treatment of certain confidential business information contained in the unredacted confidential version of the Verified Complaint and confidential exhibits 56, 57, and 59 to the Verified Complaint.

The information in the Verified Complaint and the exhibits for which Complainant seeks confidential treatment consists of proprietary commercial information, including confidential and proprietary licensing information, technical information related to domestic articles protected by Complainant's trade secrets, and financial data regarding sales, volumes, and inventories related to domestic articles.

The proprietary information described herein qualifies as confidential business information under Commission Rule 201.6 because substantially identical information is not available to the public, because the disclosure of this information would cause substantial competitive harm to Complainant or others, and because the disclosure of this information would likely impede the Commission's efforts and ability to obtain similar information in the future.

Thank you for your attention. Please contact me with any questions regarding this request for confidential treatment.

Respectfully submitted,

/s/ David Bilsker

David Bilsker
Counsel for Complainant Medytox Inc.

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **CERTAIN *BOTULINUM* TOXIN PRODUCTS AND PROCESSES FOR MANUFACTURING OR RELATING TO SAME**	**Inv. No. 337-TA-_____**

CERTIFICATION

I, David Bilsker, counsel for Complainant Medytox Inc., declare as follows:

1. I am duly authorized by Complainant to execute this certification.

2. I have reviewed the unredacted confidential version of the Verified Complaint and confidential exhibits 56, 57, and 59 to Complainant's Verified Complaint, for which Complainant seeks confidential treatment.

3. The unredacted version of the Verified Complaint which includes portions or the entireties of Paragraphs 80, 96–99, 115, 119, 126, 128, and 144, referencing the timing of Complainant's product development, manufacturing equipment specifications, licensee information, settlement agreement information, and domestic industry revenue and product units. Disclosure of this proprietary information to the public would cause substantial harm to Complainant, its licensees, and their competitive positions. Disclosure of this information also would impair the Commission's ability to obtain information necessary to perform its statutory function.

4. Confidential Exhibit 56 is a declaration of Dr. Hyun Ho Jung containing confidential information related to Complainant's proprietary commercial information, including confidential and proprietary licensing and research, development and manufacturing information. Disclosure of this information to the public would cause substantial harm to Complainant, its competitive position, and its ability to negotiate future agreements. Disclosure of this information would also impair the Commission's ability to obtain information necessary to perform its statutory function.

5. Confidential Exhibit 57 is a confidential declaration of Dr. Seong Hun Chang containing confidential information related to Complainant's proprietary commercial information, including confidential and proprietary licensing and research, development and manufacturing information. Disclosure of this information to the public would cause substantial harm to Complainant, its competitive position, and its ability to negotiate future agreements. Disclosure of this information would also impair the Commission's ability to obtain information necessary to perform its statutory function.

6. Confidential Exhibit 59 contains confidential domestic industry information related to sales, volume, and inventories. Disclosure of this proprietary information to the public would cause substantial harm to Complainant, its licensees, and their competitive positions. Disclosure of this information also would impair the Commission's ability to obtain information necessary to perform its statutory function.

7. To the best of my knowledge, information, and belief, founded after a reasonable inquiry, substantially identical information to that contained in the exhibits is not available to the public.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of March, 2022 in Washington, D.C.

/s/ David Bilsker
David Bilsker

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **CERTAIN *BOTULINUM* TOXIN PRODUCTS AND PROCESSES FOR MANUFACTURING OR RELATING TO SAME**	**Inv. No. 337-TA-_____**

COMPLAINANT MEDYTOX'S
STATEMENT REGARDING THE PUBLIC INTEREST

Complainant Medytox Inc. ("Medytox") respectfully submits this Statement Regarding the Public Interest, as required by 19 C.F.R. § 210.8(b), regarding the remedial orders that Medytox seeks against Proposed Respondents Hugel, Inc. and Hugel America, Inc. (collectively, "Hugel") and Croma-Pharma GmbH ("Croma") (collectively, "Proposed Respondents").

I. INTRODUCTION

The Accused Products are botulinum toxin ("BTX") drug products that Hugel developed and now manufactures using a proprietary strain of *Clostridium botulinum* bacteria and related trade secrets owned by and misappropriated from Medytox. The issuance of the relief requested in the Complaint, including a permanent exclusion order and cease and desist orders covering the Accused Products, would not adversely impact the public health, safety, or welfare conditions in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. Indeed, the Commission has already found that the exclusion of BTX drug products similar to the Accused Products poses no public interest threat. In Inv. No. 337-TA-1145, the Commission found "that the remedial orders [excluding BTX products manufactured using Medytox's misappropriated trade secrets] would cause little to no harm to the public health and welfare, the competitive conditions in the United States economy, the production of like or directly competitive products in the United States, and United States consumers . . . [and] determined that the public interest factors do not preclude the issuance of remedial orders in this investigation." *Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, Inv. No. 337-TA-1145, Comm'n Op. at 68 (Jan. 13, 2021) ("*Certain Botulinum Toxin Prods.*").

The requested remedial orders in this Investigation likewise would not cause any harm to the public interest. As explained further below, several companies, including Medytox's licensee Evolus, Inc. ("Evolus"), already market and sell BTX drug products in the U.S. market, satisfy the demand in the market, and will continue to do so in the future. Medytox therefore submits that this Investigation does not present an instance where the Commission, the parties, and the public should be required to undergo the time and expense of discovery into public interest issues, the presentation of evidence on the public interest before the ALJ, and the issuance of a Recommended Determination by the ALJ on the public interest.

II. PUBLIC INTEREST CONSIDERATIONS UNDER 19 C.F.R. § 210.8(b)

A. How the Accused Products Are Used in the United States

The Accused Products are BTX drug products. The U.S. market for BTX drug products is well-established, with several BTX drug products already approved by the U.S. Food and Drug Administration ("FDA") and marketed and sold on the U.S. market, including: (1) Jeuveau®, an FDA-approved BTX drug product marketed and sold by Medytox licensee Evolus; (2) Botox® and Botox® Cosmetic (collectively, Botox®), both FDA-approved BTX drug products marketed and sold in the United States by Allergan, Inc. ("Allergan"); (3) Dysport®, an FDA-approved BTX drug product marketed and sold in the United States by Ipsen Biopharmaceuticals, Inc. ("Ipsen"); (4) Xeomin®, an FDA approved BTX drug product marketed and sold in the United States by Merz Pharmaceuticals, LLC ("Merz"); and (5) Myobloc®, an FDA-approved BTX drug product marketed and sold in the United States by Supernus Pharmaceuticals ("Supernus"). Some of these BTX drug products are indicated for therapeutic uses (e.g., to treat chronic migraine headaches, cervical dystonia, and urinary incontinence); some are indicated for aesthetic (cosmetic) purposes (e.g., to treat facial "frown lines" and crow's feet"); and some are indicated for both.

In March 2021, Proposed Respondent Hugel submitted a Biologics License Application ("BLA") to the FDA seeking approval to market and sell Letybo® in the United States. Hugel has stated that it expects imminent approval of its BLA, at which time it will enter the U.S. market.[1] Hugel is currently seeking FDA approval of Letybo® for an aesthetic indication – the treatment of moderate to severe glabellar (frown) lines in adult patients. Although the Accused Products have been imported into the United States for use in extensive clinical trials, they are not yet available for sale in the United States.

B. The Accused Products Do Not Present Any Public Health, Safety, or Welfare Concerns Relating to the Requested Remedial Orders

The requested remedy would have no adverse impact on the public health, safety, or welfare in the United States. In particular, the Commission examines the effect of a remedy on the public health and welfare by looking to whether "an exclusion order would deprive the public of products necessary for some important health or welfare need[.]" *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1360 (Fed. Cir. 2010). The Accused Products, which have not been approved by the FDA, have not established a commercial presence in the U.S. market. Moreover, Jeuveau®, Botox® Cosmetic, Dysport®, and Xeomin® have already been approved by the FDA and are currently being marketed and sold in the United States to treat glabellar lines, the same indication for which Proposed Respondents are seeking FDA approval of Letybo®. Letybo® does not possess any unique properties or any health or safety-related features absent from the existing

[1] *See, e.g.*, http://www.koreabiomed.com/news/articleView.html?idxno=11413 ("According to the notification sent by the FDA, the deadline for review of product approval is March 31, 2022, based on the U.S. Prescription Drug User Fee Act (PDUFA)."); http://www.koreabiomed.com/news/articleView.html?idxno=10839 ("Hugel expects to enter the U.S. market in 2022 as it takes about one year to obtain the marketing approval from the BLA submission[.] Hugel will market its product through Hugel America . . . a joint venture between Hugel and Croma Pharma . . . .").

BTX drug products already on the U.S. market. Accordingly, just as in *Certain Botulinum Toxin Products*, there are no public health, safety, or welfare considerations that caution against excluding the Accused Products.

C. Numerous Like or Directly Competitive Articles Are Available to Satisfy Demand for the Excluded Articles

As discussed above, several BTX drug products are already approved by the FDA and currently marketed and sold in the U.S. market for the treatment of glabellar lines (the same indication for which Proposed Respondents are seeking FDA approval), as well as other aesthetic and therapeutic indications. The manufacturers of these products are adequately supplying and meeting the market demand for BTX drug products in the United States in the absence of the Accused Products. They have all met, and will continue to meet, physician and patient demands and needs for BTX drug products, for both aesthetic and therapeutic indications.[2] Thus, given the availability of competing products and alternative supplies available to consumers, the public's health and welfare would not be disserved by the proposed remedial orders.

D. Medytox's Licensee and/or Third Parties Could Replace the Volume of Excluded Articles in a Commercially Reasonable Time in the United States

The Accused Products are not yet approved by the FDA and, therefore, are not currently being sold on the U.S. market. If the FDA approves the Accused Products, and assuming Proposed Respondents gain market share, the volume of any excluded articles could be easily replaced. The requested remedy will not adversely affect the production of like or directly competitive articles in the United States, including Jeuveau®, Botox® Cosmetic, Dysport® and Xeomin®, all of which

[2] https://www.mckinsey.com/industries/life-sciences/our-insights/from-extreme-to-mainstream-the-future-of-aesthetics-injectables (BTX market steadily growing with providers meeting patients' needs).

are indicated for the treatment of glabellar lines, the same indication for which Proposed Respondents are seeking FDA approval of Letybo®. The manufacturers of these products (Medytox licensee Evolus, Allergan, Ipsen, and Merz, respectively) have met patient demands and needs for BTX drug products for aesthetic uses in the U.S. market, and can continue to do so in the future without the existence of the Accused Products.[3] Thus, any or all of these existing BTX drug products could easily replace the Accused Products if they were approved and introduced during the course of this Investigation. Moreover, because Letybo® is manufactured abroad, no U.S. manufacturing jobs would be impacted by an exclusion order.

E. The Requested Remedial Orders Would Not Negatively Affect U.S. Consumers

Given that U.S. consumers do not currently have access to Letybo® and will continue to have access to multiple BTX drug products in the U.S. market for the same indication, the proposed remedy would not adversely affect consumers. Moreover, the public interest favors the protection of intellectual property and other proprietary rights in the United States. *Certain Two-Handle Centerset Faucets & Escutcheons & Components Thereof*, Inv. No. 337-TA-422, Comm'n Op. at 9 (June 19, 2000); *Certain Hardware Logic Emulation Sys. & Components Thereof*, Inv. No. 337-TA-383, Comm'n Op. at 8-9 (Oct. 15, 1996). Thus, the issuance of the requested relief here would serve the public interest by protecting Medytox's intellectual property and other proprietary rights and preventing competitors from entering the U.S. market using unfair practices.

III. CONCLUSION

For the foregoing reasons, the Commission should institute this Investigation and need not delegate public interest to the ALJ.

[3] *Id.*

Dated: March 30, 2022

Respectfully submitted,

/s/ David Bilsker

S. Alex Lasher
Nina S. Tallon
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
1300 I Street, NW, Suite 900
Washington, D.C. 20005
Telephone.: (202) 538-8000

Steve Cherny
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Huntington Avenue, Suite 520
Boston, Massachusetts 02199
Telephone: (617) 712-7100

Sean Pak
David Bilsker
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
50 California Street, 22nd Floor
San Francisco, California 94111
Telephone: (415) 875-6600

James Baker
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
Telephone: (212) 849-7000

Attorneys for Medytox Inc.

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **CERTAIN *BOTULINUM* TOXIN PRODUCTS AND PROCESSES FOR MANUFACTURING OR RELATING TO SAME**	**Inv. No. 337-TA-_____**

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

Complainant:
Medytox Inc.
78, Gangni 1-gil,
Ochang-eup, Cheongwon-gu,
Cheongju-si, Chungcheongbuk-do,
Republic of Korea
Telephone: +82-043-217-1555

Proposed Respondents:
Hugel, Inc.
7, Samseong-ro 133-gil
Gangnam-gu, Seoul
Republic of Korea
Telephone: +82-02-6966-1601

Hugel America, Inc.
9070 Irvine Center Drive, Suite 135
Irvine, California 92618
(949) 514-8652

Croma Pharma GmbH
Cromazeile 2
2100 Leobendorf
Austria
+43-2262-68468

Counsel for Complainant:
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
Alex Lasher
Nina Tallon
1300 I Street NW,
Suite 900
Washington, D.C. 20005
Telephone: (202) 538-8000

Steven Cherny
111 Huntington Avenue, Suite 520
Boston, Massachusetts 02199
Telephone: (617) 712-7100

Sean Pak
David Bilsker
50 California Street, 22nd Floor
San Francisco, California 94111
Telephone: (415) 875-6600

James Baker
51 Madison Avenue, 22nd Floor
New York, New York 10010
Telephone: (212) 849-7000

Attorneys for Medytox Inc.

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. COMPLAINANT 5

III. PROPOSED RESPONDENTS 6

A. Hugel Respondents 6

B. Respondent Croma 8

IV. TECHNOLOGY BACKGROUND 9

V. MEDYTOX'S PROPRIETARY STRAIN AND INTELLECTUAL PROPERTY 11

A. Medytox's Proprietary Strain of *C. botulinum* 12

B. Medytox's Trade Secrets 14

C. Security Measures to Protect Medytox's Tangible Strains and Related Trade Secrets 15

VI. PROPOSED RESPONDENTS' UNLAWFUL ACTS OF THEFT AND CONVERSION AND TRADE SECRET MISAPPROPRIATION 18

A. Unfair Competition Through the Theft and/or Conversion of Medytox's *C. botulinum* Strain 18

1. Hugel's Claims Concerning the Source of Its *C. Botulinum* Lack Credibility 18

2. Hugel Had Access to the Medytox Strain in or around 2001 21

B. Hugel's Misappropriation of Medytox's Trade Secrets 24

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE 28

VIII. HARMONIZED TARIFF SCHEDULE NUMBERS 31

IX. RELATED LITIGATION 31

A. The 1145 Investigation 32

B. California Actions 33

C. Indiana State Court 34

D. Korean Actions 34

X. THREAT OF SUBSTANTIAL INJURY AND SUBSTANTIAL INJURY TO DOMESTIC INDUSTRY 35

A. Domestic Industry Exists 35

1. Domestic Industry Related to Jeuveau® 35

2. Domestic Industry Related to MT10109L 36

3. Domestic Industry Related to ABP-450 39
4. Domestic Industry Related to Other BTX Drug Products 40
(a) Botox® 41
(b) Xeomin® 41
(c) Dysport® 42
(d) Myobloc® 42
(e) DaxibotulinumtoxinA 43
B. Injury to Domestic Industry 44
XI. RELIEF REQUESTED 46

TABLE OF EXHIBITS

Exhibit	Designation	Description
1	Public	"FDA accepts Hugel's application for licensing BTX product", Korea Biomedical Review, June 17, 2021
2	Public	"Hugel applies for sales nod of BTX products in US", Korea Biomedical Review, April 1, 2021
3	Public	"Hugel names James P. Hartman, a medical aesthetics expert, as President of Hugel America", available at https://kr.investing.com/news/stock-market-news/article-398749
4	Public	Adis Insight, Drug Profile, Letibotulinumtoxina – Hugel
5	Public	"Estate Gift Offers Boon to Graduate Students", GROW, University of Wisconsin Madison, available at https://grow.cals.wisc.edu/priority-themes/basic-science/estate-gift-offers-boon-to-graduate-students
6	Public	"Industrial feud over botox origin may develop into court battle", Pulse, November 4, 2016
7	Public	"The government's poor management of 'toxin', a raw material for botox", November 23, 2021, available at https://blog.naver.com/gidongmin/220824401795
8	Public	Hugel Press Release, "Hugel to take a hard line against false information regarding its strain", October 24, 2016
9	Public	"What is the source of strains from domestic botox companies," H magazine, October 19, 2020.
10	Public	Chung *et al, The First Outbreak of Botulism in Korea*, Korean J Clin Microbiol 2003; 6(2):160-63
11	Public	Hugel website - locations
12	Public	Botulinum Toxin Treatment of Glabellar Lines: Efficacy and Safety Study I (BLESS I) study record on clinicaltrials.gov
13	Public	Botulinum Toxin Treatment of Glabellar Lines: Efficacy and Safety Study II (BLESS II) study record on clinicaltrials.gov
14	Public	Croma Press Release, "Croma-Pharma announces submission for their botulinum toxin to treat glabellar (frown) lines to the German authority BfArM", July 8, 2020
15	Public	Botulinum Toxin Treatment of Glabellar Lines: Efficacy and Safety Study III (BLESSIII) study record on clinicaltrials.gov
16	Public	Study to Compare 2 Botulinum Type A Toxins in the Treatment of Glabellar Frown Lines (H2H) study record on clinicaltrials.gov
17	Public	Approval Package for Jeuveau, FDA Center for Drug Evaluation and Research, February 1, 2019
18	Public	Jeuveau Package Insert, February 2019
19	Public	Evolus, Inc. 10-K for the fiscal year ended December 31, 2021
20	Public	Evolus S&P CapitalIQ Financials Segments
21	N/A	Intentionally omitted
22	Public	A Randomised, Double-Blind, Intra-Individual Controlled, Single-Center, Phase I Dose Escalation Healthy Volunteer Study to Determine the Safety and Tolerability of MT10109 (Clostridium

		Botulinum Toxin Type A) in Comparison to Botox® Clinical Trial
23	Public	A Randomised, Double-blind, Multi-centre, Phase II, Optimal Dose-finding Study to Determine the Safety and Efficacy of MT10109 (Clostridium Botulinum Toxin Type A) in Subjects with Moderate to Severe Glabellar Lines in Comparison to BOTOX® study record on clinicaltrials.gov
24	Public	A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of MT10109L (NivobotulinumtoxinA) for the Treatment of Glabellar Lines With or Without Concurrent Treatment of Lateral Canthal Lines study record on clinicaltrials.gov
25	Public	A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of MT10109L (NivobotulinumtoxinA) for the Treatment of Lateral Canthal Lines With or Without Concurrent Treatment of Glabellar Lines study record on clinicaltrials.gov
26	Public	A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of MT10109L (NivobotulinumtoxinA) for the Treatment of Lateral Canthal Lines study record on clinicaltrials.gov
27	Public	A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of MT10109L (NivobotulinumtoxinA) for the Treatment of Glabellar Lines study record on clinicaltrials.gov
28	Public	A Multicenter, Long-term, Open-label Study to Evaluate the Safety of MT10109L (NivobotulinumtoxinA) for the Treatment of Glabellar Lines and Lateral Canthal Lines study record on clinicaltrials.gov
29	Public	AEON press release, “AEON Biopharma Initiates Enrollment in Phase 2 Trial of ABP-450 for the Preventative Treatment of Migraine”, March 9, 2021
30	Public	AEON press release, “AEON Biopharma Doses First Patient in Phase 2 Trial of ABP-450 for the Treatment of Cervical Dystonia”, April 5, 2021
31	Public	AEON press release, “AEON Biopharma Announces FDA Acceptance of IND for ABP-450 as a Treatment for Cervical Dystonia; Secures $25 Million Investment”, September 3, 2020
32	Public	AEON Biopharma, Inc. S&P Capital IQ
33	Public	Aeon Biopharma, Inc. S-1, September 2021
34	Public	FDA website indicating approval of Botox® on December 9, 1991
35	Public	Botox® Package Insert, July 2021
36	Public	AbbVie, Inc. 10-K for the fiscal year ended December 31, 2021
37	Public	July 30, 2010 FDA letter approving Xeomin®
38	Public	Xeomin® Package Insert, August 2021
39	Public	Merz North America D&B Hoovers Report, October 8, 2021
40	Public	Merz Locations

41	Public	April 29, 2009 FDA Letter approving Dysport®
42	Public	Dysport® Package Insert, July 2020
43	Public	Ipsen-in-Brief 2022
44	Public	December 8, 2000 FDA letter approving Myobloc®
45	Public	Myobloc® Package Insert, September 2020
46	Public	Supernus 10-K for the fiscal year ended December 31, 2020
47	Public	Supernus CapitalIQ
48	Public	Efficacy and Safety of DaxibotulinumtoxinA (DAXI) for Injection for Treatment of Upper Facial Lines study report on clinicaltrials.gov
49	Public	Revance press release, "Revance Submits Biologics License Application (BLA) to the FDA for DAXI to Treat Glabellar (Frown) Lines", November 25, 2019
50	Public	Revance press release, "Revance Resubmits Biologics License Application for DaxibotulinumtoxinA for Injection for Glabellar Lines to the FDA", March 8, 2022
51	Public	Revance Therapeutics, Inc. 10-K for the fiscal year ended December 31, 2021
52	Public	D&B Hoovers Revance Therapeutics, Inc. Report, December 5, 2021
53	Public	"Hugel ends mid-cycle meeting with FDA for its BTX product," Korea Biomedical Review, September 16, 2021
54	Public	Croma press release, "Croma-Pharma GmbH Sets the Course for Entering the US Market", September 5, 2018
55	Public	Declaration of Dr. Gyu Hwan Yang
56	Confidential	Declaration of Dr. Hyun Ho Jung
57	Confidential	Declaration of Dr. Seong Hun Chang
58	Public	Declaration of Dr. Junho Lee
59	Confidential	Evolus Royalty Reports
60	Public	Evolus press release, "Evolus Reports Fourth Quarter and Full-Year 2021 Results and Provides Business Update", March 3, 2022
61	Public	"How much is a vial of Jeuveau®?", Evolus Help Center

I. INTRODUCTION

1. This Complaint is directed to unfair acts in the importation into the United States of certain botulinum neurotoxin ("BTX") drug products by Proposed Respondents Hugel, Inc. and Hugel America, Inc. (collectively, "Hugel") and Croma-Pharma GmbH ("Croma") (together with Hugel, "Proposed Respondents"). The Accused Products at issue are BTX drug products that Hugel developed and now manufactures using a proprietary strain of *Clostridium botulinum* bacteria ("*C. botulinum*") and related trade secrets owned by and stolen from Complainant Medytox Inc. ("Medytox"). Hugel markets and sells the Accused Products in foreign markets under the trade names Botulax® and Letybo®.

2. In April 2014, Hugel and Croma entered into a ten-year distribution agreement providing Croma exclusive distribution rights for the Accused Products in certain markets, including the United States. In September 2018, Hugel, Inc. and Croma formed the joint venture company Hugel America, Inc. for the development of the Accused Product in the United States. Proposed Respondents are currently seeking approval from the U.S. Food and Drug Administration ("FDA") to market and sell the Accused Products in the United States under the trade name Letybo®. Proposed Respondents have announced that they expect FDA approval in or around March 2022.

3. BTX drug products are biologic drug products that use botulinum toxin as their active ingredients. BTX drug products have both aesthetic and therapeutic applications, including the treatment of facial wrinkles (glabellar lines, crow's feet, and forehead lines), chronic migraine headaches, cervical dystonia, hyperhidrosis, spasticity, and urinary incontinence.

4. The U.S. market for BTX drug products is well established and is the most lucrative BTX market in the world, generating approximately $3.5 billion per year in revenue.

The U.S. market includes both FDA approved drug products and products currently in clinical trials in the United States. The market for BTX drug products in the United States includes: (1) Jeuveau®, an FDA-approved BTX drug product marketed and sold in the United States by Medytox licensee Evolus, Inc. ("Evolus"); (2) MT10109L, a Medytox BTX drug product currently in clinical trials in the United States and for which Medytox intends to file a Biologics License Application ("BLA") with the FDA; (3) ABP-450, a BTX drug product for which Medytox licensee Aeon Biopharma, Inc. ("Aeon Biopharma") is currently conducting clinical trials in the United States and for which Aeon Biopharma intends to file a BLA with the FDA; (4) Botox® and Botox® Cosmetic (collectively, Botox®), both FDA-approved BTX drug products marketed and sold in the United States by Allergan, Inc. ("Allergan"); (5) Dysport®, an FDA-approved BTX drug product marketed and sold in the United States by Ipsen Biopharmaceuticals, Inc. ("Ipsen"); (6) Xeomin®, an FDA-approved BTX drug product marketed and sold in the United States by Merz Pharmaceuticals, LLC ("Merz"); (7) Myobloc®, an FDA-approved BTX drug product marketed and sold in the United States by Supernus Pharmaceuticals ("Supernus"); and (8) Daxi, a BTX drug product for which Revance Therapeutics, Inc. ("Revance") has filed a BLA with the FDA (collectively, "Domestic Industry Products").

5. Proposed Respondents have stated that they intend for the Accused Products to compete directly with all the Domestic Industry Products upon FDA approval of the Accused Products. (*See* Exhibit 1 ("FDA's acceptance of our BLA is an important milestone for Hugel as it brings us one step closer to our goal of becoming a top aesthetics brand in the U.S. . . .").) Proposed Respondents have also indicated that they will seek a quick penetration into the U.S. market through a "systematic and aggressive marketing strategy." (*See* Exhibit 2 ("The company aims to make Letybo one of the top three brands in the U.S. market within three years of the

launch by establishing a systematic and aggressive marketing strategy for a fast market penetration.").) Proposed Respondents' planned entry into the U.S. market threatens to and will destroy or substantially injure the domestic industry.

6. As explained below, Proposed Respondents developed and manufacture the Accused Products through unfair methods of competition and unfair acts, in violation of 19 U.S.C. §1337(a)(1)(A). Upon information and belief, Hugel unlawfully obtained *C. botulinum* from Medytox and used the bacteria to develop and manufacture the Accused Products. In 2001, an individual named Professor Yeon Soo Seo visited Medytox's CEO, Dr. Hyun Ho Jung, at Sun Moon University in Asan, Chungcheongnam-do, Korea. Dr. Jung did not know Professor Seo personally, and their areas of research did not overlap. Professor Seo did not have a prior appointment with Dr. Jung and did not give him any prior notice of his visit. There were no conferences at Sun Moon University that day, and, upon information and belief, no other reason for Professor Seo to visit Sun Moon University. Nevertheless, as a matter of custom and courtesy, Dr. Jung allowed Professor Seo to visit his lab where he conducted research on *C. botulinum*.

7. In or around Fall 2001, shortly after Professor Seo's unexpected visit to Sun Moon University, the co-founder of Hugel, Kyeong Yeop Moon ("KY Moon"), was seen culturing a sample of *C. botulinum* in Professor Seo's lab at his place of employment. At the time, Dr. Jung understood that he was the only person in Korea in possession of the type of *C. botulinum* that Hugel now claims to use to manufacture its products (Type A1). When Dr. Jung confronted Hugel about the origin of its strain, Hugel refused to provide any information. When Dr. Jung offered to have an objective third party compare the DNA sequences of the companies' respective strains, Hugel declined. Instead, Hugel has stated that it discovered a novel strain of *C.*

botulinum from a food source in Korea in 2002. As explained below, Hugel's explanation concerning the source of its *C. botulinum* is impossible for several reasons.

8. Hugel also developed the manufacturing processes for the Accused Products using highly confidential documents and/or information unlawfully obtained from Medytox. As explained below, Medytox recently discovered that its former Head of Manufacturing, Soon Ik Kwon ("SI Kwon"), emailed to his personal email account numerous highly confidential Medytox manufacturing documents before leaving the Company in 2008. In 2009, SI Kwon formed a new company called Across (originally named TWLS), and Hugel subsequently acquired a majority stake in Across. Today, Hugel owns approximately 84% of Across.

9. Based on the unfair methods of competition and unfair acts described herein, Medytox seeks: (1) an investigation with respect to Proposed Respondents' violation of 19 U.S.C. §1337(a)(1)(A); (2) a hearing on permanent relief pursuant to 19 U.S.C. §1337(c); (3) a permanent limited exclusion order barring entry into the United States of the Accused Products that are manufactured abroad and imported into the United States by or on behalf of Proposed Respondents pursuant to 19 U.S.C. §1337(d); (4) a permanent cease and desist order under 19 U.S.C. § 1337(f) prohibiting Proposed Respondents from importing, admitting or withdrawing from a foreign trade zone, marketing, advertising, demonstrating, testing, warehousing inventory of, distributing, offering for sale, selling, licensing, programming, packaging, repackaging, bundling, updating, soliciting U.S. agents or distributors for, or aiding and abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of the Accused Products; (5) the imposition of a bond on importation of the Accused Products during the 60-day Presidential review period pursuant to 19 U.S.C. §1337(j); and (6) such other and further relief as the Commission deems just and proper.

II. COMPLAINANT

10. 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 78, Gangni 1-gil, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea. Medytox maintains subsidiary offices in the United States at Olympic Plaza, 11500 W. Olympic Blvd., Suite 400, Los Angeles, California 90064. Medytox is the owner of the proprietary strain of *C. botulinum* and related trade secrets at issue in this case.

11. Medytox was founded in 2000 for the purpose of researching, developing, and manufacturing BTX drug products. In 2006, Medytox obtained approval from the Korean Food and Drug Administration ("Korean FDA")[1] to manufacture and sell the first BTX drug product developed in Korea. Medytox currently markets and sells this BTX drug product in Korea under the trade name Meditoxin®.[2]

12. After launching Meditoxin® in 2006, Medytox quickly became prominent in the Korean and worldwide biopharmaceutical markets. Although Medytox does not yet market or sell any products in the United States, it is seeking to introduce a new BTX drug product currently designated "MT10109L" to the U.S. market. Whereas Meditoxin® and most other BTX drug products are sold in powder form (lyophilized), and therefore must be reconstituted by the physician before injection, MT10109L will be sold in liquid form, pre-packaged and ready for immediate use.

[1] In 2013, the Korean FDA changed its name to the Korean Ministry of Food and Drug Safety ("MFDS"). For ease of reference, Medytox refers herein to the Korean MFDS as the Korean FDA.

[2] In some countries, Medytox markets and sells the same BTX drug product under other trade names, such as Neuronox®, Siax®, Botulift®, Cunox®, Tonytox® and Acebloc®.

13. Medytox is the holder of an Investigational New Drug ("IND") application to the FDA in support of a planned BLA for MT10109L. Phase III clinical trials for MT10109L began in the Fall 2018 and are being conducted (or have been conducted) in various locations across the United States, including Glendale, Arizona; Scottsdale, Arizona; Newport Beach, California; Solana Beach, California; Coral Gables, Florida; Bradenton, Florida; Wilmington, North Carolina; and Austin, Texas. Following the successful completion of the clinical trials and FDA approval of its BLA, Medytox plans to market and sell MT10109L in the United States.

14. Through years of research and development, and millions of dollars in investments, Medytox has developed valuable proprietary strains and intellectual property related to its BTX drug products, including a proprietary strain of *C. botulinum* and related trade secrets. Medytox currently uses its proprietary strain and related technology in the production of its own BTX drug products. Medytox also licenses its proprietary strain and technology to Evolus and Aeon Biopharma in connection with their sales and activities in the United States related to Jeuveau® and ABP-450, respectively.

III. PROPOSED RESPONDENTS

A. Hugel Respondents

15. Proposed Respondent Hugel, Inc., is a corporation established under the laws of Korea with its principal place of business located at 7, Samseong-ro 133-gil, Gangnam-gu, Seoul, Republic of Korea.

16. Proposed Respondent Hugel America, Inc., is a corporation established under the laws of Delaware with a principal place of business located at 9070 Irvine Center Drive, Suite 135, Irvine, California 92618. Hugel America, Inc. was formed as a joint venture between Proposed Respondent Hugel, Inc. and Proposed Respondent Croma.

17. Hugel markets and sells BTX drug products in various countries throughout the world under the trade names Botulax® and Letybo®.[3] In 2009, Hugel received approval from the Korean FDA for the export of Letybo®. In 2010, Hugel received approval from the Korean FDA to market and sell Letybo® in Korea under the trade name Botulax®.

18. Hugel is now seeking to commercialize its first product in the United States under the Letybo® brand name. Upon information and belief, in 2018, Hugel, Inc. and Croma established Hugel America, Inc. with the express intent of entering the U.S. market. (*See* Exhibit 3 ("Hugel established its North America, Australia and New Zealand subsidiary 'Hugel America' in October 2018 with an Austrian-based pharmaceutical company 'Croma Pharma.' Through the subsidiary, which is 70% owned by Hugel, it directly operates distribution and marketing of its products in the U.S., Canada, Australia and New Zealand. Hugel plans to submit the BLA to FDA around the end of this year to enter the U.S. market and expects to obtain a final approval by the end of next year."); Exhibit 54.)

19. In March 2021, Hugel submitted a BLA to the FDA seeking approval to market and sell Letybo® in the United States. Upon information and belief, the BLA identifies Hugel as the exclusive manufacturer of Letybo® and states that Hugel's manufacturing site will be in Korea. Thus, if approved, all Letybo® sold by Hugel will be imported into the United States in violation of 19 U.S.C. §1337(a)(1)(A).

20. In June 2021, Hugel announced that the FDA had accepted its BLA for Letybo®. (*See* Exhibit 1 ("Hugel said that the U.S. Food and Drug Administration has accepted its biologics license application (BLA) for approving Letybo, a botulinum toxin (BTX) product.").) Hugel also announced that the FDA had issued a Prescription Drug User Fee Act ("PDUFA")

[3] In some countries, Hugel markets and sells these products under other trade names, such as Regenox®, Zentox®, Reage®, Magnion®, Hugel Toxin®, Juvenlife®, Botulim®, and Botoshot®.

action date of March 31, 2022, at which time Hugel says the FDA is likely to rule on the BLA for Letybo®. (*Id.* ("According to the notification sent by the FDA, the deadline for review of product approval is March 31, 2022, based on the U.S. Prescription Drug User Fee Act (PDUFA)."); Exhibit 2 ("Hugel expects to enter the U.S. market in 2022 as it takes about one year to obtain the marketing approval from the BLA submission[.] Hugel will market its product through Hugel America . . . a joint venture between Hugel and Croma Pharma . . . .").)

B. Respondent Croma

21. Croma is a limited liability company organized under the laws of Austria with its principal place of business located at Cromazeile 2, 2100 Leobendorf, Austria.

22. Croma is a medical aesthetics company focused on the delivery of aesthetic procedures and treatments to physicians and consumers. In April 2014, Croma and Hugel entered into a ten-year distribution agreement ("the Hugel/Croma Agreement"), under which Croma will have exclusive distribution rights for Letybo® in North America, Europe, Australia, and Oceania, following final approval in those markets. (*See* Exhibit 4.) In September 2018, Hugel, Inc. and Croma formed the joint venture company Hugel America, Inc. As part of the formation of Hugel America, Inc., Croma transferred its exclusive distribution rights for Letybo® to Hugel America, Inc. (*See* Exhibit 54.) In addition, Croma is responsible for conducting the necessary clinical trials and obtaining regulatory approvals in those markets. (*See id.*)

23. Pursuant to the Hugel/Croma Agreement, Croma has conducted and continues to conduct clinical trials for Letybo® in various locations across the United States, including Nashville, Tennessee; Santa Monica, California; and Coral Gables, Florida. Croma's Phase III clinical trials for Letybo® are titled "Botulinum Toxin Treatment of Glabellar Lines: Efficacy and Safety Studies," or the "BLESS" trials for short.

IV. TECHNOLOGY BACKGROUND

24. Pursuant to 19 C.F.R. §§210.10(b)(1) and 210.12(a)(12), Medytox states that the Accused Products are botulinum toxin drug products.

25. The active ingredient in all BTX drug products is botulinum toxin, which is one of the most poisonous substances known to humans. When given in small enough doses, however, BTX has been proven safe and effective for aesthetic and therapeutic indications.

26. BTX is produced by isolating and purifying the neurotoxin protein released by the *C. botulinum* bacteria. There are thousands of different strains of *C. botulinum*, and each is classified according to the serotype of BTX the bacterium produces. There are seven known BTX serotypes (A–G), and each is immunologically distinct from the other. There are also over 40 BTX subtypes of these seven serotypes. The subtype of BTX used in the Accused Products in this case is BTX Type A1.

27. BTX is found naturally as part of a complex that includes a nontoxic-nonhemagglutinin protein plus additional proteins that vary according to the toxin serotype and subtype. One BTX complex, known as the HA+ complex, contains three different hemagglutinin proteins in addition to the universally present nontoxic-nonhemagglutinin protein.

28. A substantial amount of the early research into *C. botulinum* and BTX can be attributed to a scientist named Dr. Ivan C. Hall. From 1920 to 1942, Dr. Hall discovered thousands of strains of *C. botulinum* and named each strain with a similar nomenclature – "Hall" followed by a unique numerical identifier. Dr. Hall's strains of *C. botulinum* are commonly referred to as "the Hall strains."

29. In 1943, Dr. Elizabeth McCoy at the University of Wisconsin discovered that one of the Hall strains produced more toxin per unit of culture than any other Hall strain. The toxin produced by the strain characterized by Dr. McCoy was an HA+ BTX Type A1 toxin, and the

strain has come to be known as "the Hall A-Hyper Strain." The whole genome for the Hall A-Hyper Strain has been sequenced using DNA from a sample kept at the U.S. Army Medical Research Institute of Infectious Diseases ("USAMRIID") in Fort Detrick, Maryland. The sequence has been deposited in GenBank® at the National Center for Biotechnology Information ("NCBI") under the accession number CP000727.1.

30. Another well-known Hall Strain is designated "Hall 174" and was discovered around 1922 in a can of peas in California. Dr. Hall deposited a sample of this strain with the American Type Culture Collection ("ATCC")[4] in Rockville, Maryland. Hall 174 is also known as ATCC 3502. Like the Hall A-Hyper Strain, Hall 174 produces a BTX Type A1 toxin.

31. In general, the manufacture of a BTX drug product is a multi-step process that involves: (1) microbial culturing, or cultivation of the *C. botulinum* 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 (3) formulation of the toxin into a stable drug product for distribution and sale.

32. Step 1 of the manufacturing process is microbial culturing and requires the creation of a "medium" that contains essential nutrients needed by the *C. botulinum* bacteria to grow and replicate. A certain quantity of bacteria is necessary to produce commercial quantities of toxin. The medium consists of a liquid broth composed of ingredients that are carefully chosen and precisely measured. The bacteria are added to the medium and kept in a temperature-controlled environment for a defined time, during which the bacteria exponentially replicate and

[4] ATCC is a private, nonprofit, global biological resource center and standards organization where researchers can, among other things, deposit microbial, cell, and biological materials (such as bacterial strains).

undergo a process called “lysis.” During lysis, the walls of the bacteria disintegrate and release the desired toxin into the liquid medium in the form of a complex with the other proteins.

33. Step 2 of the manufacturing process is separation and purification. Once the toxin complex has been released into the culture medium, it must be separated from other undesirable substances, including other proteins, remaining bacteria, and components of those bacteria. This involves several stages of biochemical processes to remove these unwanted materials. Each of these steps is chosen and carried out in a manner designed to achieve optimal productivity and purity of the required end-product. At the end of this phase, the resulting product is the final purified toxin complex used as the active pharmaceutical ingredient (the drug substance) in the finished BTX drug product.

34. Step 3 of the manufacturing process is formulation, vial filling, and preparation of the final drug product. The final purified toxin complex is combined with stabilizing and other formulation agents before being filled into vials, lyophilized, and packaged and distributed for use in a finished dosage form.

35. Because the complete production process of BTX drug products – from bacterial cultivation through finished drug product – is so complex, no two independently-developed processes are the same. The design and implementation of adequate manufacturing processes and development and construction of safe and secure facilities typically takes many years and substantial investment of capital and human resources.

V. MEDYTOX’S PROPRIETARY STRAIN AND INTELLECTUAL PROPERTY

36. Medytox has invested substantial time and resources in the acquisition, R&D, and security of its proprietary strain of *C. botulinum* and related intellectual property. Medytox considers these materials and information highly valuable assets and trade secrets that are not

generally known, and the security and secrecy of which Medytox takes significant measures to protect.

A. Medytox's Proprietary Strain of *C. botulinum*

37. Because BTX is among the most dangerous toxins in the world, the availability and transportation of *C. botulinum* is strictly controlled by national authorities around the world. In the United States, for example, the availability and transportation of *C. botulinum* is regulated by the U.S. Centers for Disease Control and Prevention ("CDC"). Under the USA PATRIOT Act, 18 U.S.C. § 175b, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Patriot Act"), the CDC classifies both *C. botulinum* and BTX as "Tier 1 Select Agents" because of the "potential to pose a severe threat to public health and safety." 42 C.F.R. § 73.3.

38. Due to the strict controls implemented by authorities around the world, acquisition of *C. botulinum* and BTX is much more difficult than other materials used in traditional pharmaceutical development and manufacturing. BTX drug manufacturers like Medytox spend substantial time and resources to lawfully source and acquire their proprietary strains of *C. botulinum*. The history of Medytox's proprietary strain of *C. botulinum*, for example, goes back at least five decades to when a Korean scientist named Dr. Gyu Hwan Yang was a graduate student at the University of Wisconsin and studied under a well-known professor named Dr. Hiroshi Sugiyama.

39. Recognized as a world-renowned expert in the field of BTX and botulism (the disease caused by BTX), Dr. Sugiyama joined the University of Wisconsin in 1961. (Exhibit 5.) Dr. Sugiyama was a principal investigator at the Food Research Institute ("FRI") at the University of Wisconsin and taught food science classes there. (*Id.*) Dr. Sugiyama studied BTX and botulism for the entirety of his career. (*Id.*)

40. While studying under Dr. Sugiyama at the University of Wisconsin, Dr. Yang conducted research into various strains of *C. botulinum* bacteria held by his mentor, including the Hall A-Hyper Strain. (Exhibit 55 at ¶ 1.)

41. In 1979, Dr. Yang obtained his Ph.D. from the University of Wisconsin and took a position at the Korea Advanced Institute of Science and Technology ("KAIST") located in Daedeok Innopolis, Daejeon, Korea. (*Id.*) Before Dr. Yang left Wisconsin to return to Korea, his mentor Dr. Sugiyama gave him several samples of *C. botulinum*, including the Hall A-Hyper Strain, so that Dr. Yang could continue his work in Korea. (*Id.*)

42. Upon his return to Korea, Dr. Yang assumed his position at KAIST and, for the next two decades, led most research and development efforts conducted in Korea concerning *C. botulinum* and BTX. (*Id.* at ¶ 3.)

43. In the mid-1980s, Dr. Yang accepted a Ph.D. student named Dr. Hyun Ho Jung into his research group at KAIST. (*Id.* at ¶ 3; Confidential Exhibit 56 at ¶¶ 3, 9.) While at KAIST, Dr. Jung devoted most of his time and efforts to the study of *C. botulinum* and BTX. (Confidential Exhibit 56 at ¶¶ 3, 9.) In 1992, Dr. Jung completed his dissertation and became the first person in Korea to receive a Ph.D. in the field of *C. botulinum* research. (*Id.* at ¶ 3.)

44. In 1995, Dr. Jung was appointed professor at Sun Moon University in Asan, Chungcheongnam-do, Korea. (*Id.* at ¶ 4.) As a professor at Sun Moon University, Dr. Jung continued his work on *C. botulinum*. (*Id.*) Because his new lab at Sun Moon University did not have adequate facilities at the time, however, Dr. Jung continued to conduct his bench work at Dr. Yang's facilities at KAIST. (*Id.*)

45. In 1999, the Korean government appointed Dr. Yang Director of the Korean Institute of Toxicology ("KIT"). (Exhibit 55 at ¶ 4.) Shortly thereafter, in 2000, the Korean

government appointed Dr. Yang Director of the Korean FDA. (*Id.*) Following these appointments, Dr. Yang closed his lab at KAIST and conveyed his strains of *C. botulinum* to Dr. Jung. (*Id.*; Confidential Exhibit 56 at ¶ 11.)

46. In 2000, Dr. Jung founded Medytox as an on-campus start-up at Sun Moon University. (Confidential Exhibit 56 at ¶ 12.) In the years that followed, Dr. Jung and his team at Medytox invested substantial time and resources in the R&D and commercialization of the first BTX drug product in Korea. (*Id.* at ¶¶ 12-14.) Medytox's line of BTX drug products used (and uses) a BTX Type A1 toxin produced from a proprietary strain of *C. botulinum* that is related to the Hall A-Hyper Strain but also has unique nucleotide differences that are not found in the Hall A-Hyper Strain. (*Id.* at ¶ 13.)

B. Medytox's Trade Secrets

47. In addition to the substantial time and resources devoted by Medytox to its tangible proprietary strain of *C. botulinum*, Medytox has also invested substantial time and resources in the research and development of trade secrets related to its BTX drug products.

48. For example, Medytox has devoted substantial time and resources to the characterization of the physical and biochemical properties that contribute to the value of Medytox's proprietary strain of *C. botulinum* and around which Medytox's manufacturing processes are designed. These physical and biochemical properties include, among other things, genetic information, structure and conformation, biologic activity, immunological properties, and purity. Medytox measures and records these physical and biochemical properties in various confidential documents. These documents, and the information contained therein, comprise economically valuable trade secrets that are not generally known, and the secrecy of which Medytox takes significant security measures to protect.

49. Medytox has also devoted substantial time and resources to the research and development of its manufacturing processes. Medytox records the details of its manufacturing processes in various confidential documents setting forth, for example, the raw materials needed and in what quantities; the equipment needed, including the proper calibration and how that equipment is used; step-by-step instructions on what to do with the raw materials and equipment; and other instructions and safety precautions. Moreover, many of these documents are integrated sequential processes, whereby the output of one step is the input for the next. These documents, and the information contained therein, comprise economically valuable trade secrets that are not generally known, and the secrecy of which Medytox takes significant security measures to protect.

50. Finally, Medytox has also devoted substantial time and resources to the design and construction of its BTX manufacturing facilities. Medytox records the design and details of its facilities in various confidential documents setting forth, for example, drawings and detailed renderings of Medytox's buildings and process flows. Medytox also keeps detailed records of the equipment used in its facilities, such as the freeze dryers and hot air sterilizers used in the production of its BTX drug products. These documents comprise economically valuable trade secrets that are not generally known, and the secrecy of which Medytox takes significant security measures to protect.

C. Security Measures to Protect Medytox's Tangible Strains and Related Trade Secrets

51. Given the importance of its proprietary strains of *C. botulinum* and related trade secrets to the success of the Company, Medytox has implemented strict security measures to protect its proprietary strains and intellectual property.

52. For example, Medytox stores its strains in a high-security storage facility equipped with a security system to restrict access to a select group of employees. (Confidential Exhibit 56 at ¶ 22.) Any access to the strains is strictly monitored, controlled, and permitted only on a need-to-know basis. (*Id.*)

53. Prior to the construction of Medytox's facilities, Medytox's proprietary strains were kept [redacted] (*Id.*)

54. In addition to the security of its proprietary strains, Medytox has strict measures in place to protect its trade secrets and other highly confidential information. For example, highly confidential documents are disclosed on a need-to-know basis, and employees are given access to such materials and information only if they need it to perform their jobs. (Confidential Exhibit 57 at ¶ 4.) Further, confidential documents are stored in the Quality Assurance ("QA") copy room or QA office and can only be accessed with approval from QA personnel. (*Id.*) Medytox maintains a ledger recording the issuance of copies of confidential documents. (*Id.*) Medytox also keeps records of the date a certain document is returned to QA or destroyed in accordance with Good Manufacturing Practice ("GMP") regulations. (*Id.*)

55. Medytox has multiple written policies and measures in place to protect the confidentiality of its documents and information, including confidentiality requirements in employment agreements, security pledge agreements, and staff training. (*Id.* at ¶ 5.) As part of their employment agreements, Medytox employees agree to comply with all Company rules

related to confidential information. (*Id.* at ¶ 6.) Employees also agree that for a specified period from the termination or suspension of the agreements, they will not use any information related to Medytox or Medytox's confidential information, including the technical secrets, such as product manufacturing methods, individually or for a company that is competing with Medytox. (*Id*.)

56. Medytox employees are required to abide by a security pledge providing that all information obtained from Medytox shall be used only for work and that Medytox information shall not be communicated or disclosed to a party outside of the Company without prior approval. (*Id.* at ¶ 7.) All Medytox employees are required to sign the security pledge agreement. (*Id.*) As part of their training, Medytox employees are also instructed not to send any of the Company's confidential information outside of Medytox by email or print out such documents and/or remove them from Company property. (*Id.* at ¶ 8.)

57. Medytox has also consistently maintained physical and technological safeguards to protect its information technology. (*Id.* at ¶ 9.) For example, Medytox's computers, tablets, and smart phones are password-protected, have security firewalls, and employ encryption technology. (*Id.*) Medytox additionally has systems in place to protect and monitor its network, including blocking physical and web source storage; monitoring company email and personal email sent from company servers; tracking the printing of company documents; and auto-encrypting all files. (*Id.*) These safeguards are intended to prevent the improper use, theft and/or disclosure of electronically stored information and other confidential and proprietary documents and materials. (*Id.*)

58. Finally, all new hires are trained on Medytox's security systems and confidentiality obligations. (*Id.* at ¶ 8.) Employees are instructed, for example, that sending data

or information, especially decrypted information, through a personal email account is prohibited. (*Id.*) Employees are also instructed that Medytox documents should not be printed and/or taken outside of the Company offices. (*Id.*)

VI. PROPOSED RESPONDENTS' UNLAWFUL ACTS OF THEFT AND CONVERSION AND TRADE SECRET MISAPPROPRIATION

59. Pursuant to 19 C.F.R. § 210.12(a)(2), the Accused Products are the result of unfair methods of competition and unfair acts by Proposed Respondents, including the torts of (1) theft and conversion of one or more Medytox strains of *C. botulinum* and (2) misappropriation of Medytox's related trade secrets.

A. Unfair Competition Through the Theft and/or Conversion of Medytox's *C. botulinum* Strain

60. Medytox was in physical control of its proprietary strains of *C. botulinum* and intended to exercise such control for its own benefit. Hugel intentionally took one or more samples of Medytox's proprietary strains without Medytox's consent. Hugel's actions amount to common law theft and constitute unfair competition under 19 U.S.C. § 1337(a)(1)(A).

61. After unlawfully taking one or more samples of Medytox's proprietary strains, Hugel intentionally exercised control over those samples and used them to develop and manufacture the Accused Products in violation of Medytox's right to control their use. Hugel's actions amount to common law conversion and constitute unfair competition under 19 U.S.C. § 1337(a)(1)(A).

1. Hugel's Claims Concerning the Source of Its *C. Botulinum* Lack Credibility

62. Hugel has stated publicly that it developed and manufactures the Accused Products using a novel strain of *C. botulinum* allegedly discovered from a food source in Korea in 2002. Upon information and belief, these claims are false. Hugel has changed the details of its

story at least four times, and Hugel could not have discovered a novel strain of *C. botulinum* from a food source in Korea in 2002 because there were no reported cases of botulism from a food source in Korea until 2003.

63. In 2006, Hugel represented to the Korean Centers for Disease Control and Prevention Agency that it had discovered *C. botulinum* from rotten canned food in 2002. (Exhibit 6; Exhibit 7.)

64. In 2007, at the Spring Meeting of the Korean Society for Biotechnology and Bioengineering, Hugel's CEO KY Moon changed the story of how Hugel obtained its *C. botulinum*, stating that Hugel had discovered its strain from "naturally decomposed cans, fish, and rotten fish." (*See* April 27, 2007 "Botulinum toxin type A" presentation by KY Moon available at https://www.ibric.org/vod/vod_detail.php?nNum=6411.)

65. Almost a decade later, Hugel changed its story again. In September 2016, Korean National Assembly Member Dong-Min Ki criticized the Korean Centers for Disease Control and Prevention Agency for not conducting epidemiological investigations even after receiving reports on the discovery of botulinum toxin in Korea from private companies that developed botulinum toxin products. (Exhibit 7.) In a press release dated October 24, 2016, Hugel responded by retracting its earlier statements that it had discovered a novel strain of *C. botulinum* from "rotten canned food" and stating instead that the source of its strain was "decomposed food waste that was disposed for passed the expiration date and cooked meat media." (Exhibit 8.)

66. On October 19, 2020, a Korean health magazine reported that Hugel had changed its story yet again, this time claiming that it found its strain in canned beans. (Exhibit 9.)

67. If Hugel had in fact discovered a novel strain from a food source in Korea in 2002, the discovery would have been a well-documented and highly publicized event. There would be no reason for Hugel to change its explanation of the source of its *C. botulinum* strain.

68. The recorded history of botulism outbreaks in Korea also undermines Hugel's claim that it discovered a novel strain of *C. botulinum* from a food source in Korea in 2002. By 2002, botulism was a reportable infectious disease in Korea. Any incidence of botulism from a food source was required to be reported. In fact, botulism is very rare in Korea, and the first reported case of botulism from a food source in Korea was not until 2003 when two patients were infected from contaminated sausage. (Exhibit 10.) Thus, Hugel could not have discovered a novel *C. botulinum* strain from a food source in Korea in 2002.

69. Hugel's allegation that it discovered a novel strain of *C. botulinum* from a food source in 2002 is also undermined by Hugel's own subsequent statements comparing its strain to the Hall 174 strain (also known as ATCC 3502). As explained above, Hall 174 is a separate and distinct strain from the Hall A-Hyper Strain.

70. Specifically, Hugel's CEO KY Moon likened Hugel's strain to Hall 174 at a public conference in 2007, likely to distract from the fact that the Hugel strain was actually derived from the Medytox strain. At the 2007 Spring Meeting of the Korean Society for Biotechnology and Bioengineering, KY Moon stated that "[t]he portion [of the Hugel strain] that has been sequenced, at 1.4 kbp fragment, is 100% identical. This strain is ATCC3502 Hall strain." (*See* April 27, 2007 "Botulinum toxin type A" presentation by KY Moon available at https://www.ibric.org/vod/vod_detail.php?nNum=6411.) KY Moon further stated that "[t]he significance of this is that all the type A botulinum toxin that has been commercialized was made from ATCC 3502 strain. When we develop the product from this strain, it's similar to a generic

drug: it will be much easier to get our product approved." (*See id.*) These statements are incorrect for several reasons.

71. First, contrary to KY Moon's statement, not all BTX drug products utilizing Type A1 toxin are made from Hall 174. As explained above, Medytox's BTX drug products are manufactured using a strain of *C. botulinum* derived from the Hall A-Hyper Strain, as are many others.

72. Second, even if the Hugel strain has 1,400 base pairs ("1.4 kbp") out of many millions in common with Hall 174, that does not mean that the Hugel strain was derived from Hall 174, as opposed to the Medytox strain. All strains of *C. botulinum* that produce Type A1 toxin, including both Hall 174 and Medytox's strain, will have conserved regions of their DNA sequences that are identical to each other.

2. Hugel Had Access to the Medytox Strain in or around 2001

73. In addition to Hugel's misleading statements about the source of its strain, Hugel's actions shortly before its alleged discovery of a novel strain of *C. botulinum* support Medytox's claims of theft and conversion.

74. As explained above, in 2000, Medytox's CEO Dr. Jung founded the Company as an on-campus start-up at Sun Moon University. (Confidential Exhibit 56 at ¶ 12.) Dr. Jung was a Professor at Sun Moon University at the time and worked primarily with the *C. botulinum* strains conveyed to him by his mentor Dr. Yang. (*Id.* at ¶ 12-13.)

75. In 2001, Dr. Jung received an unannounced and unexpected visit to Sun Moon University from a well-known Korean microbiologist named Professor Yeon Soo Seo. (*Id.* at ¶ 34.) Dr. Jung did not know Professor Seo personally and their research areas were different. Upon information and belief, however, another professor in the Department of Biotechnology at Sun Moon University, Yeon-Wook Kim, knew Professor Seo well and introduced him to Dr.

Jung. Upon information and belief, Professors Seo and Kim knew each other because they had previously worked together at Samsung Biomedical Research Institute ("SBRI").

76. At the time of Professor Seo's visit in or around mid to late 2001, Sun Moon University was a relatively small school and not particularly prestigious. (*Id.* at ¶ 35.) Upon information and belief, there were no academic conferences being held that day, and there was no other reason for Professor Seo to visit Sun Moon University. Neither Professor Seo nor Professor Kim had a prior appointment with or given prior notice to Dr. Jung. (*Id.* at ¶ 34.)

77. Nevertheless, as was customary and courteous, Dr. Jung allowed Professors Seo and Kim to visit his lab and see the work that he was conducting on *C. botulinum* during their visit. (*Id.* at ¶ 36.) Unbeknownst to Dr. Jung, Professor Seo was also an acquaintance of the future founder and CEO of Hugel, KY Moon. Upon information and belief, Professor Seo and KY Moon knew each other because both had been postdoctoral fellows in the same research group at Memorial Sloan-Kettering Cancer Center in New York, albeit at different times.

78. Shortly after Professor Seo's unannounced visit to Sun Moon University, KY Moon was seen culturing *C. botulinum* in Professor Seo's lab at SBRI. In fall 2001, a researcher at SBRI named Dr. Junho Lee detected a strong odor in the first-floor lobby of the SBRI building while working one weekend. (Exhibit 58 at ¶ 6.) Dr. Lee recognized the odor as *C. botulinum* and immediately notified security. (*Id.*) After searching for the source, Dr. Lee and the security guard found KY Moon alone in Professor Seo's lab on the third floor of the facility culturing samples of *C. botulinum.* (*Id.*)

79. Dr. Lee recognized the smell of *C. botulinum* because he had previously worked in Dr. Yang's research group at KAIST from 1998 to 2000. (*Id.* at ¶¶ 4, 6.) When Dr. Lee

confronted KY Moon about the source of his *C. botulinum*, KY Moon equivocated, stating only that "there are ways to get the strain." (*Id.* at ¶ 6.)

80. In November 2001, KY Moon founded Hugel and now claims to have discovered and isolated a novel strain of *C. botulinum* from a food source in Korea only a year later in 2002. Hugel further claims to have produced and purified BTX from its novel strain only a year after that in 2003. By comparison, Dr. Jung received his Ph.D. in the field of *C. botulinum* research (the first person to do so in Korea) in 1992, and it took Medytox approximately [redacted] to develop its first product and bring it to market in Korea.

81. After his unexpected and unannounced visit to Sun Moon University in 2001, and KY Moon's subsequent founding of Hugel, Professor Seo avoided Dr. Jung. (Confidential Exhibit 56 at ¶ 37.) Even years later when Dr. Jung was invited to speak at his alma mater KAIST on at least two separate occasions, Professor Seo did not attend the seminars or gatherings afterwards, even though Professor Seo was a professor at KAIST at the time. (*Id.*) This was very unusual for a Korean university professor, especially since Professor Seo had seemingly taken a particular interest in Dr. Jung's research, traveling all the way to Sun Moon University to meet Dr. Jung for the first time without a prior appointment or any advanced notice. (*Id.*)

82. Given the activities and conduct described above, Medytox has called into question the source of Hugel's strain on numerous occasions. Time and again, Hugel has refused to engage in productive discussions, insisting instead that Hugel obtained its strain from a food source in Korea in 2002, not from Medytox.

83. For example, on October 27, 2015, Dr. Jung sent a letter to Hugel with the subject line: "Promoting Fair Competition in the Botulinum Toxin Biopharmaceutical Market." (*Id.* at ¶

38.) In the letter, Dr. Jung pointed out that Hugel's earlier claim that it discovered its strain from canned food was highly unlikely and proposed that Medytox and Hugel have a third party conduct comparative testing and DNA analysis on the Medytox and Hugel strains to settle whether Hugel had unlawfully obtained its strain from Medytox. (*Id.*) Hugel did not respond directly to Dr. Jung's October 27, 2015 letter but instead hired an outside law firm. (*Id.*) In their response, Hugel's outside counsel threatened Medytox, stating that Hugel would hold Medytox civilly and criminally liable if Medytox continued to question the source of Hugel's strain. (*Id.*) Hugel's refusal to engage in meaningful discussions further supports the allegations described herein.

B. Hugel's Misappropriation of Medytox's Trade Secrets

84. Medytox possesses information of independent economic value that is not generally known and not readily ascertainable by proper means and could convey an economic benefit to another person who unlawfully obtains it. This information constitutes numerous trade secrets for which Medytox takes reasonable measures to maintain the secrecy. Hugel acquired Medytox's trade secrets without Medytox's authorization and used them to develop and manufacture the Accused Products. Hugel's actions amount to trade secret misappropriation and unfair competition under 19 U.S.C. § 1337(a)(1)(A).

85. Although Dr. Jung and his colleagues at Medytox had extensive experience with *C. botulinum* at the time they founded the Company in 2001, they lacked the knowledge and resources to design and construct a suitable manufacturing facility and related processes. (Confidential Exhibit 56 at ¶ 39.) Thus, in mid-2001, Dr. Jung hired the consulting firm Bio-Support to assist with the manufacturing side of the business. (*Id.*) The scope of services provided by Bio-Support was expansive, including, *inter alia*, the design and construction of a manufacturing plant and training on quality control and product release specifications. (*Id.*) To

facilitate Bio-Support's work, Medytox provided Bio-Support with a wide range of highly confidential documents and information, including the characteristics of its proprietary strain of *C. botulinum*, the contents and order of Medytox's core production steps, and specific drawings and designs needed to implement those steps. (*Id.*)

86. In September 2002, at the recommendation of Bio-Support CEO Ho Kyung Kang ("HK Kang"), Medytox hired Bio-Support's former employee SI Kwon as Medytox's Head of Manufacturing. (*Id.* at ¶ 40.)

87. As the Head of Manufacturing at Medytox, SI Kwon supervised all work related to manufacturing, *i.e.*, strain management, undiluted BTX manufacturing, manufacture of the final product and product storage. (*Id.*) SI Kwon had full access to all Medytox manufacturing processes and related materials and information. (*Id.* at ¶ 42.)

88. In mid-2003, Medytox completed construction and registration of its first manufacturing plant in Ochang, Korea ("Plant #1"). (*Id.* at ¶ 41.) Upon completion of Plant #1, Medytox no longer needed the consulting services of Bio-Support and terminated the relationship. (*Id.* at ¶ 41.)

89. In 2004, Bio-Support began consulting for Hugel and advising Hugel on the design and construction of Hugel's own manufacturing facilities. By 2006, Hugel had completed construction of its first manufacturing plant in Chuncheon, Korea.

90. In January 2008, Medytox discovered that SI Kwon had sent a highly confidential manufacturing document to a third party using his personal email account. (Confidential Exhibit 57 at ¶ 10.) Although Medytox did not suspect unlawful activity at the time, SI Kwon's actions were nevertheless a breach of Medytox's security policies and confidentiality obligations. (*Id.*)

When Medytox confronted SI Kwon about his actions, SI Kwon apologized and assured that it would not happen again. (*Id.*) Later that year, SI Kwon left the Company. (*Id.* at ¶ 11.)

91. Recently, Medytox discovered that SI Kwon's January 2008 email was not an isolated event but rather part of a course of conduct. Medytox discovered that, during 2007 and 2008 alone, SI Kwon sent at least another 20 emails with numerous confidential manufacturing documents to his personal email account or to third parties in violation of Medytox's security policies and confidentiality obligations. (*Id.* at ¶ 12.) These documents included highly confidential manufacturing instructions, validation reports, test protocols and results, and standard operating procedures. (*Id.*) All were plainly Medytox documents and required to be kept as confidential. (*Id.*)

92. In April 2009, SI Kwon founded a company called TWLS, which later changed its name to Across. Upon information and belief, the only employees were SI Kwon and an accountant.

93. In 2010, Across acquired a hyaluronic acid filler factory. In or around 2010 or 2011, Hugel acquired the filler factory from Across. Upon information and belief, in or around 2013, Hugel purchased all of SI Kwon's shares in Across and became the majority shareholder in the company. Hugel today owns approximately 84% of Across.

94. Hugel misappropriated Medytox's trade secrets by stealing its proprietary strain of *C. botulinum* and related highly confidential manufacturing documents and using those materials and information to develop and manufacture the Accused Products. Upon information and belief, Hugel's acquisition of Across was consideration for SI Kwon's role in the theft and misappropriation of Medytox's highly confidential documents and information.

95. One example of the highly confidential Medytox materials and/or information that Hugel used to develop its manufacturing processes was Medytox's original batch size.

96. Generally, the size of a commercial batch of BTX drug product is set at units of 3,000; 5,000; 10,000; 20,000 or greater, depending on the capacity of the equipment, such as the freeze dryer. (Confidential Exhibit 57 at ¶ 15.) In most cases, the batch size is set to the maximum capacity of the equipment to maximize production. (*Id.*) [redacted]

97. [redacted]

98. [redacted]

99. [redacted]

[redacted]

100. In or around 2009, Dr. Chang met with Medytox's former Head of Manufacturing SI Kwon and told him that Hugel was using the same batch size as Medytox. SI Kwon replied, "is that so" and laughed. (*Id.* at ¶ 16.) Hugel's use of Medytox's original batch size further supports Medytox's claims of misappropriation of trade secrets.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

101. Pursuant to 19 C.F.R. 210.12(a)(3), Complainant states that Proposed Respondents import and will sell within the United States after importation, the Accused Products. Specific instances of importation of the Accused Products are set forth below and are illustrative.

102. As discussed above, Hugel is the exclusive manufacturer of the Accused Products in Korea. Upon information and belief, Hugel manufactures the Accused Products in Korea at its two factory locations – Factory No. 1 [24206] 61-20, Sinbuk-ro, Sinbuk-eup, Chuncheon-si, Gangwon-do and/or Factory No. 2 [24398] 23, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do. (*See* Exhibit 11.)

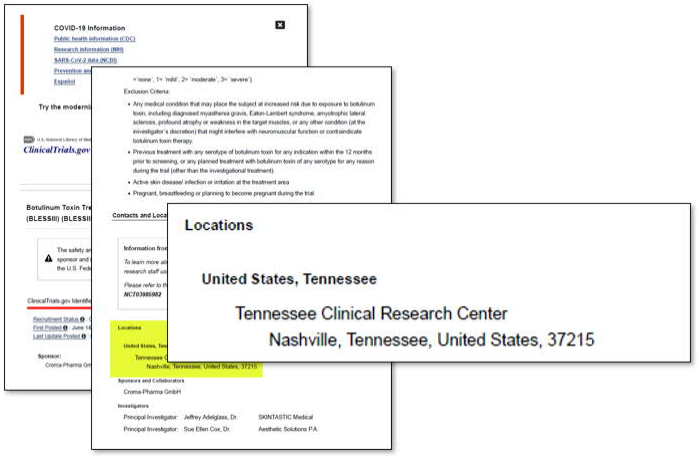
103. Upon information and belief, Hugel and/or Croma imported significant quantities of the Accused Products into the United States for purposes of the BLESS clinical trials.

104. The BLESS I clinical trial was a phase III clinical trial titled "Botulinum Toxin Treatment of Glabellar Lines: Efficacy and Safety Study I." (*See* Exhibit 12.) The BLESS I clinical trial began in February 2016 and concluded in December 2018. (*Id.*) The BLESS I clinical trial enrolled 700 individuals, and each person was administered a portion of a vial of Letybo® or placebo. (*Id.*)

105. The BLESS II clinical trial was a phase III clinical trial titled "Botulinum Toxin Treatment of Glabellar Lines: Efficacy and Safety Study II." (*See* Exhibit 13.) The BLESS II clinical trial also began in February 2016 and concluded in December 2018. (*Id.*) The BLESS II clinical trial enrolled 200 individuals, and each person was administered a portion of a vial of Letybo® or placebo. (*Id.*)

106. The BLESS I and II clinical trials were conducted in both Europe and the United States. (*See* Exhibit 14 ("Croma's botulinum toxin submission in Europe is based on 2 completed randomized, placebo-controlled Phase III pivotal trials (BLESS I and II) . . . in Europe and the US.").) Thus, upon information and belief, Hugel and/or Croma imported from Korea into the United States at least 1 and up to 900 vials of Letybo® for purposes of the BLESS I and II clinical trials.

107. The BLESS III clinical trial was a phase III clinical trial titled "Botulinum Toxin Treatment of Glabellar Lines: Efficacy and Safety Study III." The BLESS III clinical trial began in April 2019 and concluded in December 2020. (*See* Exhibit 15.) The BLESS III clinical trial enrolled 355 individuals, and each person was administered a portion of a vial of Letybo® or placebo. (*Id.*) As shown below, the BLESS III clinical trial was conducted at the Tennessee Clinical Research Center in Nashville, Tennessee. (*Id.*) Thus, upon information and belief, Hugel and/or Croma imported from Korea into the United States at least 1 and up to 355 vials of Letybo® for purposes of the BLESS III clinical trial.



108. In addition to the BLESS clinical trials, Hugel and Croma conducted a fourth clinical trial involving Letybo® titled "Study to Compare 2 Botulinum Type A Toxins in the Treatment of Glabellar Frown Lines" ("Letybo®/Botox® Comparative Study"). (*See* Exhibit 16.) The Letybo®/Botox® Comparative Study began in December 2019 and concluded in February 2021. (*Id.*) The Letybo®/Botox® Comparative Study enrolled 200 individuals, and each person was administered a portion of a vial of Letybo® or Botox®. (*Id.*) As shown below, the Letybo®/Botox® Comparative Study was conducted at the ATS Clinical Research facility in Santa Monica, California, and the Skin Research Institute LLC in Coral Gables, Florida. (*Id.*) Thus, upon information and belief, Hugel and/or Croma imported from Korea into the United States at least 1 and up to 200 vials of Letybo® for purposes of the Letybo®/Botox® Comparative Study.

109. In addition to the clinical trials described above, Hugel and Croma have stated that they intend to market and sell the Accused Products in the United States immediately upon receipt of FDA approval of the BLA for Letybo®. Hugel has announced that it expects FDA approval of its BLA for Letybo® in 2022. (*See* Exhibit 2 ("Hugel expects to enter the U.S. market in 2022 as it takes about one year to obtain the marketing approval from the BLA submission.").) Accordingly, upon information and belief, Hugel and Croma will import additional vials of Letybo® into the United States upon approval of their BLA.

VIII. HARMONIZED TARIFF SCHEDULE NUMBERS

110. Pursuant to 19 C.F.R. 210.12(a)(3), upon information and belief, the Accused Products are classified under at least the following heading of the Harmonized Tariff Schedule of the United States: 3002.90.51.50. This is an exemplary classification and not intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

IX. RELATED LITIGATION

111. Pursuant to 19 C.F.R. § 210.12(a)(5), the following litigations involve(d) the proprietary strain or intellectual property described herein and/or the same or similar unlawful activities.

A. The 1145 Investigation

112. This is the second Complaint filed with the ITC concerning Medytox's proprietary strain of *C. botulinum* and related trade secrets. Medytox filed a similar complaint at the ITC on January 25, 2019, asserting claims of trade secret misappropriation against another Korean BTX manufacturer, Daewoong Pharmaceuticals Co. ("Daewoong"), and its U.S. marketing partner, Evolus. *See Certain Botulinum Toxin Products,* Inv. No. 337-TA-1145 ("1145 Investigation"). The accused product at issue in the 1145 Investigation was Daewoong's BTX drug product designated DWP-450. Evolus was Daewoong's marketing partner for aesthetic indications and marketed and sold the commercial version of DWP-450 in the United States under the trade name Jeuveau®.

113. The ALJ issued his Final Initial Determination in the 1145 Investigation on July 6, 2020. The Commission issued its Final Determination in the 1145 Investigation on December 16, 2020.

114. In its Final Determination in the 1145 Investigation, the Commission "determine[d] that Complainants have established a violation of section 337 by Respondents based on the misappropriation of trade secrets relating to Medytox's manufacturing processes." The Commission also "determine[d] that: (1) the appropriate remedy is a [Limited Exclusion Order] directed against Respondents unfair imported products and a [Cease and Desist Order] directed against Evolus for a duration of 21 months; (2) the public interest does not preclude this remedy; and (3) the bond during the period of Presidential review is set in an amount of $441 per 100U vial of accused product."

115. Following the Commission's Final Determination in the 1145 Investigation, Medytox and Evolus reached a settlement ("the Medytox/Evolus Settlement Agreement"). (Confidential Exhibit 56 at ¶ 43.) As part of the Medytox/Evolus Settlement Agreement, [redacted]

[redacted]

B. California Actions

116. On June 6, 2017, Medytox filed suit against Daewoong in California state court. (*See Medytox Inc. v. Daewoong Pharmaceuticals Co., Ltd. and Evolus, Inc. et al.*, Case No. 30-2017- 00924912-CU-IP-CJC (Cal. Super. Ct., Orange Cty. 2017) ("the California State Action")). The California State 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.

117. On August 30, 2017, Daewoong moved to dismiss the case based on forum non conveniens and the existence of the Korean Actions. On or around October 12, 2017, the California court granted Daewoong's motion.

118. On May 14, 2021, Medytox filed an action against Daewoong and Aeon Biopharma in the United States District Court for the Central District of California. (*See Medytox, Inc. v. Aeon Biopharma, Inc. and Daewoong Pharmaceutical Co. Ltd.*, Case No. 21-CV-00903 (C.D. Cal. May 14, 2021) ("the California Federal Action").) Aeon Biopharma is Daewoong's marketing partner for therapeutic indications of DWP-450 in the United States and is conducting clinical trials for its product currently designated ABP-450. The California Federal Action alleged that ABP-450 uses the same BTX as Evolus' product Jeuveau® that the ITC previously determined Daewoong was manufacturing using trade secrets misappropriated from Medytox.

119. Shortly after the filing of the complaint in the California Federal Action, Medytox and Aeon Biopharma reached a settlement ("the Medytox/Aeon Biopharma Settlement Agreement"). (Confidential Exhibit 56 at ¶ 44.) As part of the Medytox/Aeon Biopharma

Settlement Agreement, [redacted]

[redacted]

C. Indiana State Court

120. On May 4, 2018, Medytox filed suit against its former employee Byung Kook Lee ("BK Lee") in Indiana Commercial Court in Marion County. (*See Medytox Inc. v. Byung Kook Lee*, Case No. 49D01-1805-PL-017584 (Ind. Super. Ct., Marion Cty. 2018).) The Indiana Action asserted claims solely concerning BK Lee's personal liability for his role in Daewoong's theft of Medytox's trade secrets.

121. On June 8, 2018, BK Lee filed a motion to dismiss or stay the case based on forum non conveniens. On October 4, 2018, the Indiana Court granted BK Lee's motion with respect to conduct that occurred in Korea and stayed the rest of the case.

D. Korean Actions

122. On October 30, 2017, Medytox filed an action in the Seoul Central District Court in Korea alleging that Daewoong misappropriated Medytox's trade secrets and used them to develop and market its own product under the trade name Nabota®. (*See* Korean Civil Case No. 2017Ga-Hap574026). This action is ongoing.

123. Daewoong was also the subject of an ongoing criminal investigation in Korea arising out of its misappropriation of Medytox's trade secrets. Earlier this year, the Seoul Central District Prosecutor's Office decided not to file an indictment, and Medytox has appealed this decision. The case is currently ongoing at the Seoul High Prosecutor's Office. (*See* Korean Criminal Case No. 2022Go-Bul-Hang1155.)

X. THREAT OF SUBSTANTIAL INJURY AND SUBSTANTIAL INJURY TO DOMESTIC INDUSTRY

A. Domestic Industry Exists

124. Pursuant to 19 C.F.R. §§210.12(a)(6)-(8), Medytox states that a domestic industry exists in the United States for: (1) Jeuveau®; (2) MT10109L; (3) ABP-450; and (4) other BTX drug products. For purposes of establishing a domestic industry in the United States, these products may be viewed independently or collectively. The total value of the United States BTX market is approximately $3.5 billion.

1. Domestic Industry Related to Jeuveau®

125. Jeuveau® (prabotulinumtoxinA) is an FDA approved BTX drug product marketed and sold in the United States. Evolus is the holder of the BLA for Jeuveau®, which the FDA approved in February 2019. (Exhibit 17.) Jeuveau® is currently indicated for at least one cosmetic application. (Exhibit 18.) Upon information and belief, Evolus 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 for Jeuveau®.

126. [redacted] As explained in paragraph 114 above, following the Commission's Final Determination in the 1145 Action, Medytox and Evolus entered into the Medytox/Evolus Settlement Agreement. (*Id.*) [redacted]

127. Jeuveau® first shipped to customers in the United States in May 2019. (Exhibit 19 at 3.)

128. In 2021, Evolus sold over [redacted] units of Jeuveau in the United States. (Confidential Exhibit 59). In 2021, Jeuveau® generated approximately [redacted] in net product revenue in the United States. (*Id.*) Jeuveau® is currently listed at $610 per vial in the United States. (Exhibit 61).

129. Evolus had a total of $152.2 million in assets in the United States in 2017. (Exhibit 20.) As of December 31, 2021, Evolus had over $1.7 million of Jeuveau® inventory in the United States. (Exhibit 19).

130. Evolus has its principal office in Newport Beach, California, where it leases over 17,000 square feet of space. As of December 31, 2021, Evolus had 166 full-time employees in the United States. (Exhibit 19 at 43.)

131. According to its most recent earnings report, Evolus expects total net revenues for 2022 between $143 million and $159 million, representing a year-over-year growth of 43% to 50%. (Exhibit 60).

2. Domestic Industry Related to MT10109L

132. MT10109L is a Medytox next-generation BTX drug product currently in clinical trials in the United States and for which Medytox intends to file a BLA with the FDA seeking approval to market and sell MT10109L in the United States. (Confidential Exhibit 56.) In the prior 1145 Action, the ALJ found that a domestic industry exists with respect to MT10109L. (1145 Action, Final Initial Determination, J. Shaw (July 6, 2020).)

133. Medytox is currently conducting clinical trials in support of its planned BLA. (Confidential Exhibit 56 at ¶ 24.) Millions of dollars have been invested to bring MT10109L to the U.S. market, including costs associated with research and development, clinical trials, regulatory approval, manufacturing facilities and equipment, and operations costs. (*Id.*)

134. The clinical trials of MT10109L are currently being conducted or have been conducted in various locations across the United States, including Glendale, Arizona; Scottsdale, Arizona; Newport Beach, California; Solana Beach, California; Coral Gables, Florida; Bradenton, Florida; Wilmington, North Carolina; and Austin, Texas. (Exhibit 56 at ¶ 25; Exhibits 24–28.)

135. A Phase 1 clinical trial of MT10109L was initiated in February 2011. The trial, entitled "A Randomised, Double-Blind, Intra-Individual Controlled, Single-Center, Phase I Dose Escalation Healthy Volunteer Study to Determine the Safety and Tolerability of MT10109 (Clostridium Botulinum Toxin Type A) in Comparison to Botox®," was conducted in Australia and completed in October 2011. (Confidential Exhibit 56 at ¶ 26; Exhibit 22.)

136. A Phase 2 clinical trial of MT10109L began in December 2011. The trial, entitled "A Randomised, Double-blind, Multi-centre, Phase II, Optimal Dose-finding Study to Determine the Safety and Efficacy of MT10109 (Clostridium Botulinum Toxin Type A) in Subjects with Moderate to Severe Glabellar Lines in Comparison to BOTOX®," was conducted in Australia and completed in August 2012. (Confidential Exhibit 56 at ¶ 27; Exhibit 23.)

137. The first Phase 3 clinical trial of MT10109L began in October 2018. The trial, entitled "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of MT10109L (NivobotulinumtoxinA) for the Treatment of Glabellar Lines With or Without Concurrent Treatment of Lateral Canthal Lines," completed in January 2021. The clinical trial enrolled 415 participants. This study was conducted in the United States, including in Glendale, Arizona; Newport Beach, California; Coral Gables, Florida; Metairie, Louisiana; Hunt Valley, Maryland; New York, New York; Bellaire, Texas; Arlington, Virginia; and Norfolk, Virginia; along with locations in Canada, Germany, and the United Kingdom. (Confidential Exhibit 56 at ¶ 28; Exhibit 24.)

138. The second Phase 3 study of MT10109L began in November 2018. The trial, entitled "A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of MT10109L (NivobotulinumtoxinA) for the Treatment of Lateral Canthal Lines With or Without Concurrent Treatment of Glabellar Lines," completed in January 2021. The clinical trial enrolled 424 participants. This study was conducted in the United States, including in Scottsdale, Arizona; Solana Beach, California; Bradenton, Florida; New Orleans, Louisiana; New York, New York; Rochester, New York; Raleigh, North Carolina; Wilmington, North Carolina; Dublin, Ohio; and Austin, Texas; in addition to locations in Canada and Germany. (Confidential Exhibit 56 at ¶ 29; Exhibit 25.)

139. The third Phase 3 trial of MT10109L began in December 2018. The trial, entitled "A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of MT10109L (nivobotulinumtoxinA) for the Treatment of Lateral Canthal Lines," completed in January 2021. The clinical trial enrolled 235 individuals. This study was conducted in the United States, including in Glendale, Arizona; Newport Beach, California; Coral Gables, Florida; Metairie, Louisiana; Hunt Valley, Maryland; New York, New York; Bellaire, Texas; Arlington, Virginia; and Norfolk, Virginia, along with locations in the Russian Federation and the United Kingdom. (Confidential Exhibit 56 at ¶ 30; Exhibit 26.)

140. The fourth Phase 3 clinical trial of MT10109L began in December in 2018. The trial, entitled "A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of MT10109L (NivobotulinumtoxinA) for the Treatment of Glabellar Lines," completed in January 2021. The trial enrolled 234 individuals. The study was conducted in the United States, including in Scottsdale, Arizona; Solana Beach, California; Bradenton, Florida; New Orleans, Louisiana; New York, New York; Rochester, New

York; Raleigh, North Carolina; Dublin, Ohio; and Austin, Texas; in addition to locations in Belgium and the Russian Federation. (Exhibit Confidential Exhibit 56 at ¶ 31; Exhibit 27.)

141. The fifth Phase 3 clinical trial of MT10109L began on October 23, 2019, and is ongoing. The trial, entitled "A Multicenter, Long-term, Open-label Study to Evaluate the Safety of MT10109L (NivobotulinumtoxinA) for the Treatment of Glabellar Lines and Lateral Canthal Lines," enrolled 958 patients. The study has been conducted in the United States, including in Scottsdale, Arizona; Bradenton, Florida; Austin, Texas; Rochester, New York; Raleigh, North Carolina; New Orleans, Louisiana; Dublin, Ohio; New York, New York; Glendale, Arizona; Bellaire, Texas; Newport Beach, California; Metairie, Louisiana; Arlington, Virginia; Hunt Valley, Maryland; Norfolk, Virginia; Coral Gables, Florida; Solana Beach, California; and Wilmington, North Carolina; in addition to locations in Canada, Germany, Belgium, UK, and Russia. The trial is set to be completed on January 21, 2023. (Confidential Exhibit 56 at ¶ 32; Exhibit 28.)

142. Medytox intends to submit its BLA for MT10109L upon completion of final study reports for the first four Phase 3 clinical trials referenced above. (Confidential Exhibit 56 at ¶ 33.)

3. Domestic Industry Related to ABP-450

143. Upon information and belief, ABP-450 is a BTX drug product currently in clinical trials in the United States and for which Aeon Biopharma intends to file a BLA with the FDA seeking approval to market and sell ABP-450 in the United States. (Exhibits 29–30.)

144. [redacted] As explained in paragraph 118 above, following the filing of the complaint in the California Federal Action, Medytox and Aeon Biopharma entered into the Medytox/Aeon Biopharma Settlement

Agreement. (*Id.*) [redacted]

145. On September 2, 2020, Aeon Biopharma announced that the FDA had accepted its IND for certain therapeutic indications. (Exhibit 31.) Upon information and belief, following the FDA's approval of the IND, Aeon Biopharma began importing significant quantities of ABP-450 into the United States for the purpose of conducting clinical trials.

146. On March 8, 2021, Aeon Biopharma announced the initiation of enrollment in a Phase II study of ABP-450 for the preventive treatment of migraines. (Exhibit 29.) On April 5, 2021, Aeon Biopharma announced the initiation of patient dosing in a Phase II study of ABP-450 for the treatment of cervical dystonia. (Exhibit 30.)

147. Aeon Biopharma generated approximately $2.5 million revenue in the United States in 2020. (Exhibit 32.)

148. Aeon Biopharma had $21.2 million in assets in the United States in 2020. (*Id.*)

149. Aeon Biopharma had $1.7 million in U.S. capital expenditure in 2019. (*Id.*)

150. As of June 7, 2021, Aeon Biopharma had six employees, all of whom are located in Newport Beach, California. (Exhibit 33 at 109.)

151. Aeon Biopharma occupies approximately 2,000 square feet of space in Newport Beach, California. (*Id.*)

4. Domestic Industry Related to Other BTX Drug Products

152. In addition to Jeuveau®, MT10109L and ABP-450, a domestic industry also exists in the United States for several other BTX drug products, including: (1) Allergan's Botox® products; (2) Merz's Xeomin® product; (3) Ipsen's Dysport® product; (4) Supernus' Myobloc® product; and (4) Revance's Daxi product.

(a) Botox®

153. Botox® and Botox® Cosmetic (onabotulinumtoxinA) are FDA approved BTX drug products marketed and sold in the United States. Allergan is the holder of the BLA for Botox® and Botox® Cosmetic, which the FDA approved in December 1991. (Exhibit 34.) Botox® is currently indicated for at least eight therapeutic applications, and Botox® Cosmetic is currently indicated for at least three cosmetic applications. (Exhibit 35.) Upon information and belief, Allergan continues to conduct research and development on additional therapeutic uses and indications, with different dosages, all of which are designed to exploit and expand the domestic industry for Botox® and Botox® Cosmetic.

154. In the prior 1145 Investigation, the ALJ and Commission found that there was a domestic industry for Botox® and Botox® Cosmetic. (1145 Action, Final Determination (January 13, 2021).) In its Final Determination in the 1145 Investigation, the Commission found that "there is 'an industry in the United States' with respect to Botox®." (*Id.*) The Commission further held that "Allergan's expenditures are significant based on the [active pharmaceutical ingredient's] contribution to the overall value of Botox® and the share of overall R&D performed in the United States." (*Id.*) The Commission further held that "consistent with Federal Circuit precedent, an industry in the United States may be found to exist based on qualifying investments in domestic products that 'directly compete' with the accused products – in this instance Botox®." (*Id.*)

155. Botox® generated $3.436 billion net revenue in the United States in 2021 across its therapeutic and aesthetic products. (Exhibit 36 at 38.)

(b) Xeomin®

156. Xeomin® (incobotulinumtoxinA) is an FDA approved BTX drug product marketed and sold in the United States. Merz is the holder of the BLA for Xeomin®, which the

FDA approved in July 2010. (Exhibit 37.) Xeomin® is currently indicated for at least five therapeutic applications and one cosmetic application. (Exhibit 38.) Upon information and belief, Merz 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 for Xeomin®.

157. Xeomin® generates approximately $149.7 million in revenue in the United States annually. (Exhibit 39 at 17.)

158. Merz North America is headquartered in Raleigh, North Carolina. (Exhibit 40.)

159. Merz North America operates a 20,000 square-foot facility. (Exhibit 39 at 4.)

160. Merz North America has 310 U.S. employees. (*Id.* at 3.)

(c) Dysport®

161. Dysport® (abobotulinumtoxinA) is an FDA approved BTX drug product marketed and sold in the United States. Ipsen is the holder of the BLA for Dysport®, which the FDA approved in April 2009. (Exhibit 41.) Dysport® is currently indicated for at least three therapeutic applications and one cosmetic application. (Exhibit 42.) Upon information and belief, Ipsen 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 for Dysport®.

162. Dysport® generates approximately $400 million in revenue in the United States annually. (Exhibit 43.) In 2020, 33% of Ipsen's sales were in North America.

(d) Myobloc®

163. Myobloc® (botulinum toxin type B) is an FDA approved BTX drug product marketed and sold in the United States. Supernus is the holder of the BLA for Myobloc® , which the FDA approved in 2000. (Exhibit 44.) Myobloc® is currently indicated for at least two therapeutic applications. (Exhibit 45.) Upon information and belief, Supernus 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 for Myobloc®.

164. Supernus employs 563 full-time employees in the United States. (Exhibit 46 at 30.) Supernus reported $1.5041 billion in total assets in the United States in 2020. (*Id.* at 85.) Supernus also had capital expenditures of $3.4 million in the United States in 2020. (Exhibit 47 at 1.)

(e) DaxibotulinumtoxinA

165. Upon information and belief, Daxi (daxibotulinumtoxinA) is a BTX drug product currently in clinical trials in the United States and for which Revance has filed a BLA with the FDA seeking approval to market and sell Daxi in the United States. (*See, e.g.*, Exhibit 48.)

166. On November 25, 2019, Revance announced that it had submitted a BLA to the FDA for Daxi for the treatment of one aesthetic indication, following successful Phase 3 clinical trials. (Exhibit 49.) On March 8, 2022, Revance announced that it had resubmitted its BLA to the FDA for Daxi. (Exhibit 50.)

167. As of December 31, 2021, Revance had 495 employees in the United States. (Exhibit 51 at 29.) Revance manufactures Daxi in Newark, California. (*Id.* at 1.) The Newark, California, facility includes approximately 109,000 square feet of office, laboratory, and manufacturing space which supports Revance's regulatory, pre-commercial and research and development manufacturing activities. (*Id.* at 75.) Revance also leases over 71,000 square feet of space at its Nashville, Tennessee, headquarters, along with over 9,600 square feet of office space in Irvine, California, and over 30,000 square feet of office space in Pleasanton, California. (*Id.*) Revance's assets in the United States totaled $531 million in 2021. (*Id.* at F-5.) Revance also had capital expenditures of $4.2 million in 2020. (Exhibit 52.)

B. Injury to Domestic Industry

168. Pursuant to 19 C.F.R. §§210.12(8), Medytox states that Proposed Respondents' unlawful acts are destroying, substantially injuring, and/or preventing the establishment of the domestic industry for Jeuveau®, MT10109L, ABP-450, and other FDA-approved BTX products, and/or threaten to do so in the future.

169. Proposed Respondents' unlawful acts have given them an unfair and significant competitive advantage that will substantially and irreparably injure the domestic industry pursuant to 19 U.S.C. § 1337(a)(1)(A)(i) in several ways.

170. For example, Proposed Respondents' unlawful acts have created and/or will create a new competitor (Proposed Respondents) in the market for BTX drug products that did not exist beforehand. But for Letybo®, Proposed Respondents have no product that will compete with the Domestic Industry Products. Letybo® was developed from one or more proprietary strains and intellectual property stolen from Medytox. Proposed Respondents could not have developed a BTX drug product, supplied such a product for clinical trials, and filed for FDA approval to launch Letybo® in the U.S. market in the timeframe alleged herein but for their unlawful acts. 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 drug product without dedicating the time and resources otherwise required will substantially and irreparably injure the domestic industry by, for example, allowing Proposed Respondents to undercut the Domestic Industry Products' pricing.

171. Further, Proposed Respondents' unlawful acts have allowed and/or will allow Proposed Respondents to compete directly with the Domestic Industry Products in a way and manner that would not have existed without the theft of Medytox's proprietary strain and intellectual property. Through the misuse of Medytox's proprietary strain and intellectual

property, Proposed Respondents have produced and are seeking FDA approval to launch a BTX drug product (Letybo®) for the same indications as the Domestic Industry Products. By launching a product for the same approved indications, Proposed Respondents intend "to make Letybo one of the top three brands in the U.S. market within three years of the launch." (*See* Exhibit 2.)

172. Further, Proposed Respondents' unlawful acts have destroyed and/or will destroy the secrecy and confidentiality of Medytox's proprietary strain and intellectual property, which will diminish and substantially impair the value of such proprietary strain and intellectual property to Medytox.

173. Proposed Respondents unlawful acts have also caused and/or will cause on-going and systematic damage to the competitive position of the Domestic Industry Products and the ability of the sponsors of those products to successfully launch and introduce new products (such as MT10109L and ABP-450) and new applications into the relevant marketplace.

174. Proposed Respondents are specifically targeting the domestic industry described above. For example, Hugel has indicated its express intention for Letybo® to compete directly with all Domestic Industry Products. (*Id.* (Hugel America President James Hartman stating, "The company aims to make Letybo one of the top three brands in the U.S. market within three years of the launch by establishing a systematic and aggressive marketing strategy for a fast market penetration.")). Hugel has also indicated that it intends its U.S. subsidiary Hugel America to lead the company's efforts to quickly penetrate the U.S. market. (Exhibit 53 ("We aim to rise to one of the top three local brands within three years by entering the local market more aggressively and strategically through our subsidiary . . . As we expect that the FDA's inspection will end smoothly, we plan to accelerate the entry into the U.S. market.").)

175. Croma has also indicated its express intention for Letybo® to compete directly with the Domestic Industry Products. According to Croma's Managing Director, Croma seeks to "clear another hurdle in our international expansion process, while . . . [b]oth companies will certainly benefit from the experiences we make together in North America . . . ." (Exhibit 54.) Hugel's CEO stated further that the "US is a huge market that currently accounts for the majority of the global botulinum toxin market . . . [W]e plan to further strengthen our global footprint with our long-term partner, Croma." (*Id.*)

176. Through direct competition between the Accused Products and the Domestic Industry Products, Proposed Respondents will destroy or substantially injure the U.S. BTX market within the meaning of 19 U.S.C. §1337(a)(1)(A). *See TianRui Grp. Co. v. ITC*, 661 F.3d 1322, 1335-37 (Fed. Cir. 2011) (holding that where unfair imports "directly compete" with the domestically-produced products, such competition is "sufficiently related to the investigation to constitute injury to an 'industry' within the meaning of section 337(a)(1)(A).").

XI. RELIEF REQUESTED

177. Medytox respectfully requests that the Commission:

(a) Institute an 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 the Accused Products that were developed and/or manufactured using Medytox's proprietary strain of *C. botulinum* and related trade secrets;

(b) Schedule and conduct a hearing pursuant to Section 337(c) for the purposes of (i) receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and (ii) following the hearing, determining that there has been a violation of Section 337;

(c) Issue a permanent limited exclusion order directed to products manufactured by or on behalf of each Proposed Respondent, its subsidiaries, related companies, and agents pursuant to 19 U.S.C. §1337(d) excluding entry into the United States of the Accused Products that were developed and/or manufactured using Medytox's proprietary strain of *C. botulinum* and related trade secrets;

(d) Issue a permanent cease and desist order pursuant to 19 U.S.C. §1337(f) prohibiting each Proposed Respondent, its domestic subsidiaries, related companies, and agents from engaging in the importation, sale for importation, marketing and/or advertising, distribution, offering for sale, sale, use after importation, and other transfer within the United States of the Accused Products that were developed and/or manufactured using Medytox's proprietary strain of *C. botulinum* and related trade secrets;

(e) Impose a bond upon importation of the Accused Products that were developed and/or manufactured using Medytox's proprietary strain of *C. botulinum* and related trade secrets, during the Presidential review period pursuant to 19 U.S.C. § 1337(j); and

(f) 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: March 30, 2022

Respectfully submitted,

/s/ David Bilsker

Alex Lasher
Nina Tallon
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
1300 I Street NW,
Suite 900
Washington, D.C. 20005
Telephone: (202) 538-8000

Steve Cherny
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Huntington Avenue, Suite 520
Boston, Massachusetts 02199
Telephone: (617) 712-7100

David Bilsker
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
50 California Street, 22nd Floor
San Francisco, California 94111
Telephone: (415) 875-6600

James Baker
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
Telephone: (212) 849-7000

Attorneys for Medytox Inc.

VERIFICATION OF COMPLAINT

I, Kenneth T. Kim, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), the following:

1. I am the Head of Global Legal 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;

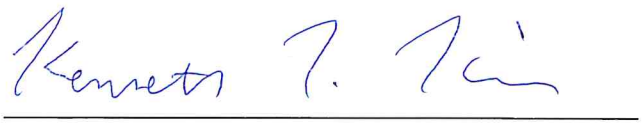
3. To the best of my knowledge, information and belief founded upon reasonable inquiry under the circumstances, the complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceedings;

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 March 29, 2022 in Seoul, Korea.



Kenneth T. Kim