UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of
CERTAIN BOTULINUM TOXIN
PRODUCTS, PROCESSES FOR
MANUFACTURING OR RELATING TO
SAME AND CERTAIN PRODUCTS
CONTAINING SAME

Inv. No. 337-TA-1145

RESPONDENTS’ SUMMARY OF THEIR PETITION FOR
REVIEW OF THE FINAL INITIAL DETERMINATION AND
REQUEST FOR ORAL ARGUMENT

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Respondents Daewoong Pharmaceutical Co., Ltd. ("Daewoong") and Evolus, Inc. ("Evolus") respectfully submit this Summary of Their Petition for Review of the Final Initial Determination and Request for Oral Argument in the above-captioned Investigation. Pursuant to 19 C.F.R. § 210.43, Respondents request review of the following holdings and findings in the ID, which are legally erroneous; clearly factually erroneous; lacking in governing precedent, rule or law; and/or affecting Commission policy:

1. The legally erroneous conclusion that the ITC has subject matter jurisdiction over this foreign dispute about exclusively foreign alleged trade secrets;

2. The legally erroneous conclusion and clearly factually erroneous finding that Allergan has independent standing to sue for wrongs to Medytox, based on alleged trade secrets that Allergan does not own, exclusively license or possess;

3. The legally erroneous conclusion that Botox can constitute a domestic industry in this investigation, despite Allergan lacking standing and Botox having no connection whatsoever to the Allergan-Medytox license agreement, the alleged trade secrets or to the dispute;

4. The legally erroneous conclusion and clearly factually erroneous finding that Medytox’s bacterial strain is a trade secret, even though its genetic sequence has been published on the Internet, it has not been genetically modified, it has been held and freely traded by dozens of entities around the world without restrictions on disclosure, and was acquired by Medytox for free;

5. The legally erroneous conclusion and clearly factually erroneous finding that Daewoong misappropriated Medytox’s bacterial strain, which the ID found despite acknowledging the lack of any concrete evidence of misappropriation;

6. The erroneous decision in Order No. 24 blocking Respondents from taking discovery of Allergan’s bacterial strain (after first granting such discovery), based on the determination that Allergan’s strain is not relevant to this Investigation, which was later conceded by Complainants’ own expert to be factually incorrect and could have conclusively discredited the ID’s only basis for finding strain misappropriation;

7. The legally erroneous conclusion and clearly factually erroneous finding that Complainants demonstrated misappropriation of a Medytox trade secret manufacturing “process,” even though that process was comprised of publicly-known steps patched together for the purposes of this Investigation, the ID never found that this “process” was a trade secret, and the ID erroneously shifted the burden to Daewoong to prove independent development without sufficient evidence of misappropriation;
8. The legally erroneous conclusion and clearly factually erroneous finding that Allergan’s domestic investments in MT10109L and Botox establish domestic industries in those products;

9. The legally erroneous conclusion and clearly factually erroneous finding that Complainants established injury to Botox (Cosmetic and Therapeutic); and

10. The legally erroneous conclusion and clearly factually erroneous finding that this Investigation was initiated within the applicable three-year statute of limitations.

I. SUMMARY OF ARGUMENT

The ID in this Investigation concluded that:

- Complainants have satisfied the jurisdictional prerequisites to ITC relief, even though the alleged trade secrets are exclusively Korean, Medytox (the owner of the alleged trade secrets) has no domestic industry at all, and Complainant Allergan, the sole basis for an injured domestic industry, does not own, exclusively license, or even possess the alleged trade secrets;

- Complainants failed to prove their allegation that a former Medytox employee misappropriated alleged trade secrets and gave them to Daewoong;

- Notwithstanding this failure of proof, Respondent Daewoong misappropriated a bacterial strain and manufacturing information from Complainant Medytox, even though there was no evidence of how this occurred; and

- The bacteria and process information are Medytox’s trade secrets, even though the bacteria is a naturally-occurring, freely-traded, unmodified organism whose genetic sequence is publicly available on the Internet, and the misappropriated “process” consists of individual process steps that have been published for decades and that have been combined only for purposes of this Investigation.

These topline conclusions, and the component determinations that factored into them, are infected by misapplications of law and clear errors of fact. Those errors are all the more critical because the resulting ruling is unprecedented and would, if adopted, significantly expand the ITC’s jurisdiction well beyond the authority granted by Congress and the strictures imposed by the Commission’s own precedent. Respondents respectfully submit that the Commission should grant review to rectify these clear errors and resolve these weighty issues of first impression and ITC policy. Respondents also request oral argument on these issues pursuant to 19 C.F.R. § 210.45(a).
II. SUMMARY OF THE ISSUES ON WHICH REVIEW IS SOUGHT

1. This Foreign Dispute Over Foreign Alleged Trade Secrets Held By A Foreign Party Exceeds The Scope Of The ITC’s Subject Matter Jurisdiction

   The ID’s finding of subject matter jurisdiction over this Korean dispute about Korean alleged trade secrets constitutes a dangerous and unprecedented expansion of the Commission’s jurisdiction. In every prior, finally adjudicated Section 337 investigation regarding trade secret misappropriation, the alleged trade secrets were U.S. intellectual property. The ID’s conclusion is also inconsistent with the statute and legislative history surrounding Section 337, see, e.g., Interdigital Commc’ns. v. Int’l Trade Comm’n, 707 F.3d 1295 (Fed. Cir. 2013) (en banc), demonstrating that the exercise of jurisdiction over Medytox’s allegations would be ultra vires, i.e., outside the bounds set by Congress. The ID, moreover, violates bedrock principles of statutory construction, as it infers broad powers from Congressional silence.

   The Commission should accept review on this issue not only to correct the legal errors described above, but to reiterate its proper role as an enforcer safeguarding American innovations and interests. If the ID’s theory of subject matter jurisdiction becomes the law, it would turn the ITC into an arbiter of foreign intellectual property rights—including those being addressed by foreign tribunals (as Medytox’s are in Korean courts). See Voda v. Cordis Corp., 476 F.3d 887, 900 (Fed. Cir. 2007) (cautioning against requiring the U.S. to “define the legal boundaries of a property right granted by another sovereign and then determine whether there has been a trespass to that right”). This is not the dynamic Congress envisioned when it created Section 337.

2. Allergan Does Not Have Independent Standing—It Does Not Own, Exclusively License, Or Possess The Alleged Trade Secrets at Issue In This Investigation

   Standing is a Constitutional requirement for any case, including at the ITC, to ensure that a court’s or agency’s remedial powers are limited to the appropriate persons. Here, for the first time in the history of the Commission, the ID held this burden satisfied by a party (Allergan) that
does not own, exclusively license, or even possess the alleged trade secrets at issue, Indeed, the ID found that Allergan Yet the ID erroneously concluded that a 2013 license agreement between Allergan and Medytox gave Allergan an exclusive license to them—an error stemming from a failure to distinguish between The provisions of the agreement make plain that Allergan does not have exclusive rights in the latter. Under the federal common law and precedent from the ITC, independent standing does not attach where, as here, the party claiming standing has no right to exclude others from the intellectual property it is asserting.

This is also the first case in which a foreign alleged trade secret owner has been permitted to circumvent its lack of any domestic industry/injury by joining as a co-complainant its U.S. distributor for an unapproved and developmental product (MT10109L), which the ID found was too speculative to support a finding of injury. (The ID also erred by denying Motion 1145-62 to admit a Korean order finding that Medytox falsified testing data, making MT10109L yet more speculative). Under the ID’s reasoning, any foreign party with no connection to the U.S. could gain admission to the ITC by bringing the case with a U.S. distributor—which may possess a “license” to use the IP in the retailed products, but not an exclusive license to that IP in the legal sense. These sweeping and unprecedented conclusions in the ID should be reviewed and reversed.

3. Allergan’s Botox Cannot Support A Domestic Industry—Allergan Has No Standing And Botox Undisputedly Has No Connection To The Alleged Trade Secrets Or The Alleged Misappropriation

The ID concluded that Allergan, which does not own, exclusively license or possess the alleged trade secrets, is entitled to obtain relief for alleged injury to Botox—a product bearing no relationship to the alleged trade secrets or the alleged conduct. See ID at 208. This boundless
formulation of domestic industry is not the law and cannot stand. The ID ignores the long line of cases at the ITC holding that the relevant domestic industry is that of the trade secret owner or trade secret exclusive licensee. See, e.g., Certain Rubber Resins and Processes for Mfg. Same, Inv. No. 337-TA-849, ID at 44 (June 17, 2013); Certain Cast Steel Ry. Wheels, Certain Processes for Mfg. or Relating to Same & Prods. Containing Same, Inv. No. 337-TA-655, ID at 17 (Oct. 16, 2009); TianRui Group Co. Ltd. v. Int’l Trade Comm’n, 661 F.3d 1322, 1337 (Fed. Cir. 2011). In every trade secret case resolved through determination, the domestic industry has belonged to the owner or exclusive licensee of the alleged trade secrets. The ID’s conclusion disregarding this principle is predicated on a misreading of TianRui, and should be rejected.

The ID’s holding, if endorsed by the Commission, would radically alter long-held principles of which parties deserve redress at the ITC. Here, the ID would allow a wholly foreign owner of foreign alleged trade secrets to access the ITC. But it would also grant an exclusion order to a company (Allergan) that did not develop and does not own, possess, or have an exclusive license to the alleged trade secrets; and to remedy alleged wrongful conduct directed not to that company but to another company altogether in a foreign country. For these additional policy-based reasons, the Commission should not adopt the holding of the ID.

4. The Determination That Medytox’s Strain Is A Trade Secret Is An Error of Fact And Law

The ID’s determination that Medytox’s copy of the widely-held Hall-A Hyper C. botulinum bacterial strain can be a trade secret is unprecedented. No tribunal has ever held that a naturally occurring organism, freely traded for decades without restriction, acquired for free and held by numerous competitors throughout an industry, can qualify for trade secret protection. This holding is contrary to every principle of trade secret protection found in ITC decisions and the common law. It is also contrary to the position Medytox took in prior litigation, where Medytox admitted
that its strain is not a trade secret. See RX-3423.6-7, 21 (Medytox California Complaint) ¶ 29, 73.

First, the undisputed, unprotected sharing and disclosure of the strain for decades terminates any potential for trade secret protection. See 1 Milgrim on Trade Secrets §§ 1.05[1] at 1-316, 1.07A at 1-468; § 1.03; FMC Corp. v. Taiwan Tainan Giant Indus. Co., 730 F.2d 61, 63 (2d Cir. 1984) ("[a] trade secret once lost is, of course, lost forever"). Second, to qualify as a trade secret the strain must either be or embody secret information that gains value from its secrecy. E.g., Certain Bone Cements, Components Thereof, and Products Containing the Same, Inv. No. 337-TA-1153, ID, 2020 WL 2617311, at *9 (May 6, 2020). Despite finding that the strain is not a secret and that any information embodied in the strain is valueless, the ID still concluded that the strain can be a trade secret. See ID at 67-68. Third, trade secrets must give their holder a competitive advantage over competitors and must be substantially exclusive to its holder, but the ID erroneously held that neither is required. See ID at 64, 86. That error is dispositive, as the ID found that the differences between Medytox’s copy of the Hall-A Hyper strain and other copies held by competitors do not provide any competitive advantage. See ID at 66-67. This too requires review and reversal.

5. The Determination That Medytox’s Strain Was Misappropriated Is Based On Errors Of Fact And Governing Law And A Misallocation Of Burden

Complainants filed their complaint and presented evidence on a single theory of strain misappropriation: that Daewoong intentionally misappropriated a sample of Medytox’s C. botulinum strain through a former Medytox employee, Dr. BK LEE. The ID, however, found that “no evidence was presented to show when and how a specific quantity of Medytox’s strain went missing” (at 94) and correctly concluded that “it has not been established that Dr. BK LEE took the strain from Medytox and, for consideration or otherwise, gave it to Daewoong”
Yet rather than holding Medytox to its burden, the ID improperly shifted the burden to Daewoong, based not on evidence of misappropriation, but based on its view that the strains were similar. See ID at 103. This is plain legal error. See Penalty Kick Management Ltd. v. Coca Cola, 318 F.3d 1284, 1296 (11th Cir. 2003).

In reaching this conclusion, the ID accorded dispositive weight to the opinion from Medytox’s expert Dr. Keim that Medytox’s ubiquitous strain and Daewoong’s strain share mutations at six particular base pairs in their DNA, called SNPs. See ID at 99. But the ID failed to reckon with the undisputed fact that the Hall-A Hyper strain has been circulated across the globe, and therefore (as Dr. Keim admitted) to come to a reliable conclusion, one would have to analyze additional Hall-A Hyper strains. Dr. Keim did not do this, and conceded that it is “impossible” to know whether the Daewoong strain comes from Medytox or another Hall-A Hyper Strain. Hearing Tr. 159:8-14, 166:2-11; RDX-0013C.4. Moreover, Complainants’ and Respondents’ experts both testified that there are genetic differences found in a slow-to-evolve region, see Hearing Tr. 826:15-827:18 and CX-0015C.51 (Keim WS) at Q/A 215, which makes it unlikely the Daewoong strain came from Medytox. The ID ignored these facts.

6. The ID Clearly Erred In Order No. 24 Blocking Respondents From Taking Discovery Of Allergan’s Bacterial Strain

As Complainants’ expert Dr. Keim admitted, in order to come to a reliable conclusion about the significance of the SNPs shared by Daewoong’s and Medytox’s strains, one would have to analyze additional Hall-A Hyper strains. See Hearing Tr. at 166:12-167:2. But in Order No. 24, the ALJ improperly reversed course on a prior order permitting Respondents to take discovery of Complainant Allergan’s Hall-A Hyper strain, and instead blocked Respondents’ attempt to obtain the very evidence that could have debunked the theory on which the ID found misappropriation. Order No. 24 should be reviewed and reversed.
7. **The Determination Of Misappropriation Based On Allegations Of Manufacturing Process Theft Is Based On Errors Of Fact And Governing Law**

The determination of misappropriation as to Medytox's asserted manufacturing process contains several errors of law and fact. *See* ID at 110-52. In examining whether Medytox had identified a trade secret process, the ID states that the asserted process trade secret is “the manufacturing process for Meditoxin.” *E.g.*, ID at 19, 122-23, 125, 127. Critically, the ID concluded that “it is the *process as a whole* that is the trade secret, even if the elements of the process can be found in various publications.” ID at 119 (emphasis added). But when assessing misappropriation, the ID does not analyze whether the Meditoxin “process as a whole” was misappropriated. Had the ID compared the whole Meditoxin process to the whole Daewoong process, it would be clear there are important and undisputed differences. *Compare* JX-0006C.6 (DWP-450 CTD Section 3.2.3.2.2) (Daewoong process) *with* CX-2068C.1-16 (SecuPrint Image of Batch Record No. 05) (Meditoxin process). Instead, the ID does what it said was improper, which is to “deconstruct [the processes] to their constituent parts, arguing that each element can be found” in Daewoong’s process. ID at 119. This failure at the outset infects all the ID’s findings on this issue.

The ID makes a further fundamental error of law by imposing an improper burden on Respondents to show independent development without sufficient evidence of misappropriation. As with the strain, the ID did not find that Dr. BK LEE misappropriated Medytox's alleged process trade secrets; rather the ID merely found that “Dr. BK LEE *could have* divulged trade secret information to Daewoong,” while conceding that “the record is not clear that he actually did so.” ID at 132 (emphasis added). This is not sufficient to support a finding of misappropriation under both ITC and other precedents. The ID’s only affirmative “evidence” of misappropriation, then, consists of superficial similarities between processes *that*
are in the public domain (as are all the steps in Medytox’s processes). This does not establish misappropriation and cannot shift the burden to Daewoong to adduce evidence of independent development, or it would do so in nearly all cases dealing with similar products. See, e.g., FERCO Enterprises, Inc. v. Taylor Recycling, 2007 WL 9701361, at *21 (N.D. Ga. Oct. 16, 2007), aff’d, 291 F. App’x 304 (11th Cir. 2008). Finally, even if Respondents had a burden to show independent development, the ID committed clear errors of fact by failing to acknowledge or address the substantial evidence in the record that Daewoong independently developed its manufacturing process, and that its development process was both lengthy and appropriately documented. This finding should be reviewed and reversed.

8. **The ID Erred By Concluding That Complainants’ Domestic Investments In MT10109L And Botox Establish Domestic Industries In Those Products**

Even if the domestic investments of Allergan can be considered, which they cannot, see *supra* II.2 and II.3, the ID committed legal error by concluding that Allergan’s proffered investments in MT10109L and Botox establish domestic industries. The entirety of Allergan’s MT10109L investments credited by the ID were in R&D, which cannot alone constitute a valid domestic industry in a trade secret case. In addition, under the “nature and significance” test, the activities of a mere importer, as Allergan is here with respect to MT10109L, cannot satisfy the domestic industry requirement. As for Botox, after stripping out mere importer activities, Allergan is left with domestic expenses that pale in comparison to those incurred abroad. These domestic investments are therefore not substantial under the proper analysis outlined in *Certain Carburetors and Prod. Containing Such Carburetors*, Inv. No. 337- TA-1123, Comm’n Op. (Oct. 28, 2019).

9. **The ID Erred By Concluding That Complainants Established Injury To Botox**

Although the ID correctly found no injury as to MT10109L (at 224-25), it incorrectly found injury to Botox by applying the wrong legal test. The ID focused on whether there was harm to
the Botox franchise generally, as opposed to the correct test of whether there was harm to the proffered Botox domestic investments (there was not). See, e.g., Certain Activity Tracking Devices, Sys. and Components Thereof, Inv. 337-TA-963, ID (unreviewed), 2016 WL 11596099 at *43 (Aug. 23, 2016). Moreover, the ID failed to consider Botox’s increasing sales, market expansion, and competition from other players; and failed to support its finding of injury to Botox Therapeutic, all of which are clearly erroneous. Finally, the ID made no finding on causal nexus, instead equating misappropriation with injury. This alone is reversible error.

10. The Determination That Complainants’ Claims Are Not Barred By A Three Year Statute Of Limitations Is Based On Misapplications Of Fact And Governing Law

Finally, the ID erred in holding that Section 337 does not have a statute of limitations and that, in any event, the limitations period in a trade secret case begins when Medytox “should have immediately concluded that” misappropriation occurred. The law is clear: the statute of limitations is three years from when the claimant was “on notice to make further inquiry if they harbor doubts or questions about the defendant’s actions.” Phillip M. Adams & Associates, LLC v. Dell Computer Corp., 519 F. App’x 998, 1007 (Fed. Cir. 2013). The ID failed to consider evidence that Medytox was on notice of its claims in April 2015, when Medytox’s CEO admitted that he suspected that Daewoong had misappropriated the strain, which is more than three years before the Complaint was filed in January 2019. This suspicion was sufficient to trigger the statute of limitations, and the ID’s failure to dismiss this Investigation was clear error.

III. CONCLUSION

For the foregoing reasons, and those set forth in the accompanying Petition, the Commission should reverse the finding of the ID that there has been a violation of Section 337, and should reverse the ALJ’s finding in Order No. 24 barring discovery of Allergan’s strain. Respondents respectfully request oral argument on any issues on which the Commission grants review.
Date: July 20, 2020

Respectfully submitted,

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I, D.B. “Brandy” Swanson, hereby certify that on July 30, 2020, of the foregoing
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