PUBLIC VERSION

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-1313**

ORDER NO. 21: DENYING RESPONDENTS HUGEL INC. AND HUGEL AMERICA, INC.'S REQUEST TO COMPEL TESTING OF COMPLAINANT MEDYTOX'S MASTER CELL BANK

(June 2, 2023)

On May 31, 2023, Respondents Hugel Inc. and Hugel America, Inc. ("Hugel") submitted a letter pursuant to Ground Rule 5.4.1.1 regarding a discovery dispute. Hugel's letter is attached as Attachment A to this Order. On June 1, 2023, Complainant Medytox, Inc. ("Medytox") filed a responsive letter. Medytox's letter is attached as Attachment B to this Order. I scheduled a teleconference to discuss the issues raised in this letter on June 2, 2023. Order No. 20. During the teleconference, the parties were able to resolve two of the three disputes raised in the letter. This order addresses the third, and final, dispute, relating to Hugel's testing of a Medytox cell bank of *Clostridium botulinum*.

At a high level, certain alleged trade secrets in this investigation relate to strains, including specific genetic markers, of Medytox's *C. botulinum* which Medytox asserts were misappropriated by Hugel. Because the DNA sequences of the parties' *C. botulinum* samples are relevant, the parties have sought testing to obtain DNA sequencing for the other party's bacterial samples. To facilitate this discovery, the parties sought information regarding cell banks of *C. botulinum*. In its discovery responses, Medytox identified its cell banks of *C. botulinum* bacteria. Attachment A, Ex 3 at 124–26. These included a master cell bank, CBAM0301, [redacted]

[redacted], along with many working cell banks. *Id.* Hugel requested that it be permitted to test a sample from CBAM0301, along with samples from various working cell banks. As Medytox explained, it only has [redacted], and therefore it objected to production of CBAM0301. Instead, Medytox proposed that Hugel be permitted to test two child cell banks of CBAM0301: [redacted]. Attachment A, Ex.4. Medytox also stated that it produced sequencing data from CBAM0301 which could be compared to the data Hugel obtained from [redacted]. *Id.* Hugel, unsatisfied with this proposal, served a letter seeking to compel Medytox to provide a tube of CBAM0301 for testing. Attachment A at 2.

Medytox opposed this request, arguing that it would be highly prejudicial to require production of [redacted] of CBAM0301. Attachment B at 2. Medytox argued that Hugel will not be prejudiced because it will be provided the sequencing data and the two child cell banks. *Id.* Medytox noted that in the 1145 Investigation, the Commission and ALJ Shaw relied on Medytox's expert analysis based on this sequencing data for CBAM0301 that one child cell bank, [redacted] (referred to in that Investigation as CB19) was "virtually identical" to CBAM0301. *Id.* (citing *Certain Botulinum Toxin Prods., Processes for Mfg. or Relating to Same, & Certain Prods. Containing Same*, Inv. No. 337-TA-1145, Initial Determination at 104 (Aug. 6, 2020); *Certain Botulinum Toxin Prods., Processes for Mfg. or Relating to Same, & Certain Prods. Containing Same*, Inv. No. 337-TA-1145, Comm'n Op. at 35–36 (Jan. 13, 2021)). Medytox also argued that because it had provided both final sequence and raw data to Hugel, and Hugel can use its result of testing of the child strains to confirm the accuracy of Medytox's own sequencing of CBAM0301. *Id.*

Hugel's motion is denied. Commission Rule 210.27(b) provides that, unless otherwise ordered by the administrative law judge, a party may obtain discovery regarding any matter, not

privileged, that is relevant to the claim or defense of the party seeking discovery. 19 C.F.R. § 210.27(b).

The administrative law judge must limit by order the frequency or extent of discovery otherwise allowed by Commission Rule 210.27 if the administrative law judge determines, among other things, that (i) "[t]he discovery sought is unreasonably cumulative or duplicative, or can be obtained from another source that is more convenient, less burdensome, or less expensive;" or (ii) "[t]he burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the investigation, the importance of the discovery in resolving the issues to be decided by the Commission, and matters of public concern." 19 C.F.R. §§ 210.27(d)(1), (4).

I am sensitive to Hugel's legitimate concerns that CBAM0301 [redacted], but the burden of testing of Medytox's CBAM0301 cell bank is heavy. The testing required in this Investigation for any individual sample is extensive and costly, as the significant motion and letter practice regarding testing has shown. The testing is, essentially, destructive: when a tube from a cell bank is taken to culture the strain of *C. botulinum* for DNA sequencing, the contents of the tube cannot be used again. Because sequencing of CBAM0301 would require destruction of [redacted], that burden is especially heavy here. This heavy burden outweighs the relevance from the testing. Although DNA sequencing is undoubtedly relevant to issues in this Investigation, Hugel has access to many other samples of Medytox's *C. botulinum* for testing and has other means to obtain a sequence for CBAM0301. Medytox produced its own 2016 sequencing data for CBAM0301. *See Botulinum Toxin Prods.*, Initial Determination at 106. Hugel has ample opportunity to question Medytox about the procedure used to create the samples for testing and the testing itself which resulted in the produced sequencing data. To confirm that these data are accurate, Hugel has been given access to test two children strains of CBAM0301 so that it can compare the data it obtains with

Medytox's data. These alternative means of discovery should be sufficient under the circumstances. Although Hugel argued at the case management conference that it was entitled to perform its own testing for accuracy, this concern is speculative at this stage of the investigation. And this does not justify the heavy burden on Medytox at this stage in the investigation.

Within seven days of the date of this document, the parties shall submit to the Office of the Administrative Law Judges a joint statement as to whether they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit to this office a copy of this document with red brackets indicating the portion or portions asserted to contain confidential business information. The submission should be emailed by the aforementioned date to Moore1313@usitc.gov and need not be filed with the Commission Secretary.

SO ORDERED.

Bryan F. Moore
Administrative Law Judge