

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUGEL, INC.

Petitioner,

v.

MEDYTOX INC.

Patent Owner.

Case No. IPR2023-00604

Patent No. 11,331,598

**MOTION FOR LEAVE TO FILE REPLY TO
PATENT OWNER PRELIMINARY RESPONSE¹**

¹ This Motion was authorized by the Board's email of June 27, 2023.

Hugel (“Petitioner”) respectfully requests leave to file a Reply to the Patent Owner Preliminary Response (“POPR”) filed by Medytox (“PO”), along with three new exhibits referenced herein. Each of the new exhibits is “relevant information that is inconsistent with a position advanced by [PO] during the proceeding.” 37 C.F.R. 42.51(b)(1)(iii). Good cause exists for this Reply because PO has taken unforeseeable positions in its POPR regarding its own Jung reference, and the Board will benefit from further briefing on the limited issues discussed below.

In a June 16, 2023 email to the Board, PO inappropriately argued that its argument in the POPR centered on Petitioner's failure to establish a *prima facie* case, not on Jung (EX1002) failing to disclose a claim element. EX1032 at 3-4. This is demonstrably false. PO expressly and repeatedly argues throughout its POPR concerning Jung’s substance, i.e, that it purportedly *fails* to disclose isolating botulinum toxin type A (“BoNTA”) macro complex. *See, e.g.*, POPR, 1 (“Jung only discloses isolating a BoNTA toxin of unspecified size.”); 22 (“Jung does not disclose isolating the BoNTA macro complex.”); 29 (“Jung fails to disclose isolating the BoNTA macro complex.”). This argument was not foreseeable at the time of filing the Petition, as it contradicts public evidence, including statements made by Medytox’s former licensee, Allergan, as well as PO’s own statements to the Office during prosecution of the challenged patent (U.S. 11,331,598 or “’598 patent”).

First, it was publicly known that PO had entered into a license agreement with Allergan through which “Allergan acquired the rights to *Medytox’s patents relating to its MT10109 technology, particularly ... U.S. Pat. No. 8,993,268* [*i.e.*, Jung].” *Tawfilis v. Allergan, Inc.*, No. 8:15-cv-00307 (C.D. Cal.), D.I. 302-3 (Allergan’s Statement of Undisputed Facts ISO Motion for Summary Judgment) at 4 (emphasis added throughout unless noted otherwise); D.I. 330-4 (Redacted License Agreement) at 18 (“Licensed Products” includes MT10109) and 19 (“MEDYTOX Patent Rights” relate to the Licensed Products). Moreover, publicly available information shows that Medytox’s *MT10109 contains the claimed macro complex* (*i.e.*, 900 kDa) of BoNTA. *Galderma S.A. v. Medy-Tox, Inc.*, PGR2019-00062, Paper 52 at 3 (“*MT10109L has 1 ng of 900 kDa serotype A botulinum toxin complex*”). Therefore, PO’s position in its POPR that it is not known whether Jung purifies the 900 kDa form of BoNTA was not only unforeseeable; it was also a highly disingenuous statement about its own Jung patent that PO licensed to Allergan as covering the very same macro complex it now says is not disclosed in Jung.

Second, during prosecution of the ’598 patent, PO submitted an inventor “Declaration that compared results from anion exchange [AEX] chromatography both below (at pH 5.5) and above (at pH 6.5) the pI of BoNT ‘**to compare the relative efficiency of [BoNT] recovery.**’” POPR at 15 (quoting EX1006 (’598

prosecution history) at 570 (emphasis original). According to PO, “**when pH 5.5 is used, [the macro complex] can be simply purified from the flow through solution with high purity and there is no need to add an additional eluting step.**”

Id. (quoting EX1006 at 568) (emphasis original); *id.* at 3 (“A central aspect of the claimed invention was the discovery that *AEX chromatography at a pH below the isoelectric point (‘pI’)* [*i.e.*, below 6.06] of botulinum toxin (‘BoNT’) was *critical and provided unexpected benefits.*”). This is *precisely* what Jung undisputedly teaches: *flow-through anion exchange chromatography at a pH of 5.5, i.e.*, a pH below the pI of BoNT. Petition at 26-29; EX1021 ¶ 112.

In light of PO’s argument during prosecution—that the claimed AEX step at *pH 5.5* was “critical” to obtaining a *highly pure macro complex of BoNTA*—it was unforeseeable that PO would argue that *the very same step in Jung* (*e.g.*, flow-through AEX at a pH of 5.5) failed to isolate the macro complex. *See In re Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011) (“[M]erely discovering and claiming a new benefit of an old process cannot render the process again patentable.”); *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) (“[T]o the extent the embodiment in the patent achieves [the limitation], so does the [prior art].”).

Finally, regarding PO’s failure of proof argument, the Petition pointed to evidence that Jung purifies the macro complex. *See, e.g.*, Petition at 13, footnote 13

(citing EX1002 at 12:30-34 (“As a result of SDS-PAGE and SEC-HPLC, it can be seen that Clostridium botulinum type A toxin is a *complex of 8 proteins*, and can be produced in a *high purity and high yield* by using the method of the present invention (data not shown).”)) In an effort to negate this evidence, PO misstates the law on footnotes, arguing that “[a]rguments raised only in footnotes ... are waived.” POPR at 62. But as the Board has previously held, “this appears to be a rule applied by the Federal Circuit to briefs filed with that Court, as opposed to a precedential rule of law the Board is compelled to follow.” *Apple Inc. v. Masimo Corp.*, IPR2020-01520, Paper 39 at 77-78 (Feb. 23, 2022). Petitioner could not have foreseen that PO would attempt to mislead the Board on basic case law, and as such, good cause exists for Petitioner to bring to the Board’s attention the *Apple v. Masimo* case.

For at least the foregoing reasons, Petitioner respectfully submits that good cause exists for a short Reply to the POPR to address PO’s inconsistent positions concerning its own Jung reference.

Dated: June 30, 2023

Respectfully Submitted,

/ Dion M. Bregman /

Dion M. Bregman, Reg. No. 45,645

Counsel for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), I certify that I caused to be served a true and correct copy of the foregoing: MOTION FOR LEAVE TO FILE REPLY TO PATENT OWNER PRELIMINARY RESPONSE, on Patent Owner's designated lead and backup counsel via email, at the addresses below.

Stephen Rabinowitz (SRabinowitz-PTAB@wolfgreenfield.com)

Jonathan Roses (JRoses-PTAB@wolfgreenfield.com)

Blaine Hackman (BHackman-PTAB@wolfgreenfield.com)

Dated: June 30, 2023

Respectfully Submitted,

/ Dion M. Bregman /
Dion M. Bregman, Reg. No. 45,645

Counsel for Petitioner