

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

**PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR
LEAVE TO FILE REPLY¹**

¹ Emphasis added throughout unless otherwise specified.

Petitioner failed to make the good cause showing required for a pre-institution reply. Consolidated Trial Practice Guide (“TPG”) at 51-52. The POPR’s argument was that the Petition was fatally flawed because its “*cited evidence does not support*” Petitioner’s assertion that Jung discloses isolating the botulinum toxin A (“BoNTA”) macro complex (POPR, 32) and because the Petition “*offered no evidence or argument explaining how or why*” Jung discloses isolating the BoNTA macro complex (POPR, 33). It is not proper reply to these arguments for Petitioner to seek to remedy the failure in its evidentiary showing by requesting leave to submit *new* evidence that could have been in the Petition. TPG, 73-74. Petitioner’s purported justification that Patent Owner (“PO”) violated 37 C.F.R. 42.51(b)(1)(iii) is baseless. No documents identified in Petitioner’s Motion contradict any POPR argument so Petitioner resorted to fabricating strawman arguments the POPR never made. Petitioner also mischaracterizes PO’s position on arguments presented in footnote 22 in the Petition (Pet., 47) in a transparent attempt to improperly present new substantive arguments based on evidence cited in a *different footnote* in the Petition (Motion, 3-4, citing Pet. n.13).

I. THE POPR’S ARGUMENTS WERE FORESEEABLE

Petitioner and its expert contended in conclusory fashion that Jung “discloses ... isolating ... the *macro complex*.” Petition, 22; EX1021 ¶64. The POPR explained that this assertion was unsupported, noting that Jung is silent

about whether the toxin isolated was “the 150 kDa toxin or any of the complexes (i.e., 300, 500 and 900 kDa) in which BoNTA naturally occurs,” (POPR, 22), that Jung’s disclosure “says nothing about what form of BoNTA is isolated” (*id.*, 33), and arguing that Petitioner accordingly failed to establish that Jung discloses isolating the BoNTA macro complex (*id.*, 32-35). If Petitioner wished to rely on evidence beyond Jung to meet this missing limitation, that evidence needed to be in the Petition. Identifying conclusory assertions and evidentiary gaps in the required *prima facie* showing in a Petition are textbook “foreseeable” POPR arguments. No evidence uncited in the Petition could be “inconsistent” (Motion, 1) with the POPR’s arguments exposing the ***Petition’s*** failure of proof. Petitioner establishes no good cause to belatedly submit “publicly known” evidence (Motion, 2) Petitioner possessed when it filed the Petition and chose to not submit.

Petitioner fabricates “unforeseeable” POPR arguments allegedly “inconsistent” with its new evidence—alleging that the POPR argued that “it is not known” today whether Jung’s method would isolate the macro complex (Motion, 2) and that Jung “failed to isolate the macro complex” (*id.*, 3). The POPR made neither argument. The POPR simply exposed the failure of Petition’s evidentiary showing, which cannot be remedied in Reply.

II. THE MOTION’S EVIDENCE FAILS TO SUPPORT GOOD CAUSE

Petitioner attempts to link Jung (EX1002) to Medytox’s MT10109 product,

which allegedly “contains the claimed macro complex.” Motion, 2. Petitioner’s belated evidence makes no such showing. Petitioner first points to a document dated 2017 (*after* the 2016 priority date of the ’598 Patent) that is an exhibit from a class action lawsuit to which Medytox was not a party. That document’s characterization of several Medytox patents (including Jung) as “relating to [Medytox’s] MT10109 technology” (Motion, 2) fails to link Jung to the macro complex.

The Motion also erroneously focuses on what is *presently known* rather than what the prior art disclosed at the time of the invention. Petitioner misleadingly asserts that “PO’s position in its POPR [is] that it is not known whether Jung purifies the 900 kDa form of BoNTA.” Motion, 2. That is incorrect: the POPR focused on the Petition’s deficient showing about what was known at the legally relevant time, i.e., the time of the invention—October 4, 2016. Petitioner’s focus on the wrong time frame highlights its failure to make the showing required—that Jung provided a *prior art* disclosure of isolating the BoNTA macro complex. The prosecution history (*id.*, 2-3)—which could have been addressed in the Petition—likewise says nothing about what Jung disclosed *at the time of the invention*.

III. THE MOTION’S IMPROPER SUBSTANTIVE ARGUMENTS FAIL

The Board only authorized a motion to establish good cause for a Reply—not substantive Reply briefing. EX1032. The Motion exceeds the Board’s

authorization by advancing unauthorized substantive Reply arguments. If considered, the Motion’s citations to inherency cases (Motion, 3, citing *In re Kao* and *MEHL/Biophile*) are irrelevant because the Petition never made an inherency argument and cannot belatedly do so now. *Google v. Mindbasehq*, IPR2021-01251, Paper 40 at 56 (PTAB Jan. 6, 2023).

Under the guise of establishing “good cause ... to bring to the Board’s attention the *Apple v. Masimo* case”—which the Motion substantively briefs and quotes without authorization—Petitioner falsely alleges the POPR sought to “negate” evidence in Petition footnote 13. *Compare* POPR, 62 (arguing for waiver of unrelated footnote 22). Petitioner transparently does so to advance the new substantive argument that the evidence in footnote 13 allegedly shows that “Jung purifies the macro complex.” Motion, 3-4. This new argument should not be considered even if made in an authorized Reply—let alone in a motion to show good cause – because the Petition cited the evidence in footnote 13 ***for a completely different purpose***. Petition, 27 (arguing a POSA would “equilibrate the resin with the same buffer as the buffer containing the botulinum toxin.”); *see also Sawai v. Astellas*, IPR2018-00079, Paper 7 at 18 n.3 (PTAB May 4, 2018) (“We decline to consider an argument made entirely in footnotes.”).

Date: July 7, 2023

Respectfully submitted,
Medytox Inc.

/Jonathan B. Roses/

Jonathan B. Roses, Reg. No. 61,115

CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (E)(4)

I certify that on July 7, 2023, I will cause a copy of the foregoing document, including any exhibits filed therewith, to be served via electronic mail, as previously consented to by Petitioner, upon the following:

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