UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

Case IPR2021-00406
Patent 10,716,793

PATENT OWNER'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE

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I. EX1037 Is not the Same Manual as EX1086 or Exhibit E to EX1087

Petitioner argues that EX1037 identified as an "English translation of OptiNeb User Manual 2005" is offered "as evidence of what it describes to an ordinary artisan." EX1037 however, is an undated, purported English translation of "an Optineb manual" and not self-authenticating (FRE 902). Petitioner failed to timely provide the underlying German document that was allegedly translated, or an affidavit attesting to the accuracy of the translation filed with the document.

In an attempt to cure the evidentiary deficiencies of EX1037, Petitioner asserts that the German document and translation attached to EX1086 and 1087 (served as supplemental evidence) establish that EX1037 "is what it is asserted to be." Paper No. 68, 4. However, they do not cure any deficiencies.

First, Petitioner relied upon EX1037 for a purported nebulization rate of "0.6 mL/min" (Petition, 23; Institution Decision, Paper No. 18, 24), but EX1087 and EX1086 recite a different nebulization rate in a range of "<u>≤0.6 mL/min</u>." EX1037, 28; EX 1087, 27 and EX1086, 31 and 50.[1] A specific rate of "0.6 mL/min" is not

[1] Liquidia's EX1086 was served as supplemental evidence, used to cross-examine Dr. Hill, and filed as an attachment to EX2108 (Hill deposition transcript). EX1086 is cited in the opposition (Paper 68, 4), but was not filed by Liquidia.

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equivalent to a range of "≤0.6 mL/min." Petitioner has failed to establish that EX1086 and EX1087 are the same documents and further, that the translation is accurate.

Second, Petitioner's identification of a 2005 date for EX1037 is misleading and inconsistent with the submitted supplemental evidence. Although Petitioner asserts EX1037 is a 2005 manual (Petition, vii), the manual provided in Exhibit E to EX1087 is from 2004 (*see* EX1087, ¶7), and EX1086 corresponds to that document (EX1086, 35).

Petitioner's undated translation of some Optineb manual is in direct contravention of 37 C.F.R. § 42.63(b) and should therefore be excluded.

II. EX1029 Should Be Excluded Under FRE 902

EX1029 (alleged Ventavis label) should be excluded. Petitioner bore the burden to prove authenticity, which it describes as a "low bar," but failed to do so. EX1029 does not identify a date, and Petitioner failed to explain where it was kept or how it was obtained. Paper No. 66, 14-15. Petitioner tries to correct these deficiencies by belatedly providing new evidence in its Opposition (Paper No. 68, 11, n.3-4). This new evidence is untimely, and these websites were accessed on April 22, 2022, not before the priority date or contemporaneously with the Petition or its supporting declarations. Petition, 17; EX1002, ¶¶36, 41, 42; EX1004, ¶¶33, 92, 104, 108, 131, n.4-6. Petitioner references the approval date for Ventavis, but

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this has no bearing on whether that version of a drug's label existed at a given point or whether it is authentic.

Petitioner's next argument asserts that EX1029 is an authentic drug label because it looks like a drug label. If that argument is sufficient, it provides yet more support for admissibility of EX2100-2103.

Regardless, because Petitioner provided new evidence of alleged authenticity for the first time with its Opposition, Patent Owner is only now able to evaluate the evidence. While public accessibility is not addressed in a Motion to Exclude, Patent Owner has no other opportunity to address the issue other than this reply. Petitioner has failed to provide any evidence that EX1029 would have been "indexed and thereby findable by a search engine" at the time it asserts (2004). *Blue Calypso, LLC v. Groupon, Inc*., 815 F.3d 1331, 1350 (Fed. Cir. 2016). Mere publication to the internet is not a sufficient showing to establish public accessibility. *See Celltrion, Inc. v. Biogen, Inc.*, IPR2016-01614, Paper No. 65 at 17-20 (PTAB Feb. 21, 2018) (citation omitted).[2] In *Celltrion*, the Petitioner

[2] Petitioner relies on *New World Med., Inc. v. Microsurgical Tech., Inc*., IPR2020-01573, Paper 63 at 9 (PTAB Feb. 16, 2022). However, *New World* addresses accessibility of abstracts, not drug labels. The *Celltrion* case provides the standards for authenticating the public availability of online drug labels.

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similarly asserted that a copy of a label posted on a website along with an Internet Archive declaration was an authenticated printed publication. *Id.* at 17. The Board disagreed, stating that even if the declaration establishes that the reference was online before the priority date, petitioner failed to adequately support its contention that the label was publicly accessible prior to the critical date. *Id.* at 20. Here, there is not even an Internet Archive declaration. Accordingly, Petitioner has not shown EX1029 was publicly accessible by the date it asserts.

III. EX1050, EX1066, EX1074, and EX1078 Should Be Excluded

Petitioner presents EX1050, EX1066, EX1074, and EX1078 as labels for various drugs, but the exhibits do not identify where they were kept or how they were obtained, are not self-authenticating under FRE 902, and Petitioner has not provided evidence these versions were publicly accessible by any given dates. Dates printed on the documents are not sufficient. *Celltrion*, Paper No. 65, 20. The fact that the experts prescribe or use the products relating to a label on patients has no bearing on whether a specific version of that product's label existed on a website or otherwise had an identifiable source to allow for authentication. There is insufficient evidence to authenticate any of these exhibits or show they were publicly accessible. *Id.*

IV. EX1114, 1117, 1120, and the Portions of EX1112 Relying Thereon Should Be Excluded

Petitioner's claim that it does not rely on these exhibits or testimony to prove

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