

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

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
MOTION TO EXCLUDE**

I. INTRODUCTION

Liquidia Technologies, Inc. (“Petitioner” or “Liquidia”) opposes Patent Owner’s Motion to Exclude EX1037, EX1087, EX1112 (partially), EX1114, EX1117, EX1120, EX1029, EX1050, EX1066, EX1074, and EX1078.

II. ARGUMENT

a. EX1037: English Translation of OptiNeb® User Manual 2005

UTC’s motion to exclude EX1037 under Federal Rule of Evidence (“FRE”) 901-902, FRE 802, FRE 402-403, or FRE 1001-1003 should be denied.

First, EX1037 does not constitute hearsay under FRE 802. UTC contends that Petitioner’s reliance on EX1037 as evidence of the OptiNeb® nebulizer’s 0.6 mL/min nebulization rate and as evidence that pulsed ultrasonic nebulizers were known violates FRE 802. Paper 66, 5-7. EX1037 is offered, however, as evidence of what it describes to an ordinary artisan and not for proving the truth of the matters addressed in the document. *BioMarin Pharm. Inc. v. Genzyme Therapeutic Prods. Ltd. P’ship*, No. IPR2013-00534, 2015 WL 1009195, Paper 81 at *14 (P.T.A.B. Feb. 23, 2015) (“[W]e agree with Petitioner that Ex. 1002 is offered as evidence of what it describes to an ordinary artisan, not for proving the truth of the matters addressed in the document. Accordingly, Ex. 1002 is not hearsay requiring the remedy of exclusion.”); *Caterpillar Inc. v. Wirtgen Am., Inc.*, IPR2017-02187, Paper 42 at 16-17 (P.T.A.B. May 21, 2019) (denying Patent Owner’s motion to exclude prior art

manual as inadmissible hearsay because “[t]he *substance* of a printed publication generally is not hearsay”).

Patent Owner's citation to *Chambers v. Mississippi*, 410 U.S. 284 (1973) and *ServiceNow, Inc. v. Hewlett-Packard Co.*, IPR2015-00716, Paper 13 (P.T.A.B. Aug. 26, 2015) is unavailing. Paper 66, 6-7. The Board's holding in *ServiceNow* dealt only with the printed publication's copyright date rather than the substance of the information contained in the reference. *ServiceNow*, IPR2015-00716, Paper 13 at 15-17; *see also Caterpillar*, IPR2017-02187, Paper 42 at 16-17. The Board, moreover, did not hold that the publication's copyright date was inadmissible hearsay. *ServiceNow*, IPR2015-00716, Paper 13 at 15-17. The Supreme Court's 1973 decision in *Chambers*, dealing with Mississippi evidentiary law, discussed only the well-known concerns with relying on hearsay, which as explained above are inapplicable here because Petitioner does not rely on EX1037 for hearsay purposes. *Chambers*, 410 U.S. at 298.

Second, Patent Owner improperly disputes the public availability of EX1037 in its motion to exclude. P.T.A.B. Consol. Trial Practice Guide (Nov. 2019) at 79 (“A motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay) *but may not be used to challenge the sufficiency of the evidence to prove a particular fact.*”) (emphasis added); *Caterpillar*, IPR2017-02187, Paper 42 at 17 (“Status as a prior art printed publication is a substantive issue, not an

evidentiary issue.”). Even assuming Patent Owner’s motion to exclude is the proper vehicle to dispute the public availability of EX1037, the sworn declaration of Mr. Christopher Butler (EX1087), an Office Manager at the Internet Archive, demonstrates the public availability of EX1037 as of the priority date. EX1087; *see also Advanced Micro Devices, Inc. v. Aquila Innovations, Inc.*, IPR2019-01526, 2021 WL 921325, Paper 37 at 29-30 (P.T.A.B. Mar. 10, 2021) (“The Butler Declaration further provides evidence that the identified [prior art] was archived (e.g., catalogued) on the Wayback Machine as of May 4, 1999”); *Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2016-00130, Paper 35 at 20 (P.T.A.B. May 8, 2017) (“Mr. Butler’s affidavit similarly indicates that, based on the available URL and date information, that Exhibit 1010 was archived in 2007.”).

Third, EX1037 has been properly authenticated under FRE 901. Authentication under FRE901 is a “low bar,” and the party authenticating an exhibit need only provide a “rational basis” that the “document is what it is asserted to be.” *Caterpillar Inc. v. Wirtgen Am., Inc.*, IPR2018-01091, Paper 49 at 72 (P.T.A.B. Nov. 27, 2019) (quoting *United States v. Turner*, 934, F.3d 794, 798 (8th Cir. 2019) and *United States v. Needham*, 852 F.3d 830, 836 (8th Cir. 2017)). The sworn declaration at the end of EX1037 alone provides a “rational basis” that EX1037 “is what it is asserted to be.” EX1037, 33.

Patent Owner asserts incorrectly that Petitioner has not provided the original German-language manual underlying EX1037 (Paper 66, 7-9) and consequently failed to authenticate EX1037 and meet the requirements of 37 C.F.R. § 42.63(b). Patent Owner overlooks, however, that Petitioner attached the underlying German-language manual as Exhibit E to Mr. Butler's declaration (EX1087). Petitioner further attaches another certified translation of the underlying German-language manual as EX1086,¹ which includes both the English-language translation and underlying German-language manual in one document. *Sumitomo Elec. Indus., Ltd. v. United Techs. Corp.*, IPR2017-00966, Paper 29 at 12 (P.T.A.B. Sept. 12, 2018) (“We see nothing in Rule 42.63(b) that prohibits a party to revisit, or even modify, its translation at a later date, given sufficient notice and opportunity to respond by the opposing party.”). Petitioner has met the “low bar” of FRE 901 by providing a “rational basis” that EX1037 “is what it is asserted to be.” *Caterpillar*, IPR2018-01091, Paper 49 at 72 (citations omitted).

Lastly, Patent Owner asserts erroneously that EX1037 is “not relevant” and “may cause confusion” because of alleged date discrepancies between EX1007 and EX1008 with EX1037. Paper 66, 8. Petitioner disagrees with Patent Owner's

¹ EX1086 was properly served by Petitioner on September 8, 2021 in response to Patent Owner's August 25, 2021 objections to evidence.

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