

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner

Case No. IPR2020-00770
U.S. Patent No. 9,604,901

**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 Exs. 1002 and 1012.

II. ARGUMENT

A. Ex. 1002

First, UTC's motion to exclude Ex. 1002 **under 35 U.S.C. § 25, 37 CFR § 42.2, and/or as hearsay** should be denied. Paper 31 at 3-4. UTC contends that Dr. Winkler inadvertently omitted the oath at the end of his declaration and, as such, his declaration should be excluded.

As an initial matter, UTC waived its argument regarding Dr. Winkler's declaration under 37 C.F.R. § 42.63, because it did not timely object to the issue with "sufficient particularity . . . to allow correction in the form of supplemental evidence." *See Campbell Soup Co. v. Gamon Plus, Inc.*, IPR2017-00091, Paper 84 at 52 (P.T.A.B Apr. 11, 2018) ("Although *Daubert* is related to FRE 702, challenging an expert as generally not being 'qualified' (Paper 16, 1) does not provide the 'sufficient particularity' as required by 37 C.F.R. § 42.64(b)(1) 'to allow correction in the form of supplemental evidence.'"). In its objections filed after the Institution Decision, UTC only generically restated FRE 802, 901, and 902, and never identified the oath as the issue. Paper 10 at 3 ("Patent Owner objects to Exhibit 1002 under FRE 802 as hearsay without exception. Patent Owner objects to Exhibit

Petitioner's Opposition to Patent Owner's Motion to Exclude
IPR2020-00770

1002 under FRE 901-902 as lacking authentication and not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.”). Because UTC failed to preserve the objection asserted here, the Board should “not consider these arguments in [the] Motion to Exclude because they have been waived.” *Campbell Soup Co.*, Paper 84 at 52.

Regardless, as addressed in Petitioner's Reply, any omissions in Dr. Winkler's declaration with respect to the oath or perjury statement were harmless and have been cured. Paper 15 at 1-2. UTC deposed him on the opinions he presented therein. *See generally* EX2026; *see also Google LLC v. CyWee Grp. Ltd.*, IPR2018-01257, Paper 69 at 2-4 (P.T.A.B. Sept. 6, 2019) (granting party authorization to correct unsworn declaration when opposing party cross-examined the expert); *Fid. Info. Servs., LLC v. Mirror Imaging, LLC*, CBM2017-00064, Paper 54 at 5-8 (P.T.A.B. Jan. 2, 2019) (same). Dr. Winkler also refiled Ex. 1002 as Ex. 1039 with no changes other swearing to the truth of his statements therein. *See* EX1039, ¶241 (declaring that “all statements made herein are identical to my declaration filed as Ex. 1002”). Importantly, UTC has not moved to exclude Ex. 1039 or any Dr. Winkler's opinions therein. UTC is exalting form over substance in renewing this objection before oral argument. Accordingly Ex. 1002 should not be excluded under 35 U.S.C. §25, 37 CFR §42.2, and/or as hearsay.

Second, UTC's argument that Dr. Winkler is unqualified to testify on the relevant subject matter **under Federal Rules of Evidence 701 and 702** should be denied. UTC is utilizing its motion to exclude as another opportunity to repeat arguments from the parties' briefing regarding whether Dr. Winkler meets UTC's expert's¹ definition of a person of ordinary skill in the art, and otherwise argues issues directed to the weight, not admissibility of his testimony.

UTC's argument is without merit. The Board stated that "for purposes of this Decision, . . . the level of ordinary skill in the art is reflected by the prior art, including Phares and Moriarty." Paper 7 at 22 (citing *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) ("The person of ordinary skill in the art is a hypothetical

¹ UTC's citation to Dr. Hall-Ellis's declaration is a distraction. Paper 31 at 4 (citing EX1015, ¶16). Dr. Hall-Ellis made a typographical mistake in her definition of a person of ordinary skill in art by inadvertently taking a definition from a different IPR proceeding. See EX1052, ¶5. This is evident from her definition referring to "radiation oncology," which clearly is unrelated to the '901 patent at issue. Dr. Hall-Ellis has filed a supplemental declaration correcting this error and explaining that her opinion relied on the same skilled artisan definition as Petitioner and Dr. Winkler. *Id.* at ¶¶6-8. Neither Petitioner nor its expert submitted any substantive testimony or argument relying on Dr. Hall-Ellis's typographical mistake.

person who is presumed to know the relevant prior art.”)). Dr. Winkler was qualified and accepted as a person of skill in the art in a prior IPR proceeding involving UTC, the '901 patent's parent, and the same “relevant prior art” Phares and Moriarty (Ex. 1008 and 1009). *See, e.g.*, EX1005 at 49, 27-28, 71 (Final Written Decision finding that the “level of ordinary skill in the art is reflected by the prior art of record” and repeatedly citing to Dr. Winkler's declaration). For the same reasons, Dr. Winkler similarly qualifies as a POSA here, as reflected by the same prior art.

Further, as detailed in Petitioner's Reply, UTC's repeated attempts to inflate the level of ordinary skill in the art is without support in the claims or specifications of the '901 patent. *See* Paper 15 at 8-10. UTC does the same again in referring to “manufacturing requirements in the United States” or “development considerations” (Paper 31 at 5-6),² without any connection to the language in the '901 Patent claims.

² UTC follows in the footsteps of its expert in mischaracterizing Dr. Winkler's testimony, stating that Dr. Winkler was “unable to answer” counsel's questions (Paper 31 at 5-6), simply because counsel did not like or disagreed with Dr. Winkler's answers. Such self-serving attorney argument is not a basis for exclusion of expert opinions. The Board is fully capable of reading Dr. Winkler's testimony for itself and assessing what weight to accord it. EX1005 at 85 (“UTC has not explained adequately why we should exclude conclusory expert testimony, instead

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