

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

Case IPR2020-00770
Patent 9,604,901

**PATENT OWNER'S REQUEST FOR PANEL REHEARING
PURSUANT TO 37 C.F.R. § 42.71(d)**

Patent Owner respectfully requests panel rehearing of the limited portion of the October 8, 2021 Final Written Decision (“FWD”) (Paper 45) finding that Petitioner established that claims 1-5, 8, and 9 of U.S. Patent No. 9,604,901 (“the ’901 patent”) are obvious over the combination of Moriarty and Phares. 37 C.F.R. § 42.71(d). The Board’s decision relied on inadmissible, unsworn expert statements submitted by Petitioner that, when timely objected to by Patent Owner, Petitioner failed to timely cure as required by 17 C.F.R. § 42.64(b)(2). Because Petitioner did not timely submit admissible evidence that would support the Board’s conclusion, the Board should find that claims 1-5, 8, and 9 are not unpatentable. The FWD found claims 1-5, 8, and 9 obvious only over the combination of Moriarty and Phares and does not address the other asserted ground of obviousness over Phares alone in relation to these claims. FWD at p. 50. To the extent that the panel grants this rehearing request, the panel should also hold that the other ground of obviousness based on Phares alone similarly fails to establish obviousness of these claims because it too is only supported by unsworn statements as to several critical elements of obviousness. Patent Owner Response (Paper No. 12) at pp. 29, 30-32, and 34.

I. APPLICABLE STANDARDS

Under 37 C.F.R. § 42.71(d), a party may request panel rehearing of a Final Written Decision by the Board. “The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.” 37 C.F.R. § 42.71(d).

II. ARGUMENT

A. Affidavits Submitted in IPRs Must Be Sworn.

Under the Board’s rules, non-deposition testimony must be in the form of an “affidavit.” 37 C.F.R. § 42.63(a). The “affidavit” must be either testimony given under oath (such as a true sworn affidavit) or a declaration acknowledging that it is given under penalty of perjury, such as “a declaration under 28 U.S.C. § 1746.” 37 C.F.R. § 42.2 (“Affidavit”). That is consistent with the statutes governing testimony in the Patent and Trademark Office. 35 U.S.C. §§ 23, 25. Under § 1746, a declaration does not qualify unless it is “subscribed by [the declarant], under penalty of perjury,” and “substantially” adheres to the form of the prescribed attestation. 28 U.S.C. § 1746. That attestation is simple, but necessary: without it, an unsworn statement is inadmissible evidence because the speaker is not prosecutable for perjury.

The procedure and time limits for identifying and curing defective declarations are straightforward. The Board's rules require a party challenging the admissibility of evidence to raise its objection promptly, 37 C.F.R. § 42.64(b)(1), and any objection must be preserved with a motion to exclude, 37 C.F.R. § 42.64(c). And the Board's rules create a simple avenue for parties to cure any defectively submitted affidavits: they afford the party relying on timely challenged evidence ten days to serve admissible supplemental evidence. 37 C.F.R. § 42.64(b)(2). But if, after receiving a timely objection, the party fails to cure, then the declaration must stand or fall as originally submitted. A party cannot see whether an objection gets traction and *then* submit untimely supplemental evidence.

B. The FWD Improperly Relied on Unsworn Statements That Were Not Timely Cured in Compliance with § 42.64(b).

The Board's decision here is inconsistent with the clear rules described above. The Winkler Declaration (EX1002) is not an affidavit: it is unsworn and did not include any attestation that it was submitted under penalty of perjury, yet the FWD specifically relies upon EX1002 at pp. 32-34, 36-38, 41, and 42. Patent Owner timely objected to it in Paper No. 10 (as acknowledged at the final hearing, *see* Paper 44 at 21:12-25), and rather than addressing that objection as required by the

rules, Petitioner ignored the objection and engaged in self-help months after the deadline (Paper 44 at 22:8-23:17, 25:3-14). The Board's reliance on the Winkler Declaration despite Patent Owner's timely, meritorious objection is contrary to the Board's own rules and the statute.

The FWD relies extensively upon the Winkler Declaration in concluding that Petitioner established obviousness of claims 1-5, 8, and 9 based on the combination of Moriarty and Phares. FWD at pp. 32-34, 36-38, 41, and 42.¹ But as noted in the Patent Owner Response (Paper No. 12) at pp. 1 and 60 and in Patent Owner's Motion to Exclude (Paper No. 31), Dr. Winkler's statements were not admissible as submitted. And when Patent Owner timely objected to its

¹ For example, the FWD relies upon EX1002 in stating "we agree with Dr. Winkler that 'Kawakami teaches the purification of a methanoprostacyclin derivative by salt formation with a secondary amine, which is the same reaction as taught in Phares for the formation of the diethanolamine salt of treprostinil.'" FWD at 42. Thus, the Board supports its conclusion that there would be an expectation of successfully purifying treprostinil by combining a diethanolamine salt formation step from Phares with Moriarty based on Dr. Winkler's testimony, as well as for other key findings at pp. 32-34 and 36-38 of the FWD.

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