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 REPLY TO OPPOSITION TO MOTION TO EXCLUDE

I. EX1002: PURPORTED WINKLER DECLARATION

Liquidia contends its failure to file a sworn expert declaration with its Petition should be excused because (1) the objections lacked "sufficient particularity" and (2) the failure was "cured." Neither contention withstands scrutiny.

First, Liquidia means that the initial objection was too "generic," but the initial objections (Paper No. 10) expressly put Liquidia on notice that its purported declaration was not authentic. Liquidia does not state that it did not understand the objection (in depositions they are far terser), that it sought clarification from UT, or that it could not identify how the exhibit lacked authentication. Significantly, Liquidia represented the exhibit as an IPR-specific declaration: essentially the only way a purported declaration could fail to be what it was represented to be would be by failing to meet the statutory and rule-based requirements for declarations. Yet Liquidia cannot claim ignorance of the applicable rules, which it followed for concurrently-filed EX1015 without any similar objection from UT (Paper No. 10). Rather than address the deficiency on which the objection is based, Liquidia objects to the objection. This defect is fatal. The failure to impress upon a witness that a statement is under oath goes to the heart of its reliability as evidence. Paper 31, *citing Chambers v. Mississippi*, 410 U.S. 284, 298 (1973).

Second, Liquidia cites authority for the Board ***authorizing*** correction of an omitted oath belatedly, but tellingly does not identify where ***Liquidia sought*** authorization to file supplemental (and belated) evidence with its reply. Instead, Liquidia simply ignored the defect. Even now, Liquidia presents its belated filing as a *fait accompli* rather than risk moving for relief.

Congress offered declarations as an alternative to testimony under oath as a convenience to the filer, but the requirements that come with that convenience are not optional. Similarly, the Director promulgated rules requiring procedural regularity and electing to require the Federal Rules of Evidence to protect the efficiency and integrity of these proceedings. 35 U.S.C. §316(b). UT is entitled to rely on Liquidia's failure to file timely supplemental evidence in filing its Response. Liquidia makes no attempt to show its flouting of the rules to file belated surprise evidence is in the interest of justice. The statute and rules must retain their explicit meaning.

Regarding Dr. Winkler's competence, Liquidia attempts to enlist the Board to do what it should have done: separate Dr. Winkler's wheat from his chaff. Paper No. 32, 4 n.2. This is not the Board's role as a neutral adjudicator, nor is the Final Written Decision the place for UT to learn what Liquidia should have made clear in its Petition.

Indeed, Liquidia provides a great example in its opposition. Paper No. 32, 3 n.1. Liquidia jettisoned Dr. Hall-Ellis's testimony undermining Dr. Winkler's relevance to testify in this proceeding. (If Liquidia's sworn testimony is now admittedly unreliable, how much less can its unsworn testimony be trusted?) Liquidia argues that UT should have known Dr. Hall-Ellis's testimony was nonsense from the context (*id.*), but Dr. Winkler's statements on which Liquidia continues to rely suffers the same defect. Yet Liquidia expressly shifts the burden to UT and the Board to figure out what is reliable (Paper 32, 4-5 n.2), ignoring Justice Scalia's admonition that discretion over ***how to determine*** expert reliability is ***not*** discretion over ***whether to exclude*** unreliable information. Paper 31, citing 526 U.S. at 159. Again and again, Dr. Winkler's statements about relevant technologies are wrong or inconsistent, revealing an inability or unwillingness to provide reliable testimony. Both UT and the reviewing court are entitled to the Board's express determination of this unreliability.

Liquidia's opposition provides a second example in its discussion of polymorphs. Rather than rebut Dr. Pinal's careful, qualified explanation of why Dr. Winkler's testimony on polymorphs is utterly wrong, Liquidia simply says it is not relevant. Paper 32, 6 n.3. Yet recall Dr. Winkler's lack of understanding about polymorphs is at the heart of his testimony about stability in the prior art. Paper 1,

27, 43-44, 51-52, 68-69. Liquidia procured institution on the basis of relative polymorph stability, but now—after the close of briefing and faced with evidence undermining its arguments— Liquidia decides that its evidence is irrelevant. Dr. Winkler is unable to testify accurately on key technical concepts in this proceeding, or else is willing to change his testimony as suits, but either way his statements are unreliable.

II. EX1012: PURPORTED KAWAKAMI APPLICATION

Once again, this exhibit is not what it purports to be: a certified Japanese application. Instead, Liquidia filed an uncertified English "translation" without filing the ***foreign-language application*** at all, much less a ***certified translation***. 37 CFR §42.63(b). Liquidia responds by belatedly filing exhibits purporting to cure these defects. Once again, Liquidia does not bother with seeking authorization, but instead, engages in self-help sandbagging long after the close of briefing on the merits. Liquidia pleads that UT is not prejudiced because the unfiled materials appear in a ***different*** proceeding (without explaining how, for example, UT would cross-examine a declarant in the other proceeding for this case). Liquidia again ignores the discussed case law. As the motion explains, materials in a different—even if related—proceeding ***do not*** cure failure to file in the present proceeding. Paper 31, 10-11, *citing Stevens v. Tamai*, 366 F.3d 1325,

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