UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, Inc.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2021-00406
U.S. Patent No. 10,716,793

PATENT OWNER'S MOTION FOR OBSERVATIONS ON APRIL 13, 2022 DEPOSITION OF DR. HILL

Patent Owner hereby submits the following observations pursuant to the March 15, 2022 teleconference and the Board's Order (Paper No. 53).

1. In EX2108 at 14:20-15:18, Dr. Hill testified that he did not attend two conferences. This is relevant to his opinions that a POSA would have attended them and alleged public availability of EX1007-1008. EX1106, ¶¶22, 28; *cf.* EX1002 ("I qualify as a POSA."). It is also relevant to Patent Owner's argument that Petitioner cannot show availability by claiming the POSA would have attended. Sur-reply at 2-5.

2. In EX2108 at 18:7-16, 20:25-21:4, Dr. Hill testified that his understanding of date stamps came from counsel, which is relevant to his opinions on public availability of the abstracts. *E.g.*, EX1107, ¶¶24, 31-32.

3. In EX2108 at 17:13-17, Dr. Hill testified that a lack of supporting evidence undermines an opinion. This is relevant to his opinions that lack supporting evidence by diminishing any weight they could carry. *E.g.*, EX1106, ¶44 ("standard" temperatures and humidity levels); ¶57 ("sheep model is well-accepted for study of the pulmonary circulation); ¶60 ("this dose calculation method was standard in the art in May 2006") (citing EX1001, 9:5-23), *but cf.* EX1001 9:5-23 (regarding Respimat® soft mist inhaler and "time following TRE application," not nebulization time); ¶60 ("POSAs in 2006 would not have accounted for these variables" and POSAs "would have understood that the prior art … already accounted for such variables"); ¶61 ("average" rate of 0.5 mL/min) (*see also* EX2108, 23:8-11); ¶73 (calculating doses using concentration, time, and

"***known*** volumes delivered" is "standard") (emphasis added).

4. In EX2108 at 22:3-24:5, 24:22-29:21, Dr. Hill testified that: he "believe[s]" he reviewed EX1087, but not the German language manual therein (*see* EX1087 at 27 ("Verneblerleistung … < 0.6 ml/min"), EX1107 at 6 (not listing EX1086)); EX1086 identifies a rate of "less than 0.6 mL/min," that 0.5, 0.3, and 0.1 are all less than 0.6, and that the manual does not identify rates the nebulizer actually provides in operation. This is relevant to Dr. Hill's calculations relying on a 0.6 mL/min rate and claims it "accounts for" all variables because it shows the calculations were based on an incorrect assumption. *E.g.*, EX1107, ¶¶63, 92.

5. In EX2108 at 36:2-37:1, 47:7-17, Dr. Hill testified that: EX1034 describes conventional nebulizers as having delivery efficiency of only 10-20%; he did not review the Cipolla article cited in EX1034; nebulizers have "variable efficiency" and "a wide range … in terms of efficiency." This testimony is relevant to Dr. Hill's calculations that used either no efficiency or an assumed 50% efficiency because they were based on incorrect assumptions.

6. In EX2108 at 38:13-39:10, 41:6-23, Dr. Hill testified that: Tyvaso® does not satisfy claim 1 of EX1001 because it is administered in "four single event doses" per day and EX1008's compassionate use patients also received four doses per day. This testimony is relevant to claim 1's "therapeutically effective single event dose" and, under Dr. Hill's interpretation of "single event dose," is relevant to any Liquidia position that the compassionate use patients in EX1008 disclose therapeutic efficacy within claim 1. *Cf.* EX1106, ¶88; Sur-reply at 22-23.

Respectfully submitted,

Date: April 15, 2022

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Motion for Observations** was served on counsel of record for Petitioner on April 15, 2022 by delivering a copy via email to the counsel of record for the Petitioner at the following addresses:

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