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 OBSERVATIONS ON THE CROSS-EXAMINATION OF DR. HILL

Petitioner files these observations on the 4/13/2022 deposition of Dr. Hill pursuant to the Board's Order authorizing both parties to file observations "no later than two business days after the conclusion of the deposition." (Paper 53, 4.)

1. **Observation #1: Voswinckel JESC and JAHA abstracts would have been accessible by conference attendees.** *(Relevant to public accessibility)*

In anticipated Exhibit 2108 (4/13/22 Hill Deposition Transcript) at 20:3-15, Dr. Hill testified that in his experience attending conferences like the European Society of Cardiology Congress and American Heart Association's Scientific Sessions, at which Voswinckel JESC and JAHA were respectively presented, the conferences "compile . . . abstract issues that are generally disseminated as a supplement to the journal to the subscribers and also are available at the meeting site." *Id*. He explains that his declaration statements and testimony about the public availability of Voswinckel JESC and JAHA "is consistent with [his] experience in attending these meetings. This is how these abstracts are handled." *Id*.

2. **Observation #2: A POSA would have expected the Voswinckel JESC authors to be using an efficient nebulizer with the typical or above average rate of delivery, not less than 0.3mL/min.** *(Relevant to Ground 1 and 2: Voswinckel JESC's disclosure of a 15-90µg dose)*

In anticipated Exhibit 2108 at 22:3-23:7, Dr. Hill testified that in his clinical experience, the average nebulization rate for continuous nebulizers in the 2006 time frame was 0.5 to 0.6 mL/min. In anticipated Exhibit 2108 at 29:17-31:10, Dr. Hill explains that even if the OptiNeb device used in Voswinckel has a "range that could

be delivered" (i.e., if it could have delivered < 0.6mL/min), in "[his] experience using continuous nebulizers, . . it would be extremely unusual to go to a dose less than around 0.3[mL/min] because there has to be a certain volume to generate a mist that the patient can then inhale[.]" In anticipated Exhibit 2108 at 45:17-46:8 and 47:7-20, Dr. Hill further testified that though "there is a wide range . . . in terms of efficiency between nebulizers," a POSA would have understood the Voswinckel JESC authors to have been "concerned about accurately dosing patients for the purposes of a study" and seen that the authors selected from a "line of nebulizers [that] are generally much more accurate in terms of the rate of delivery of aerosol to a patient, and accordingly, they would be at the higher range of efficiency[.]" Additionally, Dr. Hill testified that "as a POSA with experience using nebulizers, … [he] know[s] it would be important for authors of a study like this to select a device that they could rely on to deliver a reliable dose at a reliable delivery rate." *Id*.

3. **Observation #3: Geller (Ex. 1034) demonstrated feasibility, tolerability, and association with improvement in pulmonary function of delivering drugs via bolus inhalation dosing by 2003.** *(Relevant to Motivation to Combine in Grounds 1 and 2, and Secondary Considerations)*

In anticipated Exhibit 2108 at 33:24-35:9 and 44:18-45:5, Dr. Hill testified that the Geller article (Ex. 1034) demonstrated the feasibility, tolerability, and association with improvement in pulmonary function of delivering drugs via bolus inhalation dosing by 2003.

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COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue NW
Suite 700
Washington, DC 20004
Tel: (212) 479-6840
Fax: (212) 479-6275

By: /Erik B. Milch/
Erik B. Milch
Reg. No. 42,887
Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **PETITIONER'S OBSERVATIONS ON THE CROSS-EXAMINATION OF DR. HILL** was served on counsel of record on April 15, 2022, by delivering a copy via email to the counsel of record for the Patent Owner at the following address:

UT-793@foley.com
Stephen B. Maebius (smaebius@foley.com)
FOLEY & LARDNER
UTCvLiquidia-IPR@mwe.com

Dated: April 15, 2022

By: /Erik B. Milch/
Erik B. Milch
Reg. No. 42,887
Counsel for Petitioner

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue NW
Suite 700
Washington, DC 20004
Tel: (212) 479-6840
Fax: (212) 479-6275