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

PATENT OWNER'S IDENTIFICATION OF PORTIONS OF PETITIONER'S REPLY TO WHICH IDENTIFIED SUR-REPLY EVIDENCE AND ARGUMENTS ARE RESPONSIVE

Pursuant to the Board's emails dated March 24 and 25, 2022, Patent Owner hereby identifies portions of Petitioner's Reply to which the exhibits and arguments objected to by Petitioner in Paper No. 60 are responsive.

1) **Ex. 2092** (as attached to Ex. 2094 at 63-65); **Ex. 2094**, 20:22-24:7 (discussing Ex. 2092); and **Sur-Reply** at 8-9 (relying on the portions of Ex. 2094 related to Ex. 2092), are responsive to at least:

- Petitioner's Reply, pages 5-6 (regarding Petitioner's argument that the JESC Supplement was publicly accessible to a POSA);
- Petitioner's Reply, pages 8-9 (regarding Petitioner's argument that the JAHA Supplement was publicly accessible to a POSA);
- Petitioner's Expert's Reply Declaration (Hall-Ellis), EX1112 at ¶50 (regarding JAHA Supplement), and ¶85 (regarding JESC Supplement).

See Sur-Reply (Paper No. 55) at 7-9.

2) **Ex. 2093** (as attached to Ex. 2094 at 66-77); **Ex. 2094**, 32:11-36:18 (discussing Ex. 2093); and **Sur-Reply** at 10-11 (relying on the portions of Ex. 2094 related to Ex. 2093), are responsive to at least:

- Petitioner's Reply, page 7 (regarding Petitioner's argument that the Sulica authors were able to access the JAHA Abstract/Supplement);
- Petitioner's Expert's Reply Declaration (Hall-Ellis), EX1112 at ¶62 (page 38) (regarding testimony that the Sulica article shows that the Voswinckel JAHA Abstract can be found by a POSA).

See Sur-Reply (Paper No. 55) at 10-11.

3) Ex. 2100 (referred to as Tab 6 in Ex. 2099); **Ex. 2101** (Tab 5 in Ex. 2099); **Ex. 2102** (Tab 9 in Ex. 2099); **Ex. 2103** (Tab 4 in Ex. 2099); **Ex. 2099,** 163:23-176:5, 180:20-185:10, 198:8-201:6, 201:18-203:9 (discussing Ex. 2100-2103); and **Sur-Reply** at a) P.14: "EX2102, 27 (DeVilbiss manual: output rates of 3.0 and 2.5 mL/min)"; b) P.14: "EX2100, 28; EX2101, 28 (Multisonic manual: rates of 0.6 and 0.5 mL/min)"; c) P.16: "But if the" to "EX2100, 28"; and d) P.16: "Lieberman 2006" to "respectively" are responsive to at least the following portions of Petitioner's Reply and the exhibits cited therein:

- Pages 11-12, including n.8 (*e.g.*, regarding arguments relating to a 50% efficiency loss, that jet nebulizer art is "inapposite," that there is a "typical" nebulization rate, relying on EX1037 for a rate of 0.6 mL/min, and identifying asserted nebulizer rates);
- Pages 12-13, including their reliance on EX1107, ¶¶22-27 (*e.g.*, regarding argument that "'patient factors,' gas and flow pressure, fill and dead volumes, gas density, humidity and temperature conditions, breathing pattern, and device interface" do not affect dosage delivery because "device[s] account[] for these factors and produce consistent delivery dosage"); *see also* EX1107, ¶¶22-23 (stating "the only ultrasonic nebulizer cited by Professor McConville had an efficiency of 86%" and relying on Gessler to imply ultrasonic nebulizers all have "higher efficiency"), ¶24 (alleging a "known nebulization rate of 0.6 mL/min," "assuming that 50% of the output may be lost," and "the output is the amount arriving at the mouthpiece"), ¶25 (arguing "POSA would have

reasonably assumed the OptiNeb device was employed in Voswinckel JESC," relevant to at least EX2099 at 171:4-172:11 and 173:19-174:9, and relying on EX1037 and reported rates from EX1097-1099), ¶26 ("assum[ing] that the values in the literature are applicable to estimate the range of doses delivered in [JESC]"); ¶27 (arguing nebulizer efficiency factors are "taken into account" and relying on EX1062).

- Pages 13-14 (*e.g.*, "Any 'delivery efficienc[y] … ' differences between continuous and pulsed nebulizers are irrelevant," and asserting that there are "standard nebulizers");
- Page 14 (*e.g.*, "multiple milliliters of solution would have been delivered to and inhaled by the patient");
- Page 15, including n.10 (*e.g.*, "a POSA would reasonably have understood the authors to be referring to use of the particular device disclosed in the manual" and "A POSA would expect device design choices like baffle plates or operation frequency to not make a meaningful difference in delivery amount and to be accounted for in the manual's reported 0.6[ ]mL/min delivery rate");
- Pages 10, 12, 14 (*e.g.*, citing Petitioner's Expert's Reply Declaration (Gonda), EX1107, ¶¶18-21, 47-50 (regarding expert's testimony on "typical values of output of ultrasonic nebulizers used prior to May 15, 2006")).

See Sur-Reply (Paper No. 55) at 13-16.

Date: April 14, 2022

Respectfully submitted,

/Stephen B. Maebius/

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Patent Owner's Identification of Reply Arguments to which Identified Sur-Reply Evidence Is Responsive

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