UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ETON PHARMACEUTICALS, INC.,

Petitioner

v.

EXELA PHARMA SCIENCES, LLC,

Patent Owner

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U.S. PATENT NO. 10,653,719

PGR2020-00086

PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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Petitioner files this Reply to Patent Owner's Preliminary Response ("POPR").[1]

I. The Petition Establishes A Reasonable Expectation of Success

Patent Owner ("PO") argues that the Petition fails to establish a reasonable expectation of success in achieving the claimed aluminum levels, urging the Board to adopt the reasoning from the decisions denying institution in related PGR2020-00064 and PGR2020-00068. Paper 6 at 1, 24-25, n.61, 54-55, n.120. However, PO neglects to address Petitioner's pending Requests for Rehearing in those PGRs, copies of which are submitted herewith.[2] As explained in those Requests, regardless of how the Sandoz Label's "no more than 5,000 [ppb]" of aluminum is interpreted, the POSITA would have had a reasonable expectation of success of achieving the claimed aluminum levels by simply preventing the ***known*** sources of aluminum contamination. Ex. 1125 at 5-9; Ex. 1126 at 5-9.[3]

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[1] The Board authorized a 10-page reply. Ex. 1124 at 16.

[2] Exhibit 1125 (PGR2020-00064 Paper 13) and Exhibit 1126 (PGR2020-00068 Paper 12).

[3] The Requests for Rehearing also explain that the POSITA would have interpreted "no more than 5,000 [ppb]" to disclose aluminum levels ranging between 0 up to

Similarly, the current Petition demonstrated that a reasonable expectation of success existed regardless of how the Sandoz Label's "no more than 5,000 [ppb]" of aluminum is interpreted. The POSITA motivated to reduce aluminum would have reasonably expected that the Sandoz Label product could have been optimized to achieve the claimed aluminum levels by simply removing the known sources of aluminum contamination; namely, (1) using starting ingredients substantially free of aluminum, (2) ensuring that the manufacturing process did not contaminate the drug product with aluminum, and (3) storing the Sandoz Label product in a container that substantially prevents aluminum from leaching into the drug product, such as the Schott coated glass vials. Paper 1 at 32-33, 38 (last bullet point), 40, 44.[4] By

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5,000 ppb, depending on the age of product. Ex. 1125 at 9-11; Ex. 1126 at 9-11. The current Petition explained this, as well. Paper 1 at 27.

[4] The Schott coated glass vials (aka Schott Type I Plus® vials) were known to substantially eliminate glass leachables including aluminum. Ex. 1003, ¶61 (and n.86), 70, 94; Ex. 1014 at 7-8 (explaining that the Schott coated glass vials include an inner surface coated "with an ultrathin film of silicon dioxide [that] forms a highly efficient diffusion barrier that practically eliminates glass leachables"); Ex. 1048 at 12, 12:20-39 (the Schott coated glass vials substantially prevent aluminum leachables in an Ibuprofen Lysine solution) *see also* Ex. 1048 at 14, Tables 16-18

eliminating the known sources of aluminum, the POSITA—quite logically—would have had a reasonable expectation of achieving the claimed aluminum levels, regardless of how the POSITA interpreted the Sandoz Label's "no more than 5,000 [ppb]." Paper 1 at 44.[5]

Attempting to bolster its alleged no expectation of success argument, PO incorrectly argues that others tried but failed to solve the aluminum problem. However, PO does not cite to any failed attempts. To the contrary, years before the alleged invention, the Sandoz Label product manufactured by Allergy Labs had the claimed aluminum levels shortly prior to product release; namely, 17 ppb, 61 ppb, 37 ppb, 18 ppb, 50 ppb, 54 ppb, 46 ppb, 47 ppb, 48 ppb, and 43 ppb. Paper 1 at 28-

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(aluminum below 9 ppb in solutions stored in the Schott coated glass vials after 9 months storage). The POSITA would have reasonably expected that the Schott coated glass vials would be similarly effective in preventing aluminum from leaching into the Sandoz Label product. Paper 1 at 43-44; Ex. 1003, ¶61.

[5] Although the Petition also asserted *prima facie* obviousness based upon overlapping ranges (Paper 1 at 42), the reasonable expectation of success did not require overlapping ranges. *Id.* at 43-44.

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