UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETON PHARMACEUTICALS, INC.,
Petitioner

v.

EXELA PHARMA SCIENCES, LLC,
Patent Owner

Case PGR2020-00086
Patent No. 10,653,719

PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

Patent Owner files this sur-reply pursuant to the Board's Oral Order of February 8, 2021 (Exhibit 1124).

Eton's Reply further highlights the deficiencies of its Petition. The Reply is based almost entirely on new arguments, despite the Board's clear admonition not to do so.[1] Many of those new arguments come from Requests for Rehearing Eton recently filed in related PGR matters (where the Board declined to institute), on which Eton now relies.[2] This approach speaks volumes; Eton has so little confidence in its Petition that it seeks a wholesale redo. But as discussed below, even with its new, improper arguments, Eton cannot remedy the shortcomings of its Petition regarding the reasonable expectation of success and the lack of particularity of Eton's Ground.

I. THE PETITION FAILS TO ESTABLISH A REASONABLE EXPECTATION OF SUCCESS

Eton's argument regarding what the Sandoz Label discloses to a POSITA as to aluminum content continues to morph throughout these proceedings. Originally, Eton argued that the Sandoz Label discloses "a range of aluminum extending from

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[1] Ex. 1124 at 15:1-8, 18:21-19:5.

[2] Exs. 1125 and 1126.

0-5,000 ppb," which "encompasses the claimed range" of aluminum.[3] The Board correctly rejected this argument—twice[4]—and also found that Eton had not provided sufficient evidence to show that a POSITA would have reasonably expected to achieve the claimed aluminum levels through routine optimization.[5]

In its Reply, Eton now argues that a POSITA would have a reasonable expectation of success ***regardless*** of how the Sandoz label is interpreted.[6] This argument does not appear in Eton's Petition, as evidenced by Eton's citation that simply points back to Eton's defective 0-5,000 ppb range argument.[7] Instead, Eton now argues that the aluminum problem "was to a large extent already solved by the Sandoz Label product."[8] This assertion is not only new, but false. As Eton

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[3] Paper 1 at 27, 42.

[4] Ex. 2015 at 20-22; Ex. 2017 at 19-20

[5] Ex. 2015 at 22; Ex. 2017 at 19-20.

[6] Paper 8 at 1.

[7] Paper 8 at 1-2, n.3 (citing Paper 1 at 27). The footnote also cites the Requests for Rehearing (Ex. 1125 at 9-11 and Ex. 1126 at 9-11), but these passages merely rehash Eton's argument that the Sandoz Label discloses a range.

[8] Paper 8 at 4.

acknowledges, "product quality must be guaranteed both at the time of manufacture and throughout the product's expected shelf-life."[9] Even if, as Eton contends, the alleged Sandoz product had low aluminum levels "prior to product release,"[10] Eton has admitted those levels were known to increase over the shelf life of the product,[11] and for that reason "the POSITA would have interpreted 'no more than 5,000 [ppb]' to disclose aluminum levels ranging between 0 up to 5,000 ppb, ***depending on the age of product***"[12] – the exact problem that Exela's claimed invention solved. Leaving no doubt, Eton admitted in its Petition that this problem had gone ***unsolved*** by Sandoz: "the POSITA would have been motivated to

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[9] Paper 1 at 39; *see also id.* at 17 (stating that "[t]he '719 patent is generally directed to 'compositions for parenteral administration comprising L-cysteine that are stable and have desirable safety attributes for extended periods of time.'"); *id.* at 36 ("specifications (*e.g.*, tests, procedures, and acceptance criteria) 'play a major role in assuring the quality of the new drug product ***at release and during shelf life***.'") (emphasis in original); Ex. 1106 at 16:44–48 (defining "stable").

[10] Paper 8 at 3.

[11] Paper 1 at 29; Ex. 1003 at ¶ 33.

[12] Paper 8 at 1-2, n.3 (emphasis added).

substantially reduce and eliminate aluminum from parenteral nutritional drug products such as the Sandoz product disclosed by the Sandoz Label."[13]

Eton also now argues that by 2019, "the POSITA motivated to reduce aluminum contamination would not have opted for the 'historically'-used glass vials, because they were not coated or otherwise treated to prevent leachables such as aluminum."[14] But again, Eton's own evidence shows otherwise. According to Eton, the Schott Type I Plus vial with the silicon dioxide lining was available at least as early as 2006.[15] Yet, as of May 2019 Sandoz still had not solved the problem and instead sought to license Exela's low-aluminum ELCYS® product within weeks of Exela's NDA approval.[16] Eton itself (collaborating with AL Pharma) similarly failed; after seeking approval of an L-cysteine injection with "not more than 5,000 ppb aluminum" in January 2018, and that application being

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[13] Paper 1 at 32; *see also id.* at 39–40.

[14] Paper 8 at 5.

[15] Ex. 1014 at 2, 8 (published in 2006 and describing Schott glass vials coated "with an ultrathin film of silicon dioxide [that] forms a highly efficient diffusion barrier that practically eliminates glass leachables").

[16] Paper 6 at 5-6.

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