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 REQUEST FOR REHEARING

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.71(d), Petitioner requests rehearing of the Board's decision denying post grant review entered April 23, 2021 (Paper 11, hereinafter "Decision").[1]

II. BASIS FOR REHEARING

A request for rehearing "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each such matter was previously addressed in a motion, opposition, or reply." 37 C.F.R. § 42.71(d). The Board will review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion results from an erroneous interpretation of law, a factual finding that is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing the relevant evidence. *Blue Coat Systems, Inc. v. Finjan, Inc.*, IPR2016-01444, Paper 11 at 2 (P.T.A.B. July 18, 2017).

Respectfully, the Decision's conclusion that the Petition allegedly failed to demonstrate a reasonable expectation of success in achieving the claimed aluminum

[1] On December 18 and 22, 2020, respectively, Petitioner requested re-hearings in post-grant reviews of related patents, U.S. Patent Nos. 10,478,453 and 10,583,155, for which the Board previously denied institution. Both of those requests for re-hearing are currently pending.

levels is based upon both a misapprehension of the Petition and findings that either lack substantial evidentiary support or are based upon an unreasonable judgment of the allegedly conflicting evidence in three fundamental respects, any one of which standing alone warrants rehearing and institution of post-grant review.

A. Error No. 1: The Reasonable Expectation of Success Argument is Not New

In refusing to address the Petition's straightforward analysis that a POSITA would have had a reasonable expectation of achieving the claimed aluminum levels by simply removing the known sources of aluminum contamination from the Sandoz Label product, the decision erroneously concludes that this is a "new argument" that is not found in the Petition. Paper 11 at 23, n. 7. That finding is demonstrably incorrect, as illustrated below.

The Petition at Section VIII.C.2, which is titled "The Sources of Aluminum Contamination Were Well-Known and Easily Rectified," not only identifies known sources of aluminum contamination in parenteral drug products (*e.g.* the drug product ingredients and the container closure system), but also that the POSITA would have addressed these known sources by using raw materials and manufacturing process substantially free of aluminum and a container closure system that did not leach aluminum into the final drug product. Paper 1 at 32. The Petition also expressly states at Section VIII.C.2: "By addressing and eliminating these known sources of aluminum contamination, the POSITA would have had a

reasonable expectation of substantially reducing and eliminating aluminum during manufacture and storage of the drug product." (citations omitted). *Id.* at 32-33. Later, at Section VIII.E. tilted "Claims 1-30 Are Unpatentable," the Petition

expressly states in the fifth and sixth bullet points:

- The potential sources of aluminum in the Sandoz product were the drug product ingredients, the manufacturing process, and/or the drug product container. *Supra* Part VIII.C.2; *see also* Ex. 1003, ¶¶58-62.
- Aluminum could be eliminated by using ingredients free of aluminum, removing sources of aluminum contamination from the manufacturing process, and selecting a product container that does not leach aluminum. Ex. 1003, ¶¶50-62.

Id. at 38-39. This same Section of the Petition then states:

> Armed with this knowledge, the POSITA who would have been motivated to optimize the product disclosed by the Sandoz Label to substantially reduce and eliminate aluminum while also preventing the oxidative degradation of L-Cysteine and the formation of visually detectable particulate matter to predictably arrive at the claimed invention with a reasonable expectation of success. Ex. 1003, ¶¶57-75.
>
> First, the POSITA could and would have optimized the Sandoz product by screening and selecting ingredients that are substantially aluminum free, by optimizing the manufacturing process to prevent aluminum contamination, and by packaging the final drug product in a container that prevents aluminum from leaching into the product during storage. Ex. 1003, ¶¶57-62.

Id. at 39-40.

In connection with claim limitation 1[c] (the "less than about 150 ppb of aluminum" limitation), the Petition again explains the reasonable expectation of

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