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. 10,478,453

PGR2020-00064

PETITIONER'S REQUEST FOR REHEARING

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.71(d), Petitioner requests rehearing of the Board's decision denying post grant review entered November 18, 2020 (Paper 12, hereinafter "Decision").

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).

A. The Petition Demonstrates The POSITA Would Have Had A Reasonable Expectation Of Success In Achieving The Claimed Aluminum Levels

The claimed aluminum levels were not new. As the Petition[1] demonstrates, numerous batches of the Sandoz product manufactured by Allergy Labs prior to the

[1] The term "Petition" also includes the Rabinow Declaration, Johnson Declaration and the prior art cited therein.

alleged invention contained aluminum within the claimed ranges shortly after manufacture (*i.e.*, at product release) without Allergy even taking affirmative steps to control aluminum levels; namely, 17 ppb, 61 ppb, 37 ppb, 18 ppb, 50 ppb, 54 ppb, 46 ppb, 47 ppb, 48 ppb, and 43 ppb. (Pet., p. 41; Ex. 1022, Ex. B (pp. 103-112), and Ex. C (pp. 113-123).)[2] Post-release, aluminum was known to leach into the Sandoz product from the glass vials in which the Sandoz product was stored, and could rise to several hundred ppb by the product's two-year expiration date (Ex. 1022, ¶ 15)[3], which was at the lower end of the "[c]ontains no more than 5,000 [ppb] of aluminum" disclosed on the Sandoz Label. The POSITA motivated to reduce aluminum would have reasonably expected that an optimized Sandoz Label product would achieve and maintain low aluminum levels (as claimed) for long periods of time by simply removing the known sources of aluminum contamination.

As the Petition explains, the POSITA would have known that the potential sources of aluminum contamination in the Sandoz Label product included (1) the drug product starting ingredients, (2) the manufacturing process, and/or (3)

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[2] The Sandoz product attributes are included within the knowledge of the POSITA. (Paper 9, Pet. Reply, p. 2, n.4; Pet., p. 41.)

[3] The Decision "accepts the disclosures for the matter asserted in the Johnson declaration (Ex. 1022)." (Paper 12, p. 21, n.11.)

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