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

_____

U.S. PATENT NO. 10,583,155

PGR2020-00068

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 December 15, 2020 (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 (which was the basis for the denial) is premised upon a misapprehension of the Petition, which does ***not*** require that the

[1] On December 18, 2020, Petitioner requested rehearing in the post-grant review (PGR2020-00064) of related patent, U.S. Patent No. 10,478,453, for which the Board previously denied institution.

claimed aluminum ranges overlap with those disclosed by the Sandoz Label. Moreover, the Decision's finding that the ranges do not overlap is not supported by substantial evidence. For either one of these reasons, rehearing is warranted.

The claimed aluminum levels were not new. As the Petition[2] demonstrates, numerous batches of the Sandoz product manufactured by Allergy Labs under the Sandoz Label prior to the 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. 33; Ex. 1022, ¶ 15 (Ex. B (pp. 103-112), and Ex. C (pp. 113-123)).)[3] 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), which was within (and as Petitioner asserts, 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

[2] The term "Petition" also includes the cited materials, including the Rabinow Declaration, the Johnson Declaration and the prior art cited in the Petition.

[3] The Sandoz product attributes are included within the knowledge of the POSITA. (Paper 8, Pet. Reply, p. 1, n.3; Pet., pp. 42-43.)

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