IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner.

Case No.: IPR2017-01768
U.S. Patent No. 9,095,559

PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 42.71(d)

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I. INTRODUCTION

Per the Board's Order (Paper 37), Petitioner Par Pharmaceutical, Inc. submits this opposition to Patent Owner Horizon Therapeutics, LLC's request for reconsideration of the Board's Order (Paper 36) denying Horizon's request to submit the Declaration of Dr. Neal Sondheimer filed in IPR2018-01550 ("the '197 Declaration") in this proceeding.

II. ARGUMENT

A. Horizon Has Not Met Its Burden to Show that the Board's Decision Should be Modified.

"The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked." 37 C.F.R. § 42.71(d).

Horizon's request for reconsideration appears to be based on the belief that the Board misapprehended or overlooked the relevance of the '197 Declaration. The Board, however, did not deny Horizon's request based on a determination that the '197 Declaration was irrelevant to these proceedings. The Board instead relied on the fact that the discovery period for these proceedings was still open:

> Because Horizon will have an opportunity to cross-examine Dr. Sondheimer on the testimony Par presented in the instant proceedings, Horizon has an opportunity to elicit Dr. Sondheimer's opinions on information relevant to these proceedings. There is no need for Horizon to present prepared testimony from a different proceeding.

(Paper 36 at 2).

Horizon's citation to *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267 (Fed. Cir. 2017) is inapposite. (Paper 38 at 2.) There, the patent owner sought to submit testimony from the petitioner's expert that (1) "did not exist *during* the IPR discovery period" and (2) "address[ed] the *same* patents, references, and limitations at issue in the IPRs." *Ultratec*, 872 F.3d at 1272-73 (emphases added). Unlike in *Ultratec*, the '197 Declaration became available during Horizon's discovery period for its sur-reply, being served the same day as Par's Reply in this proceeding. The '197 Declaration also addresses (1) a different patent that is not familially-related to the '559 patent, (2) different prior art, and (3) completely different limitations than those at issue in this IPR. *See* Section II.B. Horizon, thus, has not met its burden to demonstrate that the Board should grant its request.

B. The '197 Declaration Is Not Relevant and Is Not Inconsistent.

The '197 Declaration also has no relevance to this proceeding. First, the patent at issue in IPR2018-01550 does not stem from any application in the '559 patent family. Second, the claims at issue in IPR2018-01550 relate to methods of adjusting the dosage of GPB based on the ratio of PAA to PAGN in view of the well-known dynamics of PAA-to-PAGN conversion. They are not based on using a patient's fasting plasma ammonia levels, as they are here. Third, only one secondary reference used in the Grounds in this proceeding, Lee, is used in the ground demonstrating the unpatentability of the claims at issue in IPR2018-

01550. And Par cites to different disclosures in Lee to demonstrate unpatentability of the challenged claims in this proceeding and in IPR2018-01550.

Lastly, there are no inconsistencies in Dr. Sondheimer's testimony. As his Reply Declaration states, the '559 patent claims "encompass administering any amount of initial dosage or adjusted dosage" to lower a patient's fasting plasma ammonia level, which could still remain within the range of safe and effective dosing. (EX1028, ¶14.) This would not give rise to the same concerns of PAA-dependent toxicity at issue in IPR2018-01550. There, the claims relate to determining the safe and effective dosing range for GPB. (*See* the '197 Declaration, *e.g.*, ¶¶36-37, 55-58, 61-67.) The '197 Declaration also states that a POSA would have been aware of the possibility of PAA's toxicity, which would have been "remote for practitioners using nitrogen scavenging medications within dosing guidelines." (*Id.*, ¶78.) This is entirely consistent with Dr. Sondheimer's testimony discussed above regarding lowering a patient's fasting plasma ammonia level using safe and effective dosing.

III. CONCLUSION

Par requests that the Board deny Horizon's request for reconsideration.[1]

[1] Should the Board grant Horizon's request, Par requests the ability to submit a paper limited to responding to Horizon's discussion of the '197 Declaration.

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