

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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PAR PHARMACEUTICAL INC.,  
Petitioner

v.

HORIZON THERAPEUTICS, LLC,  
Patent Owner

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Case IPR2017-01768  
Patent 9,095,559

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**PATENT OWNER'S REQUEST FOR RECONSIDERATION**  
*37 C.F.R. 42.71(d)*

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## **I. INTRODUCTION AND STATEMENT OF RELIEF REQUESTED**

Pursuant to 37 C.F.R. § 42.71(d) and the Board’s Order (Paper 37), Horizon respectfully requests reconsideration of the Board’s Order (Paper 36) denying it authorization to submit with its sur-reply the Declaration of Dr. Neal Sondheimer, Petitioner Par’s expert in the instant IPR, as submitted recently by Par in IPR2018-01550, *Par Pharm., Inc. v. Horizon Therapeutics, LLC* (“the ’197 Declaration”).

## **II. LEGAL STANDARDS**

A request for rehearing “must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.” 37 C.F.R. § 42.71(d). To submit supplemental information under 37 C.F.R. § 42.123(b), a party must show why it reasonably could not have been obtained earlier and that its consideration is in the interests of justice.

## **III. ARGUMENT**

The ’197 Declaration contains relevant evidence in the form of sworn testimony from Dr. Sondheimer that conflicts with positions he adopted in the present IPR. Specifically, Dr. Sondheimer opined that a POSA would have been motivated to continue increasing the dosage of RAVICTI® given to a patient to achieve fasting plasma ammonia levels below half the ULN. He testified that the prior art taught to “reduce plasma ammonia levels as low as possible,” including to

“one tenth ULN.” (Ex. 1002 at ¶¶ 117-19, 121.) He expressed no concern about the possibility of the increased dosages causing toxicity due to increased levels of PAA in the patient.

However, in his '197 Declaration, Dr. Sondheimer testified that there was prior art concern that increased dosages of PAA-prodrugs (such as RAVICTI® (“GPB”)) could cause PAA neural toxicity. ('197 Decl. at, e.g., ¶¶ 27-35, 53-60, 64, 66-71 (relying on art which predates the '559 patent's priority date).) He testified that a POSA “would have known about the saturability of the PAA-to-PAGN conversion process, which would have further bolstered concerns about the well-known toxicity of PAA.” (*Id.* at ¶ 33.) He further testified that “it was well-known that at a certain plasma concentration, PAA begins to cause neurotoxicity,” and a POSA “would have expected PAA's efficacy in removing waste nitrogen could not be increased once there was saturation [of its conversion].” (*Id.* at ¶¶ 27, 33.) Dr. Sondheimer did not express such concern in this IPR when testifying regarding the motivation to increase dosage for patients already within the normal range for plasma ammonia.

The '197 Declaration is thus relevant to the Board's evaluation of Par's obviousness grounds and Dr. Sondheimer's credibility, and should be considered in the interests of justice. *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1272-75 (Fed. Cir. 2017) (finding the Board abused its discretion in failing to

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