UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

PAR PHARMACEUTICAL INC.,
Petitioner

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner

_____

Case IPR2017-01767
Patent 9,254,278

_____

PATENT OWNER'S REQUEST FOR RECONSIDERATION

37 C.F.R. 42.71(d)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Regulations

I. INTRODUCTION AND STATEMENT OF RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.71(d) and the Board's Order (Paper 38), Horizon respectfully requests reconsideration of the Board's Order (Paper 37) 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 ¶¶ 89-91, 97, 130-32, 134.) 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 '278 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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.