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 IPR2017-01769
Patent 9,326,966

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

I. INTRODUCTION

The '966 patent claims are drawn to methods that are essentially identical those found unpatentable by the Board in *Lupin Ltd. v. Horizon Therapeutics, Inc.*, IPR2016-00829, Paper 42 (P.T.A.B. Sept. 26, 2017) ("the Lupin IPR"), and have significant overlap with the claims found unpatentable by the Board in *Par Pharmaceutical, Inc. v. Horizon Therapeutics, LLC*, IPR2015-01127, Paper 49 (P.T.A.B. Sept. 29, 2016). As explained in Par's Petition and in those prior decisions, the art prior to the filing of the '966 patent disclosed that medical professionals diagnosing and treating patients with urea-cycle disorders ("UCDs") obtained fasting plasma ammonia levels and compared those levels to an upper limit of normal ("ULN") for plasma ammonia to make dosing decisions. Those dosing decisions include adjusting a subject's dosage if its fasting plasma ammonia level was between one-half ULN and ULN. The prior art teaches or suggests the '966 patent claims and thus renders them obvious.

Horizon's Patent Owner's Response relies on legally and factually flawed arguments that do not rebut Par's showing that the challenged claims are unpatentable. Indeed, Horizon relies on arguments already twice rejected by the Board in previous IPRs involving the '966 patent family. Horizon should not be allowed to advance these arguments yet a third time. Horizon additionally ignores

the express disclosures of the prior art, relies on a misreading of the claims that excludes using biomarkers other than plasma ammonia levels to make dosing decisions, relies on inaccurate assertions of teaching away, and meritless attacks on Dr. Sondheimer's testimony.

For these reasons, and for the reasons discussed in the Petition, Dr. Sondheimer's declarations, and below, Par respectfully submits that the Board should find the '966 patent claims unpatentable as obvious.

II. THE BOARD'S FINDINGS IN THE IPR OF THE '215 AND '559 PATENT APPLY TO THE '966 PATENT.

Horizon alleges that the Board's findings in the Final Written Decision regarding the unpatentability of the '215 patent (IPR2015-01127, Paper 49) are not applicable to this proceeding because the '215 patent does not concern drug adjustments for patients having plasma ammonia levels between one-half ULN and ULN. (Paper 22, 17-18.) But, Horizon does not challenge that, other than this one limitation, the steps of the claims in the '215 and '966 patents are essentially identical, as set forth in Par's Petition.

Moreover, Horizon fails to provide any reason why it should not be bound by the previous IPR decision. Nor can it, because it is estopped from doing so. *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994); *Webpower, Inc. v. WAG Acquisition, LLC*, IPR2016-01239, Paper 21, 27-28 (P.T.A.B. Dec. 26, 2017)

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.