

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 IPR2017-01768
Patent 9,095,559

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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I. INTRODUCTION

The '559 patent claims were already 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 are essentially identical to those 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 '559 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 each element of the '559 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 '559 patent family. Horizon should not be allowed to advance these arguments 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 each of the '559 patent claims unpatentable as obvious.

II. THE BOARD'S FINDINGS IN THE PREVIOUS IPRS OF THE '215 AND '559 PATENTS APPLY TO THE '559 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, 16-17.) But, Horizon does not challenge that, other than this one limitation, the steps of the claims in the '215 and '559 patents are essentially identical, as set forth in Par's Petition.

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)

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