IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case IPR: Unassigned
Patent 9,095,559

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,095,559 PURSUANT TO 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42

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Par Pharmaceutical, Inc. ("Petitioner" or "Par") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. Part 42 of claims 1 to 15 ("Challenged Claims") of U.S. Patent No. 9,095,559 ("'559 Patent"). (Ex. 1001.)

I. INTRODUCTION

The Challenged Claims cover methods of selecting an initial dose and adjusting a dose of a known prior art drug in accordance with prior art standard-of-care methods for treating urea cycle disorders ("UCD") to achieve a known result–reducing and maintaining low levels of toxic ammonia in the subject's blood.

At the time of filing of the '559 Patent, it was already known in the prior art that the standard of care for managing urea cycle disorders was to use nitrogen scavenging drugs, which react with chemical precursors to ammonia, including the amino acid glutamine, before it can be metabolized into ammonia. (Ex. 1015, 216, 219; Ex. 1004, [0005, 0015]; Ex. 1009, 1.) Glyceryl tri-[4-phenylbutyrate][1] ("GPB"), the drug in the Challenged Claims, was a well-known nitrogen

[1] GPB is also known in the prior art as HPN-100, glycerol PBA, glycerol phenylbutyrate and GT4P. (Ex. 1004, [0020]; Ex. 1020, 2077; Ex. 1021, 276; Ex. 1001, 1:66-2:2; Ex. 1002 ¶13 fn. 1.)

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