

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 9,254,278

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT
NO. 9,254,278 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42**

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 1

II. BACKGROUND REGARDING THE UREA CYCLE,
UCDs, AND NITROGEN SCAVENGING DRUGS. 3

 A. The Urea Cycle.....3

 B. Urea Cycle Disorders4

 C. Nitrogen Scavenging Drugs6

 D. GPB8

 E. The Standard Of Care For Administering Nitrogen
 Scavenging Drugs.....9

III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))..... 11

IV. PAYMENT OF FEES (37 C.F.R. § 42.103)..... 11

V. MANDATORY NOTICES (37 C.F.R. § 42.8)..... 11

 A. Real-Parties-In-Interest11

 B. Related Matters.....12

 C. Lead And Backup Counsel (37 C.F.R. § 42.8(b)(3))
 And Service Information (37 C.F.R. § 42.8(b)(4))13

VI. SUMMARY OF THE '278 PATENT 13

VII. PERSON OF ORDINARY SKILL IN THE ART 18

VIII. STATEMENT OF THE PRECISE RELIEF REQUESTED
AND THE REASONS THEREFORE (37 C.F.R. §§ 42.22(a)
and 42.104(b))..... 19

 A. Claim Construction22

IPR Petition of U.S. Patent No. 9,254,278

| | | |
|----|---|----|
| 1. | “Plasma Ammonia Level” Means “The Level Of Ammonia Found In Blood Or Plasma” | 23 |
| B. | Brief Overview Of Prior Art Underlying The Grounds | 24 |
| 1. | Fernandes (Ex. 1015) | 24 |
| 2. | The ’859 Publication (Ex. 1004) | 25 |
| 3. | Blau (Ex. 1006) | 26 |
| 4. | Simell (Ex. 1007) | 26 |
| 5. | Lee (Ex. 1010) | 27 |
| 6. | Lichter-Konecki (Ex.1017) | 27 |
| C. | Ground 1: Independent Claim 1 And Dependent Claims 2 And 3 Are Anticipated Under 35 U.S.C. § 102 By The ’859 Publication | 28 |
| 1. | Independent Claim 1 | 28 |
| 2. | Dependent Claims 2 and 3 | 30 |
| D. | Ground 2: Independent Claim 1 And Dependent Claims 2 And 3 Are Obvious Under 35 U.S.C. § 103(a) Over Fernandes In View Of The ’859 Publication And Lee Or Lichter-Konecki, Optionally In Further View Of Blau Or Simell | 31 |
| 1. | Independent Claim 1 | 31 |
| 2. | Dependent Claims 2 and 3 | 37 |
| 3. | Motivation To Combine Prior Art Applied In Ground 2 | 37 |

IPR Petition of U.S. Patent No. 9,254,278

| | | |
|-----|---|----|
| E. | Ground 3: Independent Claims 4, 8 And 12 And Dependent Claims 6, 7, 10, 11, 14 And 15 Are Obvious Under 35 U.S.C. § 103(a) Over Fernandes In View Of The '859 Publication, Optionally In View Of Blau, Simell And/Or Lee..... | 39 |
| 1. | Independent Claims 4, 8 And 12 | 39 |
| 2. | Dependent Claims 6, 7, 10, 11, 14 And 15 | 53 |
| 3. | Motivation To Combine Prior Art Applied In Ground 3 | 54 |
| F. | Ground 4: Dependent Claims 5, 9 And 13 Are Obvious Under 35 U.S.C. § 103(a) Over Fernandes In View Of The '859 Publication And Lee Or Lichter- Konecki, Optionally In Further View Of Blau Or Simell..... | 56 |
| G. | Secondary Considerations | 63 |
| IX. | CONCLUSION..... | 63 |

...

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. 9,254,278 (“’278 Patent”). (Ex. 1001.)

I. INTRODUCTION

The Challenged Claims cover methods of selecting a 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 ’278 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.)

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.