

**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

---

**PATENT OWNER'S PRELIMINARY RESPONSE**

**TABLE OF CONTENTS**

I. INTRODUCTION ..... 1

II. RELATED PROCEEDINGS ..... 6

III. BACKGROUND AND STATE OF THE ART ..... 6

IV. THE '966 PATENT CLAIMS ..... 9

V. CLAIM INTERPRETATION ..... 12

VI. PERSON OF ORDINARY SKILL IN THE ART ..... 13

VII. THE PETITION FAILS TO DEMONSTRATE A REASONABLE  
LIKELIHOOD THAT ANY CHALLENGED CLAIM IS  
UNPATENTABLE ..... 15

    A. The Board's Finding of Unpatentability of the '215 Patent is  
    Inapplicable to the '966 Patent Claims ..... 16

    B. Ground 1 Should be Denied ..... 18

        1. The Prior Art Did Not Recognize that UCD Patients  
        Having a Plasma Ammonia Level Within the Normal  
        Range Required an Increased Dosage of Nitrogen  
        Scavenging Medication ..... 18

            (a) The Prior Art in the Petition Provides no  
            Motivation to Increase the Dosage of Nitrogen  
            Scavenging Medication for a Patient with a  
            Normal Plasma Ammonia Level ..... 20

            (b) The Prior Art as a Whole Refutes Petitioner's  
            Assertion that a POSA Would Have Been  
            Motivated to Perform the Claimed Methods ..... 27

        2. The Variability in Plasma Ammonia Levels Discouraged  
        Reliance on Normal Plasma Ammonia Levels in Making  
        Dosage Adjustments ..... 32

        3. The Prior Art Does Not Suggest Reliance on Fasting  
        Plasma Ammonia Measurements for Dosage Adjustment ..... 37

4.	The Petition Fails to Demonstrate a Reasonable Expectation of Success .....	41
5.	Dr. Sondheimer’s Unsupported and Hindsight-Driven Testimony Should be Given no Weight.....	43
6.	Dependent Claims 2, 3, 5, 8 and 11 are Not Obvious Over the Prior Art .....	47
C.	Grounds 2 and 3 Should be Denied.....	47
1.	The Prior Art Does Not Suggest Targeting a Fasting Plasma Ammonia Level at or Below Half the ULN.....	47
2.	Dr. Sondheimer’s Unsupported and Hindsight-Driven Testimony Should be Given no Weight.....	50
VIII.	THE PETITION SHOULD BE REJECTED UNDER 35 U.S.C. § 325(D).....	54
IX.	THE PETITION SHOULD BE REJECTED UNDER 35 U.S.C. § 312(A)(3) .....	55
IV.	CONCLUSION.....	56

**TABLE OF AUTHORITIES**

**Cases**

*Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*,  
776 F.2d 281 (Fed. Cir. 1985) ..... 32, 44, 54

*Belden Inc. v. Berk-Tek LLC*,  
805 F.3d 1064 (Fed. Cir. 2015) .....22

*Broadcom Corp. v. Emulex Corp.*,  
732 F.3d 1325 (Fed. Cir. 2013) .....42

*Cultec, Inc. v. Stormtech LLC*,  
IPR2017-00777, Paper 7 (Aug. 22, 2017).....56

*Disney Entm't., Inc. v. Kappos*,  
923 F. Supp. 2d 788 (E.D. Va. 2013).....30

*Envtl. Designs, Inc. v. Union Oil Co.*,  
713 F.2d 693 (Fed. Cir. 1983) .....15

*Hospira, Inc. v. Genentech, Inc.*,  
IPR2017-00739, Paper 16 (July 27, 2017).....56

*Hospitality Core Services LLC v. Nomadix, Inc.*,  
IPR2016-0052, Paper 8 (Apr. 27, 2016) .....12

*In re Am. Acad. of Sci. Tech. Ctr.*,  
367 F.3d 1359 (Fed. Cir. 2004) .....44

*In re Cyclobenzaprine Extended-Release Capsule Patent Litigation*,  
676 F.3d 1063 (Fed. Cir. 2012) .....42

*In re Kahn*,  
441 F.3d 977 (Fed. Cir. 2006) .....44

*In re Paulsen*,  
30 F.3d 1475 (Fed. Cir. 1994) .....13

*In re Rijckaert*,  
9 F.3d 1531 (Fed. Cir. 1993) .....22

*In re Smith Int'l, Inc.*,  
No. 2016-2303, slip op. at 12-13 (Fed. Cir. Sept. 26, 2017).....12

*In re Zurko*,  
258 F.3d 1379 (Fed. Cir. 2001) .....50

*Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*,  
821 F.3d 1359, 1369 (Fed. Cir. 2016). ..... 33

*Leo Pharm. Prods. Ltd. v. Rea*,  
726 F.3d 1346 (Fed. Cir. 2013) .....19

*Oil States Energy Servs., LLC v Greene's Energy Group, LLC*,  
No. 16-712 (cert. granted June 12, 2017).....57

*Tissue Transplant Tech. Ltd. et al. v. Mimedx Group, Inc.*,  
IPR2015-00320, Paper 13 (June 29, 2015) .....45

*Unified Patents Inc. v. Berman*,  
IPR2016-01571, Paper 10 (Dec.14, 2016) .....56

*W.L. Gore & Assocs. Inc. v. Garlock, Inc.*,  
721 F.2d 1540 (Fed. Cir. 1983)..... 52, 55

**Statutes**

35 U.S.C. § 103(a) ..... 18, 48

35 U.S.C. § 253(a) .....1

35 U.S.C. § 312(a)(3)..... 56, 57

35 U.S.C. § 313 .....1

35 U.S.C. § 314(a) ..... 15, 16

35 U.S.C. § 325(d) ..... 5, 55, 56

**Regulations**

37 C.F.R. § 42 .....57

37 C.F.R. § 42.22(a)(2).....5

# 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.