

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

**PAR PHARMACEUTICAL, INC.**

**Petitioner**

**v.**

**HYPERION THERAPEUTICS, INC.**

**Patent Owner**

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,642,012  
PURSUANT TO §§ 35 U.S.C. 311–319 AND 37 C.F.R. § 42**

**Mail Stop PATENT BOARD**  
Patent Trial and Appeal Board  
United States Patent and Trademark Office  
PO Box 1450  
Alexandria, Virginia 22313–1450

**Table of Contents**

	<b><u>Page</u></b>
I. INTRODUCTION .....	1
II. OVERVIEW .....	1
A. Summary of the '012 Patent.....	1
B. Summary of the Prosecution History of the '012 Patent .....	3
III. BACKGROUND ON THE UREA CYCLE, UREA CYCLE DISORDER, AND NITROGEN SCAVENGING DRUGS .....	4
IV. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a)).....	6
V. PAYMENT OF FEES (37 C.F.R. § 42.103) .....	6
VI. MANDATORY NOTICES (37 C.F.R. § 42.8).....	7
A. Real-Parties-in-Interest.....	7
B. Related Matters.....	7
C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4)) .....	8
VII. PERSON OF ORDINARY SKILL IN THE ART .....	8
VIII. CLAIM CONSTRUCTION .....	9
A. Broadest Reasonable Interpretation Standard .....	9
B. Terms of the '012 Patent .....	10
IX. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFORE (37 C.F.R. §§ 42.22(a) & 42.104(b)) .....	12
A. Ground 1: Independent Claims 1 and 8 and Dependent Claims 3, 4, 7, 10, and 12 Are Obvious under § 103(a) over <i>Brusilow '91</i> in View of <i>Sherwin and Shiple</i> .....	15
1. Overview of Prior Art Applied in Ground 1 .....	15
2. Motivation to Combine Art Applied in Ground 1 .....	16
3. Independent Claim 1 .....	18
(a) Determining – Part (a) of Independent Claim 1 .....	18
(b) Calculating – Part (b) of Independent Claim 1 .....	18
(c) Administering – Part (c) of Independent Claim 1 .....	23

Petition for *Inter Partes* Review of U.S. Patent No. 8,642,012

4.	Independent Claim 8 .....	23
(a)	Administering – Part (a) of Independent Claim 8 .....	23
(b)	Measuring – Part (b) of Independent Claim 8 .....	24
(c)	Calculating - Part (c) of Independent Claim 8 .....	24
(d)	Administering – Part (d) of Independent Claim 8 .....	26
5.	Dependent Claims 3, 4, 7, 10, and 12 .....	27
B.	Ground 2: Dependent Claim 5 Is Obvious under § 103(a) over <i>Brusilow '91</i> in view of <i>Sherwin, Shiple, and Fernandes</i> .....	28
1.	Overview of Prior Art Applied in Ground 2.....	29
2.	Motivation to Combine Art Applied in Ground 2 .....	29
3.	Dependent Claim 5 .....	30
C.	Ground 3: Dependent Claims 2 and 9 Are Obvious under § 103(a) over <i>Brusilow '91</i> in view of <i>Sherwin, Shiple, and the '647 Patent</i> ...	31
1.	Overview of Prior Art Applied in Ground 3.....	31
2.	Motivation to Combine Prior Art Applied in Ground 3 .....	32
3.	Dependent Claims 2 and 9 .....	33
D.	Ground 4: Dependent Claims 6 and 11 Are Obvious under § 103(a) over <i>Brusilow '91</i> in view of <i>Sherwin, Shiple, Kasumov, and the '979 Patent</i> .....	34
1.	Overview of Prior Art Applied in Ground 4.....	34
2.	Motivation to Combine Prior Art Applied in Ground 4 .....	35
3.	Dependent Claims 6 and 11 .....	35
E.	Ground 5: Independent Claims 1 and 8 and Dependent Claims 3, 4, 7, 10, and 12 Are Obvious under § 103(a) over <i>Brusilow '91</i> in view of <i>Simell</i> .....	36
F.	Ground 6: Dependent Claims 5 Is Obvious under § 103(a) over <i>Brusilow '91</i> in view of <i>Simell and Fernandes</i> .....	45
1.	Overview of Prior Art Applied in Ground 6.....	45
2.	Motivation to Combine Art Applied in Ground 6 .....	46
3.	Dependent Claim 5 .....	46

Petition for *Inter Partes* Review of U.S. Patent No. 8,642,012

G.	Ground 7: Dependent Claims 2 and 9 Are Unpatentable under 35 U.S.C. § 103(a) as Obvious over <i>Brusilow '91</i> in view of <i>Simell</i> , and the '647 Patent.....	47
1.	Overview of Prior Art Applied in Ground 7.....	47
2.	Motivation to Combine Prior Art Applied in Ground 7.....	48
3.	Dependent Claims 2 and 9.....	48
H.	Ground 8: Dependent Claims 6 and 11 are Obvious under 35 U.S.C. § 103(a) over <i>Brusilow '91</i> in view of <i>Simell</i> , <i>Kasumov</i> , and the '979 Patent.....	49
1.	Overview of Prior Art Applied in Ground 8.....	50
2.	Motivation to Combine Prior Art Applied in Ground 8.....	50
3.	Dependent Claims 6 and 11.....	51
I.	Ground 9: Claims 1–4, 7, 9, 10, and 12 Are Obvious under § 103(a) over <i>Brusilow '91</i> .....	51
5.	Dependent Claims 2 and 9.....	59
J.	Ground 10: Claims 6 and 11 Are Obvious under § 103(a) over <i>Brusilow '91</i> in view of <i>Kasumov</i> and the '979 Patent.....	59
X.	CONCLUSION.....	60

**List of Exhibits**

- Ex. 1001: U.S. Patent No. 8,642,012 to Scharschmidt (“the ’012 patent), filed January 7, 2009, issued February 4, 2014.
- Ex. 1002: Declaration of Dr. Neal Sondheimer.
- Ex. 1003: *Curriculum vitae* of Dr. Neal Sondheimer.
- Ex. 1004: Reserved.
- Ex. 1005: Simell, et al., *Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance*, 20 *Pediatric Research*, 1117–1121 (1986). (“*Simell*”).
- Ex. 1006: Reserved.
- Ex. 1007: Reserved.
- Ex. 1008: Reserved.
- Ex. 1009: Reserved.
- Ex. 1010: Reserved.
- Ex. 1011: Fernandes, Saudubray Berghe (editors), *Inborn Metabolic Diseases Diagnosis and Treatment*, 219–220 (3d ed. 2000). (“*Fernandes*”).
- Ex. 1012: Brusilow, *Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion*, 29 *Pediatric Research*, 147–150 (1991). (“*Brusilow ’91*”).
- Ex. 1013: Reserved.

# 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.