

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.,
Patent Owner

IPR2019-00690
U.S. Patent No. 9,468,747

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,468,747
AS OBVIOUS OVER DAVIES**

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	IPR REQUIREMENTS UNDER 37 C.F.R. § 42.104	2
	A. Grounds for Standing Under 37 C.F.R. § 42.104(a)	2
	B. Identification of Challenge Under 37 C.F.R. § 42.104(b)	2
	1. Statutory Grounds of Challenge.....	2
	2. Statement of Non-Redundancy	3
	3. Relief Requested	4
	C. Mandatory Notices Under 37 C.F.R. § 42.8	5
	1. Real Party-in-Interest Pursuant to 37 C.F.R. § 42.8(b)(1).....	5
	2. Related Matters Under 37 C.F.R. § 42.8(b)(2)	5
	3. Identification of Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)	6
	4. Service Information Under 37 C.F.R. § 42.8(b)(4).....	7
III.	LEVEL OF ORDINARY SKILL IN THE ART.....	7
IV.	OVERVIEW OF THE '747 PATENT	9
	A. Summary of the Specification	9
	B. Summary of the Claims	10
	C. Summary of Relevant Portions of the File History.....	10
	D. The '747 Patent Lacks Priority to the Filing Date of the '379 Provisional.	10
V.	BACKGROUND AND OVERVIEW OF TECHNOLOGY.....	12
	A. A POSA Would Have Been Motivated to Develop Improved Intranasal Naloxone Formulations to Combat the Opioid Epidemic.....	12
	B. A POSA Would Have Had the Know-How to Readily Develop an Improved Intranasal Naloxone Formulation.....	15
	1. The volume of the nasal cavity naturally limits the volume of a naloxone nasal spray to about 100 μ L per spray.	16
	2. A POSA would have been motivated to use a 4-6 mg naloxone dose to achieve desirable naloxone exposure levels.	17

3.	A POSA would have had adequate know-how and ability to select commonplace excipients to make a stable, well-tolerated intranasal naloxone formulation.....	18
4.	A POSA would have been motivated to load an intranasal naloxone formulation into an easy-to-use single-dose, pre-primed nasal sprayer.	20
VI.	CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(b)(3)	20
A.	“pre-primed”	21
B.	“patient”	21
C.	“delivery time”	22
D.	“90% confidence interval for dose delivered per actuation is \pm about 2.0%” and “95% confidence interval for dose delivered per actuation is \pm about 2.5%”	22
VII.	SUMMARY OF THE PRIOR ART.....	23
A.	Davies (PCT Patent Publication WO 00/62757).....	23
B.	Additional References	23
C.	Public Accessibility of the April 12, 2012 FDA Materials.....	25
VIII.	THE CHALLENGED CLAIMS ARE UNPATENTABLE	26
A.	Ground 1: Claims 1–4, 16–24, and 30–33 are obvious over Davies (Nalox1009) in view of HPE (Nalox1012), Bahal (Nalox1014), and Kushwaha (Nalox1013).....	27
1.	Claim 1	27
2.	Claim 2	36
3.	Claim 3	37
4.	Claim 4	40
5.	Claim 16	40
6.	Claims 17 and 18.....	41
7.	Claim 19	41
8.	Claims 20–23.....	42
9.	Claim 24	43
10.	Claim 30	44
11.	Claim 31	44
12.	Claim 32	44

13. Claim 33	45
B. Ground 2: Claims 28–29 and 34–39 are obvious over Davies (Nalox1009) in view of HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Wyse (Nalox1007).....	45
C. Ground 3: Claims 40–45 are obvious over Davies (Nalox1009) in view of HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Wyse (Nalox1007) or Wang (Nalox1008) and Pharmacologist POSA Knowledge or Wermeling 2013 (Nalox1016).....	47
D. Ground 4: Claims 5–7 and 10–14 are obvious over Davies (Nalox1009) in view of Djupesland (Nalox1010), HPE (Nalox1012), Bahal (Nalox1014), and Kushwaha (Nalox1013).....	50
1. Claim 5	50
2. Claim 6	52
3. Claim 7	52
4. Claims 10–11.....	52
5. Claims 12–14.....	53
E. Ground 5: Claims 8–9 are obvious over Davies (Nalox1009) in view of Djupesland (Nalox1010), HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and the '291 patent (Nalox1015).	54
F. Ground 6: Claims 25–27 are obvious over Davies (Nalox1009) in view of Djupesland (Nalox1010), HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Wyse (Nalox1007).	56
G. Ground 7: Claim 15 is obvious over Davies (Nalox1009) in view of Djupesland (Nalox1010), HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Wyse (Nalox1007) or Wermeling 2013 (Nalox1016) or Wang (Nalox1008) and Pharmacologist POSA Knowledge	58
IX. SECONDARY CONSIDERATIONS	60
A. No teaching away	60
B. No commercial success	64
C. No long-felt but unmet need or failure of others.....	65
D. No unexpected superior results	66
X. CONCLUSION	66

TABLE OF EXHIBITS

Exhibit Number	Description
Nalox1001	U.S. Patent No. 9,468,747 (the '747 patent)
Nalox1002	Expert Declaration of Maureen Donovan
Nalox1003	Expert Declaration of Günther Hochhaus
Nalox1004	Excerpt of File History of U.S. Patent No. 9,561,177, Aug. 22, 2016 Office Action, Non-Final Rejection (Aug. 22, 2016 Non-Final Rejection)
Nalox1005	Excerpt of File History of U.S. Patent No. 9,561,177, Oct. 21, 2016 Amendment and Response to Office Action (Oct. 21, 2016 Response to Office Action)
Nalox1006	Excerpt of File History of U.S. Patent No. 9,561,177, Dec. 21, 2016 Office Action, Notice of Allowance and Fees Due (Notice of Allowance)
Nalox1007	U.S. Patent No. 9,192,570 (Wyse)
Nalox1008	Chinese Patent No. 1,575,795 (Wang)
Nalox1009	PCT International App. Pub. No. WO00/62757 (Davies)
Nalox1010	Djupesland, P., <i>Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review</i> , 3 Drug Deliv. & Transl. Res. 42–62 (2013) (Djupesland)
Nalox1011	Grassin-Delyle, S. et al., <i>Intranasal Drug Delivery: An Efficient and Non-invasive Route for Systemic Administration, Focus on Opioids</i> , 134 Pharm. & Ther. 366–79 (2012) (Grassin-Delyle)
Nalox1012	Handbook of Pharmaceutical Excipients, 56–60, 64–66, 78–81, 220–22, 242–44, 270–72, 441–45, 517–22, 596–98 (Rowe, R. et al. eds., 6th ed. 2009) (HPE)
Nalox1013	Kushwaha, S. et al., <i>Advances in Nasal Trans-Mucosal Drug Delivery</i> , (1)7 J. Applied Pharm. Sci. 21–28 (2011) (Kushwaha)
Nalox1014	U.S. Patent No. 5,866,154 (Bahal)
Nalox1015	U.S. Patent No. 8,198,291 (the '291 patent)

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.