

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA LTD,
OPIANT PHARMACEUTICALS, INC.,
Patent Owners

IPR2019-00698
U.S. Patent No. 9,775,838

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,775,838
AS OBVIOUS OVER WANG**

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)	3
1.	Statutory Grounds of Challenge.....	3
2.	Statement of Non-Redundancy	3
3.	Relief Requested	5
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)	6
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 '838 PATENT	9
A.	Summary of the Specification	9
B.	Summary of the Claims	10
C.	Summary of the Relevant Portions of the File History	11
D.	The '838 Patent Lacks Priority to the Filing Date of the '379 Provisional.	11
V.	BACKGROUND AND OVERVIEW OF TECHNOLOGY.....	13
A.	A POSA Would Have Been Motivated to Develop Improved Intranasal Naloxone Formulations to Combat the Opioid Epidemic.....	13
B.	A POSA Would Have Had the Know-How to Readily Develop an Improved Intranasal Naloxone Formulation.	16
1.	The volume of the nasal cavity naturally limits the volume of a naloxone nasal spray to about 100 µL per spray.	17
2.	A POSA would have been motivated to use a 4–6 mg naloxone dose to achieve desirable naloxone exposure levels.	18

3.	A POSA would have had adequate know-how and ability to select commonplace excipients to make a stable, well-tolerated intranasal naloxone formulation.....	19
4.	A POSA would have been motivated to load an intranasal naloxone formulation into an easy-to-use single-dose, pre-primed nasal sprayer.	21
VI.	CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(b)(3)	22
A.	“pre-primed”	23
B.	“patient”	23
C.	“delivery time”	24
D.	“wherein the patient experiences a geometric mean naloxone C_{max} ” and “wherein the patient experiences a plasma naloxone concentration such that the geometric mean of area under a plasma concentration versus time curve ($AUC_{0-\infty}$)”	24
VII.	SUMMARY OF PRIOR ART CONSIDERED	25
A.	Wang (Chinese Patent Publication CN 1575795).....	25
B.	Additional References.....	26
C.	Public Accessibility of the April 12, 2012 FDA Materials.....	27
D.	Zomig Review Was Publicly Accessible	28
VIII.	THE CHALLENGED CLAIMS ARE UNPATENTABLE	29
A.	Ground 1: Claims 1–2, 4–12, 18, 24, 30–31, 35, and 37 are obvious over Wang (Nalox1008) in view of HPE (Nalox1012) and Djupesland (Nalox1010).....	29
1.	Claim 1	29
2.	Claims 2 and 4–9.....	33
3.	Claims 10–12.....	34
4.	Claim 18	35
5.	Claim 24	35
6.	Claim 30	36
7.	Claim 31	36
8.	Claim 35	36
9.	Claim 37	37

B.	Ground 2: Claims 3 and 32–34 are obvious over Wang (Nalox1008) in view of HPE (Nalox1012), Djupesland (Nalox1010), Bahal (Nalox1014), and Kushwaha (Nalox1013).....	37
1.	Claim 3	37
2.	Claim 32	42
3.	Claim 33	43
4.	Claim 34	44
C.	Ground 3: Claims 13–17 are obvious over Wang (Nalox1008) in view of HPE (Nalox1012), Djupesland (Nalox1010), and the '291 patent (Nalox1015).....	45
D.	Ground 4: Claims 19–23, 25–29, 36, and 39–40 are obvious over Wang (Nalox1008) in view of HPE (Nalox1012), Djupesland (Nalox1010), and Wyse (Nalox1007).....	46
1.	Claims 19 and 20.....	46
2.	Claim 21	48
3.	Claims 22 and 23.....	48
4.	Claims 25-29	50
5.	Claim 36.....	51
6.	Claims 39 and 40.....	53
E.	Ground 5: Claim 38 is obvious over Wang (Nalox1008) in view of HPE (Nalox1012), Djupesland (Nalox1010), and Zomig Review (Nalox1024).....	54
F.	Ground 6: Claims 41–46 are obvious over Wang (Nalox1008) in view of HPE (Nalox1012), Djupesland (Nalox1010), the '291 patent (Nalox1015), and Wyse (Nalox1007).....	57
1.	Claim 41	57
2.	Claims 42–44.....	60
3.	Claim 45	60
4.	Claim 46	61
IX.	SECONDARY CONSIDERATIONS.....	62
A.	No teaching away	62
B.	No commercial success	66
C.	No long-felt but unmet need or failure of others.....	66

Petition for *Inter Partes* Review of U.S. Patent No. 9,775,838

D. No unexpected superior results 67
X. CONCLUSION 68

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.