Paper 1 Filed: February 19, 2019

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

IPR2019-00693 U.S. Patent No. 9,561,177

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,561,177
AS OBVIOUS OVER DAVIES



Table of Contents

I. IN	VTRODUCTION	.1
II. IP	R 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	.4
3.	Relief Requested	.6
C.	Mandatory Notices Under 37 C.F.R. § 42.8	.7
1.	Real Party-in-Interest Under 37 C.F.R. § 42.8(b)(1)	.7
2.		
3.		
4.	Service Information Under 37 C.F.R. § 42.8(b)(4)	.9
III. I	LEVEL OF ORDINARY SKILL IN THE ART	.9
IV. (OVERVIEW OF THE '177 PATENT	1
A.	Summary of the Specification	11
В.	Summary of the Claims	12
C.	Summary of the Relevant Portions of the File History	12
D.	The '177 Patent Lacks Priority to the Filing Date of the '379 Provisional 1	14
V. B	ACKGROUND AND OVERVIEW OF TECHNOLOGY	16
A. Nalo	A POSA Would Have Been Motivated to Develop Improved Intranas exone Formulations to Combat the Opioid Epidemic	
B. Intra	A POSA Would Have Had the Know-How to Readily Develop an Improvenant and American States of the Company of the	
1. na	The volume of the nasal cavity naturally limits the volume of a naloxon sal spray to about 100 μL per spray	
2. ac	A POSA would have been motivated to use a 4–6 mg naloxone dose thieve desirable naloxone exposure levels.	



3. A POSA would have had adequate know-how and ability to select commonplace excipients to make a stable, well-tolerated intranasal naloxon formulation
4. A POSA would have been motivated to load an intranasal naloxon formulation into an easy-to-use single-dose, pre-primed nasal sprayer24
VI. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(b)(3)2
A. "pre-primed"
B. "patient"
C. "wherein no more than about [x]% of the droplets have a diameter less than 10 µm," "wherein the median droplet size is between about [x] µm and about [y µm," and "wherein approximately 90% of droplets have a diameter less than about 100 µm."
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 _{∞})" 27
E. "bioavailable"2
VII. SUMMARY OF PRIOR ART2
A. Davies (PCT Patent Publication WO 00/62757)2
B. Additional References
C. Public Accessibility of the April 12, 2012 FDA Materials30
D. Zomig Review (Nalox1024) was Publicly Accessible
VIII. THE CHALLENGED CLAIMS ARE UNPATENTABLE32
A. Ground 1: Claims 1–2 are obvious over Davies (Nalox1009) and HPI (Nalox1012)
1. Claim 1
2. Claim 2
B. Ground 2: Claims 3–5 are obvious over Davies (Nalox1009), HPI (Nalox1012), Bahal (Nalox1014), and Kushwaha (Nalox1013)
1. Claim 3
2. Claim 4
3 Claim 5



C. Ground 3: Claims 6–8 are obvious over Davies (Nalox1009), HPI (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Djupesland
(Nalox1010)42
1. Claim 6
2. Claim 7
3. Claim 8
D. Ground 4: Claim 9 is obvious over Davies (Nalox1009), HPE (Nalox1012) Bahal (Nalox1014), Kushwaha (Nalox1013), and Wyse (Nalox1007)44
E. Ground 5: Claims 10–11 are obvious over Davies (Nalox1009), HPI (Nalox1012) and Wyse (Nalox1007)
F. Ground 6: Claims 12–15 and 21 are obvious over Davies (Nalox1009), HPI (Nalox1012), Djupesland (Nalox1010), and the '291 patent (Nalox1015)48
1. Claim 1248
2. Claim 13
3. Claim 14
4. Claim 1550
5. Claim 215
G. Ground 7: Claims 16–20, 22–23, and 29 are obvious over Davie (Nalox1009), HPE (Nalox1012), Djupesland (Nalox1010), the '291 paten (Nalox1015), and Wyse (Nalox1007).
1. Claim 16
2. Claim 17
3. Claim 1854
4. Claim 1955
5. Claim 20
6. Claim 22
7. Claim 23
8. Claim 29
H. Ground 8: Claims 24–27 are obvious over Davies (Nalox1009), HPI (Nalox1012), Djupesland (Nalox1010), Bahal (Nalox1014), Kushwahi (Nalox1013), the '291 patent (Nalox1015), and Wyse (Nalox1007)



Petition for Inter Partes Review of U.S. Patent No. 9,561,177

Dju and	Ground 9: Claim 28 is obvious over Davies (Nalox1009), HPE (Nalox101) upesland (Nalox1010), the '291 patent (Nalox1015), and Wyse (Nalox100'd optionally Wang (Nalox1008) and Pharmacologist POSA knowledge, ermeling 2013 (Nalox1016)	7) 01
Djι	Ground 10: Claim 30 is obvious over Davies (Nalox1009), HPE (Nalox101) upesland (Nalox1010), the '291 patent (Nalox1015), Wyse (Nalox1007), a mig Review (Nalox1024).	nc
IX.	SECONDARY CONSIDERATIONS	62
A.	No teaching away	62
В.	No commercial success	65
C.	No long-felt but unmet need or failure of others	66
D.	No unexpected superior results	67
X (CONCLUSION	68



DOCKET

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.

