UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC, Petitioner,

v.

OPIANT PHARMACEUTICALS, INC., Patent Owner.

Case IPR2019-00694 Patent 9,629,965

PRELIMINARY RESPONSE OF PATENT OWNER OPIANT PHARMACEUTICALS, INC.



TABLE OF CONTENTS

I.	BAC	CKGROUND		3		
II.	THE BOARD SHOULD DENY INSTITUTION IN LIGHT OF THE PARALLEL DISTRICT COURT ACTIONS					
	A.	The Teva Case Involves a Generic Manufacturer with Final Approval for an Intranasal Naloxone Product.				
	B.	The Teva Case Is Nearing Its Final Stages9				
	C.	The Factual Record Developed in the Teva Case Will Be Onerous, If Even Possible, To Re-create in This Proceeding13				
III.	PETITIONER HAS NOT DEMONSTRATED A REASONABLE LIKELIHOOD OF SUCCESS WITH RESPECT TO ANY CLAIMS CHALLENGED IN THE PETITION					
	A.		The POSA Would Not Have Been Motivated to Use a Single Intranasal Naloxone Dose of 4 mg			
		1.	Petitioner Ignores Clinical Evidence and Provides No Testimony from a Clinician.	.19		
		2.	The Prior Art Taught That an Initial Intranasal Dose of 2 mg of Less Was Therapeutically Effective			
		3.	The Prior Art Disclosed That Too Much Liquid Was a Proble for Nasal Delivery, Not Lack of Efficacy			
		4.	Wyse Taught, and the POSA Would Have Understood, That Higher Doses of Naloxone Risked Withdrawal Symptoms and Other Significant Negative Effects.			
		5.	Contrary to Petitioner's Misreading, Wyse Does Not Teach 4 mg Doses of Naloxone.			
		6.	The Pharmacokinetic Data in Wyse Would Not Lead the POS to a Single 4 mg Dose of Intranasal Naloxone.			



	B.	The POSA Would Not Have Been Motivated To Use BZK, Much Less With EDTA.		
		1.	Wyse Teaches Away from BZK and BZK with EDTA	.50
		2.	HPE Also Teaches Away From BZK and EDTA and Would Not Override Wyse's Teach Away Anyway.	.56
IV	CON	CLUS	ION	59



TABLE OF AUTHORITIES

CASES

Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356 (Fed. Cir. 2016)	5
In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063 (Fed. Cir. 2012)	13
<i>In re Gurley</i> , 27 F.3d 551 (Fed. Cir. 1994)	53
Neptune Generics, LLC v. Eli Lilly & Co., 921 F.3d 1372 (Fed. Cir. 2019)	8
St. Regis Mohawk Tribe v. Mylan Pharms., Inc., 896 F.3d 1322 (Fed. Cir. 2018)	5, 14
Tec Air, Inc. v. Denso Mfg. Mich. Inc., 192 F.3d 1353 (Fed. Cir. 1999)	57
W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)	58
Chevron Oronite Co. LLC v. Infineum USA L.P., Case IPR2018-00923, Paper 9 (P.T.A.B. Nov. 7, 2018)	50
Deeper, UAB v. Vexilar, Inc., Case IPR2018-01310, Paper 7 (P.T.A.B. Jan. 24, 2019)	50
E-One, Inc. v. Oshkosh Corp., Case IPR2019-00161, Paper 16 (P.T.A.B. May 15, 2019)	0, 11
Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC, Case IPR2012-00001, Paper 26 (P.T.A.B. Mar. 5, 2013)	15
Gen. Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha, Case IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017)7,	9, 10
Mylan Pharmaceuticals, Inc. v. Bayer Intellectual Property GMBH, Case IPR2018-01143, Paper 13 (P.T.A.B. Dec. 3, 2018)	10



Neptune Generics, LLC v. Aventis Generics S.A., Case IPR2019-00136, Paper 15 (P.T.A.B. May 6	, 2019)8
NHK Spring Co. v. Intri-Plex Techs. Inc., Case IPR2018-00752, Paper 8 (P.T.A.B. Sept. 12	2, 2018)9, 11
Valve Corp. v. Elec. Scripting Prods., Inc., Case IPR2019-00062, Paper 11 (P.T.A.B. Apr. 2	, 2019)12
STATUTES	
35 U.S.C. § 314	12, 16, 50
35 U.S.C. § 316	12, 15
35 U.S.C. § 325	11
REGULATIONS	
37 C F R 8 42 108	20



DOCKET A L A R M

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.

