UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,

Petitioners

V.

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC, Patent Owners.

U.S. Patent No. 9,173,942 to Giorgio Calderari *et al*.

Issue Date: November 3, 2015

Title: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

\_\_\_\_

Post Grant Review No. PGR2016-00008

PETITION FOR POST GRANT REVIEW OF CLAIMS 1-19 OF U.S. PATENT NO. 9,173,942 UNDER 35 U.S.C. §§ 321-329 AND 37 C.F.R. § 42.200 ET SEQ.

Mail Stop "PATENT BOARD" Patent Trial and Appeal Board U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450



### **TABLE OF CONTENTS**

	ŀ	Page
TABl	LE OF AUTHORITIES	iii
EXH	IBIT LIST	V
	ICE OF LEAD AND BACKUP COUNSEL PURUSANT 7 C.F.R. § 42.8(b)(3)	1
	ICE OF EACH REAL PARTY IN INTEREST PURSUANT 7 C.F.R. § 42.8(b)(3)	1
	ICE OF RELATED MATTERS PURSUANT TO F.R. § 42.8(b)(2)	2
	ICE OF SERVICE INFORMATION PURSUANT TO F.R. § 42.8(b)(4)	3
GRO	UNDS FOR STANDING UNDER 37 C.F.R. § 42.204	4
	TIFICATION OF CHALLENGE STATEMENT OF PRECISE RELIEF UESTED PURSUANT TO 37 C.F.R. §§ 42.22(a)(1) AND 42.204(b)	6
SUPF	PORTING EVIDENCE UNDER 37 C.F.R. § 42.204(b)(5)	7
STA	ΓΕΜΕΝΤ OF REASONS FOR RELIEF REQUESTED	7
I.	INTRODUCTION AND SUMMARY OF ARGUMENT	7
II.	THE CLAIMS UNDER CONSIDERATION	10
III.	THE SPECIFICATION AND PROSECUTION HISTORY OF THE '942 PATENT	10
	A. The Specification Of The '942 Patent	10
	B. The Prosecution History Of The '942 Patent And Its Ancestors	14
	1. The Original Formulation Claims Of The Priority Applications Required A Stable Solution For Preventing Emesis	14



		2.	The Patent Owners' Earlier-Issued U.S. Patents Claimed Various Combinations Of Ingredients, Method Steps, And The Like, But Always A Stable Solution		
IV.	CL	AIM	CONSTRUCTION PURSUANT TO 37 C.F.R. § 42.204(B)(3)	.20	
V.	ANALYSIS				
	A.		ound 1: Claims 1-19 Are Invalid Under The Written Description vision of 35 U.S.C. § 112(a)	.24	
	B.		ound 2: Claims 1-19 Are Invalid Under The On-Sale Bar Of O2(a)(1)	.30	
		1.	The Supply And Purchase Agreement Between Patent Owner and MGI	.30	
		2.	The Supply Agreement Was A Commercial Offer for Sale Of The Claimed Invention	.34	
		3.	The Invention Was Ready For Patenting Prior To The Critical Date	.36	
		4.	The Offer For Sale Complied With Post-AIA Section 102	.39	
			a. The AIA Did Not Change The Law To Require That "On Sale" Activity Be "Public" In Order To Qualify As Invalidating Prior Art	.39	
			b. The Supply Agreement Was A Public Offer For Sale In Any Event	.43	
		5.	Claims 1-19 Are Invalid Because Of The Supply Agreement	.44	
VI	CC	NCI	LISION	61	



### **TABLE OF AUTHORITIES**

CASES	Page(s)
<i>A-Transp. Nw. Co. v. United States</i> , 36 F.3d 1576 (Fed. Cir. 1994)	35
Air Wis. Airlines Corp. v. Hoeper, 134 S. Ct. 852 (2014)	42
Anascape, Ltd. v. Nintendo of Am., Inc., 601 F.3d 1333 (Fed. Cir. 2010)	30, 31
Buildex, Inc. v. Kason Indus., Inc., 849 F.2d 1461 (Fed. Cir. 1988)	36, 44
Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317 (Fed. Cir. 2002)	25, 27
Enzo Biochem, Inc. v. Gen-Probe Inc., 424 F.3d 1276 (Fed. Cir. 2005)	9, 35
FAA v. Cooper, 132 S. Ct. 1441, 1449 (2012)	43
F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502 (2009)	43
Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1988)	27
Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041 (Fed. Cir. 2001)	
ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368 (Fed. Cir. 2009)	29, 30
<i>In re Caveny</i> , 761 F.2d 671 (Fed. Cir. 1985)	44



793 F.3d 1268 (Fed. Cir. 2015), cert. granted, 2016 U.S. L (Jan. 15, 2016)	
<i>In re Nuijten</i> , 500 F.3d 1346 (Fed. Cir. 2007)	42
J.A. LaPorte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577 (Fed. Cir. 1986)	44
Neder v. United States, 527 U.S. 1 (1999)	42
Netscape Commc'n Corp. v. Konrad, 295 F.3d 1315 (Fed. Cir. 2002)	33
Pfaff v. Wells Elec., Inc., 525 U.S. 55 (1998)	33, 37
<i>PIN-NIP, Inc. v. Platte Chem. Co.</i> , 304 F.3d 1235 (Fed. Cir. 2002)	28, 29
Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345 (Fed. Cir. 2000)	28
Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353 (Fed. Cir. 2002)	40
<i>Univ. of Rochester v. G.D. Searle &amp; Co.</i> , 358 F.3d 916 (Fed. Cir. 2004)	27, 28
Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368 (Fed. Cir. 1998)	40, 41
Zacharin v. United States, 213 F.3d 1366 (Fed. Cir. 2000)	35
STATUTES, RULES & OTHER AUTHORITIES	
35 U.S.C. § 101	42



# 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.

