### UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

## BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

V.

GALDERMA LABORATORIES, INC.
Patent Owner

U.S. Patent No. 8,603,506 Issue Date: Dec. 10, 2013 Title: Method of Treating Acne

Case IPR2015-01777

\_\_\_\_\_

## PATENT OWNER'S PRELIMINARY RESPONSE



# **TABLE OF CONTENTS**

I.	INTRODUCTION			
II.	BACKGROUND			
III.	OVE	ERVIEW OF THE '506 PATENT	∠	
IV.	PERS	ERSON OF ORDINARY SKILL IN THE ART		
V.	CLAIM CONSTRUCTION			
	A.	"Rosacea"	8	
	B.	"Papules" and "Pustules"	10	
VI.	THE PETITION FAILS TO SHOW A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM IS UNPATENTABLE			
	A.	All Grounds in the Petition rely on conclusory statements in the Payette Declaration (Ex. 1004) that are unsupported by the alleged prior art	12	
		1. The Petitioner has provided no evidence a POSA at the '506 Patent's priority date would have "known" rosacea to be "not bacterial"	13	
		2. The Petitioner has provided no evidence a POSA at the '506 Patent's priority date would have been motivated to use a periodontitis treatment for the treatment of rosacea	17	
	В.	Response to Ground 1: The Petitioner shows no reasonable likelihood that claims 1, 7, 8, 14, 15 and 20 are invalid over the combination of Sneddon (Ex. 1006), Golub (Ex. 1048), Torresani (Ex. 1010), and PERIOSTAT PDR (Ex. 1042)	23	
		1. There would have been no motivation to combine Sneddon and Torresani with Golub and PERIOSTAT PDR	25	



	2.	Ground 1 should be denied under § 325(d) because similar arguments were already addressed and overcome during original prosecution	29
	3.	The Petitioner does not sufficiently substantiate its inherency allegation regarding treating rosacea with no reduction of skin microflora over a six-month treatment	30
	4.	The combination of Sneddon, Golub, Torresani, and PERIOSTAT PDR provides no reasonable expectation that papules and pustules of rosacea could be treated as claimed	34
	5.	The Petitioner's allegations are wholly driven by hindsight	36
	6.	The Petitioner attempts to rely on hypothetical and unproven alleged prior uses rather than printed publications	41
	7.	The Petitioner does not demonstrate that claims reciting a doxycycline serum concentration in the range of about 0.1 to about 0.8 µg/ml would have been obvious	42
C.	Response to Ground 2: The Petitioner shows no reasonable likelihood that claims 1, 8 and 15 are invalid over the combination of Golub (Ex. 1048), Torresani (Ex. 1010), and Jansen (Ex. 1034)		43
D.	Response to Ground 3: The Petitioner shows no reasonable likelihood that claims 7, 14 and 20 are invalid over the combination of Golub (Ex. 1048), Torresani (Ex. 1010), Jansen (Ex. 1034) and PERIOSTAT PDR (Ex. 1042)		46
E.	"Secondary considerations" demonstrate nonobviousness of the claimed methods		
	1.	The claimed invention of the '506 Patent satisfied a long- felt, unmet need for an effective treatment of papules and pustules of rosacea with reduced side effects	48



	2.	Commercial success of ORACEA® further establishes nonobviousness of the claimed methods	
	3.	The Petitioner attempts to copy the 40 mg/day dosage claimed in the '506 Patent, despite the availability of generic 50 mg and 100 mg doxycycline	51
VII.		TION SHOULD BE DENIED AS REDUNDANT OVER 782	52
VIII.	CONCLUS	ION	59

# **TABLE OF AUTHORITIES**

## **CASES**

Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563 (Fed. Cir. 1996)	48
Berk-Tek, LLC v, Belden Inc., IPR2013-0058, Paper 13 (P.T.A.B. May 2, 2013)	8
Cheese Sys., Inc. v. Tetra Pak Cheese & Powder Sys., Inc., 725 F.3d 1341 (Fed. Cir. 2013)	25
Coalition for Affordable Drugs V LLC v. Biogen MA Inc., IPR2015-01136, Paper 23 (P.T.A.B. Sept. 2, 2015)	41
Crocs, Inc. v. Int'l Trade Comm'n, 598 F.3d 1294 (Fed. Cir. 2010)	47
Ferrum Ferro Capital, LLC v. Allergan Sales, LLC, IPR2015-00858, Paper 10 (P.T.A.B. Sept. 21, 2015)	31
Forest Labs., Inc. v. Ivax Pharms., Inc., 438 F. Supp. 2d 479 (D. Del. 2006), aff'd, 501 F.3d 1263 (Fed. Cir. 2007)	51
In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig 676 F.3d 1063 (Fed. Cir. 2012)	
In re Newell, 891 F.2d 899 (Fed. Cir. 1989)	33
<i>In re Rijckaert</i> , 9 F.3d 1531 (Fed. Cir. 1993)	32
<i>In re Spormann</i> , 363 F.2d 444 (C.C.P.A. 1996)	33



# 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.

