IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC

Petitioners

v.

ALMIRALL, LLC,

Patent Owner

Case IPR2019-00207

Patent 9,517,219

PATENT OWNER'S RESPONSE TO PETITION FOR INTER PARTES REVIEW

TABLE OF CONTENTS

			<u>Page</u>		
PAT	ENT (OWNER'S EXHIBIT LIST	v		
I.	INTRODUCTION				
II.	THE	THE '219 PATENT			
III.	SCOPE AND CONTENT OF THE PRIOR ART CONCERNING ACNE AND ROSACEA TREATMENTS				
	A.	A. Acne			
	B.	Prior Art Acne Treatments	9		
		1. First-Line Treatments	9		
		2. Combination Therapies	10		
		3. Emerging Treatments	13		
	C.	Rosacea	14		
IV.	SCOPE AND CONTENT OF THE PRIOR ART CONCERNING DAPSONE AND DAPSONE/ADAPALENE COMPOSITIONS FOR THE TREATMENT OF DERMATOLOGICAL CONDITIONS				
	A.	Topical Dapsone for Treatment of Acne or Rosacea	15		
	B. Formulation of Topical Dapsone Products				
	C.	Adapalene Combination Products	26		
V.	POSA		27		
VI.	CLAIM CONSTRUCTION		28		
VII.	THE PRIOR ART OF PETITIONERS' GOUNDS DOES NOT RENDER OBVIOUS THE CHALLENGED CLAIMS OF THE '219 PATENT				



TABLE OF CONTENTS (Continued)

			Page	
A.	A POSA Had No Genuine Reason to Treat Acne or Rosacea with a New Dapsone Topical Formulation			
B.	A POSA Would Not Reasonably Have Considered Garrett a Motivation to Make a New Topical Dapsone Formulation for Treatment of Acne or Rosacea			
	1.	By 2012, a POSA Would Not Have Desired a Product Containing Undissolved Dapsone	33	
	2.	Garrett Itself Teaches Dapsone Is Not Effective	39	
	3.	Closer Art Teaches that Dapsone Is Not Effective	41	
C.	Petitioners Fail to Show Motivation to Increase Dapsone Concentration to the Claimed About 7.5%			
D.	The Prior Art Taught That Adapalene/Dapsone Combinations Were Superior to Dapsone-Only Topicals			
E. No		Motivation to Use the Claimed Polymeric Viscosity Builder	47	
	1.	Petitioners Have Not Demonstrated A Credible Motivation to Combine with Nadau-Fourcade	51	
	2.	Petitioners Have Not Demonstrated A Credible Motivation to Combine with Bonacucina	54	
F.	Neither Nadau-Fourcade Nor Bonacucina Teaches the Claimed Concentrations of Polymeric Viscosity Builder Comprising A/SA Copolymer for Use With the Dapsone Topical Formulations Allegedly Disclosed in Garrett			
G.	Objective Indicia of Non-Obviousness Further Support Denial of the Petition			
CON	CLLI	ISION	61	



TABLE OF AUTHORITIES

	Page(s)
CASES	
Altana Pharma AG v. KUDCo, No. 04-2355-JLL, 2010 WL 10804666 (D.N.J. Jul. 15, 2010)	42
Altana Pharma AG v. Teva Pharm. USA, Inc., 566 F.3d 999 (Fed. Cir. 2009)	41
Graham v. John Deere Co., 383 U.S. 1 (1966)	29, 64
Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359 (Fed. Cir. 2016)	29, 48
Intendis GMBH v. Glenmark Pharms. Inc., USA, 822 F.3d 1355 (Fed. Cir. 2016)	53
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)	29
Leo Pharm. Prods., Ltd. v. Rea, 726 F.3d 1346 (Fed. Cir. 2013)	29
Optivus Tech., Inc. v. Ion Beam Applications S.A., 469 F.3d 987 (Fed. Cir. 2006)	48
Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc., 520 F.3d 1358 (Fed. Cir. 2008)	41
Polaris Indus. Inc. v. Arctic Cat, Inc., 882 F.3d 1056 (Fed. Cir. 2018)	36
Süd-Chemie, Inc. v. Multisorb Techs., Inc. 554 F.3d 1001 (Fed. Cir. 2009)	46



IPR2019-00207 Patent Owner Response

TABLE OF AUTHORITIES (Continued)

	,	Page(s)
STATUTES AND RULES		
35 U.S.C. § 316(e)	 	28
OTHER AUTHORITIES		
37 C.F.R. § 42.1(d)	 	28



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.

