

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner

v.

ALMIRALL, LLC

Patent Owner

Case: IPR2019-01095

U.S. Patent No. 9,517,219

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,517,219
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.123**

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

TABLE OF CONTENTS

I. INTRODUCTION 1

II. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))..... 6

III. PRECISE RELIEF REQUESTED AND SUPPORTING REASONS 6

IV. OVERVIEW OF LEVEL OF SKILL AND PRIOR ART 7

 A. Person of ordinary skill in the art (“POSA”). 7

 B. Scope and content of the art before November 20, 2012..... 8

 1. Dapsone was known for treating both inflammatory and non-inflammatory acne and rosacea. 8

 2. Topical dapsone compositions were well-known..... 9

 3. Petitioners’ grounds rely specifically on the following prior art publications. 13

 (a) Garrett (MYLAN1004)..... 13

 (b) Nadau-Fourcade (MYLAN1005) 15

 (c) Bonacucina (MYLAN1015) 16

V. OVERVIEW OF THE ’219 PATENT 18

 1. The Claims 18

 2. Prosecution history..... 19

VI. CLAIM CONSTRUCTION 20

VII. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))..... 22

 A. GROUND 1: Claims 1-8 are obvious over Garrett in view of Nadau-Fourcade. 23

 1. Claims 1 and 6..... 23

(a)	Garrett teaches treating acne vulgaris and rosacea with topical dapsone formulations.....	26
(b)	Garrett also teaches a composition having “about 7.5% w/w dapsone,” “water,” and “about 30% w/w to about 40% w/w ethoxydiglycol” “wherein the composition does not comprise adapalene.”	27
(c)	It would have been obvious to a POSA to substitute the “acrylamide copolymer” in Nadau-Fourcade for the thickening agent in Garrett.	33
(d)	Using “about 4% w/w” of the acrylamide copolymer as recited in claim 6 would have been obvious.	38
(e)	A POSA would have had a reasonable expectation of successfully combining the components of the claimed topical dapsone formulations.....	38
2.	Claim 2	41
3.	Claim 3	41
4.	Claims 4 and 7.....	42
5.	Claims 5 and 8.....	42
B.	GROUND 2: Claims 1-8 are obvious over Garrett in view of Bonacucina.	43
1.	Claims 1 and 6.....	43
(a)	Garrett discloses methods of administering dapsone formulations to patients with acne vulgaris and rosacea.	47
(b)	Garrett also teaches a composition having “about 7.5% w/w dapsone,” “water,” and “about 30% w/w to about 40% w/w ethoxydiglycol” “wherein the composition does not comprise adapalene.”	47

(c)	A POSA would have had a reason to use the claimed acrylamide copolymer in a 7.5% w/w dapsone compositions.....	49
(d)	The claimed “about 4% w/w” copolymer limitation would have been obvious as a routine optimization.....	54
(e)	A POSA would have had a reasonable expectation of successfully combining the components of the claimed topical dapsone formulations.....	55
2.	Claim 2.....	57
3.	Claim 3.....	57
4.	Claims 4 and 7.....	57
5.	Claims 5 and 8.....	58
C.	There are no objective indicia that could overcome the strong obviousness showing here.....	59
1.	Allergan’s “unexpected” compatibility and smaller particle size arguments would have been expected.	60
2.	There are no other objective indicia of non-obviousness.	65
3.	The prior art did not teach away from combining the claimed components in the claimed amounts.	66
VIII.	THERE IS NO BASIS TO DENY THE PETITION UNDER 35 U.S.C. §§ 314(a) or 325(d).....	66
IX.	CONCLUSION.....	68
X.	MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)).....	68

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Abbott Labs. v. Andrx Pharm., Inc.</i> , 452 F.3d 1331 (Fed. Cir. 2006)	7
<i>Amneal Pharms. LLC et al. v. Almiral, LLC</i> , IPR2018-00608, Paper 10 (P.T.A.B. Aug. 29, 2018).....	1, 19
<i>Amneal Pharms. v. Supernus Pharms.</i> , IPR2013-00368, Paper 8 (P.T.A.B. Dec. 17, 2013)	59
<i>Conopco, Inc. v. Procter & Gamble Co.</i> , IPR2013-00505, Paper 69 (P.T.A.B. Feb. 10, 2015).....	35
<i>Cuozzo Speed Techs., LLC v. Lee</i> , 136 S. Ct. 2131 (2016).....	20
<i>DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.</i> , 567 F.3d 1314 (Fed. Cir. 2009)	66
<i>E.I. DuPont de Nemours & Co. v. Synvina C. V.</i> , 2018 WL 4390796 (Fed. Cir. September 17, 2018).....	<i>passim</i>
<i>Galderma Labs., L.P. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013)	<i>passim</i>
<i>Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.</i> , 340 U.S. 147 (1950).....	41, 57
<i>Hotchkiss v. Greenwood</i> , 52 U.S. 248 (1850).....	3, 31
<i>In re Applied Materials, Inc.</i> , 692 F.3d 1289 (Fed. Cir. 2012)	31, 38, 49, 55
<i>In re Boesch</i> , 617 F.2d 272 (C.C.P.A.1980).....	31, 38, 49, 55
<i>In re Fout</i> , 675 F.2d 297 (C.C.P.A. 1982).....	35

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.