Paper No. _____ Filed: June 3, 2016

Filed on behalf of: Mylan Pharmaceuticals Inc.

By: Steven W. Parmelee
Michael T. Rosato
Jad A. Mills
WILSON SONSINI GOODRICH & ROSATI
701 Fifth Avenue, Suite 5100
Seattle, WA 98104-7036

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
MYLAN PHARMACEUTICALS INC., Petitioner,
V.
ALLERGAN, INC.,

Case No. IPR2016-01128 Patent No. 8,629,111

Patent Owner.

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,629,111



TABLE OF CONTENTS

			<u>Page</u>			
I.	Introduction					
	A.	Brief Overview of the '111 Patent				
	B.	Brief Overview of the Prosecution History				
	C. Brief Overview of the Scope and Content of the Prior Art					
		i. U.S. Patent No. 5,474,979 to Ding <i>et al.</i> ("Ding '979," EX1006)	7			
		ii. Sall et al., Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease, 107 OPHTH. 631 (2000) (EX1007)	8			
		iii. A. Acheampong et al., Cyclosporine Distribution into the Conjunctiva, Cornea, Lacrimal Gland, and Systemic Blood following Topical Dosing of Cyclosporine to Rabbit, Dog, and Human Eyes, 2 LACRIMAL GLAND, TEAR FILM, AND DRY EYE SYNDROMES 1001 (1998) ("Acheampong," EX1008)				
	D.	Brief Overview of the Level of Skill in the Art				
II.	Gro	OUNDS FOR STANDING				
III.	Man	IANDATORY NOTICES UNDER 37 C.F.R. § 42.8				
IV.		STATEMENT OF THE PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED.				
V.	STA	ATEMENT OF NON-REDUNDANCY				
VI.	CLAIM CONSTRUCTION					
	A.	A. "buffer"				
	В.	"substantially no detectable concentration"	14			



	C.	"effective," and "therapeutically effective"			
VII.	I. BACKGROUND KNOWLEDGE IN THE ART PRIOR TO SEPTEMBER 15, 200				
VIII.	DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY				
	A.	[Ground 1] Claims 1-27 are Anticipated under 35 U.S.C. § 102(b) by Ding '979			
		i.	Claims 1-10, 12-15, and 18-19	20	
		ii.	Claims 17, 20-27	27	
		iii.	Claims 11 and 16	28	
	B.	[Ground 2] Claims 1-27 are Obvious under 35 U.S.C. § 103 over Ding '979 and Sall			
		i.	Claims 1-16, and 18-19	35	
		ii.	Claims 17, 20-27	37	
		iii.	Claims 11 and 16	38	
	C.	[Ground 3] Claims 11 and 16 are Obvious under 35 U.S.C. § 103 over Ding '979, Sall, and Acheampong			
IX.	No Objective Indicia of Non-Obviousness				
	A.	No Unexpected Results			
	B.	No Evidence of Commercial Success			
	C.	No Industry Praise			
	D.	No Long-Felt, Unmet Need			
	E.	No Failure of Others			
X.	Conclusion.				
XI.	CERTIFICATE OF COMPLIANCE				
XII.	PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15(A) AND 42.10360				





I. Introduction

Mylan Pharmaceuticals Inc. ("Petitioner") requests review of U.S. Patent No. 8,629,111 to Acheampong *et al.* ("the '111 patent," EX1001) that issued on January 14, 2014. PTO records indicate the '111 patent is assigned to Allergan, Inc. ("Patent Owner"). This Petition demonstrates that there is a reasonable likelihood that claims 1-27 of the '111 patent are unpatentable for failure to distinguish over the asserted prior art. Additional petitions are being filed to address related patents that are assigned to Patent Owner. All challenged patents are continuations from the same family and are terminally disclaimed over one another. The patents claim an ophthalmic emulsion for the treatment of overlapping ocular disorders, or conventional methods of administering the emulsion.

In particular, the '111 patent claims a topical ophthalmic emulsion as in related U.S. Patent No. 8,685,930, but further recites that cyclosporin A ("CsA") is the only peptide present in the emulsion. Each element of the emulsion, however, including the claimed CsA and castor oil percentages, preferred ratios for combining them, and CsA as the only peptide present in the emulsion, was disclosed in a single prior art reference (Ding '979) for use in topical ophthalmic emulsions to treat the same dry eye disease, such as keratoconjunctivitis sicca ("KCS"). In fact, during prosecution of a parent application, applicants admitted that the claimed emulsion containing 0.05% CsA and 1.25% castor oil "is squarely within the teaching of the Ding ['979] reference" and "would have been obvious" to a person of skill in the art at the time of the invention. EX1005, 0435; EX1002,



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.

