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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.,
Patent Owner.

Case No. IPR2016-01132
Patent No. 9,248,191

**PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 9,248,191**

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
A. Brief Overview of the '191 Patent	2
B. Brief Overview of the Prosecution History	3
C. Brief Overview of the Scope and Content of the Prior Art.....	6
i. U.S. Patent No. 5,474,979 to Ding <i>et al.</i> ("Ding '979," EX1006)	6
ii. Sall <i>et al.</i> , <i>Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease</i> , 107 OPTH. 631 (2000) (EX1007).....	7
iii. A. Acheampong <i>et al.</i> , <i>Cyclosporine Distribution into the Conjunctiva, Cornea, Lacrimal Gland, and Systemic Blood following Topical Dosing of Cyclosporine to Rabbit, Dog, and Human Eyes</i> , 2 LACRIMAL GLAND, TEAR FILM, AND DRY EYE SYNDROMES 1001 (1998) ("Acheampong," EX1008).....	8
iv. U.S. Patent No. 5,578,586 to Glonek <i>et al.</i> ("Glonek," EX1009)	9
D. Brief Overview of the Level of Skill in the Art	9
II. GROUNDS FOR STANDING	10
III. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8	10
IV. STATEMENT OF THE PRECISE RELIEF REQUESTED.....	12
V. STATEMENT OF NON-REDUNDANCY	12
VI. CLAIM CONSTRUCTION	13
A. "buffer"	13

B.	“substantially no detectable concentration”	14
C.	“effective,” “lacrimal gland tearing,” “overall efficacy substantially equal to,” “as much therapeutic efficacy as”	14
D.	“demonstrates a reduction in adverse events”	16
E.	“breaks down”	16
VII.	BACKGROUND KNOWLEDGE IN THE ART PRIOR TO SEPTEMBER 15, 2003	16
VIII.	DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY	22
A.	[Ground 1] Claims 1-16 and 21-27 are Obvious under 35 U.S.C. § 103 over Ding ’979 and Sall.....	22
i.	Claims 1-16	25
ii.	Claims 21-27	34
B.	[Ground 2] Claims 1-16 and 21-27 are Obvious under 35 U.S.C. § 103 over Ding ’979, Sall, and Acheampong	43
C.	[Ground 3] Claims 17-20 are Obvious under 35 U.S.C. § 103 over Ding ’979, Sall, and Glonek.....	44
D.	[Ground 4] Claim 20 is Obvious under 35 U.S.C. § 103 over Ding ’979, Sall, Glonek, and Acheampong.	47
IX.	NO OBJECTIVE INDICIA OF NON-OBVIOUSNESS: NO UNEXPECTED RESULTS	48
X.	CONCLUSION.....	59
XI.	CERTIFICATE OF COMPLIANCE	60
XII.	PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15(A) AND 42.103	61
XIII.	APPENDIX – LIST OF EXHIBITS	62

I. INTRODUCTION

Mylan Pharmaceuticals Inc. (“Petitioner”) requests review of U.S. Patent No. 9,248,191 to Acheampong *et al.* (“the ’191 patent,” EX1001) that issued on February 2, 2016. PTO records indicate the ’191 patent is assigned to Allergan, Inc. (“Patent Owner”). This Petition demonstrates that there is a reasonable likelihood that claims 1-27 of the ’191 patent are unpatentable for failing to distinguish over 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 ’191 patent claims concern conventional methods of treating dry eye disease, such as keratoconjunctivitis sicca (“KCS”) by the “twice a day” topical ophthalmic administration of an emulsion containing cyclosporin A (“CsA”), castor oil, and other standard ingredients, as generally claimed in related U.S. Patent No. 8,685,930. Each element of the emulsion, including the claimed CsA and castor oil percentages and methods for administering them to treat dry eye disease/KCS, were disclosed in a single prior art reference (Ding ’979) for use in topical ophthalmic emulsions to enhance and restore lacrimal gland tear production and treat dry eye disease. During prosecution of a parent application, applicants admitted the claimed emulsion containing 0.05% CsA / 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, ¶20. A second 102(b) prior art reference, Sall, discloses twice-daily administration of a 0.05% CsA-in-castor oil emulsion for the same purpose.

In prosecuting a continuation application, applicants changed course and attempted to withdraw the admissions regarding Ding '979, arguing that data collected *after* their earlier admissions established patentability. EX1004, 0803. In a parent application of the '191 patent before the same examiner, Patent Owner alleged that patentability was established by an unexpected result that the emulsion was “equally or more therapeutically effective for the treatment of dry eye/keratoconjunctivitis sicca than the formulation containing 0.10% by weight cyclosporin A and 1.25% by weight castor oil.” EX1023, 0195; EX1002, ¶¶22-24. But the supposed “unexpected results” are weak, at best, and fail to rebut the strong evidence of obviousness. The data relied upon by applicants lack scientific parameters necessary to demonstrate statistical significance and materiality and, in many cases, appear to be copies of previously published graphs from the 102(b) prior art reference, Sall. Thus, Patent Owner’s cited evidence does not support non-obviousness of the claims, and merely confirms that the results were expected in view of and were already disclosed in the prior art.

A. Brief Overview of the '191 Patent

The '191 patent has an earliest claimed priority date of September 15, 2003. Claims 1, 13, 17, and 21 are independent claims that each recite administering a first topical ophthalmic emulsion comprising 0.05% CsA, 1.25% castor oil, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer (“cross-polymer”), and water, twice-daily. They state that the method is either for treating dry eye

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