Paper No. _____ Filed: June 3, 2016

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V.

MYLAN PHARMACEUTICALS INC., Petitioner,

ALLERGAN, INC., Patent Owner.

Case No. IPR2016-01131 Patent No. 8,648,048

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,648,048



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	A.	"buffer"				
	B.	"substantially no detectable concentration"				
	C.	"effective," "substantially therapeutically effective as," and "as much therapeutic effectiveness as"				
	D.	"adverse events" and "side effects"				
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I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") requests review of U.S. Patent No. 8,648,048 to Acheampong *et al.* ("the '048 patent," EX1001) that issued on February 11, 2014. PTO records indicate the '048 patent is assigned to Allergan, Inc. ("Patent Owner"). This Petition demonstrates that there is a reasonable likelihood that claims 1-23 of the '048 patent are unpatentable for failure 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 patent 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 '048 patent claims concern conventional methods of treating the dry eye disease keratoconjunctivitis sicca (hereinafter "dry eye disease/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 drye eye disease/KCS, were disclosed in a single prior art reference (Ding '979). 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



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