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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case No. IPR2016-01129
Patent No. 8,642,556

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,624,556

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I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") requests review of U.S. Patent No. 8,642,556 to Acheampong *et al*. ("the '556 patent," EX1001) that issued on February 4, 2014. PTO records indicate the '556 patent is assigned to Allergan, Inc. ("Patent Owner"). This Petition demonstrates that there is a reasonable likelihood that claims 1-20 of the '556 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.

The '556 patent claims a topical ophthalmic emulsion as in related U.S. Patent No. 8,685,930, but further recites a comparative clause, where an effect of the emulsion is compared to a prior art emulsion. Yet each element of the claimed emulsion, including the claimed cyclosporin A ("CsA") and castor oil percentages and other standard emulsion ingredients, was disclosed in a single prior art reference (Ding '979) for the same therapeutic uses, *i.e.*, treating dry eye disease. During prosecution of a parent application, applicants even 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, ¶18.

Four years later, in prosecuting the '556 patent as a continuation application, applicants changed course and attempted to withdraw these admissions. EX1004, 0007. They argued that data collected ***after*** their earlier admissions established patentability because of an alleged 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." EX1004, 0007, 0205; EX1002, ¶¶20-22. 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 a 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 already disclosed in the prior art.

A. Brief Overview of the '556 Patent

The '556 patent has an earliest claimed priority date of September 15, 2003. Independent claim 1 recites an emulsion of 0.05% CsA, 1.25% castor oil, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer ("cross-polymer") and water that is therapeutically effective in treating dry eye disease and "provides overall efficacy substantially equal to a second topical ophthalmic emulsion comprising cyclosporin A in an amount of about 0.1% by weight and castor oil in an amount of about 1.25% by weight." Claims 2-6 and 9-10 recite that the emulsion comprises a tonicity or demulcent agent, specifically glycerine, and/or a

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