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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. IPR2016-01127
Patent No. 8,685,930

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,685,930

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I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") requests review of U.S. Patent No. 8,685,930 to Acheampong *et al*. ("the '930 patent," EX1001) that issued on April 1, 2014. PTO records indicate the '930 patent is assigned to Allergan, Inc. ("Patent Owner"). This Petition demonstrates that there is a reasonable likelihood that claims 1-36 of the '930 patent are unpatentable for failure to distinguish over 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 '930 patent claims a topical ophthalmic emulsion for treating dry eye disease, such as keratoconjunctivitis sicca ("KCS"), which contains 0.05 percent by weight ("%") cyclosporin A ("CsA"), 1.25% castor oil, and other standard emulsion ingredients in a combination well known in the art. EX1001, 14:41-16:49. In fact, each element of the emulsion, including the claimed CsA and castor oil percentages and preferred ratios for combining them, was disclosed in a single prior art reference (Ding '979) for use in topical ophthalmic emulsions to treat dry eye disease/KCS. Indeed, 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, ¶18.

Four years later, in prosecuting the '930 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, 0195; 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 expected in view of and were already disclosed in the prior art.

A. Brief Overview of the '930 Patent

The '930 patent has an earliest claimed priority date of September 15, 2003. Independent claim 1 recites an emulsion of 0.05% CsA in 1.25% castor oil, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer ("cross-polymer") and water, wherein the topical ophthalmic emulsion is therapeutically effective in treating keratoconjunctivitis sicca. Independent claims 13 and 25 recite an identical emulsion but state respectively that it is "therapeutically effective in treating dry eye" or "therapeutically effective in increasing tear production" in the

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