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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case No. IPR2017-00578
Patent No. 8,629,111

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

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I. INTRODUCTION

Pursuant to the provisions of 35 U.S.C. § 311 and § 6 of the Leahy-Smith America Invents Act (“AIA”), and to 37 C.F.R. Part 42, Teva Pharmaceuticals USA, Inc. (“Petitioner” or “Teva”) hereby 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, by a preponderance of the evidence, 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; EX1025, ¶18.

Four years later, in prosecuting the ’111 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; EX1025, ¶¶20-22. 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 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.

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