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Filed on behalf of Teva Pharmaceuticals USA, Inc.
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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. IPR2017-00586
Patent No. 9,248,191

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

TABLE OF CONTENTS

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. 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; EX1026, ¶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; EX1026, ¶¶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-

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