Paper No. _____
Filed: January 6, 2017

Filed on behalf of Teva Pharmaceuticals USA, Inc.
By: Gary J. Speier
Mark D. Schuman
CARLSON, CASPERS, VANDENBURGH,
LINDQUIST & SCHUMAN, P.A.
225 South Sixth Street, Suite 4200
Minneapolis, MN 55402

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

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. 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.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.