

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.
APOTEX, INC.
Petitioner

v.

ALLERGAN, INC.
Patent Owner

U.S. Patent No. 8,642,556

Inter Partes Review Case No. Unassigned

DECLARATION OF ERNING XIA, PH.D

TABLE OF CONTENTS

I.	Introduction.....	1
II.	My Background and Qualifications.....	3
III.	Summary of Opinions.....	5
IV.	List of Documents I Considered in Formulating My Opinions	13
V.	Person of Ordinary Skill in the Art.....	15
VI.	The '556 Patent Specification	16
VII.	Claim Construction.....	17
VIII.	State of the Art Before September 15, 2003.....	23
IX.	Summary Chart of Analysis Over the Art	43
X.	The Basis of my Analysis with Respect to Anticipation.....	44
A.	Ground 1: The '979 Patent Discloses Every Limitation of Claims 1-20	45
XI.	The Basis of my Analysis with Respect to Obviousness	96
A.	Ground 2: The '607 Patent, as it Incorporates the '979 Patent, and Sall Provide a Reason to Arrive at the Invention of Claims 1-10, 12, 13, and 15-17 with a Reasonable Expectation of Success.....	98
B.	Ground 3: The '607 Patent, as it Incorporates the '979 Patent, Sall, and the '586 Patent Provide a Reason to Arrive at the Invention of Claim 14 with a Reasonable Expectation of Success	156
C.	Ground 4: The '607 Patent, as it Incorporates the '979 Patent, Sall, and Acheampong Provide a Reason to Arrive at the Invention of Claims 11, 18, and 20 with a Reasonable Expectation of Success.....	166
D.	Ground 5: The '607 Patent, as it Incorporates the '979 Patent, Sall, the '586 patent, and Acheampong Provide a Reason to Arrive at the Invention of Claim 19 with a Reasonable Expectation of Success.....	173
E.	Secondary Considerations of Non-obviousness.....	173
1.	No Unexpectedly Superior Results.....	175
2.	No Long-Felt, Unmet Need	186
3.	No Failure of Others	189

*Inter Partes Review of USPN 8,642,556
Declaration of Erning Xia, Ph.D (APO1005)*

4.	No Industry Praise.....	189
5.	Commercial Success	191
6.	Other Objective Evidence	193
XII.	Conclusion	193

I, Erning Xia, Ph.D, hereby declare as follows.

I. Introduction

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of APOTEX, CORP., and APOTEX, INC. ("APOTEX") for the above-captioned *inter partes* review (IPR). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$400 per hour.

3. I understand that the petition for *inter partes* review involves U.S. Patent No. 8,642,556 ("the '556 patent"), APO1001, which resulted from U.S. Patent Application No. 13/967,189 ("the '189 application"), which is a continuation of U.S. Patent Application No. 13/961,808 ("the '808 application"), filed August 7, 2013, which is a continuation of U.S. Patent Application No. 11/897,177 ("the '177 application"), filed August 28, 2007, now U.S. Patent No. 8,618,064, which is a continuation of U.S. Patent Application No. 10/927,857 ("the '857 application"), filed August 27, 2004. I also understand that the '556 patent claims priority to U.S. Provisional Patent Application No. 60/503,137, filed on September 15, 2003. The '556 patent names Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power as the inventors. The '556 patent issued on February 4, 2014, from the '189 application. I understand that, according to the United States Patent and

Trademark Office ("USPTO") records, the '556 patent is currently assigned to Allergan, Inc. ("the patentee"). The patentee is referred to herein as "Allergan."

4. I understand that the '556 patent is directed generally to the field of ophthalmic drug delivery and formulation, and more specifically to methods and compositions for treating an eye of a human or animal having dry eye disease (also referred to as keratoconjunctivitis sicca). APO1001, 1, Abstract; APO1002, 11, 6:25-27; APO1003, 4, 5:10-12. I also understand that the compositions of the '556 patent contain several components, including 0.05% cyclosporine¹ A ("CsA") and 1.25% castor oil. APO1001, 11, 15:65 to 16:10.

5. In preparing this Declaration, I have reviewed the '556 patent and each of the documents cited herein, in light of general knowledge in the art. In formulating my opinions, I have relied upon my experience, education, and knowledge in the relevant art. In formulating my opinions, I have also considered the viewpoint of a person of ordinary skill in the art ("POSA") (*i.e.*, a person of

¹ This declaration uses the term "cyclosporine." However, several prior art references that are quoted in this declaration use the term "cyclosporin." It was known in the art that both terms are used interchangeably and encompass the same class of compounds. *See* APO1003, 2, 1:11-13.

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