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. 8,629,111

Inter Partes Review Case No. Unassigned

DECLARATION OF ERNING XIA, PH.D

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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. 8,629,111 ("the '111 patent"), APO1001, which resulted from U.S. Patent Application No. 13/967,163 ("the '163 application"), which is a continuation of U.S. Patent Application No. 13/961,828 ("the '828 application"), filed August 7, 2013, now U.S. Patent No. 8,685,930, 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, and a continuation of U.S. Patent Application No. 10/927,857 ("the '857 application"), filed August 27, 2004. I also understand that the '111 patent claims priority to U.S. Provisional Patent Application No. 60/503,137, filed on September 15, 2003. The '111 patent names Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power as the inventors. The '111 patent issued on January 14, 2014, from the '163 application. I

understand that, according to the United States Patent and Trademark Office ("USPTO") records, the '111 patent is currently assigned to Allergan, Inc. ("the patentee"). The patentee is referred to herein as "Allergan."

4. I understand that the '111 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, and 4, 2:65-67; APO1002, 11, 6:25-27; APO1003, 4, 5:10-12. I also understand that the compositions of the '111 patent contain several components, including 0.05% cyclosporine[1] A ("CsA") and 1.25% castor oil. APO1001, 11, 15:14-20.

5. In preparing this Declaration, I have reviewed the '111 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.

ordinary skill in the field of drug delivery and formulation, defined further below in Section V) prior to September 15, 2003.

II. My Background and Qualifications

6. I am an expert in the field of topical ophthalmic drug formulation, and I have been an expert in this field since prior to 2003. I am presently employed by Fulcrum International Technologies, Inc. I obtained a Bachelor of Science degree in Pharmacy from Nanjing College of Pharmacy in 1982, a Master of Science degree in Biopharmaceuticals from China Pharmaceutical University in 1985, and a Ph.D. in Pharmaceutics from the University of Iowa in 1995.

7. I was an Assistant Professor and Research Associate for the College of Pharmacy at the China Pharmaceutical University from August 1985 to December 1987, a Research Associate at Illinois State University from January 1988 to December 1989, and a Research and Teaching Assistant for the University of Iowa College of Pharmacy from 1990 to 1995. After receiving my Ph.D. in Pharmaceutics, I held the positions of Senior Formulation Process Scientist and Principal Formulation Process Scientist with Bausch & Lomb in Rochester, NY from 1995-1999 and 1999-2001, respectively. I subsequently held the positions of Senior Principal Formulation Process Scientist from 2001-2004, Research Fellow from 2004-2005, and Site Leader/Research Fellow from 2006-2008 at Bausch & Lomb.

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