

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS, LLC

PETITIONER

V.

ALCON RESEARCH, LTD

PATENT OWNER

U.S. PATENT NO. 8,791,154

INTER PARTES REVIEW CASE NO. IPR2016-00544

DECLARATION OF ERNING XIA, PH.D

000001

ARGENTUM PHARM. 1002

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

I. Introduction

1. I have been retained as an expert witness on behalf of ARGENTUM PHARMACEUTICALS, LLC., ("ARGENTUM") for the above-captioned *inter partes* review (IPR). I am being compensated for my time by the hour in preparing this declaration, but my compensation is not tied to the outcome of this matter.

2. I understand that this Declaration accompanies a petition for IPR involving U.S. Patent No. 8,791,154 ("the '154 patent"), Ex. 1001, which resulted from U.S. Patent Application No. 13/475,607 ("the '607 application"), filed May 18, 2012. I also understand that the '154 patent claims priority to U.S. Provisional Patent Application No. 61/548,957, filed Oct 19, 2011 and U.S. Provisional Patent Application No. 61/487,789, filed May 19, 2011.

3. The '154 patent names Daniel A. Gamache, Laman Alani, Malay Ghosh, Francisco Javier Galán, Núria Carreras Perdiguier, and Onkar N. Singh as the inventors. The '154 patent issued on June 29, 2014 from the '607 application. I understand that, according to the United States Patent and Trademark Office ("USPTO") records, the '154 patent is currently assigned to Alcon Research, Ltd. ("Alcon".)

4. In preparing this Declaration, I have reviewed the '154 patent, the granted claims (1-27), the file history of the '154 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 ordinary skill in the art of ophthalmic drug formulations and treatment). Throughout this declaration, in rendering my opinion, I have considered what the viewpoint of a POSA would have been prior to May 19, 2011, the filing date of U.S. Provisional Patent Application No. 61/487,789, to which the challenged '154 patent claims priority. In the event that the priority claim to the '789 patent is deemed invalid, I have also considered what the viewpoint of a POSA would have been prior to October 11, 2011, the filing date of U.S. Provisional Patent Application No. 61/548,957, to which the challenged '154 patent also claims priority.

II. Background and Qualifications

5. I am an expert in the field of 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.

6. 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.

7. I have served as Program Director and Research Fellow at Valeant Pharmaceuticals in Rochester, NY from 2009-2013. I currently hold the position of Distinguished Research Fellow and Chief Technology Officer ("CTO") at Fulcrum International Technologies, Inc. ("Fulcrum") and have served in this position since September of 2013.

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