UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
ARGENTUM PHARMACEUTICALS, LLC Petitioner
${f v}.$
ALCON RESEARCH LIMITED Patent Owner
U.S. Patent No. 8,268,299
Inter Partes Review Case No. <u>Unassigned</u>

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 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.
- 3. I understand that this Declaration accompanies a petition for IPR involving U.S. Patent No. 8,268,299 ("the '299 patent"), Ex. 1001, which resulted from U.S. Application No. 11/858,781 ("the '781 application"), filed on September 20, 2007, and alleging an earliest priority date of September 21, 2006.
- 4. The '299 patent names Bhagwati P. Kabra, Masood A. Chowhan, L. Wayne Schneider and Wesley Wehsin Han as inventors. The '299 patent issued on September 18, 2012, from the '781 application. I further understand that, according to the United States Patent and Trademark Office ("USPTO") records, the '299 patent is currently assigned to Alcon Research Limited ("Alcon" or "the patentee").



5. In preparing this Declaration, I have reviewed the '299 patent and considered 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 field of ophthalmic drug formulations and antimicrobial preservation of such compositions, defined further below in Section IV. Throughout this declaration, in rendering my opinion, I have considered what the viewpoint of a POSA would have been prior to September 21, 2006, the filing date of U.S. Provisional Patent Application No. 60/826,529, to which the challenged '299 patent claims priority.

## II. My Background and Qualifications

- 6. I am an expert in the field of ophthalmic drug formulation and antimicrobial preservation of such formulations, and I have been an expert in this field since prior to 2006. 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.
  - 8. I have served as Program Director and Research Fellow at Valeant



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