UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARGENTUM PHARMACEUTICALS LLC
Petitioner
v.

ALCON RESEARCH, LTD
Patent Owner

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

Inter Partes Review No. 2016-00544

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DECLARATION OF LEONARD BIELORY, MD

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I, Leonard Bielory, MD., 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 Galan, Núria Carreras Perdiguer, 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), 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 Allergy and Immunology. I am currently a Professor at Rutgers University, Center for Environmental Prediction, and an affiliate Member, NIEHS Center for Environmental Health Sciences at the Environmental and Occupational Health Sciences Institute, Rutgers University and

Robert Wood Johnson Medical School, Piscataway, New Jersey, as well as Professor of Medicine, Thomas Jefferson University. I am also currently the Chair, Joint Council of Allergy and Immunology – Joint Task Force - Practice Parameters of Allergic Eye Disease – Diagnosis and Management. Additionally, I have private practice as an allergist at Springfield, New Jersey.

6.   I received a Bachelor's Degree in Fundamental Science from Lehigh University in 1976. I received a Doctor of Medicine (M.D.) degree from - University of Medicine and Dentistry of New Jersey (UMDNJ)-New Jersey Medical School (now Rutgers University –New Jersey Medical School), Newark, N.J. I completed postdoctoral training in Medicine at the University of Maryland Hospitals, Baltimore, Maryland, and in Allergy and Immunology and Hematology at the National Institutes of Health, National Heart, Lung and Blood Institute, Bethesda, Maryland. Subsequent to my education, I joined UMDNJ – NJ Medical School in 1985 as an Assistant Professor of Medicine and Pediatrics. I also worked as Associate Professor of Medicine, Pediatrics and Ophthalmology before being promoted to Professor of Medicine, Pediatrics, Ophthalmology and Visual Sciences. I was also appointed to the positions of Director of the Division of Allergy and Immunology, Department of Medicine, Co-Director Immuno-Ophthalmology Service, Department of Ophthalmology, and Director, Division of Allergy, Immunology & Rheumatology, Department of Medicine at UMDNJ – NJ

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