UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.,
Patent Owner

Case IPR2016-01131
Patent 8,648,048

DECLARATION OF THORSTEINN LOFTSSON, PH.D.

I, Thorsteinn Loftsson, Ph.D., declare as follows:

I. Experience and Qualifications

1. I graduated in 1972 with a degree in Pharmacy from the University of Iceland. I then received a M.Sc. in Pharmacy from the University of Copenhagen in 1975. Next, I attended the University of Kansas as a Fulbright Fellow, obtaining an M.S. in 1978 and a Ph.D. in 1979, both in Pharmaceutical Chemistry. My Ph.D. thesis related to drug delivery systems and methods.

2. Following my studies, I joined the faculty of the University of Iceland in 1979. I first served as an Assistant Professor (1979-1983), then as an Associate Professor (1983-1985), and I am now a Professor of Physical Pharmacy, which I have been since 1986. I have also been employed at the College of Pharmacy at the University of Florida as an Adjust Associate Professor (1980-1987) and as an Adjunct Professor (1987-2011).

3. Over the years, I have worked on many different ophthalmic and other drug formulations. For example, I have worked on the ophthalmic drug loteprednol etabonate, currently on the market, and two drugs now in phase II studies, dexamethasone and dorzolamide. I also have experience in changing delivery mechanisms, changing the membranes, changing the drug molecules, and changing drug concentrations. My experience includes working with the ocular penetration enhancer cyclodextrin and working with prodrugs to change drug

penetration. I have also worked with and published on research involving cyclodextrin-based aqueous cyclosporin A (CsA) eye drop formulations. I have studied the effects of various solubilizers on CsA solubility in aqueous eye drop media, the permeation of CsA through membranes, the chemical stability of CsA in aqueous solutions, and the interactions of CsA with various cyclodextrins. I note that each formulation poses unique challenges such as the drugs' physicochemical properties (i.e. solubility, chemical stability, physical stability, lipophilicity, molecular weight and molecular structure) and the type of eye drop formulation (i.e. aqueous *versus* non-aqueous, instant release *versus* sustained release, single phase [e.g., aqueous solution or oil solution] *versus* disperse phase [e.g., microsuspension, nanosuspension, emulsion or microsuspension]).

4. In addition, I have authored more than 200 publications, including journal articles, textbook chapters and case reports, many of which focus on formulation of ophthalmic formulations and ophthalmic drug delivery systems, as well as two textbooks one on drug stability and drug stabilization and the other one on drug pharmacokinetics.

5. I am a member of a number of professional organizations including the American Chemical Society (Division of Medicinal Chemistry), the American Association of Pharmaceutical Scientists for which I am a Fellow, the European

Federation of Pharmaceutical Science, the Icelandic Pharmacists Association, the Icelandic Biochemical Society and Societas Scientiarum Islandica.

6. I also serve or have served on the editorial boards for the Journal of Pharmaceutical Sciences, the Journal of Pharmacy and Pharmacology, the Journal of Drug Delivery Science and Technology, the International Journal of Pharmaceutics, the European Journal of Pharmaceutical Sciences, Drug Stability and Die Pharmazie. Currently I am the Review Editor of the International Journal of Pharmaceutics.

7. In addition, I have served on numerous advisory boards. For example, I currently serve or have previous served on boards for Pharmatec, Inc. (Scientific Advisory Board), Cyclops ehf., Oculis ehf. and Lipid Pharmaceuticals ehf.

8. Over the course of my career, I have received several honors and awards, including for example, a Fulbright Fellowship, two NATO Awards, a Faculty Research Award for the University of Iceland Faculty of Medicine, an International Scholarship from the Nagai Foundation Tokyo, a Fellow for the American Association of Pharmaceutical Scientists, a Thomson Reuters Highly Cited Researcher, a member of Thomson Reuters' list of the World's Most Influential Scientific Minds and the Asa Wright Prize. In 2016, I received the AAPS Research Achievement Award in Physical Pharmacy and Biopharmaceutics.

9. A more thorough summary of my education, employment, honors, fellowships, memberships, lectures and publications is provided in my CV, which is attached to this declaration as Exhibit A.

II. Scope of Work

10. I understand that the United States Patent Trial and Appeal Board ("PTAB") has instituted *inter partes* review of U.S. Patent Nos. 8,629,111, 8,633,162, 8,642,556, 8,648,048, 8,685,930 and 9,248,191 (collectively "the patents-in-suit"). (IPR2016-01128, -01130, -01129, -01131, -01127 and -01132, respectively). I have been engaged in the present matter by counsel to provide my independent analysis of the issues raised in the petitions for *inter partes* review of the patents-in-suit.

11. I am being compensated for my work at the rate of $400 per hour. My compensation does not in any way depend on the outcome the litigation or the *inter partes* reviews.

12. In writing this Declaration, I have reviewed the patents-in-suit assigned to Allergan, Inc. and the declaration submitted by Dr. Amiji in this proceeding.[1] I have also considered the following: my own knowledge and experience in the field of ophthalmic formulation, including my work experience

[1] I note the specifications of the patents-in-suit are seemingly identical.

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