UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.


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Patent No. 9,248,191


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**DECLARATION OF MANSOOR AMIJI, PH.D.**

# TABLE OF CONTENTS

I, Mansoor Amiji, declare as follows:

## I. QUALIFICATIONS

1. My name is Mansoor Amiji. I am currently the Bouvé College Distinguished Professor in the Department of Pharmaceutical Sciences in the School of Pharmacy at Northeastern University. I have been a member of the faculty at Northeastern since 1993. I am also an affiliate faculty member in the Departments of Chemical Engineering and Biomedical Engineering within the College of Engineering at Northeastern, as well as a Distinguished Adjunct Professor within the Faculty of Pharmacy at King Abdulaziz University.

2. I received a B.S. in Pharmacy from Northeastern University in 1988, and a Ph.D. in Pharmaceutics/Biomaterials Science from Purdue University in 1992. I have also conducted research as a Senior Research Scientist at the Columbia Research Laboratories in Madison, Wisconsin, as well as served as a Visiting Research Scholar in the Department of Chemical Engineering at MIT.

3. My current research focuses on the development of biocompatible materials from natural and synthetic polymers, target-specific drug and gene delivery systems for cancer and infectious diseases, and nanotechnology applications for medical diagnosis, imaging and therapy. I have extensive experience with pharmaceutical formulations, including oil-in-water emulsions containing various types of oils, including castor oil, as well as with sterile formulations and dosage forms for use in the eye. I have also taught courses on the development and

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characterization of ophthalmic formulations to undergraduate pharmacy and graduate students.

4.     I have had extensive experience in the development and characterization of lipid-based drug delivery systems, including oil-in-water emulsion formulations intended for parenteral and oral administration.  I have also worked on emulsion formulations that are targeted to different parts of the body, including the brain.

5.     My research has been funded by such organizations as the National Institute of Health (NIH) and the National Science Foundation (NSF), as well as other government agencies and foundations.  I also serve, or have served, on the editorial board of thirteen peer-reviewed journals such as *Drug Design: Development and Therapy*, *Expert Opinion on Drug Delivery*, *Pharmaceutical Formulations and Quality*, and *Tissue Barriers*.  I have also served as a reviewer for 39 peer-reviewed journals including *Science*, *Angewandte Chemie International Edition*, *European Journal of Pharmaceutical Sciences*, *Journal of Pharmaceutical Sciences*, and *Nature Communications*.

6.     I have authored or co-authored more than 200 peer-reviewed journal articles.  I have also authored 43 book chapters and been listed as an inventor on 16 patents and patent applications.  I have given over 170 invited seminars at scientific symposia and educational institutions.

7.     I have received numerous honors and awards, including my 2014 induction into the College of Fellows at the Controlled Release Society, appointment as an Honorary Member in the Phi Lambda Sigma Pharmacy Leadership Society, a

fellowship as well as the Meritorious Manuscript Award from the American Association of Pharmaceutical Sciences, and the Eurand Award for Outstanding Research in Oral Drug Delivery.

8.     A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately. Ex. 1003.

## II.     SCOPE OF WORK

9.     I understand that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 9,248,191 ("the '191 patent," Ex. 1001).  I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the '191 patent. I have reviewed the '191 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office. Ex. 1004.  I have also reviewed and considered various other documents in arriving at my opinions, and cite them in this declaration.  For convenience, documents cited in this declaration are listed in the Appendix in Section XII.

10.     I am compensated at the rate of $870/hour for my work.  I have no financial interest in the outcome of this matter.

## III.     OVERVIEW OF THE '191 PATENT

11.     The '191 patent issued February 11, 2014. The '191 patent is entitled "Methods of Providing Therapeutic Effects using Cyclosporin Components."  The first page of the patent states that an application for the '191 patent (U.S. Application

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