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Filed on behalf of Teva Pharmaceuticals USA, Inc. By: Mark D. Schuman

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
TEVA PHARMACEUTICALS USA, INC. Petitioner,
v.
ALLERGAN, INC., Patent Owner.
Patent No. 8,648,048

DECLARATION OF WALTER CHAMBLISS, PH.D.



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I, Walter G. Chambliss, declare as follows:

I. QUALIFICATIONS

- My name is Walter Chambliss. I received a B.S. in Pharmacy in
 1977, an M.S. in Pharmaceutics in 1980, and a Ph.D. in Pharmaceutics in 1982
 from the University of Mississippi.
- 2. I worked for seventeen years in research and development in the pharmaceutical industry at G.D. Searle, Bristol-Myers and Schering-Plough, where I was involved in formulation development and/or process development of over 300 products. I was Vice President of Research and Development for the HealthCare Products Division of Schering-Plough for five years.
- 3. For the past seventeen years, I have been a Professor of Pharmaceutics at the University of Mississippi, where I teach graduate courses in pharmaceutics. I am also a Research Professor in the Research Institute of Pharmaceutical Sciences where I am responsible for managing pharmaceutical development projects. In addition, I am the Director of Technology Management and oversee the technology transfer activities for the University.
- 4. I provide broad research and development consulting to the pharmaceutical industry, and have been an invited speaker in the areas of formulation and product development.



- 5. I have authored or co-authored over twenty publications in the field of pharmaceutical development, including a book chapter concerning delivery of pharmaceutical products to the eye, and I am a co-inventor of a U.S. patent.
- I am a member of numerous technical societies, including the 6. Academy of Pharmaceutical Research and Sciences of the American Pharmacists Association, and the American Association of Pharmaceutical Scientists. I am also a member of Rho Chi, a national professional honor society. I am a Past President of the Academy of Pharmaceutical Research and Sciences, and previously served as a member of the Board of Trustees of the American Pharmacists Association. I received the Distinguished Alumni Award from the University of Mississippi School of Pharmacy, and have served on several external scientific advisory boards of profit and non-profit organizations. I am also a Fellow of the Academy of Pharmaceutical Research and Science of the American Pharmacists Association and the American Association of Indian Pharmaceutical Scientists. I served on the International Steering Committee for the 2nd, 3rd and 4th Editions of the Handbook of Pharmaceutical Excipients and wrote monographs for excipients included in several editions.
- 7. I was responsible for the formulation development of numerous oilbased and water-based formulations at Bristol-Myers and Schering-Plough including formulations designed to be administered to the eye. A majority of these



formulations were oil-in-water emulsions for topical administration consisting of the active pharmaceutical ingredient(s) dispersed or dissolved in oil. I have significant experience in the use of polymers, including acrylate/C10-30 alkyl acrylate cross-polymer, and surfactants, including polysorbate 80, as inactive ingredients in oil-in-water emulsion formulations. In addition, I have significant experience in the selection of other inactive ingredients commonly used in oil-in-water emulsion formulations including tonicity agents, demulcents, pH adjusting agents, and buffers.

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. 1026.

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. 8,648,048 ("the '048 patent," Ex. 1001). I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the '162 patent. I have reviewed the '048 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office. Ex. 1004. I understand that the '048 patent is currently subject to another IPR, Mylan Pharmaceuticals Inc., v. Allergan, Inc., Case IPR2016-01130 (the "Mylan IPR"). I understand that Petitioner Teva seeks



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