

Paper No. \_\_\_\_\_  
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Filed on behalf of Teva Pharmaceuticals USA, Inc.  
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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TEVA PHARMACEUTICALS USA, INC.  
Petitioner,

v.

ALLERGAN, INC.,  
Patent Owner.

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Patent No. 8,629,111

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**DECLARATION OF WALTER G. CHAMBLISS, PH.D.**

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I, Walter G. Chambliss, declare as follows:

## **I. QUALIFICATIONS**

1. 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.

6. I am a member of numerous technical societies, including the 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 oil-based 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. 8,629,111 (“the ’111 patent,” Ex. 1001). I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the ’111 patent. I have reviewed the ’111 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office. Ex. 1004. I understand that the ’111 patent is currently subject to another IPR, *Mylan Pharmaceuticals Inc., v. Allergan, Inc.*, Case IPR2016-01127 (the “Mylan IPR”). I understand that Petitioner Teva seeks

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