UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.

Petitioner

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Patent Owner

Case No. IPR2015-00643

Patent No. 8,232,250

DECLARATION OF EDWARD J. FOX, M.D., PH.D. IN SUPPORT OF PATENT OWNER YEDA'S RESPONSE TO INSTITUTION OF INTER PARTES REVIEW

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I. INTRODUCTION

1. I, Edward J. Fox, M.D., Ph.D., have personal knowledge of the facts set forth in this Declaration and am competent to testify to the same.

2. I have been retained by counsel for Teva (Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc.) on behalf of Yeda Research and Development Co. Ltd. ("Patent Owner") in this proceeding regarding U.S. Patent No. 8,232,250 ("the '250 patent").

3. I hereby offer this Declaration in support of Patent Owner's Response to Institution of Inter Partes Review.

4. A list of materials that I have reviewed is attached hereto as Exhibit A.

II. QUALIFICATIONS AND EXPERIENCE

5. I have been involved in research and clinical treatment of patients suffering from multiple sclerosis ("MS") for more than 25 years. I specialize in the diagnosis and treatment of MS, and my research is directed toward various facets of MS, including the study of pharmaceutical agents, including glatiramer acetate, and their mechanism of action, as well as methods of managing MS as it progresses.

6. I was named Clinical Assistant Professor of Neurology at the University of Texas Medical Branch in 2004. I am currently the Director of the

MS Clinic of Central Texas. I also maintain a private neurology practice at Central Texas Neurology Consultants.

7. For the last 25 years, I have specialized in the diagnosis and treatment of multiple sclerosis, during which time I have treated thousands of patients with multiple sclerosis. In my private neurology practice at Central Texas Neurology Consultants, I currently have approximately 1,000 patients. I have been prescribing Copaonxe 20 mg to patients with multiple sclerosis since 1997. I have been prescribing Copaxone 40 mg to patients with multiple sclerosis since 2014.

8. I graduated from Washington University in St. Louis in 1981, after which I attended the M.D./Ph.D. Medical Scientist Training Program at Baylor College of Medicine. I received a Ph.D in Immunology in 1987 and an M.D. in 1988.

9. I finished my internship in Internal Medicine at Baylor in 1989, and I was a Resident in the Neurology Residency Program at Baylor from 1989 through 1992. In 1991, I was appointed to the position of Chief Resident.

10. Throughout my career, I have held multiple appointments to various committees and advisory boards that deal with neurology and MS, and I am currently a Fellow with the American Academy of Neurology as well as a member of the Executive Board of the American Academy of Neurology's MS Section. I am also on the Healthcare Advisory Committee for the Five Star Chapter of the

National Multiple Sclerosis Society (NMSS) and am on the Board of Directors of the Texas Neurological Society.

11. I have authored or co-authored over 250 articles and abstracts related to neurology, MS, and the treatment of MS with pharmaceutical agents such as glatiramer acetate.

12. In my capacity as Director of the MS Clinic of Central Texas, I serve as an Investigator in Phase I, II, III and IV studies. I have participated in more than one hundred clinical trials and extensions as principal investigator, including several major trials involving Copaxone including the following:

- Phase IIIb, ENCORE: Evaluation of Two Copaxone Formulations Plus Autojects in Relapsing-Remitting Multiple Sclerosis Patients ("ENCORE");
- Phase IV, A Multicenter, Open-Label, Two-Arm Prospective Study to Evaluate the Impact of Patient Readiness to Self-Inject on Outcomes When Using the Copaxone Prefilled Syringes ("READY");
- Phase III, A Multinational, Multicenter, Randomized, Parallel-Group, Double-Blind Study to Compare the Efficacy, Tolerability and Safety of Glatiramer Acetate Injection 40 mg/ml to That of Glatiramer Acetate Injection 20 mg/ml Administered Once Daily by Subcutaneous Injection in Subjects With Relapsing Remitting (R-R) Multiple Sclerosis (MS) ("FORTE");
- Phase IIIb, An Open-Label, Multicenter Randomized Study Evaluating the Tolerability and Safety of Two Formulations of Glatiramer Acetate (GA) for Subcutaneous Injection ("SONG"); and
- Phase IV, A Multi-Centered, Randomized, Double-Blind, Placebo Controlled Study Assessing the Add-on Effect of Oral Steroids in

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