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. IPR2015-00644

Patent No. 8,399,413

DECLARATION OF HENRY G. GRABOWSKI, PH.D., IN SUPPORT OF PATENT OWNER YEDA'S RESPONSE TO INSTITUTION OF INTER PARTES REVIEW

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Table of Contents

I. Qualifications 1

II. Assignment 2

III. Summary of Opinions 3

IV. Background on Copaxone® and Other Drugs for the Treatment of Relapsing-Forms of Multiple Sclerosis 5

V. Commercial Success of Copaxone® 40mg/mL 6

A. Indicators of Commercial Success 6

B. Copaxone® 40mg/mL's High Level of U.S. Sales and Continued Sales Growth Are Evidence of Its Commercial Success 7

C. Copaxone® 40mg/mL's High Level of U.S. Prescriptions and Continued Growth in Prescriptions are Evidence of Its Commercial Success 7

D. Copaxone® 40mg/mL's Performance Relative to Other Drugs for the Treatment of Relapsing-Forms of Multiple Sclerosis is Evidence of Its Commercial Success 8

E. Analyst Reports Discuss Copaxone® 40mg/mL's Commercial Success 9

VI. The Commercial Success of Copaxone® 40mg/mL is the Result of Its Patented Features 10

A. The Patented Features of Copaxone® 40mg/mL Were Marketed by Teva and Valued by Physicians and Patients 10

B. The Continued Success of Copaxone® 40mg/mL in the Face of Generic Glatopa™ Entry Demonstrates that Physicians, Patients, and Payers Obtain Benefits from the Patented Features of the Drug 14

C. The Patents Covering the Active Ingredient of Copaxone® Did Not Block Other Companies from Researching Other Formulations of Glatiramer Acetate 16

D. The Success of Copaxone® 40mg/mL is Not Attributable to the Marketing and Promotional Activities of Copaxone® 40mg/mL Apart from their Educational Function 18

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I. Qualifications

1. I, Henry G. Grabowski, Ph.D., have personal knowledge of the facts set forth in this Declaration and am competent to testify to the same.

2. I am currently Professor Emeritus of Economics and the Director of the Program in Pharmaceuticals and Health Economics at Duke University. I received my Bachelor of Science degree in Engineering Physics from Lehigh University in 1962. In 1967, I obtained a doctorate in economics from Princeton University. My academic and research specialties are in the pharmaceutical industry—health economics, economics of innovation, and government regulation.

3. I have studied the economics of the pharmaceutical industry over much of my career, and I have published numerous articles and books on this industry. I created a graduate course at Duke on economics and policy issues in the pharmaceutical industry. Under a series of grants from the National Science Foundation, I have examined the economics of pharmaceutical research and development ("R&D") and the effect of various government policy actions on drug innovation. I have testified several times before Congressional committees in the United States on pharmaceutical industry issues. For example, since 1994, I have testified on issues involving effective patent life and generic competition in pharmaceuticals, biosimilars, the Clinton Administration's health reform legislation, and the federal government's policy toward children's vaccines.

4. I have been an advisor and consultant to the National Academy of Sciences, Institute of Medicine, Federal Trade Commission, General Accounting Office, and Office of Technology Assessment. I have also held visiting scholar appointments at the International Institute of Management in Berlin, Germany, the Health Care Financing Administration in Washington, D.C., the Office of Health Economics in London, and the Centre for Medicines Research in London. Until its acquisition by Gilead Sciences in 2003, I served on the Board of Directors of Triangle Pharmaceuticals, Inc., a development-stage company that specialized in antiviral drug therapies.

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5. I have done extensive research on the economics of competition in the pharmaceutical industry, including the role of patents and the importance of R&D. I have also performed several studies on pharmaceutical R&D costs and profits. The Congressional Budget Office has used my work in this regard to analyze the effects of the Hatch-Waxman Act on R&D returns, and to analyze the proposed changes associated with the Clinton Health Reform Act of 1993.

6. I attach as Exhibit 2104 a copy of my curriculum vitae, which includes a more detailed description of my education and professional experience, as well as a list of my publications from the last forty years.

7. I have served as an expert witness in several prior cases. A list of all cases in which I have testified at trial or by deposition in the last four years is provided in Exhibit 2105.

II. Assignment

8. I have been asked by counsel for Teva to determine, as a matter of economics, whether Teva's drug Copaxone® 40mg/mL, a drug for the treatment of relapsing-forms of multiple sclerosis, is a commercial success. I have also been asked to analyze the determinants of Copaxone® 40mg/mL's commercial success, if any, and whether a nexus exists between the commercial success and the inventions claimed in U.S. Patent Nos. 8,232,250 (the "'250 patent"), 8,399,413 (the "'413 patent"), and 8,969,302 (the "'302 patent"). In that context, I have been asked to discuss the marketing of prescription drug products, both generally and for Copaxone® 40mg/mL in particular.

9. In connection with the opinions and conclusions contained within this report, I reviewed and considered the references cited throughout the report and the attached Exhibits. I have also reviewed the expert declaration of Dr. Fox and the deposition transcript of Dr. Green. Finally, I have relied on my training, my years of experience as an economist, my regular review and knowledge of the economics literature, and presentations at academic and industry conferences. A complete list of materials I relied upon for this report is provided in Exhibit 2106.

10. I am being compensated for my time and services at my regular hourly rate of $800. I will also be reimbursed for my expenses. I have been assisted in this matter by staff of Cornerstone Research, who worked under my direction. I receive compensation from Cornerstone Research based on its collected staff billings for its support of me in this matter.

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Neither my compensation in this matter nor my compensation from Cornerstone Research is in any way contingent or based on the content of my opinions or the outcome of this or any other matter.

11. My opinions are based on currently available information. I reserve the right to supplement my analyses and opinions if new information becomes available that is pertinent to this case.

III. Summary of Opinions

12. Based on my research and analysis summarized in this report, I conclude that Copaxone® 40mg/mL is a commercial success. In addition, I conclude that Copaxone® 40mg/mL is a success due to the patented features of the product, in particular its dosage regimen of three injections per week, and corresponding benefits. I further conclude that the commercial success of Copaxone® 40mg/mL is not attributable to excessive marketing or promotion of the drug or the presence of patents covering the active ingredient of Copaxone® (*i.e.*, glatiramer acetate).

13. Copaxone® 40mg/mL's commercial success is demonstrated by its levels of, and growth in, prescriptions, dollar sales, and extended unit sales. Since Copaxone® 40mg/mL launched in January 2014, the drug has generated over $[redacted] billion in wholesale sales and sales of over [redacted] million extended units. In addition, total prescriptions of Copaxone® 40mg/mL have exceeded [redacted] and new prescriptions have achieved nearly [redacted] since the launch of the drug.

14. The commercial success of Copaxone® 40mg/mL is further demonstrated by its performance relative to other drugs prescribed for the treatment of relapsing-forms of multiple sclerosis. Copaxone® 40mg/mL's share of wholesale sales and prescriptions among drugs prescribed for relapsing-forms of multiple sclerosis has steadily increased since it was first launched. Moreover, for the most recent quarter with available data, Copaxone® 40mg/mL had the highest number of total prescriptions, the second highest number of new prescriptions, and the second highest wholesale sales out of all drugs approved for the treatment of relapsing-forms of multiple sclerosis.

15. Copaxone® 40mg/mL's commercial success is attributable to its patented features, most notably its dosage regimen of three injections per week. Teva's promotional materials consistently highlight the Copaxone® 40mg/mL dosing regimen, and surveys of physicians and

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