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.

BIOGEN MA INC.,
Patent Owner.

Case IPR2018-01403
Patent 8,399,514 B2

DECLARATION OF GILMORE O'NEILL, M.D.

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I, Gilmore O'Neill, have personal knowledge of the facts stated herein and provide the following testimony:

I. Personal Background and Introduction

1. I am currently Executive Vice President, R&D and Chief Medical Officer at Sarepta Therapeutics, a position I have held since June of 2018. Prior to this position, I was employed at Biogen for nearly fifteen years, where I held several positions, including Associate Director, Medical Research from 2003 to 2005; Director, Medical Research from 2005 to 2007; Senior Director, Experimental Neurology from 2007 to 2010; Vice President, Experimental Neurology (Early Stage) from 2010 to 2012; Vice President, Global Late Stage Clinical Development from 2012 to 2013; Vice President, Global Neurology Clinical Development from 2013 to 2014; Vice President, Research and Development MS Franchise from 2014 to 2015; Senior Vice President, Drug Innovation Units from 2015 to 2016; and Senior Vice President, Late Stage Clinical Development from 2016 to 2018.

2. I received my medical degree from University College Dublin in 1988 and completed residencies and fellowship training in internal medicine, pulmonology and neuropathology in 1993 at Beaumont Hospital, Dublin. I completed my residency in Neurology at Massachusetts General Hospital in 1997 and was Chief Resident from 1996 to 1997. I also received a Master of Medical

Science degree from Harvard Medical School in 1999. I am a Neurologist at Massachusetts General Hospital and have held that position since 1997.

3. I understand that the U.S. Patent and Trademark Office has instituted an *Inter Partes* Review, IPR2018-01403, involving Biogen's U.S. Patent No. 8,399,514 ("the '514 patent"), of which I am a named co-inventor.

4. I also understand that Mylan has submitted the following exhibits in that proceeding:

- **Ex. 1007:** L. Kappos et al., *Efficacy of a Novel Oral Single-Agent Fumarate, BG0012, in Patients with Relapsing-Remitting Multiple Sclerosis: Results of a Phase 2 Study*, 253 (Supp. 2) J. Neurol. II27, O108 (2006)

- **Ex. 1046:** L. Kappos et al., *Efficacy of a Novel Oral Single-Agent Fumarate, BG0012, in Patients with Relapsing-Remitting Multiple Sclerosis: Results of a Phase II Study*, 253 (16th Meeting of the European Neurological Society, May 20, 2006)

- **Ex. 1016:** NewsRoom document, *Oral Compound BG-12 Achieves Primary Endpoint in Phase II Study of Relapsing-Remitting Multiple Sclerosis; Treatment with BG-12 Led to Statistically Significant Reductions in MRI Measures* (May 30, 2006)

5. I provide this declaration based on my personal knowledge and my role in the Phase II trial of BG-12 for the treatment of multiple sclerosis (MS).

II. Biogen's Phase II Clinical Trial of BG-12

6. Mylan's Exhibits 1007, 1046 and 1016 relate to Biogen's Phase II trial of BG-12 (dimethyl fumarate, now marketed as Tecfidera®) in patients with multiple

sclerosis (MS). As the Medical Director of Biogen's MS BG-12 program, the Phase II subject matter described in those exhibits represents solely my work and the work of those working under my direction and supervision. This is described more fully in the paragraphs below.

A. My Role as Medical Director of the MS BG-12 Team

7. I was Biogen's Medical Director for its MS BG-12 program: the person in charge of Biogen's Phase II trial. In that role, I was responsible for all aspects of the Phase II trial, including design, execution, and assessment and reporting of results.

8. For example, I presented the initial clinical trial concept, including four proposed dosing options, to Biogen's Clinical Trial Review Board (CTRB) in February of 2004. *See* Ex. 2088. One of my proposed dosing options—120 mg/day, 360 mg/day, 720 mg/day—was the option we ultimately selected to move forward with.

9. I also supervised and directed the numerous people, both within and outside Biogen, that were involved in carrying out the clinical trial. For example, I supervised Rebecca Conaghan, the Clinical Trial Manager of the Phase II study. Her role was to coordinate, under my direction and supervision, the administrative aspects of the trial, such as study initiation, monitoring, and data management. On August 16, 2004, Ms. Conaghan and I sent correspondence to members of the

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