UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2018-01403
Patent 8,399,514 B2

DECLARATION OF REBECCA CONAGHAN

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I, Rebecca Conaghan, have personal knowledge of the facts stated herein and provide the following testimony:

I. Personal Background and Introduction

1. I am a Regulatory Affairs Manager for Biogen Idec Ltd. in Maidenhead, United Kingdom. I have worked for Biogen for approximately 15 years as a permanent employee or a contractor in various clinical trial and regulatory roles. I attended school at the King's College of London, where I obtained my Msc in Human and Applied Physiology, and the University of St. Andrews, where I obtained by BSc Honors in Physiology.

2. 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").

3. 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)

4. 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. My Role in the Phase II Trial

5. I was Biogen's Clinical Trial Manager of its Phase II trial of BG-12 in patients with MS. I worked as part of the team to set up all aspects of the clinical trial, including chairing weekly meetings of the Study Management Team (SMT), which were attended by Biogen's Medical Director for the MS BG-12 program, Dr. Gilmore O'Neill, the lead statistician, Minhua Yang, and others. At the weekly SMT meetings, members would update Dr. O'Neill and members of the SMT on the status of the various activities involved in executing a clinical trial. I was also involved in numerous other activities, including setting up the labs and selecting and managing the external vendors including the contract research organization (CRO). In my role as Clinical Trial Manager, I worked closely with Dr. O'Neill, Minhua Yang, and others on the SMT. I also interacted with the individuals and groups outside Biogen, including Clinical Investigators, who came together to execute the Phase II clinical trial.

6. I was present from the very beginning of the BG-12 MS program, when Dr. O'Neill presented his clinical trial concept at a meeting of the Clinical Trial Review Board (CTRB). *See* Ex. 2088. As shown in the meeting minutes, Dr. O'Neill presented four dosing regimens, the first and second of which included the dose of 480 mg/day of DMF, which is the dose approved for Biogen's MS treatment Tecfidera®. *Id.* The decision was made to go forward with his third proposed dosing option—120 mg/day, 360 mg/day, and 720 mg/day. Once the protocol was finalized, we quickly got to work undertaking the numerous activities required for a Phase II trial, including setting up our initial Clinical Investigators meeting in Versailles, France. *See* Ex. 2089.

7. As with all clinical trials, there were of course many individuals involved in the clinical trial, both inside and outside Biogen. All of us who worked on the Phase II project, both inside and outside Biogen, did so under the direction and supervision of Dr. O'Neill and the members of Biogen's SMT who were acting at his direction. For example, each trial site had a designated Principal Investigator or Investigators who were responsible for overseeing the site, executing the approved study protocol, and receiving monitors who regularly visited the site to ensure the protocol was being adhered to. Dr. Ludwig Kappos was designated "Coordinating Investigator." A Scientific Advisory Committee was also formed to provide scientific and medical advice for the study and oversee its progress.

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