UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC;
HAYMAN CREDES MASTER FUND, L.P.;
HAYMAN ORANGE FUND SPC – PORTFOLIO A;
HAYMAN CAPITAL MASTER FUND, L.P.;
HAYMAN CAPITAL MANAGEMENT, L.P.;
HAYMAN OFFSHORE MANAGEMENT, INC.;
HAYMAN INVESTMENTS, LLC;
NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC;
J KYLE BASS; and ERICH SPANGENBERG,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01993
Patent 8,399,514 B2

SECOND 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 Senior Vice President, Drug Innovation Units at Biogen and have held this position since October 2015. In this position, I am responsible for leading multi-disciplinary groups accountable for research and development in Pain, Immunology, Hemophilia and Rare Diseases, and Gene and Cell therapeutics. Since joining Biogen in 2003 and prior to my current title, I have 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 2011; Vice President, Global Late Stage Clinical Development from 2011 to 2013; Vice President, Global Neurology Clinical Development from 2013 to 2014, and Vice President, Research and Development MS Franchise from 2014 to 2015.

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 during that time. I also received a

Master of Medical Science degree from Harvard Medical School in 1999. I am a Clinical Instructor in Neurology at Harvard Medical School and a Neurologist at Massachusetts General Hospital and have held those positions since 1997. I joined Biogen in 2003 as Associate Director, Medical Research and, through my work at the company over approximately the past 12 years, am now Senior Vice President, Drug Innovation Units. My CV is attached to this declaration as Appendix 1.

3. I understand that the U.S. Patent and Trademark Office has instituted a review of Biogen's U.S. Patent No. 8,399,514 ("the '514 patent," **Ex. 1001**).

4. I am a named co-inventor on the '514 patent based on my contribution to the claimed subject matter. I am aware that the original priority application, U.S. Provisional Application No. 60/888,921 ("the provisional application") was filed on February 8, 2007. I generally understand that the '514 patent is directed to my idea to treat multiple sclerosis (MS) with 480 mg/day of DMF, MMF, or a combination thereof. As detailed below, by no later than February 2004, I had the idea to treat MS with 480 mg/day of DMF, specifically in two equal doses of 240 mg/day. Because MS is a chronic disease, I also envisioned that a daily dose of 480 mg/day of DMF would be a long-term treatment.

5. As Medical Director from September 2003 to July 2006 of Biogen's MS drug-development program called "BG-12," I led a team at Biogen through approximately the first three years of drug development of Tecfidera®, Biogen's

drug product containing DMF as the sole active agent (also referred to as "a DMF-only" product) and one or more pharmaceutically acceptable excipients. *See* **Ex. 2373** at 5, Table 2. Tecfidera® is approved as an oral therapy using 480 mg per day of DMF to treat MS patients.

6. I previously provided a declaration in Biogen's Interference No. 106,023 involving the '514 patent to document my idea behind the '514 patent as well as to document the work that I and others at Biogen[1] were doing from 2003 to 2011 on the BG-12 program. I provide this declaration to document my idea behind the '514 patent. I also describe my work as Medical Director of the MS BG-12 team, specifically in February 2004 and from May 2006 to July 2006, which was the month I transitioned out of my immediate responsibilities in the program.

7. The BG-12 program was a high priority at Biogen. Biogen and its employees and contractors, including me, worked diligently to develop the MS treatment approved, marketed and patented as Tecfidera® through the immense, collective efforts of numerous individuals within the BG-12 program, spanning Clinical Development, Planning and Operations, Drug Safety and Risk

[1] As used herein, activities by "Biogen" refers to activities by me, other Biogen employees, and/or Biogen's contracted agents.

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