BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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.

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Case IPR2015-01993
Patent 8,399,514 B2

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**DECLARATION OF CARMEN BOZIC, M.D.**

Biogen and have held this position since April 2015. My department is responsible for developing and obtaining regulatory approval of therapies in Biogen's therapeutic focus areas of Neurology, Immunology and Hematology. I have held several positions within Biogen, including Senior Director, Medical Research from 2003 to 2005; Senior Director, Clinical Trial Drug Safety and Risk Management in 2005; Senior Director and Global Head, Drug Safety and Risk Management from 2005 to 2006; Vice President and Global Head, Drug Safety and Risk Management from 2006 to 2009; Senior Vice President and Global Head, Safety and Benefit-Risk Management from 2009 to 2013; and Senior Vice President, Clinical and Safety Sciences from 2013 to 2015. In addition to these positions, I was chairman of Biogen's Clinical Trial Review Board (CTRB) from at least 2003 to 2009.

2. I received a Doctor of Medicine at McGill University in Montreal, Canada, where I also did a residency in internal medicine. I completed a fellowship in Pulmonary and Critical Care Medicine at Brigham and Women's Hospital in Boston and was an Associate Physician at Beth Israel Deaconess Medical Center and Harvard Medical School before joining industry.

4. I oversaw the development of Biogen's multiple sclerosis (MS) treatment Tecfidera®, specifically as to the approval of clinical trial protocols and safety and risk management throughout Biogen's drug-development program called BG-12. Tecfidera® is 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. Tecfidera® is approved as an oral therapy using 480 mg per day of DMF to treat MS patients.

5. I provide this declaration to document Dr. O'Neill's idea to use 480 mg/day of DMF to treat MS. I also detail the work that I and others at Biogen[1] were doing between May 2006 and February 2007, when I understand Biogen's priority application for the '514 patent was originally filed.[2] The project leading to

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

[2] I previously provided a declaration in Biogen's Interference No. 106,023 involving the '514 patent to document the work that I and others at Biogen

requiring several years of nonclinical and clinical testing and the efforts of numerous groups within a company to plan, prepare for, carry out, and evaluate the tests and to thoroughly prepare required submissions and documentation to one or more regulatory agencies throughout the clinical development process.

6. Biogen's tremendous efforts throughout this process to develop, obtain approval for and bring to market Tecfidera® were diligently and simultaneously advanced by numerous groups within Biogen, such as Clinical development, Clinical Operations, Regulatory Affairs, Drug Safety and Risk Management, Biostatistics, Medical Writing, Data Management, and other important groups.

7. More specifically, Biogen[3] planned and conducted several non-clinical (animal) trials to provide critical, required support for the development and

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performed beginning in 2003 and continuing into 2011 and to document Dr. O'Neill's idea to use 480 mg/day of DMF to treat MS.

[3] Within the context of preparing for and carrying out nonclinical (animal) and clinical (human) trials, reference to "Biogen" throughout this declaration also

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