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

DECLARATION OF TAMMY SARNELLI

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I, Tammy Sarnelli, have personal knowledge of the facts stated herein and provide the following testimony:

I. Introduction and Personal Background

1. I am currently the Senior Director, Regulatory Affairs, at Biogen Idec, Inc. ("Biogen"), and have held that position since 2014. As Senior Director, Regulatory Affairs, I serve as the regulatory lead on new drug development programs (small molecule and biologic), and in this capacity provide oversight of independent review markets and global emerging markets for Tecfidera®, Biogen's newly-marketed multiple sclerosis product. I also serve as the regulatory representative on Biogen's Clinical Trial Review Board, which evaluates clinical trial protocols across all therapeutic areas. My daily activities at Biogen include providing regulatory input and strategic guidance for new products, coordinating interactions with regulatory authorities on new product development, working to enhance the capabilities of Biogen's Regulatory Affairs department, and supervising regulatory personnel (Associate Directors, Managers, and Senior Associates) within the department. I have been a Biogen employee for more than twenty-five years, the past fifteen of those as a member of Biogen's Regulatory Affairs department.

2. I understand that the U.S. Patent and Trademark Office has initiated a proceeding involving Biogen's U.S. Patent No. 8,399,514 (the "'514 patent").

3. I provide this declaration to document my work on the project that led to the regulatory approval of Tecfidera®, a multiple sclerosis ("MS") treatment involving the daily, oral administration of 480 mg of dimethyl fumarate ("DMF").[1] I also document work done by others at Biogen, and also those contracted to do work on Biogen's behalf, in developing Tecfidera®, from at least May 2006 up to and including February 2007.

A. Education and Work Experience

4. Attached hereto as **Appendix A** true and correct copy of my current resume is being filed herewith as **Appendix A**. *See* **Appendix A** (resume of Tammy Sarnelli, hereinafter the "Sarnelli Resume").

5. I am a graduate of Saint Anselm College, where I earned a Bachelor of Arts degree in biology in 1988. I later attended Suffolk University, where I was awarded a Master's Degree in Public Administration/Health Care in 1995. *See* **Sarnelli Resume** at 1.

6. From 1988 to 1989 I worked as a Research Technician at the Dana Farber Cancer Institute, where I was responsible for managing laboratory testing

[1] I previously provided a declaration in Biogen's Interference No. 106,023, which also involves the '514 patent.

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