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: IPR2016-01993
U.S. Patent No. 8,399,514

DECLARATION OF KATHERINE T. DAWSON, M.D.

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I, Katherine T. Dawson, have personal knowledge of the facts stated herein and provide the following testimony:

I. Personal Background and Introduction

1. I am currently the Vice President of U.S. Medical at Biogen. Since joining Biogen in 2004, I have held several positions, including Associate Director, Medical Research/Clinical Development (March 2004 - November 2006), Director, Clinical Development Neurology, November 2006 - November 2009), Senior Director of Neurology Clinical Development (November 2009 - January 2013), Vice President of Global Medical Neurology (January 2013 - March 2015) and Vice President, U.S. Medical from March 2015 until the present.

2. I received a B.A. in biology/psychology from Columbia College in 1987, and an M.D. from Albert Einstein College of Medicine of Yeshiva University in 1993. Thereafter, I was a Neurology Resident at Massachusetts General Hospital until 1997, then a fellow of Clinical Neurophysiology at Massachusetts General Hospital until 1998. I then became a Clinical Instructor of Neurology at Massachusetts General Hospital. I continued to hold this position even after joining Biogen and stayed in this position until March 2014.

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

4. Biogen's Tecfidera® is a multiple sclerosis ("MS") product, which is administered as an oral therapy of 480 mg per day of dimethyl fumarate ("DMF") and one or more pharmaceutically acceptable excipients to treat MS. In June 2006, I joined the Tecfidera® team and, in July 2006, officially took over as medical director of the project and oversaw the preparation and operation of Biogen's pivotal Phase III trials. A Phase III clinical trial is a study to demonstrate whether or not a product offers a treatment benefit to a specific population, in this case, humans suffering from MS. Phase III trials are usually tested on anywhere from 300 to 3,000 patients and last from one to four years. *See* www.fda.gov/forpatients/approvals/drugs/ucm405622.htm#Clinical Research Phase Studies. Phase III studies, like all clinical trials, are conducted under the guidance and guidelines set out by regulatory agencies such as the U.S. Food and Drug Administration ("FDA").

5. I provide this declaration to document the work that I and others at Biogen were doing prior to and after Biogen filed the patent applications leading to the '514 patent, from 2006 and continuing through 2011. Throughout this time period, the project leading to the development and approval of Tecfidera® was a high priority of Biogen. Biogen's Phase III trials were large and intensive undertakings requiring years of testing and the efforts of numerous groups across

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