UNITED STATES PATENT AND TRADEMARK OFFICE

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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.

Case IPR2015-01993
Patent 8,399,514 B2

DECLARATION OF RICHARD A. RUDICK, M.D.

I. Introduction

1. I, Richard A. Rudick, M.D., am a medical doctor with expertise in the field of multiple sclerosis (MS). I have over thirty-five years of experience in MS-related research, teaching, and clinical practice.

2. Since 2014, I have been Vice President of Development Sciences, Value-Based Medicine Group at Biogen. This group focuses on using new technology to develop innovative programs and tools to better understand, measure, and manage the treatment of MS.

3. I am serving as an expert consultant for this *inter partes* review proceeding. I am not being compensated for my time beyond my compensation as a Biogen employee. Neither my employment with Biogen nor my salary is contingent upon my opinions or the outcome of this or any other proceeding. I understand that the patent at issue is U.S. Patent No. 8,399,514 ("the '514 patent"; **Ex. 1001**), owned by Biogen.

II. Qualifications

A. Education

4. I earned my medical doctorate (M.D.) from Case Western Reserve University School of Medicine in Cleveland, Ohio in 1975. Before that, I earned a

bachelor of science (B.S.) in zoology from Ohio University in Athens, Ohio in 1971.

5. From 1975 to 1977, I served as Resident in Medicine at the University of Connecticut School of Medicine in Farmington, Connecticut. I was Resident in Neurology at Strong Memorial Hospital in Rochester, New York from 1977 to 1979, and then Chief Resident in Neurology from 1979 to 1980.

B. Research Experience Related to MS

6. My over thirty-five years of experience in research related to MS includes pivotal clinical trials involving MS treatments that are now approved by the U.S. Food and Drug Administration (FDA). I was the co-principal investigator on a National Institutes of Health (NIH)-supported, investigator-initiated clinical trial of intramuscular recombinant interferon beta (rIFNβ) for relapsing MS (1990-1994). This study was supported in part by Biogen, and led to registration of the rIFNβ product and marketing under the trade name Avonex®. Over the subsequent years, I conducted numerous studies on Avonex®, with support from Biogen, the NIH, and the National MS Society. I was Chairman of the Advisory Committee for the Biogen-sponsored clinical trial of natalizumab in combination with Avonex® (the SENTINEL trial, 2002 to 2005). The SENTINEL trial was one of two pivotal trials of natalizumab that resulted in registration of natalizumab and marketing

under the name Tysabri®. I have conducted many clinical research studies of natalizumab. I have also participated in many other clinical trials, and in clinical research protocols in the general field of MS, translational research, outcome measures, magnetic resonance imaging (MRI), clinical trials, and biomarkers.

7. I have been awarded dozens of research grants and fellowships totaling over $170 million, including for "Evaluating Selected Monitoring Techniques in MS Clinical Trials" from the National MS Society ($118,852 from 1989 to 1990), "IM Recombinant Beta Interferon as Treatment for MS" from the NIH ($4,200,000 from 1990 to 1994), "Monitoring Brain Atrophy During the Course of MS" from the NIH ($1,303,967 from 1999 to 2004), and "Biomarkers of the Therapeutic Response to Interferon in MS" from the NIH ($1,106,015 from 2004 to 2009). I have also received research grants and fellowships from pharmaceutical companies, including two from Biogen ($70,000 from 1993 to 1995 and $624,900 from 1994 to 2001). I was co-principal investigator on two cycles of a grant to Case Western Reserve University School of Medicine, the Cleveland Clinical and Translational Research Collaborative (CTRC) ($64,000,000 from 2007-2012; and $64,600,000 from 2012-2017). The purpose of this grant was to establish educational programs for clinical and translational research, and infrastructure to accelerate clinical research progress across the medical institutions

in Cleveland, Ohio. This grant covered research in neurology as well as many other fields. I transitioned to Biogen in 2014, prior to completion of the second cycle of this grant.

8. I was Director of the Mellen Center for MS Treatment and Research at the Cleveland Clinic from 1987 to 2014. During this time, I also served as Chairman of the Division of Clinical Research at the Cleveland Clinic (2001-2007), Vice-Chairman of Research and Development at the Neurological Institute at the Cleveland Clinic (2007-2014), and Co-Director of the Cleveland CTSC (2004-2014).

C. Teaching Experience Related to MS

9. My over thirty-five years of experience teaching others about MS includes teaching at the Rochester University School of Medicine as Instructor in Neurology (1979-1980), Assistant Professor of Neurology (1980-1986), Associate Professor of Neurology (1986-1987), and Adjunct Associate Professor of Neurology (1987-1995).

10. From 1995 to 2014, I was Hazel Prior Hostetler Professor of Neurology at the Cleveland Clinic. I was also Professor in the Department of Medicine, Primary Appointment, in the Cleveland Clinic Lerner College of Medicine (CCLCM) from 2003 to 2014, and Professor in the Department of

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