UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., Petitioner

v.

BIOGEN MA INC., Patent Owner

Case IPR2018-01403 Patent 8,399,514 B2

DECLARATION OF RONALD A. THISTED, PH.D.

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	A.		esults reported in Kappos 2006 and
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	D. Biogo A. B.	 information to perform Dr. Benet's subtraction and division calculations accurately C. A person of ordinary skill would not have conducted the analysis in Fox 2011 before February 2007 D. The post hoc sensitivity analyses in EMA 2013 demonstrated the robustness of Biogen's Phase II results Biogen's Phase III trials demonstrated unexpected results A. The DEFINE and CONFIRM Phase III studies had the unexpected result that the effectiveness of 480 mg/day was similar to that of 720 mg/day. B. The 480 mg/day and 720 mg/day dosing arms may properly be compared, as confirmed by multiple regulatory agencies

I, Ronald A. Thisted, Ph.D., hereby declare the following:

I. Introduction and Qualifications

 I have been retained by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP as an expert consultant for this *inter partes* review proceeding. I understand that the patent at issue is U.S. Patent No. 8,399,514 ("the '514 patent";
 Ex. 1001) and that it is owned by Biogen MA Inc. I am being compensated for my time at my standard hourly rate. My compensation is not contingent upon my opinions or the outcome of this or any other proceeding.

2. I am Professor Emeritus in the Departments of Statistics and Public Health Sciences at the University of Chicago. At the time of my retirement in 2018, I also held faculty appointments in the Department of Anesthesia & Critical Care and the Committee on Clinical Pharmacology and Pharmacogenomics. As a Professor in this Committee, I participated as faculty in the clinical pharmacology course for fourth-year medical students, lectured on pharmacoepidemiology, and mentored and advised advanced medical residents' research as part of their advanced training fellowships in clinical pharmacology.

3. I received a bachelor's degree (B.A.) in mathematics and philosophy in 1972 from Pomona College in Claremont, California. In 1973 and 1977,

respectively, I completed a master's degree (M.S.) and a doctorate of philosophy (Ph.D.) in statistics at Stanford University in Palo Alto, California.

4. I have more than forty years of research, academic, and practical experience in the area of biostatistics. My research has focused on biostatistics and epidemiology, statistical computation, and the effectiveness of medical intervention from a statistical perspective.

5. I have held positions on the faculty of the University of Chicago since 1976. I was Co-Director of the Clinical Research Training Program (1999–2012), Chairman of the Department of Health Studies [now Public Health Sciences] (1999–2012), Director of Population Sciences for the Institute for Translational Medicine (2007–2014), and Scientific Director for the Biostatistics Core Facility at the University of Chicago Cancer Research Center (1999–2014). From 2014 until my retirement, I was Vice Provost for Academic Affairs at the University.

 I have taught courses on statistics and biostatistics for over forty years. I have also taught courses on statistical methods, computation,
 epidemiology, and clinical research methods. I have been awarded the Llewellyn
 John and Harriet Manchester Quantrell Award for Excellence in Undergraduate
 Teaching.

7. I am an Elected Fellow of the American Association for the Advancement of Science (1992) and of the American Statistical Association

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