

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SAWAI USA, INC. AND  
SAWAI PHARMACEUTICAL CO., LTD.

Petitioners,

v.

BIOGEN MA, INC.

Patent Owner.

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Patent No. 8,399,514

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Inter Partes Review IPR2019-00789

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**DECLARATION OF RONALD G. MARKS, Ph.D.  
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF  
U.S. PATENT NO. 8,399,514**

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I, Ronald G. Marks, Ph.D., do hereby declare:

## **I. INTRODUCTION**

1. I am making this declaration at the request of Petitioners Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. (“Petitioners” or “Sawai”), in the matter of the *Inter Partes* Review (“IPR”) of U.S. Patent No. 8,399,514 (the “’514 patent”), as set forth in the above caption.

## **II. EDUCATION AND PROFESSIONAL BACKGROUND**

2. I received a B. Ed. In mathematics from Millersville State College in 1970. I received a M.S. and Ph.D. in statistics from the University of Florida in 1972 and 1974, respectively. I authored a Ph.D. thesis titled *An Analysis of Data with Multiple Outliers*. My *curriculum vitae* is attached as Exhibit A.

3. After completing my Ph.D., I took a position as a Visiting Professor and then Assistant Professor in the Department of Statistics at University of Florida. I held that position until 1980, when I was promoted to Associate Professor, a title I held until 1990, when I was promoted to Professor. In 1975, I was appointed Director of the Division of Biostatistics and I held that position until 1985 and then again from 1995-2000. In 2009, I took a position as Chief Scientific Officer and Director of Biostatics at Clinipace. In 2018, I transitioned to Contract Chief Scientific Officer, a position I hold to this day. In addition, I have held joint appointments in other colleges including Department of Pharmacy Practice (1976-

2004), Department of Occupational Therapy (1980-2004), and College of Nursing (1981-2004).

4. During my academic career, I served on the Editorial Board of Occupational Therapy in Mental Health and as a journal referee for Journal of Dental Research, Occupational Therapy in Mental Health, Statistics in Medicine, Archives of Ophthalmology, Medical and Pediatric Oncology, Journal of Public Health Dentistry, and Journal of Myocardial Ischemia. I also served as a grant reviewer for numerous NIH groups during my academic career.

5. As a biostatistician, I have more than forty years of experience in clinical trial design, statistical analysis, and the reporting of results from these studies from Phase 1 through Phase 4 clinical trials. In particular, I have been involved in the clinical trials, randomization, and proper protocols and practices for clinical studies. I have published dozens of papers analyzing clinical trial data. I have also presented widely at conferences, symposia, and seminars on clinical trials. For example, I was the Keynote Speaker and Conference Chair at the e-Clinical Trials 2003, Vision in Business conference in Las Vegas, Nevada in 2003. I am a named author on 137 peer-reviewed articles and 6 books, including *Analyzing Research Data: The Basics of Biomedical Research Methodology*. I have received grants from a number of organizations including the NIDR and NHBI.

6. I taught biostatistics courses for 25 years on the design and analytical methods required for research. I taught graduate students in MS, PhD, and MD programs who were required to conduct their own research to receive their graduate degree. In 2003, I received the Exemplary Teacher Award from the College of Medicine.

7. I am being compensated at an hourly rate of \$350/hour and am available to appear live for testimony in support of my opinions. My compensation in no way depends on the outcome of this proceeding. The opinions to which I will testify are based on the education, experience, training, and skill that I have accumulated in the course of my career as a biostatistician and researcher, as well as materials I have reviewed in connection with this case.

### **III. MATERIALS CONSIDERED**

8. The list of materials I considered in forming the opinions set forth in this declaration is set forth in Exhibit B.

### **IV. LEGAL STANDARDS**

9. I understand that this IPR involves U.S. Patent No. 8,399,514 (the “’514 patent”), which claims treating multiple sclerosis (“MS”) with about 480 mg dimethyl fumarate (“DMF”) per day. Ex. 1001. I understand that a previous IPR proceeding, brought by the Coalition for Affordable Drugs, was instituted against the same ’514 patent (“the CFAD IPR”). *See* IPR2015-01993. I have reviewed

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