For the Patent Owner
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Neifeld IP Law, PC

Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Coalition For Affordable Drugs V LLC
Petitioner
v.

Biogen MA Inc.
Patent Owner

Case IPR2015-01136
Patent 8,399,514
Title: TREATMENT FOR MULTIPLE SCLEROSIS

DECLARATION OF STEVEN E. LINBERG Ph. D.

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Coalition Exhibit 1005A
Coalition v. Biogen
IPR2015-01136

DECLARATION OF STEVEN E. LINBERG PH.D.

I, Steven E. Linberg Ph.D., hereby declare, affirm and state the following:

I. Introduction

1. I have been retained by Neifeld IP Law, PC for this inter partes review proceeding. I understand that this Declaration is being submitted along with a Petition for inter partes review of US Patent No. 8,399,514 ("the '514 patent"). I opine only with respect to certain issues that are discussed in this declaration.

II. RESOURCES CONSULTED

2. I have reviewed the '514 patent (**Exhibit 1001A**) including claims 1-20. I have also reviewed the *Kappos 2005* reference (**Exhibit 1003A**), the *ICH Guideline E4* (**Exhibit 1004A**), the *Werdenberg* reference (**Exhibit 1016A**), the *ClinicalTrials NCT00168701* reference (**Exhibit 1022A**), the *Talalay* reference (**Exhibit 1026A**), and the *Begleiter* reference (**Exhibit 1027A**). I have reviewed other documentation supporting and relevant to this declaration as cited below.

III. BACKGROUND, QUALFICATIONS AND COMPENSATION

3. I received a Ph.D. in Physiology from Pennsylvania State University in 1978. I worked for over 35 years in academic clinical research and commercial drug and biologics development, with particular attention to the overall strategy of drug development programs, to individual clinical trial design, execution, and reporting, and to regulatory interactions with the FDA. Over the course of that time I participated in the design, conduct, reporting or oversight of more than 100

clinical trials. I have held senior positions in companies which were developing drugs, developing biologics, and at contract research organizations. I am the principal editor of, and a contributing author in the text *Expediting Drug and Biologics Development*, now in its 3rd edition. I developed and taught graduate-level courses in Drug and Biologics Development, Clinical Trial Design, and Clinical Trial Operations for the Johns Hopkins University; and An Overview of Clinical Research, for the University of Maryland.

4. From 1978 to 1984, I was a Clinical Physiology Research Associate for the Shock Trauma – Maryland Institute for Emergency Medical Services Systems at the University of Maryland. From 1980 to 1984 I was an Assistant Professor of Pathology, Graduate Faculty at the University of Maryland School of Medicine. From 1985 to 1986 I was a Project Leader and Clinical Research Scientist in the Medical Division of Burroughs Wellcome Co. and from 1986 to 1992 I was an Associate Director of Clinical Research at Boehringer Mannheim Pharmaceuticals. In 1992 I was the Director of Clinical Research at Univax Biologics, Inc.. From 1992 to 1995 I was a consultant at, and owner of, Linberg Research, Inc.. From 1995 to 1996 I was the Vice President of Clinical Development at Collaborative Clinical Research, Inc.. From 1996 to 2001 I was the Vice President of Clinical Development at Cato Research Limited, and from 2001 to 2002 I was promoted to Managing Director and Senior Vice President of Drug Development at the same

company. From 2002 to 2009 I was the Managing Director of Chiesi Pharmaceuticals, Inc. and from 2009 to 2010 I was also Vice President and Treasurer at the same company. From 2011 to 2012 I was the founding President and CEO of Airway Therapeutics, LLC and continue as a Member of Airway Therapeutics, LLC. From 2013 to present I have been a consultant to the pharmaceutical industry, and formed S.E. Linberg Consulting, LLC in 2015 to further that effort.

5. I have published numerous academic papers and have served in various advisory, board and leadership positions for research centers, universities and a charitable foundation. My CV is submitted in this proceeding as **Exhibit 1017A**.

6. I am being compensated for my time at my standard hourly rate for this proceeding. My compensation is in no way contingent upon my performance or the outcome of this case.

IV. LEVEL OF ORDINARY SKILL IN THE ART

7. I have been informed by counsel to regard a person of ordinary skill in the art as being a hypothetical person who is presumed to know all of the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational

level of active workers in the field. I have been informed by counsel that it is from the viewpoint of a person of ordinary skill in the art that legal issues, such as claim construction and obviousness, are determined.

8. In my opinion and based on my reading of the '514 patent, the field of the '514 patent is: treating a disease with an orally administered drug.

9. A person of ordinary skill in the art at the time of the alleged invention of the '514 patent ("POSITA") would most likely have held an advanced degree, such as a Ph.D. in one of the life sciences, an M.D., a D.O., or a Pharm.D. Additionally, POSITA would have had some experience with clinical trials.

10. The '514 patent was filed on February 13, 2012. For the purposes of this Declaration, I have been asked to assume that the challenged claims may be entitled to the priority date of U.S. provisional application 60/888,921, filed Feb. 8, 2007. I have been advised by counsel that because no inventor of the provisional application was named, the '514 patent may not be entitled to the benefit of that 2007 date. At this time I have not investigated or formed any opinions about the contents of provisional application 60/888,921.

11. My opinion regarding the level of ordinary skill in the art for the '514 patent is based on my review of the patent and relevant file history, as well as my knowledge of the level of skill of individuals in this field. In forming my opinions, I have also considered the nature of problems that the '514 patent was intended to

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