

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 IPR2015-01993
Patent 8,399,514 B2

DECLARATION OF RONALD A. THISTED, PH.D.

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

I. Introduction and Qualifications

1. 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 a Professor and Vice Provost, Academic Affairs, at the University of Chicago. I hold faculty appointments in the departments of Statistics, Public Health Sciences, and Anesthesia & Critical Care. I am also a Professor in the Committee on Clinical Pharmacology and Pharmacogenomics.

3. I received bachelor’s degrees (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 Stanford, California.

4. I have more than forty years of research, academic, and practical experience in the area of biostatistics. My research focuses 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 (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).

6. I have taught courses on biostatistics for over thirty-five years. I have also taught courses on statistical methods, 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 (1988). I have also been a member of several professional societies related to statistics and computation, including the Association for Computing Machinery, the International Biometric Society, the Institute of Mathematical Statistics, the Royal Statistical Society, and the Society for Industrial and Applied Mathematics.

8. I have authored over one hundred publications in the area of biostatistics and epidemiology, many in peer-reviewed journals including the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and *The Lancet*. I also served as the Associate Editor of the *Journal of the American Statistical Association* (1979–1985, 1987–1988) and *ACM Transactions on Mathematical Software* (1990–1992).

9. I have served as Database Editor (1994), Managing Editor (1995), and Editor (1996–1998) for *Current Index to Statistics*. I sat on the editorial board of *SIAM Journal of Scientific and Statistical Computing* from 1983 to 1985. I have served as a referee for several journals related to biostatistics, including *Annals of Statistics*, *PLoS One*, and *Statistics in Medicine*. As a journal referee, I reviewed submitted articles for scientific quality. I have also acted as a referee for the National Institutes of Health (NIH) and the National Science Foundation (NSF). As a referee for NIH and NSF, I reviewed grant proposals for potential funding.

10. Since the late 1970s, I have consulted for the pharmaceutical and medical device industries on the design of clinical trials and statistical analysis of clinical trial results. I have consulted regarding the design of Phase I, Phase II, and Phase III clinical trials; designed data collection methods; planned and overseen

statistical analysis of results; prepared reports for use by the FDA; and presented statistical aspects of clinical studies to the FDA.

11. As part of my consulting practice, I have served as the principal biostatistician for studies involving MS patients. In particular, I was the principal biostatistician on two randomized clinical trials for treating specific symptoms in MS patients. *See Panitch et al., Annals of Neurology 59:780-87 (2006) (Ex. 2027); Pioro et al., Annals of Neurology 68(5):693-702 (2010) (Ex. 2028).*

12. A copy of my current curriculum vitae is provided as **Exhibit 2039**.

II. Documents Considered

13. My opinions are based on my knowledge and experience. In forming my opinions, I have also considered the documents listed in **Appendix A**.

III. Legal Standards

14. I am not an attorney and do not purport to offer legal opinions.

15. I understand that a claim is unpatentable if it would have been obvious to a person of ordinary skill in the art at the time of the invention. I understand that an obviousness analysis involves considering the following factors: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective indicia of

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