UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Lassen Therapeutics 1, Inc.

Petitioner

v.

Singapore Health Services PTE LTD., and

National University of Singapore

Patent Owner

CASE: Unassigned

Patent No. 10,106,603

DECLARATION STEPHEN LEDBETTER, PH.D.

IN SUPPORT OF

PETITION FOR POST GRANT REVIEW

I, Steven Ledbetter, declare as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I, Steven Ledbetter, Ph.D., have been retained by Drinker Biddle & Reath, LLP ("Counsel") on behalf of Lassen Therapeutics 1, Inc. ("Lassen") as an independent expert in the field of fibrosis.

2. I am currently a consultant at BioRepair Consulting, LLC, which I founded in 2015. As a consultant, I provide my scientific expertise to the biotechnology industry.

3. I obtained my Bachelor of Science degree in Biology from the Alma College, Alma, Michigan in 1974. I obtained my Doctoral degree in Cell Biology and Anatomy from the University of Michigan, Department of Anatomy and Cellular Biology, in 1980 with my dissertation on "Deposition of Extracellular Matrix by Cultured Corneal Endothelial Cells." I performed post-doctoral training in ophthalmology research at the Medical College of Wisconsin and in the Laboratory of Developmental Biology and Anomalies at the National Institutes of Health ("NIH") in Bethesda Maryland. At the NIH, my research focused on the identification, functional characterization and cloning of the basement membrane heparan sulfate proteoglycan (Perlecan).

4. From 1984 to 1996, I was a Research Scientist and then Senior Research Scientist at the Upjohn Company, Kalamazoo, Michigan. I continued my

research on basement membrane structure and function at Upjohn where I also established a laboratory focused on diabetic nephropathy. During my 12 years at Upjohn, my research efforts expanded to include studies in epithelial and hair follicle regeneration, and the role of matrix metalloproteinases as regulators of tumor angiogenesis.

5. In 1996, I joined Genzyme Corporation as a Principal Scientist and in 2000, I became the Director of Genzyme's Cell Biology department and a Project leader for its TGFβ (transforming growth factor β) antagonist program. My responsibilities in those roles included establishing a research laboratory focused on the role of TGFβ in chronic tissue injury and fibrosis. In collaboration with Cambridge Antibody Technology (Cambridge, UK), I and my team identified and characterized a novel, pan-neutralizing, human antibody against TGFβ. This antibody was studied in three phase 1 clinical trials for idiopathic pulmonary fibrosis, metastatic melanoma and focal segmental glomerulosclerosis (FSGS). Additional investigator studies with this antibody were also conducted in scleroderma, pulmonary radiation fibrosis, osteogenesis imperfecta, and metastatic breast cancer. A phase 2 study in FSGS was completed in 2015.

6. At Genzyme, I held various positions of increasing responsibilities. I was Renal Portfolio Director and Senior Director of Cell Biology in 2002, became Vice-President for the Renal and Fibrotic Diseases Research in 2003, and then

Group Vice-President responsible for renal, cardiovascular and bone and joint diseases in 2008. The acquisition of Genzyme by Sanofi in 2010 expanded my responsibilities to further include allied research efforts based in Paris and the newly created Tissue Injury and Fibrosis portfolio, containing 135 research personnel, and was closely aligned with a dedicated clinical development team. I retired from Genzyme in April 2015.

7. In 2016, I co-founded Omdana Therapeutics and served as Chief Development Officer until April 2017.

8. I have been involved in active fibrosis research beginning in 1978 as part of my doctoral dissertation and continuing to the present time via my consulting activities. My experience, as indicated in my attached curriculum vitae, includes the isolation, characterization of connective tissue proteins in the setting of normal tissue homeostasis and in pathologic fibrosis. Beginning in 1984, my activities were focused entirely on the functional and physiologic impact of maladaptive tissue remodeling (fibrosis) and exploration of potential therapeutic approaches for the treatment of fibrotic diseases with principal focus in heart, lung, kidney, liver, skin and bone diseases.

9. I have published or co-authored more than 80 journal publications, conference proceedings, technical reports, and technical presentations, and have been named as an inventor on numerous U.S. patents and patent applications. A

complete list of my publications is also contained in my curriculum vitae attached as **Appendix A**.

10. I have actively participated as a speaker at multiple national and international meetings. Recent examples include co-organizer of the 2014 Keystone Symposium on Fibrosis, 2014 International Society of Nephrology meeting on novel renal therapeutics (co-organizer and speaker) and scientific advisor to the EU program on systemic kidney diseases (SysKid).

11. My professional qualifications are described in further detail in my curriculum vitae, which is attached as **Appendix A.**

12. I am being compensated at my usual rate of $300 per hour for work on this case. My compensation does not depend in any way on my opinions, my performance, or the outcome of the case. I have no current or past financial ties with Drinker, Biddle, and Reath LLP outside of my engagement in this proceeding.

13. I am currently a paid consultant to Lassen separately from providing this Declaration. I own no Lassen stocks.

14. I have not testified in a U.S. court or in any U.S. administrative proceeding in the past ten years.

15. I have reviewed United States Patent No. 10,106,603 ("the '603 patent") to Cook *et al* and its file history.

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