

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.

Petitioners,

v.

HORIZON THERAPEUTICS, LLC.

Patent Owner.

DECLARATION OF KEITH VAUX, M.D.

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I, Keith Vaux, M.D., declare and state as follows:

I. QUALIFICATIONS

1. I am a medical doctor with specialty training in Pediatrics and Clinical Genetics. I am currently the co-founder of Point Loma Pediatrics, where I maintain a pediatrics practice.

2. From 2009 through 2017, I was an Associate Professor and then Professor in the Division of Medical Genetics in the Department of Medicine at UC San Diego. From 2014 through 2017, I was the Clinical Chief and Director of the Division of Genetics in the Department of Medicine at UC San Diego. I also had an appointment as Professor of Neurosciences at UC San Diego from 2015 through 2017. Since 1994, I have regularly diagnosed and treated patients with urea cycle disorders (“UCD”), and continue to do so today. In treating UCD patients, I regularly prescribe nitrogen scavenging drugs and treat patients who are maintained on therapy with nitrogen scavenging drugs.

3. I received a B.A. in History, Philosophy and Social Studies of Science and Medicine from the University of Chicago in 1987, and an M.D. from the University of Chicago in 1994. I have an unrestricted license to practice medicine in the State of California.

4. After medical school, I completed a three year residency in pediatrics, including a year as Chief Resident, from 1994-1997. The recognition, immediate

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and long-term management, and consideration of the long-term prognosis, of Urea Cycle Defects is a core competency for training and board certification in Pediatrics. Following two years of isolated clinical pediatric practice and critical care transport in Guam and two years as a practicing pediatrician and faculty member at the Naval Medical Center, I completed a three-year fellowship in dysmorphology and medical genetics with an additional certificate in teratology (environmentally induced birth defects) at UC San Diego from 2001 to 2004. I am Board Certified by the American Board of Pediatrics (received in 1997 and recertified in 2007 and 2015), am a Fellow of the American Academy of Pediatrics and serve on the AAP National Council on Children with Disabilities and Society on Genetics and Birth Defects. I am a member of the California Department of Public Health, Genetic Diseases Screening Program Biobank Committee which address policy issues surrounding metabolic screening in newborns.

5. As a professor, I taught Medical Students, Medical and Pediatric Residents and Specialty Fellows in Genetics, Complex Care Pediatrics and Metabolic Diseases. I have published in peer-reviewed journals on metabolic disorders. I regularly speak at national and international conferences on a variety of genetic, metabolic and genomic medicine topics.

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