

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, INC.

Patent Owner.

IPR2016-00829

DECLARATION OF KEITH VAUX, M.D.

LUPIN EX. 1002

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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 Professor and Clinical Chief of the Division of Medical Genetics in the Department of Medicine at UC San Diego. I also have an appointment as Professor of Neurosciences at UC San Diego, and I am a physician at Point Loma Pediatrics. 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.

2. 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.

3. After medical school, I completed a three year residency in pediatrics including a year as Chief Resident from 1994-1997, and 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.

4. I teach 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.

5. A copy of my curriculum vitae, which sets forth my education and experience in further detail, is provided herewith as Exhibit 1003.

6. I have been engaged as an expert on behalf of Petitioners Lupin, Ltd. and Lupin Pharmaceuticals, Inc. I am being compensated for my time at my standard consulting rate of \$670/hour. My compensation in no way depends on the outcome of this proceeding or the content of my opinions.

7. In the previous four years, I have testified by trial or deposition in the following matters:

- Montgomery v. USS/Clicker; mediation; July 2012;
- Fields v. Eli Lilly and Company; October 2014;

- Schomake v. Eli Lilly and Company; November 2014;
- Brookes Issue; February 2015.

II. INFORMATION CONSIDERED

8. In forming the opinions set forth herein, I have relied on my own experiences and knowledge. I have also considered the documents discussed herein, which include the following:

- a. U.S. Patent No. 9,059,559 (the “’559 Patent) (Ex. 1001);
- b. Brusilow, *et al.*, *Treatment of Episodic Hyperammonemia in Children with Inborn Errors of Urea Synthesis*, 310 *The New England Journal of Medicine*, 1630-1634 (1984) (“*Brusilow’84*”) (Ex. 1004);
- c. Simell, *et al.*, *Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance*, 20 *Pediatric Research*, 1117-1121 (1986) (“*Simell*”) (Ex. 1005);
- d. *Blau, Duran, Blaskovics, Gibson* (editors), *Physician’s Guide to the Laboratory Diagnosis of Metabolic Diseases*, 261-276 (2d ed. 1996) (“*Blau*”) (Ex. 1006);
- e. U.S. Patent Publication No. 2010/0008859, filed January 7, 2009, published January 14, 2010 (the “’859 Publication”) (Ex. 1007);
- f. Scientific Discussion for Ammonaps, EMEA 2005, available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-

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