

**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.**

LUPIN EX. 1002

1 of 16

**Table of Contents**

I. QUALIFICATIONS..... 4

II. INFORMATION CONSIDERED ..... 6

III. SUMMARY OF OPINIONS AND EXPECTED TESTIMONY ..... 9

IV. LEGAL STANDARDS ..... 10

    A. Law of Obviousness .....10

    B. Person of Ordinary Skill in the Art .....12

    C. Claim Construction.....13

V. BACKGROUND AND STATE OF THE ART ..... 13

    A. The Urea Cycle.....13

    B. Use of Nitrogen Scavenging Drugs.....16

    C. The Metabolic Fate of PBA and PAA.....19

    D. Overview of Applied Prior Art References.....21

        1. MacArthur .....21

        2. Enns 2010 .....23

        3. Thibault .....25

        4. Piscitelli .....26

        5. Zeitlin .....27

        6. Simell.....28

VI. OVERVIEW OF THE '197 PATENT ..... 29

    A. The '197 Patent Claims .....31

VII. THE '197 PATENT CLAIMS ARE OBVIOUS IN VIEW OF THE PRIOR ART ..... 31

    A. Claims 1 and 2 of the '197 Patent Would Have Been Obvious Over Enns 2010, MacArthur, and Piscatelli, in View of the Knowledge of a Person of Ordinary Skill in the Art .....31

        1. Overview of Applied Prior Art .....31

        2. Motivation to Combine Applied Prior Art.....32

        3. Independent Claim 1 .....36

        4. Independent Claim 2 .....39

5. There is No Teaching Away .....43  
VIII. SIGNATURE ..... 45

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

LUPIN EX. 1002

4 of 16

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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.