

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,

Petitioner

v.

HORIZON THERAPEUTICS, INC.,

Patent Owner

Case IPR 2016-00829

Patent 9,095,559

DECLARATION OF DR. GREGORY M. ENNS

Horizon Exhibit 2001

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I, Dr. Gregory M. Enns, hereby declare as follows:

I. Introduction

1. I, Dr. Gregory M. Enns, have been retained by Finnegan on behalf of Horizon Therapeutics, Inc. as an independent expert in the field of clinical biochemical genetics. My curriculum vitae establish my qualifications in this area. (Ex. 2007.) I am being compensated for the time I spend on this matter, but no part of my compensation depends on the outcome of this proceeding.

2. I understand that this proceeding involves U.S. Patent No. 9,095,559 (“the ’559 patent”). (Ex. 1001.) I understand that the application for the ’559 patent was filed on February 22, 2013, as U.S. Patent Application No. 13/775,000 (“the ’000 application”), and that the patent issued on August 4, 2015. (Ex. 1001.) I understand that the ’559 patent claims priority to Provisional Application No. 61/542,100 (“the ’100 application”), filed on September 30, 2011. (Ex. 1001.) I have therefore considered the state of the art and the prior art available as of September 30, 2011.

3. None of my opinions would change if I were to assume in the alternative that the date of invention was February 22, 2013, which is the date on which the application for the ’559 patent was filed.

4. I understand that Petitioner has asserted that a combination of the ’859 Publication (Ex. 1007), Blau (Ex. 1006), and Simell (Ex. 1005) render obvious

claims 1, 2, 4, 5, 7-10, 12, and 13 of the '559 patent and that this combination with the addition Brusilow '84 (Ex. 1004) renders obvious claims 3, 6, 11, 14, and 15. (Petition at 13.) In preparing this declaration, I have considered the '559 patent and its prosecution history, the Petition for *Inter Partes* Review of U.S. Patent No. 9,095,559, the Declaration of Dr. Vaux (Ex. 1002), the prior art and references identified in the Petition and Dr. Vaux's Declaration, my knowledge and expertise in the art, and any additional references cited herein.

II. Qualifications

A. Education

5. I received a Bachelor of Arts degree in Biology from Pomona College in 1984. In 1987, I obtained a Diploma in Medical Science from the University of St. Andrews, Scotland. In 1990, I received my U.K. Medical Degree from the University of Glasgow, Scotland.

6. From 1990 to 1991, I was a Junior House Officer at the Royal Hospital for Sick Children and the Glasgow Royal Infirmary, working in both Pediatric Surgery and General Medicine. I then completed my U.S. residency training in Pediatrics at the Children's Hospital of Los Angeles ("CHLA"), beginning as Intern and Resident from 1991 to 1994, and serving as Chief Resident from 1994 to 1995. From 1995 to 1998, I completed a fellowship in Medical Genetics at the University of California, San Francisco, including training in

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