

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

Case IPR2017-01160

Patent 9,326,966

DECLARATION OF DR. GREGORY M. ENNS

Horizon Exhibit 2006

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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 Green, Griffith & Borg-Breen LLP on behalf of Horizon Therapeutics, LLC, as an independent expert in the field of clinical biochemical genetics. My curriculum vitae establishes 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. 9,326,966 (“the ’966 patent”). (Ex. 1003.) I understand that the application for the ’966 patent was filed on December 3, 2015, as a continuation of U.S. Patent Application No. 14/816,674, filed August 3, 2015 (“the ’674 application”), now U.S. Patent No. 9,254,278 (“the ’278 Patent”), which is a continuation of U.S. Application No. 13/775,000, filed February 22, 2013, now U.S. Patent No. 9,095,559 (“the ’559 Patent”). The ’559 patent is the subject of IPR No. 2016-00829. As discussed further below, I have submitted an expert declaration on behalf of Patent Owner, Horizon Therapeutics, LLC in the IPR proceeding concerning the ’559 patent claims. (See Ex. 2001, Declaration of Dr. Gregory M. Enns, M.D., *Horizon Therapeutics, Inc. v. Lupin Ltd. et al.*, IPR2016-00829 (“Enns ’559 Declaration”).) I note that Lupin’s expert in this proceeding, Dr. Keith Vaux, has also submitted a declaration in support of Lupin’s Petition in the IPR proceeding concerning the ’559 patent, which relies on the same prior art references and largely the same arguments as those included in the instant matter.

3. I understand that the ’966 patent issued on May 3, 2016, and that the ’966 patent claims priority to Provisional Application No. 61/564,668 (“the ’668 application”), filed on November 29, 2011, and Provisional Application No. 61/542,100, filed on September 30, 2011.

(Ex. 1003.) I have therefore considered the state of the art and the prior art available as of September 30, 2011.

4. I understand that Petitioner has asserted that a combination of Blau (Ex. 1006), Simell (Ex. 1005), and the '859 Publication (Ex. 1007) render obvious claims 1-15 of the '966 patent. (Petition at 14.) In preparing this declaration, I have considered the '966 patent and its prosecution history, the Petition for *Inter Partes* Review of No. U.S. Patent 9,326,966, the Declaration of Dr. Vaux (Ex. 1002) ("Vaux"), the prior art and references identified in the Petition and the Vaux Declaration, my knowledge and expertise in the art, and any additional materials 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 Clinical Biochemical Genetics from 1997 to 1998. During my training at the University of California, San Francisco I frequently diagnosed and managed patients with urea cycle disorders, including

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