

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 IPR2018-00459
Patent 9,561,197

DECLARATION OF VERNON REID SUTTON, M.D.

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I, Vernon Reid. Sutton, M.D., hereby declare as follows:

I. INTRODUCTION

1. I have been retained by Green, Griffith & Borg-Breen LLP on behalf of Horizon Therapeutics, LLC as an independent expert in the field of Molecular & Human Genetics, including the clinical care and treatment of patients with inborn errors of metabolism including patients with urea cycle disorders (“UCDs”). My curriculum vitae establishes my qualifications in this area.¹ 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. 9,561,197 (“the ’197 patent”). I understand that the application for the ’197 patent was filed on September 11, 2012, as U.S. Patent Application No. 13/610,580 (“the ’580 application”), and that the patent issued on February 7, 2017. I understand that the ’197 patent claims priority to Provisional Application No. 61/636,256 (“the ’256 application”), filed on April 20, 2012. I have therefore considered the state of the art and the prior art available as of April 20, 2012. None of my opinions would

¹ Ex. 2002 (Sutton CV).

change if I were to assume in the alternative that the date of invention was September 11, 2012, which is the date on which the application for the '197 patent was filed.

3. I understand that Petitioner has asserted that a combination of Enns 2010, MacArthur, and Piscitelli, in view of the knowledge of a person of ordinary skill in the art, renders obvious all claims (claims 1 and 2) of the '197 patent.

4. In preparing this declaration, I have considered the '197 patent and its prosecution history, the Petition for *Inter Partes* Review of U.S. Patent No. 9,561,197 (Paper No. 3, "Petition"), the Declaration of Keith Vaux, M.D.,² 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. EXPERT QUALIFICATIONS

5. I am currently a Professor in the Department of Molecular & Human Genetics at Baylor College of Medicine, the Medical Director of the Baylor Biochemical Genetics Laboratory, and the Director of the Inborn Errors of Metabolism service at Texas Children's Hospital.

² Ex. 1002 ("Vaux").

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