## UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

Petitioners

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

Case IPR 2017-01767

Patent 9,254,278

## DECLARATION OF ROBERT F. GREEN IN RESPONSE TO PETITIONER'S OBJECTIONS TO EVIDENCE

I, Robert F. Green, declare as follows:

1. I am an attorney with Green, Griffith & Borg-Breen LLP, counsel for Patent Owner. I am a member of the Bar of the State of Illinois. I have personal knowledge of the matters stated in this declaration and would testify truthfully to them if called upon to do so.

 Exhibit 2002 is a true and correct copy of the Notice of Allowance dated December 23, 2015 from the Prosecution History of U.S. Patent No.
9,254,278, which is publicly available and was downloaded from the United States Patent and Trademark Office Public PAIR website at https://portal.uspto.gov/pair/PublicPair.

3. Exhibit 2005 is a true and correct copy of pages 16-22 of Par Pharmaceutical, Inc.'s Initial Invalidity Contentions and Non-Infringement Contentions for U.S. Patent Nos. 8,404,215 and 8,642,012, as served in *Hyperion Inc. v. Par Pharmaceutical, Inc.*, C.A. No. 2:14-cv-00384(JRG)(RSP) (E.D. Texas) on November 13, 2014. Exhibit 2043 is a true and correct copy of the Certificate of Service which was served with Par's Contentions in the above-referenced litigation.

4. Exhibit 2026 is a true and correct copy of "Specialties of Genetics," as it was publicly available on January 17, 2017, and which was downloaded from the

American Board of Medical Genetics and Genomics website at http://abmgg.org/pages/training\_specialties.shtml on that date.

5. Exhibit 2027 is a true and correct copy of "About Us," as it was publicly available on October 25, 2017, and which was downloaded from the Urea Cycle Disorders Consortium website at

https://www.rarediseasesnetwork.org/cms/ucdc/About-Us on that date.

6. Exhibit 2033 is a true and correct copy of Chapter 85: Urea Cycle Enzymes, which is available online and was downloaded from The Online Metabolic and Molecular Bases of Inherited Disease website at http://ommbid.mhmedical.com/book.aspx?bookid=971. Exhibit 2044 is a true and correct copy of the table of contents for The Online Metabolic and Molecular Bases of Inherited Disease dated February 27, 2017, showing Chapter 85.

7. Exhibit 2038 is a true and correct copy of the drugs@FDA: FDA Approved Drug Products entry for BUPHENYL® which is publicly available on the FDA's website: http://www.accessdata.fda.gov/scripts/cder/daf/ by searching for "BUPHENYL" and selecting the entry for "BUPHENYL (SODIUM PHENYLBUTYRATE) | NDA #020572 | TABLET;ORAL | Prescription | HORIZON PHARMA INC." (Ex. 2045.) Exhibit 2045 is a true and correct copy of the search results for "BUPHENYL" obtained through the FDA website's search function dated February 27, 2017. The full URL for the FDA's website for

## BUPHENYL® is:

http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process &ApplNo=020572.

Exhibit 2040 is a true and correct copy of the full prescribing information PDF for RAVICTI®, as it was publicly available on February 10, 2017, and which was downloaded from

https://hznp.azureedge.net/public/ravicti\_1-1g-ml\_vial\_pi\_effective\_us.PDF on or before such date.

9. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: February 28, 2018

By: <u>/ Robert F. Green /</u> Robert F. Green