

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 TIFFANY MAHMOOD

LUPIN EX. 1024

1 of 2

I, Tiffany Mahmood, declare under penalty of perjury as follows:

1. I am an associate at the law firm Goodwin Procter LLP.
2. I make this Declaration in support of Lupin's petition for *inter partes* review of U.S. Patent No. 9,561,197.
3. Exhibit 1013 is a true and correct copy of a document I downloaded on December 11, 2017 from the Drugs@FDA section of the U.S. Food and Drug Administration's website, relating to the Drug Approval Package for RAVICTI (glycerol phenylbutyrate) Oral Liquid, NDA 203284. Specifically, I navigated to the Drugs@FDA: FDA Approved Drug Products database, available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. At this page, I ran a search for "Ravicti" which returned a page of information relating to RAVICTI, available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process>. On this page, I navigated to the section for "Approval Date(s) and History, Letters, Labels, Reviews for NDA 203284." Under the header for "Original Approvals or Tentative Approvals," I clicked on "Review," which led me to the Drug Approval Package for RAVICTI, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/203284Orig1s000TOC.cfm. On this page, I clicked on "Summary Review," which returned a pdf of a document, a true and correct copy of which is marked as Ex. 1013.

LUPIN EX. 1024

2 of 2

4. Exhibit 1020 is a true and correct copy of the prosecution history of U.S Patent No. 9,561,197 which I downloaded on December 11, 2017 from the U.S. Patent and Trademark Office's Patent Application Information Retrieval website, at <https://portal.uspto.gov/pair/PublicPair>. Specifically, I ran a search on the Public Pair portal for U.S. Patent No. 9,561,197 which provided all patent information for U.S. Patent No. 9,561,197. I then navigated to the "Image File Wrapper" tab. I sorted all documents listed in a chronological order, and selected for download all documents marked as "PROSECUTION." A true and correct copy of the compilation of all documents downloaded is marked as Ex 1020.

5. 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 further 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: December 14, 2017

By: 
Tiffany Mahmood

LUPIN EX. 1002

3 of 3