UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC., Petitioner,

v.

MERCK SERONO SA, Patent Owner.

Case IPR2023-00480 Patent 7,713,947

Case IPR2023-00481 Patent 8,377,903

DECLARATION OF Cindy Kan IN SUPPORT OF EXHIBITS 2038, 2040, 2041, 2042, 2060, and 2070



- I, Cindy Kan, declare as follows:
- 1. I am an attorney at the law firm of Wilmer Cutler Pickering Hale and Dorr LLP in New York, NY, which represents the patent owner Merck Serono S.A. in the following *Inter Partes* Review proceedings: IPR2023-00480 and IPR2023-00481.
- 2. Exhibit 2038 is a true and accurate copy of a printout of the webpage appearing at https://www.fiercebiotech.com/biotech/merck-receives-complete-response-letter-from-fda-on-cladribine-tablets-new-drug-application retrieved on December 20, 2023.
- 3. Exhibit 2040 is a true and accurate copy of a printout of the webpage appearing at https://www.fda.gov/news-events/press-announcements/fda-approves-new-oral-treatment-multiple-sclerosis retrieved on November 25, 2023.
- 4. Exhibit 2041 is a true and accurate copy of a printout of the webpage appearing at https://clinicaltrials.gov/study/NCT00213135 and of the webpage appearing at https://clinicaltrials.gov/study/NCT00213135?tab=history&a=13 retrieved on November 25, 2023.
- 5. Exhibit 2042 is a true and accurate copy of a printout of the webpage appearing at https://www.neurologylive.com/view/shortcommitment-dosing-regimen-gives-cladribine-an-advantage-in-ms retrieved on November 10, 2023.



- 6. Exhibit 2060 is a true and accurate copy of a printout of the webpage appearing at https://web.archive.org/web/20220119143645/https://www.fiercepharma.com/pharma/better-8-years-late-than-never-merck-kgaa-nabs-fda-nod-for-ms-drug-mavenclad retrieved on December 18, 2023. This exhibit was prepared under my supervision by searching the Wayback Machine for the URL of Exhibit 2060 and selecting the capture at January 19, 2022 at 14:36:45 GMT. This date and time are included in the URL of Exhibit 2060.
- 7. Exhibit 2070 is a true and accurate copy of a printout of the webpage appearing at https://web.archive.org/web/20231004232146/https://www.mavenclad.com/en/home/why-mavenclad/safety-and-side-effects.html retrieved on December 19, 2023. This exhibit was prepared under my supervision by searching the Wayback Machine for the URL of Exhibit 2070 selecting the capture at October 4, 2023 at 23:21:46 GMT. This date and time are included in the URL of Exhibit 2070.
- 8. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place



IPR2023-00480, IPR2023-00481 U.S. Patent Nos. 7,713,947 & 8,377,903

within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

9. I hereby 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: December 21, 2023 By: /Cindy Kan/

Cindy Kan
WILMER CUTLER PICKERING HALE
AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

Tel: (212) 295-6470

E-mail: cindy.kan@wilmerhale.com

