

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWI PHARMACEUTICALS, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00049
Patent 7,713,947

Case IPR2023-00050
Patent 8,377,903

**DECLARATION OF CINDY KAN
IN SUPPORT OF EXHIBITS 2037, 2038, 2043, 2062, 2063, and 2064**

Merck 2068

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: IPR2023-00049 and IPR2023-00050.

2. Exhibit 2037 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 March 12, 2024.

3. Exhibit 2038 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.

4. Exhibit 2043 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.

5. Exhibit 2062 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.

6. Exhibit 2063 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.

7. Exhibit 2064 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 2064 selecting the capture at October 4, 2023 at 23:21:46 GMT. This date and time are included in the URL of Exhibit 2064.

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

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: March 12, 2024

By: /Cindy Kan/

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