UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. AND
SAWAI PHARMACEUTICAL CO., LTD.
Petitioners,

v.

BIOGEN MA, INC.
Patent Owner.

Patent No. 8,399,514

Inter Partes Review IPR2019-00789

DECLARATION OF TATSUFUMI HIRAMATSU IN SUPPORT OF PETITIONERS' RESPONSE REGARDING THE IDENTIFICATION OF REAL PARTY-IN-INTEREST

I, Tatsufumi Hiramatsu, declare as follows:

1. I either have personal knowledge of the facts stated in this Declaration or believe them to be true based on my experience, review of business records, or information I have otherwise received in the course of my duties.

2. Sawai Pharmaceutical Co. Ltd. ("Sawai Japan") is a publicly traded Japanese company.

3. Sawai, USA, Inc. ("Sawai USA") is incorporated in the state of Delaware. Sawai USA is a wholly owned subsidiary of Sawai Japan. Sawai USA is the holder of Abbreviated New Drug Application No. 210285 ("ANDA 210285," "Sawai USA's ANDA," or the "ANDA"), which seeks marketing approval in the United States for delayed release dimethyl fumarate capsules.

4. Sawai America Holdings, Inc. ("Sawai America Holdings") is a Delaware corporation. Sawai America Holdings is a wholly owned subsidiary of Sawai Japan.

5. Sawai America, LLC ("Sawai America") is a Delaware limited liability company. Sawai America is a wholly owned subsidiary of Sawai America Holdings.

6. Stason Pharmaceuticals, Inc. ("Stason") is a California corporation.

7. Upsher-Smith Laboratories, LLC ("Upsher-Smith") is a Minnesota

limited liability company. Upsher-Smith is a wholly owned subsidiary of Sawai America.

8. Sumitomo Corporation is a publicly traded Japanese company. To the best of my knowledge, Sumitomo Corporation has a number of wholly owned subsidiaries, one of which is Sumitomo Corporation of Americas ("SCOA").

9. Sawai America Holdings is the majority owner (80%) of Sawai America. SCOA is the minority owner (20%) of Sawai America.

10. I am Senior Director, Corporate Strategy for Uspher-Smith LLC. ("Upsher-Smith"). Upsher-Smith currently pays my salary. Before December 11th, 2017, I was Specialist for "Sawai Japan".

Sawai USA's ANDA and the Delaware Litigation

11. Sawai USA, through its agent Stason, submitted ANDA No. 210285 seeking to market in the United States dimethyl fumarate delayed release capsules. Sawai USA was (and continues to be) the sole named applicant for, and owner of all right and title to, Sawai USA's ANDA.

12. As part of filing the ANDA, Sawai USA submitted a Paragraph IV Certification to the FDA, indicating that U.S. Patent Nos. 6,509,376; 7,320,999; 7,619,001; 7,803,840; 8,759,393; and 8,399,514 ("the '514 patent") are invalid and not infringed. In connection with that Certification, Sawai USA, by its

outside counsel, served, among others, Biogen MA, Inc. ("Biogen") with a Paragraph IV Notice Letter, which provided a detailed legal and factual basis supporting the invalidity of the 6,509,376; 7,320,999; 7,619,001; 7,803,840; 8,759,393; and 8,399,514 patents. Stason was named in Sawai USA's ANDA and the Paragraph IV Notice Letter as an agent in the United States authorized to accept service of process for Sawai USA in connection with ANDA No. 210285. Stason also had a role in the development of the products described in ANDA No. 210285.

13. On June 30, 2017, in response to the Paragraph IV Notice Letter, Biogen sued both Sawai USA and Sawai Japan in the U.S. District Court for the District of Delaware, alleging infringement of, among other patents, the '514 patent (the "Delaware Litigation").

14. On October 16, 2017, Sawai USA and Sawai Japan filed their Answer and Counterclaims asserting, among other things, that the '514 patent is invalid and not infringed. The Delaware Litigation remains pending against Sawai USA and Sawai Japan. All aspects of the Delaware Litigation are controlled, overseen and paid for by either Sawai Japan or Sawai USA.

The Pending IPR Proceeding

15. On or about February 2019, Sawai Japan and Sawai USA decided to prepare a petition for *inter partes* review of the '514 patent. That decision was

solely made by Sawai Japan and Sawai USA. Neither Sumitomo Corporation nor SCOA had any involvement in that decision making process.

16. On March 5, 2019, Sawai Japan and Sawai USA filed: (i) a petition for *inter partes* review of the '514 patent; and (ii) a motion for joinder with a pending *inter partes* review filed by Mylan Pharmaceuticals, Inc., *Mylan Pharmaceuticals, Inc. v. Biogen MA, Inc.*, IPR2018-01403 (together the "IPR Proceeding"). All aspects the IPR Proceeding are controlled, overseen and paid for by Sawai Japan.

17. It is my understanding that on April 5, 2019, Biogen MA, Inc. filed an Opposition to the Motion for Joinder, wherein it cited a press release (Ex. 2001) and website (Ex. 2002), alleging that Sumitomo Corporation "meets the criteria of an RPI as it has 'management participation'" in Upsher-Smith. Biogen Opposition, p. 9.

Neither Sumitomo Corporation Nor SCOA Have Any Role in Sawai USA's ANDA, the Delaware Litigation, or the IPR Proceeding

18. Neither Sumitomo Corporation nor SCOA have any control, influence, decision-making authority, or otherwise participate in any actions regarding Sawai USA's ANDA, the Delaware Litigation, or the IPR Proceeding.

19. In January 2018, SCOA – not Sumitomo Corporation – became a 20% minority owner of Sawai America. Sawai America is in turn the 100% owner of Upsher-Smith.

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