

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA, LLC,
Petitioner,

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.,
Patent Owner.

Case IPR2020-01053
U.S. Patent 9,815,827

DECLARATION OF SCOTT STANCELL-CONDON

I, Scott Stancell-Condron, declare as follows:

1. I am the Associate Director, Records & Information Management and Co-Chair Information Governance Office for Sunovion Pharmaceuticals, Inc. (“Sunovion”) and Sumitomo Dainippon Pharma America, Inc. (“SDPA”).
2. I have been employed with Sunovion for approximately five years and have held the role described above during that time.
3. I make this declaration based on my personal knowledge.
4. As part of my role at Sunovion and SDPA, I have personal knowledge of Sunovion and SDPA’s regularly conducted business practices and activities for creating, recording, maintaining, and storing information and documents. The regular practice of Sunovion and SDPA when creating a record of an act, event, condition, or information is for an employee or representative of Sunovion or SDPA with knowledge of the respective act event, condition, or information to make the record or to transmit the information to be included in the record at or near the time of the act, event, condition, or information gathering or reasonably soon thereafter.
5. Given my role at Sunovion and SDPA, I further have general familiarity with the regularly conducted business practices and activities for creating, recording, maintaining and storing information and documents of Sunovion and SDPA’s parent organization, Sumitomo Dainippon Pharma Co., Ltd.

(“Sumitomo”). Like Sunovion and SDPA, Sumitomo’s regular practice when creating a record of an act, event, condition, or information is for an employee or representative of Sumitomo with knowledge of the respective act event, condition, or information to make the record or to transmit the information to be included in the record at or near the time of the act, event, condition, or information gathering or reasonably soon thereafter

6. Attached hereto as Exhibit 2058 is a SDPA Clinical Study Report D1050231 dated October 23, 2009 titled “A Phase 3 Randomized, Placebo- and Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Two Doses of Lurasidone HCl in Acutely Psychotic Patients with Schizophrenia.” Exhibit 2058 is a document included in Sunovion’s NDA No. 200603 for Latuda®.

7. Exhibit 2058 is a true and accurate copy of the original document.

8. The document attached as Exhibit 2058 is a copy of an original document that was created and/or kept by SDPA and Sunovion in the course of their regularly conducted business practices and activities.

9. Attached hereto as Exhibit 2059 is a Sunovion Clinical Study Report D1050233 dated May 3, 2011 titled “A Phase 3 Randomized, Double-Blind, Placebo- and Active Comparator-Controlled Clinical Trial to Study the Efficacy and Safety of Two Doses of Lurasidone in Acutely Psychotic Patients with Schizophrenia.” Exhibit 2059 is a document included in Sunovion’s NDA No.

200603 for Latuda®.

10. Exhibit 2059 is a true and accurate copy of the original document.

11. The document attached as Exhibit 2059 is a copy of an original document that was created and/or kept by Sunovion in the course of its regularly conducted business practices and activities.

12. Attached hereto as Exhibit 2060 is a SDPA Clinical Study Report D1050249 dated October 5, 2009 titled “A Double-Blind, Double-Dummy, Active Controlled, Randomized, 3-Arm, Parallel Study to Evaluate the Effects of Therapeutic and Supratherapeutic Doses of MK-3756 on QTC Interval in Male and Female Schizophrenic or Schizoaffective Patients.” Exhibit 2060 is a document included in Sunovion’s NDA No. 200603 for Latuda®.

13. Exhibit 2060 is a true and accurate copy of the original document.

14. The document attached as Exhibit 2060 is a copy of an original document that was created and/or kept by SDPA and Sunovion in the course of their regularly conducted business practices and activities.

15. Attached hereto as Exhibit 2069 is a PowerPoint presentation dated October 1, 2009 titled “Lurasidone, Strategic Business Plan”.

16. Exhibit 2069 is a true and accurate copy of the original document.

17. The document attached as Exhibit 2069 is a copy of an original document that was created and/or kept by Sunovion in the course of its regularly

conducted business practices and activities.

18. Attached hereto as Exhibit 2074 is a document entitled “Latuda Financial Information FY11-FY20 YTD” that contains Latuda® financial information for fiscal year 2011 through December 2020 prepared on or around February 3, 2020.

19. Exhibit 2074 is a true and accurate copy of the original document.

20. The document attached as Exhibit 2074 is a copy of an original document that was created and/or kept by Sunovion in the course of its regularly conducted business practices and activities.

21. Attached hereto as Exhibit 2075 is a PowerPoint presentation dated June 2016 titled “LATUDA Monthly Commercial Analytics Meeting”.

22. Exhibit 2075 is a true and accurate copy of the original document.

23. The document attached as Exhibit 2075 is a copy of an original document that was created and/or kept by Sunovion in the course of its regularly conducted business practices and activities.

24. Attached hereto as Exhibit 2076 is a PowerPoint presentation dated August 2, 2020 titled “LATUDA Situational Assessment – FY 2020, Sunovion Commercial Insights & Analytics”.

25. Exhibit 2076 is a true and accurate copy of the original document.

26. The document attached as Exhibit 2076 is a copy of an original

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