

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EISAI INC.
Petitioner

v.

CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD.
Patent Owner

Patent No. 10,759,779

**DECLARATION OF DONNA M. MEUTH IN SUPPORT OF PETITION
FOR POST-GRANT REVIEW OF U.S. PATENT NO. 10,759,779**

I, Donna M. Meuth, based on my personal knowledge and information, hereby declare as follows:

1. I have been an employee of Eisai, Inc. (“Eisai”) since 2009. Between April 2013 and the present, I have held the position of Associate General Counsel for Intellectual Property. Before then, I held the positions of Senior Patent Counsel and Associate Senior Patent Counsel.

2. As part of my regular job duties, I support outside counsel in various forms of patent prosecution and intellectual property litigation, including post-grant proceedings before the U.S. Patent and Trademark Office. My responsibilities also include regularly conversing with current and former Eisai employees and reviewing and understanding documents that Eisai generated during the ordinary course of its business. My regular job duties further include supervising the collection of documents from electronic databases storing documents that Eisai has submitted to governmental agencies, such as the U.S. Food and Drug Administration, as part of its regular business activities.

3. In performing my regular job duties, I have become familiar with the general record keeping practices relating to both hard-copy and electronic documents that Eisai employees generate as part of their regular business activities to support the development of new drug products, such as technical reports, records of experimental results, laboratory notebooks, and project status reports, as

well as the storage and maintenance of such documents in the regular course of business.

4. For purposes of preparing Eisai's petition for Post-Grant Review of U.S. Patent No. 10,759,779 ("Petition"), I supervised the collection of the following documents, which I understand are exhibits cited in the Petition:

- **Exhibit 1011:** This document is a true and correct copy of a report titled "Manufacture of GMP 8th and 9th lots of E2006 (ER-562007-00) for formal stability study" signed on February 22, 2017, which provides the method that Eisai used to manufacture Lot 169R2601. As part of their regular business activities, I understand Eisai scientists routinely generate reports memorializing methods that were used to prepare lots of a given drug substance, such as lemborexant. I also understand a true and correct copy of this document was collected from Eisai's study report management system, which is where such documents are electronically kept in the course of regularly conducted business activity.
- **Exhibit 1012:** This document is a true and correct copy of an X-ray powder diffraction ("XRPD") pattern for lemborexant from Lot 169R2601, which was used for formal stability studies, that is dated December 1, 2016. I understand Eisai scientists routinely generate XRPD patterns for samples of drug substance used for formal stability studies. I also understand a true and correct copy of this document was collected from Eisai's shipping inspection records in Kashima, Japan, which is where the originals of such documents are kept in the course of regularly conducted business activity.
- **Exhibit 1015:** This document is a true and correct copy of an entry from the laboratory notebook of Dr. George Moniz that was created on December 3, 2010. As part of his regular job duties, I understand that Dr. Moniz was involved in the synthesis of lemborexant and memorialized such experiments in his laboratory notebook. I also understand that a true and correct copy of this document was collected from Eisai's electronic notebook system, which is where notebooks of

Eisai scientists are electronically kept in the course of regularly conducted business activity.

- **Exhibit 1016:** This document is a true and correct copy of a monthly report from the Eisai Andover PST – Analytical Chemistry group for December 2010 concerning the “HAND” project. As part of their regular business activity, I understand that members of the Eisai Andover PST – Analytical Chemistry group prepared monthly reports in 2010 detailing their activity in the development of lemborexant as a drug substance, which included obtaining XRPD patterns of lemborexant that scientists in the group prepared. I understand that a true and correct copy of this document was collected from the hard drive folder of Jianxun (Joe) Zhou, who is a former Senior Scientist, Analytical Chemistry, in the Eisai Andover PST group. I understand the document was obtained from Dr. Zhou’s folder named “Monthly Report” on Eisai’s internal “eris03” server, which is where such documents are electronically kept in the course of regularly conducted business activity.
- **Exhibit 1017:** This document is a true and correct copy of an entry from the laboratory notebook of Dr. Annie Wearing that was created on December 5, 2010. As part of her regular job duties, I understand Dr. Wearing was involved in the synthesis of lemborexant and memorialized such experiments in her laboratory notebook. I understand that a true and correct copy of this document was collected from Eisai’s electronic notebook system, which is where notebooks of Eisai scientists are electronically kept in the course of regularly conducted business activity.
- **Exhibit 1018:** This document is a true and correct copy of the “Manufacturing Process Development” section (Section 3.2.S.2.6) from Eisai’s New Drug Application (“NDA”) for lemborexant. As part of its regular business activity, Eisai submits NDAs for new drug products, which includes, *inter alia*, discussion of manufacturing processes and data and results from experiments that Eisai scientists conducted. I understand that a true and correct copy of this document was collected from Eisai’s U.S. Regulatory database, which is where such documents are electronically kept in the course of regularly conducted business activity.

I hereby declare that all statements made herein are of my own knowledge and 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.

Date: February 3, 2021

By: /Donna M. Meuth/
Donna M. Meuth, Esq.