

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EISAI INC.
Petitioners

v.

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

Patent No. 10,759,779

**DECLARATION OF WILLIAM MAYO, PH.D.
IN SUPPORT OF PETITION FOR POST-GRANT REVIEW
OF U.S. PATENT NO. 10,759,779**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND AND QUALIFICATIONS	1
III.	MATERIALS REVIEWED	6
IV.	TECHNICAL BACKGROUND	7
A.	Crystalline Forms of Compounds	7
1.	Crystalline Solids	7
2.	Amorphous Solids.....	8
3.	Polymorphic Solids.....	9
B.	X-Ray Powder Diffraction Testing (XRPD).....	10
C.	Interpreting XRPD Results.....	14
V.	CRYSTALLINE FORM OF LEMBOREXANT PREPARED USING PROCEDURES IN EXAMPLE G OF THE '109 PATENT	16
A.	XRPD Patterns Disclosed in the '779 Patent	17
B.	XRPD Patterns of Samples Dr. Bihovsky Prepared by Following the Procedures in Example G of the '109 Patent.....	18
C.	XRPD Patterns of Eisai's Prior Lemborexant Lots	23
VI.	CONCLUSION.....	27

I, William Mayo, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained by Eisai Inc. (“Petitioner”) as an independent expert consultant in this proceeding before the United States Patent and Trademark Office (“PTO”) regarding U.S. Patent No. 10,759,779 (“the ’779 patent”) (Ex. 1001).¹ I have been asked to determine whether (1) the lemborexant samples I obtained from Dr. Ron Bihovsky, and (2) certain batches of lemborexant that Eisai prepared, contain the features recited in Claims 1-3 of the ’779 patent.

2. I am being compensated at my normal consulting rate for my time working on this proceeding. My compensation is not contingent on the nature of my findings, the presentation of my findings in testimony, or the outcome of this or any other proceeding. I have no other interest in this proceeding.

II. BACKGROUND AND QUALIFICATIONS

3. I presently serve as a Professor Emeritus at Rutgers University and am the Co-Founder and former Chief Scientist at H&M Analytical Services, which I sold in 2015. All of my opinions stated in this Declaration are based on my own

¹ Where appropriate, I refer to exhibits that I understand are to be attached to the petition for Post-Grant Review of the ’779 patent.

personal knowledge and professional judgment. In forming my opinions, I have relied on my knowledge and more than 50 years of experience in X-Ray Powder Diffraction (“XRPD”).

4. I am over 18 years of age and, if I am called upon to do so, I would be competent to testify as to the matters set forth herein. I understand that a copy of my current *curriculum vitae*, which details my education and professional and academic experience, is being submitted by Petitioner as Exhibit 1024. The following provides an overview of some of my experience that is relevant to the matters set forth in this Declaration.

5. I taught material sciences and engineering at Rutgers for the period 1982 to 2008. I joined the faculty in the Department of Mechanics and Material Science in 1982 as an Assistant Professor and then progressed to Associate Professor in 1988, Full Professor in 1995, and Emeritus Professor in 2008.

6. I received a Bachelor of Science Degree in Physics from Carnegie Mellon University in 1971. I received a Master’s Degree in Metallurgy and Materials Science from Carnegie Mellon University in 1974. In 1978, I began graduate studies at Rutgers, where I received a Ph.D. in Mechanics and Materials Science in 1982. I also served as a Post-doctoral fellow at Bell Laboratories in 1982.

7. I have co-founded five companies (H&M Analytical Services, Nano Pac, XStream Systems/Veracity Networks, XRD Associates, and XID LLC) in the private sector that were closely linked to my Rutgers research and experiences. XStream (later reconstituted as Veracity) focused on the detection of counterfeit pharmaceuticals utilizing a novel XRPD method that I developed with Federal Aviation Administration (“FAA”) funding for rapid detection of explosives hidden inside checked baggage. The XRPD method developed in that early work was later used by XID to develop an instrument to detect opioids being smuggled through the international postal system and was funded by the US Postal Service (“USPS”) and the Department of Homeland Security (“DHS”). Nano Pac commercialized work that I had done with National Science Foundation (“NSF”) and Department of Defense (“DOD”) funding to develop nanoscale materials via a controlled transformation of metastable starting materials. H&M Analytical Services was founded as a consulting and testing company to take advantage of my nearly 50 years of experience in XRPD methods. Finally, I founded XRD Associates as a consulting company focusing mostly on XRPD analysis of pharmaceutical materials. I have been involved with these companies on a part-time (1997-2008) or full time (2008-present) basis for more than 20 years.

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