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 YOGESH DANDIKER, Ph.D.

Merck 2055

I, Yogesh Dandiker, declare as follows:

I. INTRODUCTION

1. I am over eighteen years of age, and I am competent to testify as to the matters set forth herein if I am called upon to do so.

2. I have prepared this Declaration for consideration by the Patent Trial and Appeal Board in the following *Inter Partes* Review proceedings: IPR2023-00049 ("'049 IPR") and IPR2023-00050 ("'050 IPR"). I understand that the subject of the '049 IPR is U.S. Patent No. 7,713,947 ("the '947 patent") and the subject of the '050 IPR is U.S. Patent No. 8,377,903 ("the '903 patent").

3. I am a named inventor of U.S. Pat. No. 7,888,328 ("Bodor '328"), as well as PCT Application, WO 2004/087101, "Oral Formulations of Cladribine" ("Bodor PCT"), which Bodor '328 claims priority to. I understand Bodor '328 has been numbered Ex. 1029 and the Bodor PCT has been numbered Ex. 1007, in both the '049 IPR and in the '050 IPR. I have been asked to provide a declaration as an inventor of Bodor '328.

4. I am being compensated for my time in preparing this declaration at my usual consulting rate of $800.00/hour. My compensation is in no way contingent on the substance of my testimony or the outcome of this or any other proceeding. I have no interest in this proceeding.

5. I have personal knowledge of the facts stated herein and can testify competently to those facts.

II. BACKGROUND

6. I am the CEO of Celista Pharmaceuticals, a start-up company based in Minnesota. My professional qualifications are stated more fully in my curriculum vitae, which is attached as Appendix A. Below is a brief summary of my relevant education, work experience, and other qualifications.

7. I received my B.S., M.S., and Ph.D. all from the University of Salford in the United Kingdom. I received my B.S. and M.S. in 1979 and 1981, respectively, in biochemistry. During my M.S. studies I was involved in the development of a diagnostic radiotracer for a company in the UK; the company was later acquired by GE Healthcare. I received my Ph.D. in Physical Chemistry in 1984. My Ph.D. research focused on polymers for applications including dental fillings and drug delivery systems.

8. After graduating with my Ph.D., I joined Pfizer as a research scientist, where I researched liquid formulations of drugs including prostaglandins and cytotoxic drugs. I worked at Pfizer until 1987. Then, from 1987 to 1997, I worked at GlaxoSmithKline (GSK), where I held several positions and ultimately became a project team leader. At GSK, I was involved in the development of the Accuhaler range of respiratory devices and researched a number of new drugs, including

ranitidine. In 1997, I moved to Roche to be the Head of Pharmacy Research & Development. At Roche, I worked on the first protease inhibitors and combination therapy for HIV and many other products, including Tamiflu. I was also on a committee which selected drugs from screening to be progressed for development.

9. In 2001, I joined IVAX as Director of R&D. When I joined, IVAX was a generic manufacturer accustomed to conducting bioequivalence studies for generic drugs. IVAX did not have the capability to conduct the more onerous Phase II and Phase III clinical trials required for the approval of a drug. At IVAX, I worked on the development of an oral formulation of cladribine as a treatment for multiple sclerosis (MS), in partnership with Serono. Cladribine ultimately was approved by the FDA as an oral treatment for multiple sclerosis, which is sold under the brand name Mavenclad®.

10. I left IVAX in 2004 to join Apotex as Vice President of Product Development. In 2008, I joined Paddock Laboratories where I led research and development, leading to the successful sale of Paddock to Perrigo in 2012.

11. In 2012, I started my own pharmaceutical company, named Celista Pharmaceuticals LLC, where I am developing several orphan drugs in the areas of oncology and infectious diseases. Celista has successfully developed multiple drugs which have orphan drug designation from the FDA. We are also working on several women's health products for conditions for which there are currently no

effective treatments, such as cervical cancer. I am also running clinical trials for products to treat neurogenic orthostatic hypotension, another orphan drug indication.

III. DEVELOPMENT OF CLADRIBINE FORMULATION

12. Cladribine is a chlorinated purine analog, 2-chloro-2'-deoxyadenosine ("2-CdA"). I joined IVAX in the UK in 2001, after IVAX licensed the right to develop cladribine for treating MS from the SCRIPPS Research Institute and Johnson & Johnson. As director of R&D at IVAX, I was responsible for managing the development of formulations for cladribine. My colleagues at IVAX included Dr. Nicholas Bodor, who was IVAX's Chief Scientific Officer and my co-inventor of Bodor '328; Dr. Stephen Marcus; and other team members.

13. Ultimately, my team at IVAX focused on developing an oral cladribine formulation, while we partnered with Serono to design and conduct Phase III clinical trials for MS patients, as discussed below. My team at IVAX investigated many potential formulations of cladribine. We particularly investigated cyclodextrin-cladribine complexes, which resulted in our invention of an oral formulation of cladribine including a cladribine-cyclodextrin complex, as described in Bodor '328.

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