UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO S.A.,
Patent Owner.

Case IPR2023-00480
Patent 7,713,947

Case IPR2023-00481
Patent 8,377,903

DECLARATION OF ALAIN MUNAFO, Ph.D.

I, Alain Munafo, Ph.D., 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 submit this Declaration on behalf of Merck Serono S.A. ("Patent Owner") for consideration by the Patent Trial and Appeal Board in the following *Inter Partes* Review proceedings: IPR2023-00480 ("'480 IPR") and IPR2023-00481 ("'481 IPR"). I understand that the '480 IPR corresponds to *Inter Partes* Review of U.S. Patent No. 7,713,947 ("the '947 patent") ('480 Ex. 1001) and the '481 IPR corresponds to *Inter Partes* Review of U.S. Patent No. 8,377,903 ("the '903 patent") ('481 Ex. 1001).

3. I am being compensated for my time in preparing this declaration at my usual consulting rate of 450 Swiss Francs per hour. My compensation is in no way contingent on the substance of my testimony or the outcome of this or any other proceeding.

4. I am a named co-inventor of both the '947 patent and the '903 patent. When U.S. Provisional Application No. 60/638,669 and European Provisional Application No. EP04106909, to which the '947 patent and the '903 patent claim priority, were filed on December 22, 2004, and for more than two years before

then, I was working with other co-inventors of the '947 patent and the '903 patent to design and develop an oral dosing regimen for cladribine.

5. I am providing this declaration as a co-inventor of the '947 patent and the '903 patent and as someone knowledgeable about the relationship and joint research and development agreement between the teams at Serono[1] and IVAX.[2]

6. I have reviewed a copy of PCT Application WO 2004/087101 ("Bodor PCT") which was provided to me by counsel. I understand it is numbered Ex. 1022. The Bodor PCT names Drs. Bodor and Dandiker as co-inventors.

7. The Bodor PCT includes the following disclosure of a regimen for treating multiple sclerosis (MS) using cladribine:

> At the present time, it is envisioned that, for the treatment of multiple sclerosis, 10 mg of cladribine in the instant

[1] Serono S.A. is a subsidiary of Patent Owner, Merck Serono S.A. I collectively refer to Ares Trading S.A., its parent Serono S.A., and their other affiliates including Serono International S.A. and Serono Inc., between 2002 and 2004, as "Serono" throughout this declaration.

[2] I understand that IVAX Corporation is an affiliate of IVAX International GmbH. I collectively refer to IVAX Corporation and IVAX International GmbH as "IVAX" throughout this declaration.

> complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment.

'480 Ex. 1022, 23:15-20; '481 Ex. 1022, 23:15-20.

8. The Bodor PCT also includes a disclosure of an "alternative" regimen for treating multiple sclerosis (MS) using cladribine:

> Alternatively the patient would be treated with 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant dosage form once per day for a period of five to seven days per month for a total of six months, followed by eighteen months of no treatment.

'480 Ex. 1022, 23:20-24; '481 Ex. 1022, 23:20-24.

9. The Bodor PCT also includes a reference to two provisional applications apparently filed by IVAX. '480 Ex. 1022, 23:24-29; '481 Ex. 1022, 23:24-29. I was not aware of these provisional applications. And I do not know their subject matter.

10. In addition to my recollection and my review of the Bodor PCT, I reviewed the materials cited herein, which refreshed my memory about some details of what occurred from 2002 to 2004.

II. BACKGROUND

11. I was the former Global Head of Quantitative Pharmacology and then Executive Scientific Director in Translational Medicine at Merck Serono and am currently retired. My whole professional career relates to clinical pharmacology and pharmaceutical experience, including 27 years in the pharmaceutical industry. My work at Serono (including at Merck Serono) focused on clinical pharmacology, pharmacodynamics and pharmacokinetics, and translational aspects thereof. My work supported Merck Serono's drug development from concept phase in discovery through late-stage clinical development programs, including regulatory submissions. I have also lectured on bioanalytics, clinical pharmacology, and drug development science, in particular at the School of Pharmacy, Lausanne University, and Lausanne University Hospital, Switzerland. A copy of my current CV is attached as Appendix A.

12. I received my Pharmacists Diploma from Lausanne University in 1980 and a Ph.D. in Pharmacy from Lausanne University in 1985. I completed a 1.5-year postdoctoral fellowship in Pharmacokinetics at UCSF with Professor L.Z.

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