

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00480
Patent 7,713,947

Case IPR2023-00481
Patent 8,377,903

DECLARATION OF DR. BERND MEIBOHM

MERCK 2052

I, Dr. rer. nat. Bernd Meibohm, declare as follows:

I. INTRODUCTION

1. I have been asked by counsel for Merck Serono S.A. (“Patent Owner”) to provide my opinion in connection with the following *Inter Partes* Review proceedings: IPR2023-00480 (“’480 IPR”) and IPR2023-00481 (“’481 IPR”). I understand that the subject of the ’480 IPR is U.S. Patent No. 7,713,947 (“the ’947 patent”) and the subject of ’481 IPR is U.S. Patent No. 8,377,903 (“the ’903 patent”).

2. I am providing this declaration as an expert in pharmaceuticals and clinical pharmacology.

3. In forming my opinions set forth in this Declaration, I have considered and relied on my education and experience in the field of pharmaceutical science, including pharmacokinetics, pharmacodynamics, clinical trial design, and pharmaceutical drug development. In preparing this Declaration, I have also reviewed and considered the documents identified in Appendix B.

4. This Declaration identifies my opinions to date. I reserve the right to amend or supplement this Declaration, if allowed under the relevant rules, to address any issues raised by Petitioner, Petitioner’s expert(s) or resulting from further discovery relating to any of the opinions stated herein.

II. BACKGROUND AND QUALIFICATIONS

5. I am currently a Distinguished Professor, Associate Dean for Research and Graduate Programs, and Chair of the Department of Pharmaceutical Sciences at the College of Pharmacy, The University of Tennessee Health Science Center located in Memphis, Tennessee.

6. A detailed recitation of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is attached as Appendix A to this Declaration. A brief discussion of my experience and qualifications is included below.

7. I trained as a pharmacist at the Technical University Carolo-Wilhelmina in Braunschweig, Germany from 1984 to 1988. From 1988 to 1989, I completed practical training as a pharmacist in Germany. From September 1989 to July 1994, I completed my doctoral degree (Dr. rer. nat., *i.e.* Doctor of Natural Sciences) in Pharmaceutics at the Technical University Carolo-Wilhelmina.

8. After receiving my board certification in clinical pharmacy from the Pharmacist Guild of Lower Saxony in 1992, I undertook a postdoctoral research fellowship in Clinical Pharmacology at the University of Florida from November 1995 to October 1997.

9. From November 1997 to December 1998, I was a Visiting Assistant Professor of Pharmaceutics in the Department of Basic Pharmaceutical Sciences at

the College of Pharmacy, the University of South Carolina, and from January 1999 to July 1999 I was an Assistant Professor of Pharmaceutics at the University of South Carolina.

10. In 1999, I joined the University of Tennessee. From August 1999 to June 2002, I was an Assistant Professor of Pharmaceutical Sciences in the Department of Pharmaceutical Sciences at the College of Pharmacy. From July 2002 to June 2007, I was an Associate Professor and in 2007, I became a tenured member of the faculty. From July 2007 to the present, I have been a Professor of Pharmaceutical Sciences at the University of Tennessee Health Science Center. In 2021, I became a UTHSC Distinguished Professor. I also hold the Harriet S. Van Fleet Endowed Professorship in Pharmaceutics, and I serve as Chair of the Department of Pharmaceutical Sciences at the University of Tennessee Health Science Center.

11. In addition to my Professorship, I have been the Associate Dean for Research and Graduate Programs for the College of Pharmacy at the University of Tennessee Health Science Center since 2008.

12. In the course of my career, my research focus has primarily been on pharmacokinetic and pharmacodynamic principles for pre-clinical and clinical drug development and applied pharmacotherapy. My focus has been on small molecule drugs.

13. I have also worked with biologic drugs (also referred to as ‘biologics’), which include therapeutic proteins derived from living cells and organisms.

14. Additionally, I have worked on the development of various anti-infective drugs and anti-viral drugs. Specifically, my research has included profiling pharmacodynamic and pharmacokinetic properties of novel chemical entities, to identify which compounds have the potential for therapeutic use and how they can best be used to achieve maximum efficacy and minimal toxicity. This includes the exploration of different routes of administration (including oral, intravenous, subcutaneous, and pulmonary drug delivery) as well as different dosing regimens for approved and new drug candidates. Part of my research has included working on developing dosing regimens for drugs in different patient subgroups.

15. Throughout my career, I have been a member of and served the American Association of Pharmaceutical Scientists, the American College of Clinical Pharmacology, and the International Society of Pharmacometrics. I have published more than 200 books, book chapters and peer-reviewed scientific journal articles.

16. In addition to my above qualifications and experiences, I have served as a consultant to drug manufacturers in pre-clinical and clinical capacities. In the

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