UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner

v.

ASTRAZENECA AB

Patent Owner

Case IPR2016-01325

U.S. Patent No. 8,329,680

DECLARATION OF RONALD J. SAWCHUK, Ph.D. IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE

I. INTRODUCTION

1. I have been retained by AstraZeneca AB ("AstraZeneca") in connection with this *inter partes* review proceeding (IPR2016-01325) before the United States Patent and Trademark Office Patent Trial and Appeal Board ("Board").

2. I understand that Mylan Pharmaceuticals Inc. ("Mylan") has challenged AstraZeneca-owned U.S. Patent No. 8,329,680, which relates to a method of treating hormonal dependent disease of the breast or reproductive tract, and, more specifically, hormonal dependent breast cancer.

3. I further understand that Mylan has petitioned institution of this *inter partes* review proceeding on the basis of several references identified in its Petition (IPR2016-01325, Paper 1) ("Petition").

4. I am being compensated $750 per hour for my time consulting in this matter. I have no financial interest in the outcome of this proceeding and my compensation is in no way contingent upon my opinions or the outcome of this proceeding.

II. QUALIFICATIONS

5. I am a Professor of Pharmaceutics, Emeritus, and Morse Alumni Distinguished Teaching Professor at the University of Minnesota. I also served as the Director of the Bioanalytic and Pharmacokinetic Services Laboratory at the

University of Minnesota until August of 2014. I have studied and carried out clinical and pre-clinical research in the field of pharmacokinetics and biopharmaceutics for over forty years.

6. I joined the University of Minnesota in 1971 as an Instructor in Pharmaceutics after having obtained a Bachelor and Masters of Science Degree from the University of Toronto in 1963 and 1996, respectively, and completing my Doctoral Degree (Ph.D.) in Pharmaceutical Chemistry (pharmacokinetics emphasis) at the University of California, San Francisco, which was granted in 1972.

7. At the University of Minnesota I served as an Assistant Professor of Pharmaceutics from 1972 to 1977, an Associate Professor of Pharmaceutics from 1977 to 1983, and a full Professor of Pharmaceutics from 1983 until my retirement in July of 2010. During this period, I was course director for instruction in pharmacokinetics, clinical pharmacokinetics, advanced pharmacokinetics, and pharmacokinetic modeling and simulation. I was also a participating instructor in biopharmaceutics, and advanced pharmacokinetics. I continue to provide lectures relating to preclinical and clinical pharmacokinetics to scientists in the pharmaceutical industry.

8. I also served as a member of the graduate programs in Pharmaceutics, Neurosciences, and Experimental and Clinical Pharmacology. From 1983 to 1989

and 1991 to 1994, I was the Director of Graduate Studies in Pharmaceutics at the University. From 1982 to 1995, I also served as Director of the Clinical Pharmacokinetics Laboratory at the College of Pharmacy at the University of Minnesota. From 1998 to 1999 I served as the Head of the Department of Pharmaceutics at the University of Minnesota.

9. Although I have formally retired from the University, my Graduate Faculty appointment in the Department of Pharmaceutics is still in effect, allowing me to teach graduate students in the program. I have advised on the order of forty graduate students, postdoctoral fellows, and visiting scholars, on projects relating to preclinical and clinical pharmacokinetics, biopharmaceutics, and bioanalytical chemistry.

10. A major focus of my research was preclinical and clinical pharmacokinetics. I have been involved with many different preclinical and clinical human trials, and in particular with the analysis of the pharmacokinetic and other data generated during those trials. I also focused my research on drug bioavailability and bioequivalence. I have taught, and continue to teach, pharmacokinetics, and pharmacokinetic modeling and simulation in professional, graduate, and elective courses at the University of Minnesota and to the pharmaceutical industry. This instruction includes lectures on the assessment of bioavailability and bioequivalence.

11. I have expertise in the determination of pharmacokinetic parameters and metrics for orally administered drugs, bioanalytical chemistry, biopharmaceutics, and pharmacodynamics. I have devoted a large part of my career to the study of the pharmacokinetics of drugs. And, in addition to authoring numerous publications in this area, I have received funding from various sources in the public and private sector to support my research in pharmacokinetics, including support from the National Institutes of Health ("NIH") and the U.S. Food and Drug Administration ("FDA").

12. During my career, I received several honors, scholarships and awards, including the Weaver Medal of Honor in 2001, the Meritorious Manuscript Award from the American Association of Pharmaceutical Scientists in 1999 and the Hallie Bruce Memorial Lecture Award in 1996. In 2007, I received the American Pharmacists Association (APhA) Research Achievement Award in the Basic Pharmaceutical Sciences.

13. I have been a member of numerous scientific and clinical societies. I am a Fellow of the American Association of Pharmaceutical Scientists and of the American Association for the Advancement of Science. I have been a member of the International Society of Anti-infective Pharmacology and the International Society for the Study of Xenobiotics (ISSX). I served a three-year term as a

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