IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KVK-TECH, INC.,

Petitioner,

v.

SHIRE LLC,

Patent Owner.

Case IPR2018-00290
US Patent No. 8,846,100

DECLARATION OF SARA ROSENBAUM, Ph.D.

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TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. EXPERIENCE AND QUALIFICATIONS 1

A. Professional Background 1

B. Materials Considered for This Declaration 2

III. LEGAL PRINCIPLES 4

IV. THE PERSON OF ORDINARY SKILL IN THE ART 6

V. THE '100 PATENT CLAIMS ARE DIRECTED TO A THREE-COMPONENT (IR-DPR-SR) AMPHETAMINE DOSAGE SYSTEM WITH SPECIFIC PHARMACOKINETICS AND WITHOUT A FOOD EFFECT 7

A. Amphetamines 8

B. Drug Release from an Oral Dosage Form 8

a. The GI Tract Is a Complex Environment 9

b. The '100 Patent Dosage System Combines Three Different Types of Amphetamine Delivery - IR-DPR-SR 11

C. Pharmacokinetics, Pharmacodynamics, and the Unpredictability of In Vivo from In Vitro and Vice Versa 13

a. Pharmacokinetics 14

b. Pharmacodynamics 24

VII. THE '100 PATENT PK CLAIMS AND FOOD EFFECT CLAIM 25

VIII. THE PK CLAIMS AND THE FOOD EFFECT CLAIM ARE NOT ANTICIPATED BY BURNSIDE; NOR ARE THEY OBVIOUS OVER BURNSIDE OR ADDERALL XR IN VIEW OF BURNSIDE 27

A. The PK Claims Are Not Anticipated 27

B. The Food Effect Claim Is Not Anticipated 29

C. The PK Claims Are Not Obvious over Burnside Alone or ADDERALL XR in view of Burnside 32

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TABLE OF CONTENTS
(continued)

Page

D. THE FOOD EFFECT CLAIM (CLAIM 21) IS NOT OBVIOUS OVER BURNSIDE OR ADDERALL XR IN VIEW OF BURNSIDE 46

APPENDIX A CURRICULUM VITAE 1

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DECLARATION OF SARA ROSENBAUM, Ph.D.

I, Sara Rosenbaum, Ph.D., do hereby declare and say as follows:

I. INTRODUCTION

1. I am a citizen of the United States of America and am more than twenty-one (21) years of age. I have been retained by counsel for Patent Owner Shire LLC as an expert in pharmacokinetics to address topics relevant to the subject matter of *KVK-Tech, Inc. v. Shire LLC,* IPR2018-00290, involving the claims of U.S. Patent No. 8,846,100 (the "'100 patent"). EX. 1001. I am being compensated at my usual rate for consultation on patent matters, and I am being provided with, or reimbursed for, my expenses. My compensation is in no way dependent on the outcome of this case.

II. EXPERIENCE AND QUALIFICATIONS

A. Professional Background

2. I am a tenured Professor of Pharmacokinetics in the Department of Biomedical and Pharmaceutical Sciences at the University of Rhode Island College of Pharmacy. I am also an Adjunct Professor of Molecular Pharmacology, Physiology, and Biotechnology at Brown University. I received my Ph.D. (1980) in Pharmacology from Liverpool University. I have taught courses in biopharmaceutics, pharmacokinetics, and pharmacodynamics. I have published more than 40 books and peer-reviewed publications in the field, and have

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presented at conferences around the world. I have been Editor-in-Chief and Editor Emeritus of *Clinical Research and Regulatory Affairs* and am a reviewer for *Annals of Clinical Pharmacology* and *Clinical Pharmacokinetics*. Over the course of my career, I have more than three decades of experience in the study of pharmacokinetics.

3. My *curriculum vitae* is attached as Appendix A.

B. Materials Considered for This Declaration

4. In making this Declaration, I relied on over three decades of experience in pharmaceutical studies and have studied and considered: (a) the '100 patent (EX1001) and its file history (EX1005); (b) KVK's Petition and Exhibits in this IPR (EX1001-1042), including the declarations of its experts (EX1004 and EX1006) and its grounds for this IPR (EX1002, EX1003, EX1031, EX1015-1018); (c) KVK's Petition and Exhibits in related IPR2018-00293; and (d) each of the documents I cite in the body of this Declaration. This includes U.S. Patent 9,173,857 ("the '857 patent"), which is EX1001 in the related IPR, and its file history (EX1030 here). I am also submitting a Declaration in IPR2018-00293.

5. I understand that this is an *inter partes* review ("IPR") proceeding conducted before the Patent Trial and Appeal Board ("Board") of the U.S. Patent and Trademark Office ("USPTO") to determine if claims 1-31 of the '100 patent (the challenged claims) should be cancelled as unpatentable, in view of certain

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