

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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KVK-TECH, INC.,

Petitioner,

v.

SHIRE LLC,

Patent Owner.

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Case IPR2018-00293  
US Patent No. 9,173,857

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**DECLARATION OF SARA ROSENBAUM, Ph.D.**

SHIRE EX. 2002  
KVK v. SHIRE  
IPR2018-00293

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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*, IPR2018-00293, involving the claims of U.S. Patent No. 9,173,857 (the “857 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

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 ‘857 patent (EX1001) and its file history (EX1030); (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 IPR2018-00290; and (d) each of the documents I cite in the body of this Declaration. This includes U.S. Patent 8,846,100 (“the ‘100 patent”), which is EX1001 in the related IPR, and its file history (EX1005 here). I am also submitting a Declaration in IPR2018-00290.

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 1-29 of the ‘857 patent (the challenged claims) should be cancelled as unpatentable, in view of certain

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