

Filed on behalf of: KVK-Tech, Inc.

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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 PLC  
Patent Owner

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U.S. Patent No. 8,884,100

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**DECLARATION OF WILLIAM J. JUSKO, Ph.D.**

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I, William J. Jusko, Ph.D., declare as follows:

**I. INTRODUCTION**

1. I have been retained by KVK-Tech, Inc. as an independent expert consultant in this proceeding before the United States Patent and Trademark Office. Although I am being compensated at my normal consulting rate for the time I spend on this matter, no part of my compensation is dependent on the outcome of this proceeding, and I have no other interest in this proceeding.

2. I understand that this proceeding involves U.S. Patent No. 8,884,100 (“the ‘100 patent”), the application for which was filed on May 12, 2006, as U.S. Patent Application No. 11/383,066 (“the ‘066 application”), and issued on September 30, 2014. I further understand that the ‘100 patent is assigned on its face to Shire LLC (“Patent Owner”).

3. I understand that the claims of the ‘100 patent recite, among other things, a pharmaceutical composition comprising pharmaceutically active mixed amphetamine salts in three beads: (1) immediate release beads; (2) delayed pulsed release beads; and (3) delayed sustained release beads. I refer to this composition as a three-bead composition.

4. I have been asked to consider whether, from a pharmacokinetics perspective, the pharmacokinetic properties recited in claims 5-12 of the ‘100

patent and the lack of food effect in claim 21 are inherent in the three-bead composition of claim 1.

5. I have also been asked to opine on whether any of the beads in Burnside Examples 1-4 could provide the prolonged drug release needed to augment Adderall XR®.

6. Finally, I was also asked to opine on whether the dosages recited in claims 22-30 of the '100 patent are doses a POSA would use in the routine dose optimization of the composition in claim 1 of the '100 patent. My opinions are set forth below.

## **II. QUALIFICATIONS**

7. I am a SUNY Distinguished Professor at the State University of New York at Buffalo in the Department of Pharmaceutical Sciences. I was Chair of the Department of Pharmaceutical Sciences during 2001 - 2016 and have been Director of the Center of Excellence in Pharmacokinetics and Pharmacodynamics since 2005. My primary area of expertise is in pharmaceutical sciences, particularly pharmacokinetics and pharmacodynamics.

8. I received a B.S. in Pharmacy from the State University of New York at Buffalo in 1965. During my undergraduate studies and after receiving my Bachelor's degree, I worked as a pharmacist, at Children's Hospital of Buffalo and then at Soby's Pharmacy in Buffalo.

9. I earned my Ph.D. in pharmaceutical sciences with an emphasis on pharmacokinetics from the State University of New York at Buffalo in 1970. Following my doctoral studies, I became Assistant Professor of Pharmacology at Boston University School of Medicine and served as a Clinical Pharmacologist at the Boston Veterans Administration Hospital.

10. In 1972, I returned to the State University of New York at Buffalo as an Assistant Professor of Pharmaceutics and Director of the Clinical Pharmacokinetics Laboratory at Millard Fillmore Hospital and have remained a professor at the University ever since. I have taught a wide variety of courses during that time, including those that cover the pharmacokinetics and pharmacodynamics of various types of drugs. For over 20 years, I have given post-graduate courses in which professionals from the industry and FDA come to Buffalo for instruction in pharmacokinetics and pharmacodynamics. I also provide such instruction to industry professionals at their companies as well as other locations throughout the world.

11. During my 50-year career as a researcher in the field of pharmaceutical sciences, I have served as a consultant for the National Institutes of Health (NIH), United States Food and Drug Administration (FDA), and various pharmaceutical companies, such as Amgen, Genentech Inc., Pfizer Inc., Roche, and Wyeth (now Pfizer), among others.

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