

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

CORRECTED DECLARATION OF JAMES MCCRACKEN, M.D.

KVK-TECH EXHIBIT 1058

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DECLARATION OF JAMES MCCRACKEN, M.D.

KVK-TECH EXHIBIT 1045

TABLE OF CONTENTS

I.	OVERVIEW	1
II.	QUALIFICATIONS	3
III.	SUMMARY OF OPINIONS	7
IV.	ACUTE TOLERANCE DOES NOT TEACH AWAY FROM THE USE OF SR BEADS IN ADHD FORMULATIONS TO PROLONG CLINICAL EFFICACY	9
A.	Acute Tolerance is not a Clinically Significant Issue with Amphetamine Formulations for ADHD	9
B.	POSA would not Expect Acute Tolerance to Affect Mixed Pulsatile and Sustained Release Amphetamine Formulations.....	36
C.	Burnside Does Not Teach Away from Using SR Beads in Combination with Pulsatile Beads Due to Acute Tolerance.....	42
V.	FOOD EFFECT IS NOT FORMULATION-DEPENDENT	46

DECLARATION OF JAMES MCCRACKEN, M.D.

I, James McCracken, do hereby declare and say as follows:

I. OVERVIEW

1. I am over the age of 18 and otherwise competent to make this declaration. I understand that this declaration is being submitted together with a petition for Inter Partes Review (“IPR”) of claims 1-31 of U.S. Patent No. 9,173,857 (the “’857 patent”).

2. I have been retained as an independent expert on behalf of KVK-Tech, Inc. (“KVK”), the Petitioner, in this proceeding. I am being compensated for my time in connection with this IPR at my standard legal consultant rate. I have no personal or financial interest in KVK or in the outcome of this proceeding.

3. I understand that this proceeding involves the ‘857 patent, which has an effective filing date of May 12, 2006, having been filed as U.S. Patent Application No. 11/383,066 (“the ‘066 application”), and which issued on November 3, 2015. I understand that the earliest possible filing date of the ‘857 patent is May 12, 2006. I further understand that the patent is assigned to Shire LLC (“Shire”). I have been asked to provide my analysis of the ‘857 patent based on prior art and the knowledge in the art before May 12, 2006.¹

¹ My opinions would be unaffected if Shire established an earlier filing date in 2005 or 2006.

4. I further understand that the claims of the '857 patent recite, among other things, a method of treating ADHD with a pharmaceutical composition comprising pharmaceutically active mixed amphetamine salts in three types of beads: (1) immediate release beads ("IR beads"); (2) delayed pulsed release beads ("DR beads"); and (3) delayed sustained release beads ("SR beads"). I refer to this claimed three bead composition as the "Mixed Bead Formulation."

5. I have been asked to address alleged issues concerning "acute tolerance" and "food effect" – as raised by Dr. James Polli Ph.D. on pages 74-93 and 100-103 of his declaration (Polli Decl. EX. 2060) – and what effect, if any, they may have on the therapeutic efficacy of amphetamine-containing medications. Specifically, Dr. Polli contends that acute tolerance and food effect are characteristic to amphetamine formulations, and that these characteristics made the addition of a third sustained release bead to a formulation containing two pulsed release beads unlikely to extend therapeutic efficacy of the pulsed beads. I understand that these questions are relevant to the patentability of the Mixed Bead Formulation claimed in the '857 patent.

6. First, I have been asked to opine on whether acute tolerance was known to diminish the therapeutic efficacy of amphetamines, and whether this would have discouraged the use of the Mixed Bead Formulation for treating ADHD.

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