

Filed on behalf of: KVK-Tech, Inc.

By: Jonathan A. Harris (jharris@axinn.com)
James T. Evans (jevans@axinn.com)
Axinn, Veltrop & Harkrider LLP

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KVK-Tech, Inc.

Petitioner

v.

Shire PLC

Patent Owner

U.S. Patent No. 8,846,100

DECLARATION OF DIANE J. BURGESS, PH.D.

TABLE OF CONTENTS

I.	Overview.....	1
II.	My Background and Qualifications.....	3
III.	List of Documents Considered in Formulating My Opinion	6
IV.	POSA	6
V.	State of the Art before May 12, 2006	7
	A. Modified Release Dosage Forms Were Well-Known before May 12, 2006.....	7
	B. Using Enteric Release Coatings to Delay Release of an Active Pharmaceutical Ingredient Was Well-Known before May 12, 2006	9
	C. Adderall IR [®] and Adderall XR [®] Were Well-Known ADHD Treatments before May 12, 2006	10
	D. Amphetamine Formulations with Sustained Release Beads Were Well-Known before May 12, 2006.....	12
VI.	The ‘100 Patent and Its Claims.....	15
	A. Independent Claim 1	18
	B. Dependent Claims 2-31	19
	C. Claim Construction	20
	1. “About” (claims 5-12 and 22-30)	20
	2. “Food effect” (claim 21)	21
VII.	The Basis of My Analysis with Respect to Anticipation	21
	A. The ‘300 Patent Discloses All the Elements of Claims 1-21 and 31, Arranged as Claimed and in a Manner Enabling to a POSA.....	23
	1. Claim 1	23

2.	Claims 2-4	35
3.	Claims 5-12	38
4.	Claims 13-18 and 31	40
5.	Claims 19 and 20.....	44
6.	Claim 21	46
VIII.	The Basis of My Analysis with Respect to Obviousness.....	48
A.	Claims 1-31 Are Obvious to a POSA Reading the ‘300 Patent Alone or Adderall XR® in Combination with the ‘300 Patent.....	50
1.	The ‘300 Patent Alone (Petition Ground 2) Teachings and Rationales	52
a.	Independent claim 1.....	52
b.	Claims 2-4, 13-20 and 31	54
c.	Claims 5-12 and 21	57
d.	Claims 22-30.....	58
e.	Reasonable Expectation of Success.....	59
2.	Adderall XR® plus the ‘300 Patent (Petition Ground 3) Teachings and Rationales	60
a.	Independent Claim 1	60
b.	Claims 2-4.....	67
c.	Claims 5-12.....	69
d.	Claims 13-18 and 31	69
e.	Claims 19 and 20	72
f.	Claim 21.....	73
g.	Claim 22-30	74
3.	Motivation to Combine	74
4.	Reasonable Expectation of Success	80

B.	Objective Indicia	81
1.	No Unexpectedly Superior Results.....	82
2.	Any Alleged Commercial Success Resulting from the '100 Patent Has No Nexus to the Claims	84
IX.	Conclusion	84

I, Diane J. Burgess, do hereby declare as follows:

I. Overview

1. I am over the age of 18 and otherwise competent to make this declaration. This declaration is based on my personal knowledge as an expert in pharmaceutical formulation. I understand this declaration is being submitted together with a petition for Inter Partes Review (“IPR”) of claims 1-31 of U.S. Patent No. 8,846,100 (the “‘100 patent”).

2. I have been retained as an expert on behalf of KVK-Tech, Inc. (“KVK”), the Petitioner, for this IPR. 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 the ‘100 patent issued on September 30, 2014, and resulted from U.S. Application No. 11/383,066, filed on May 12, 2006. I understand that, based on that date, the earliest possible filing date of the ‘100 patent is May 12, 2006. I have been asked to provide my analysis of the ‘100 patent based on prior art and the knowledge in the art before May 12, 2006.¹ I also understand that the patent is assigned to Shire LLC (“Shire”) on its face.

¹ My opinions would not be affected should Shire establish an earlier invention date in 2005 or 2006.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.