

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

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

CORRECTED PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

EXHIBIT LISTvi

I. Introduction.....1

II. Mandatory Notices under 37 C.F.R. § 42.8.....3

 A. Real Parties-in-Interest 37 C.F.R. § 42.8(b)(1).....3

 B. Related Matters.....3

 C. Lead and Back-Up Counsel 37 C.F.R. § 42.8(b)(3)-(4)3

III. Payment of Fees 37 C.F.R. §§ 42.15(a) and 42.103.....4

IV. Grounds for Standing 37 C.F.R. § 42.104(a)4

V. Identification of Challenge - Proposed grounds.....4

VI. State of the Prior Art as of 2006.....5

 A. Amphetamine Was a Well-Known ADHD Treatment5

 B. Drug Coating Release Timings and Characteristics Were Well-Known In the Prior Art.....6

 C. Adderall IR[®] and Adderall XR[®].....7

 D. Amphetamine Formulations with Sustained Release Beads.....8

VII. The ‘857 Patent.....9

 A. Summary of the ‘857 Patent Specification.....9

 B. Summary of the ‘857 Patent Claims11

 C. Summary of the ‘857 Patent Prosecution History.....12

VIII. Level of Ordinary Skill in the Art16

IX. Claim Construction.....17

X. Detailed Explanation of Grounds17

 A. Ground 1: Burnside Anticipates Claims 1-19 and 2917

 1. Independent Claim 119

 2. Claims 2-429

 3. Claims 5-1230

4.	Claims 13-16 and 29	31
5.	Claims 17-18	33
6.	Claim 19	34
B.	The Obviousness Grounds - Ground 2 (Burnside alone) and Ground 3 (Adderall XR [®] in view of Burnside).....	35
1.	Scope and Content of the Prior Art.....	36
2.	Limitation-by-Limitation Analysis	36
3.	Rationales for Combination	52
C.	Reasonable Expectation of Success (Grounds 2 and 3).....	59
D.	Alleged Evidence of Secondary Considerations Does Not Support Non-obviousness (Grounds 2 and 3).....	61
XI.	The Board Should Adopt All Proposed Grounds	63
XII.	Section 325(d) Does Not Apply Here	63
XIII.	Conclusion	66

TABLE OF AUTHORITIES

	Page(s)
Cases	
<u>In re Aller</u> , 220 F.2d 454 (C.C.P.A. 1955)	38
<u>In re Applied Materials, Inc.</u> , 692 F.3d 1289 (Fed. Cir. 2012)	38
<u>Blue Calypso, LLC v. Groupon, Inc.</u> , 815 F.3d 1331 (Fed. Cir. 2016)	27
<u>Cuozzo Speed Techs., LLC v. Lee</u> , 136 S. Ct. 2131 (2016).....	17
<u>Galderma Labs., L.P. v. Tolmar, Inc.</u> , 737 F.3d 731 (Fed. Cir. 2013).....	56
<u>In re Harza</u> , 274 F.2d 669 (C.C.P.A. 1960)	47
<u>In re Huai-Hung Kao</u> , 639 F.3d 1057 (Fed. Cir. 2011)	34, 37, 62
<u>In re Nomiya</u> , 509 F.2d 566 (C.C.P.A. 1975)	10
<u>Ormco Corp. v. Align Tech., Inc.</u> , 463 F.3d 1299 (Fed. Cir. 2006)	63
<u>Pfizer, Inc. v. Apotex, Inc.</u> , 480 F.3d 1348 (Fed. Cir. 2007)	59, 60
<u>Santarus, Inc. v. Par Pharm., Inc.</u> , 694 F.3d 1344 (Fed. Cir. 2012)	37
<u>Shire LLC et al. v. Abhai, LLC</u> , 1:15-cv-13909-WGY (D. Mass. Nov. 20, 2015)	14
<u>In re Spada</u> , 911 F.2d 705 (Fed. Cir. 1990)	30

Statutes

35 U.S.C. § 102(b)6, 8
35 U.S.C. § 325(d)2, 64

Other Authorities

37 C.F.R. § 42.83
37 C.F.R. § 42.8(b)(1).....3
37 C.F.R. § 42.8(b)(3)-(4).....3
37 C.F.R. § 42.10(b)4
37 C.F.R. §§ 42.15(A) and 42.103.....4
37 C.F.R. § 42.100(b)17
37 C.F.R. § 42.104(A).....4

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.