

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 IPR2018-00290  
US Patent No. 8,846,100

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**PETITIONER'S RESPONSE TO PATENT OWNER'S SUR-REPLY**

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## UPDATED EXHIBIT LIST

1001	U.S. Patent No. 8,846,100 (the “100 patent”)
1002	U.S. Patent No. 6,605,300 (“Burnside”)
1003	PHYSICIANS’ DESK REFERENCE® 3144-3146 (58th ed. 2004) (“2004 PDR”)
1004	Declaration of Diane J. Burgess, Ph.D.
1005	Prosecution History of the ‘100 Patent
1006	Declaration of William J. Jusko, Ph.D.
1007	Rong-Kun Chang et al., <i>A Review of Aqueous Coating Techniques and Preliminary Data on Release from a Theophylline Product</i> , 11 Pharm. Tech. 3, 56-68 (1987)
1008	FDA: Center for Drug Evaluation and Research, Application No. 11-522, Approval Letter (Feb. 13, 1996)
1009	ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, ADDERALL®, <a href="https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm">https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm</a> . (last visited Aug. 16, 2017)
1010	Christopher J. Kratochvil, MD, <i>ADHD: Treatment and Outcome</i> , 4 Managing ADHD 3A, 1-4 (2004)
1011	David J. Heal et al., <i>Amphetamine, Past and Present - a Pharmacological and Clinical Perspective</i> , 27 J. Psychopharmacology 6, 479-496 (2013)
1012	C. Bradley, <i>The Behavior of Young Children Receiving Benzedrine</i> , 94 Am. J. Psychiatry 1, 154-162 (1937)
1013	Drugs@FDA U.S. Food and Drug Administration, FDA Approved Drugs, Adderall XR®, <a href="https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=021303">https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=021303</a> (last visited Aug. 16, 2017).
1014	Simon J. Tulloch et al., <i>SLI381 (Adderall XR), a Two-Component, Extended-Release Formulation of Mixed Amphetamine Salts: Bioavailability of Three Test Formulations and Comparison of Fasted, Fed, and Sprinkled Administration</i> , 22 Pharmacotherapy 11, 1405-1415 (2002)
1015	U.S. Patent No. 4,728,512
1016	U.S. Patent No. 5,326,570

1017	U.S. Patent No. 8,313,776
1018	U.S. Patent No. 6,555,136
1019	U.S. Patent No. 6,322,819
1020	U.S. Food and Drug Administration, Clinical Pharmacology and Biopharmaceutics Review, Application No. 21-303/S-001
1021	ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, ADDERALL XR®, <a href="https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm">https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm</a> . (last visited Aug. 25, 2017)
1022	THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 62-83 (Alfred Goodman Gilman et al. eds., 8th ed. 1990)
1023	U.S. Patent Application Publication No. US2004/0059002
1024	Agyilirah, G.A. and Banker, G.S., POLYMERS FOR CONTROLLED DRUG DELIVERY 39-66 (Peter J. Tarcha ed., 1991)
1025	Walter G. Chambliss, "The forgotten dosage form: enteric-coated tablets," <i>Pharmaceutical Technology</i> , 7: 124-132, 138-140 (1983)
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1033	Susan B. Clausen et al., <i>Single- and Multiple-Dose Pharmacokinetics of an Oral Mixed Amphetamine Salts Extended-Release Formulation in Adults</i> , 10 CNS Spectrums 12 (Suppl 20), 6 (2005)
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1035	WO 98/27967
1036	Pltff.'s Reply Claim Construction Brief, <i>Shire LLC et al. v. Abhai, LLC</i> , 1:15-cv-13909-WGY (D. Mass. July 21, 2016), D.I. 73
1037	James T. McCracken et al., <i>J. Am. Acad. Child Adoles. Psych.</i> (2003)
1038	Clive G. Wilson, GASTROINTESTINAL TRANSIT AND DRUG ABSORPTION, in DRUGS AND THE PHARMACEUTICAL SCIENCE: ORAL DRUG ABSORPTION

	PREDICTION AND ASSESSMENT (Jennifer Dressman & Hans Lennernäs, Vol. 106,2000.)
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1045	Declaration of James McCracken, M.D.
1046	POLLI DEPOSITION TRANSCRIPT (January 17, 2019)
1047	Polli Deposition Exhibit 100, “Clinical Pharmacology/Biopharmaceutics Review” for Adderall XR (FDA April 2007).
1048	Polli Deposition Exhibit 101, U.S. Patent No. RE41,148
1049	FDA Review of Chemistry, Manufacturing, and Controls for Adderall XR (2000)
1050	FDA Approvable Letter for Mydayis (2007)
1051	FDA Summary Review for Mydayis (2017)
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1053	James et al., “Double-Blind, Placebo-Controlled Study of Single-Dose Amphetamine Formulations in ADHD,” <i>J. Am. Acad. Child Adolesc. Psychiatry</i> , 40:11 (November 2001)
1054	Dexedrine® Spansule® Sustained Release Product Label 2007
1055	Dyanavel XR® Product Label (2017)
1056	Adzenys ER® Product Label (2017)
1057	McGough et al., “Pharmacokinetics of SLI381 (ADDERALL XR), an Extended-Release Formulation of Adderall,” <i>J. Am. Acad. Child Adolesc. Psychiatry</i> , 42:6 (June 2003)
1058	Corrected Declaration of James McCracken, M.D., Feb. 26, 2019

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