

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

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

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UPDATED EXHIBIT LIST

1001	U.S. Patent No. 9,173,857 (the “857 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®, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm . (last visited Aug. 16, 2017)
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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)
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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®, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm . (last visited Aug. 25, 2017)
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1027	REMINGTON THE SCIENCE AND PRACTICE OF PHARMACY (Limmer, 20 th ed., 2000)
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1038	Clive G. Wilson, GASTROINTESTINAL TRANSIT AND DRUG ABSORPTION, in DRUGS AND THE PHARMACEUTICAL SCIENCE: ORAL DRUG ABSORPTION

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1046	POLLI DEPOSITION TRANSCRIPT (January 17, 2019)
1047	Polli Deposition Exhibit 100, “Clinical Pharmacology/Biopharmaceutics Review” for Adderall XR (FDA April 2007).
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1055	Dyanavel XR® Product Label (2017)
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