### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE PATENT TRIAL AND APPEAL BOARD

## KVK-TECH, INC.,

Petitioner,

v.

SHIRE LLC,

Patent Owner.

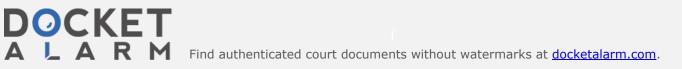
Case IPR2018-00293 US Patent No. 9,173,857

# PATENT OWNER RESPONSE

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IPR2018-00293 Patent Owner's Response

# **LIST OF EXHIBITS**

<ul> <li>DECLARATION OF BERNHARDT L. TROUT, Ph.D. (with CV)</li> <li>DECLARATION OF SARA ROSENBAUM, Ph.D. (with CV)</li> <li>DECLARATION OF SARA ROSENBAUM, Ph.D. (with CV)</li> <li>FDA Orange Book Listing for MYDAYIS® (NDA N022063)</li> <li>MYDAYIS® FDA Label (06-2017)</li> <li>MYDAYIS® FDA Label (06-2017)</li> <li>MYDAYIS® Website Pages</li> <li>Moto, U.S. Patent No. 5,229,131</li> <li>Mehta, U.S. Patent No. 5,837,284</li> <li>BR2017-00011 Decision Denying Institution (RE41, 148 (300 Patent)</li> <li>Excerpts from Merck, 11th Ed</li> <li>Ansel, Popovich &amp; Allen 6th, Ch. 3-5 (1995)</li> <li>Sonsalia, Remington Ch. 74, - CNS Stimulants (1995)</li> <li>Robinson, Remington, Ch. 94 - Sustained Release (1995)</li> <li>Porter, Remington, Ch. 93 - Coating (1995)</li> <li>Porter, Remington, Ch. 53 - Bioequivalence (2000)</li> <li>Stempel, 7th Ed Dispensing of Medication (1971)</li> <li>USP 23 NF 18 1995 - Excerpts (1955)</li> <li>USP 23 NF 18 1995 - Excerpts (1955)</li> <li>Patrick, Human Psychopharmacology, 12:527-546 (1997)</li> <li>Spencer, Arch Gen Psych, 58:775-78 (2001 Aug)</li> <li>Lehninger, Principles of Biochemistry, Excerpt (1993)</li> <li>Benet, Toxicologic Pathology, 23:115-123 (1995)</li> <li>Shargel, Applied Bio &amp; Pharmacokinetics, Ch. 2, 10 (1999)</li> <li>Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.5 (1991)</li> <li>Chiao, Remington, Ch. 94 - Sustained Release (1995)</li> <li>Winters, Basic Clinical Pharmacokinetics (1994)</li> <li>Winters, Basic Clinical Pharmacokinetics (1994)</li> <li>Rowland, Clinical Pharmacokinetics (1994)</li> </ul>					
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<ul> <li>2016 Stempel, 7th Ed Dispensing of Medication (1971)</li> <li>2017 USP 23 NF 18 - Uniformity Sec. 905 (1955)</li> <li>2018 USP 23 NF 18 1995 - Excerpts (1955)</li> <li>2019 Patrick, Human Psychopharmacology, 12:527-546 (1997)</li> <li>2020 Spencer, Arch Gen Psych, 58:775-78 (2001 Aug)</li> <li>2021 Lehninger, Principles of Biochemistry, Excerpt (1993)</li> <li>2022 Benet, Toxicologic Pathology, 23:115-123 (1995)</li> <li>2023 Shargel, Applied Bio &amp; Pharmacokinetics, Ch. 2, 10 (1999)</li> <li>2024 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.1 (1991)</li> <li>2025 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.5 (1991)</li> <li>2026 Chiao, Remington, Ch. 94 – Sustained Release (1995)</li> <li>2027 Hinsvark, J. Pharmacokin. Biopharm., 1:319-328 (1973)</li> <li>2028 Benet, Transplantation Proc., 31 (Suppl 3A), 7S-9S (1999)</li> <li>2029 Winters, Basic Clinical Pharmacokinetics (1994)</li> </ul>	2014	Franz, Remington Vol. II, Ch. 57 - Sympathomimetic Drugs (1995)			
<ul> <li>2017 USP 23 NF 18 - Uniformity Sec. 905 (1955)</li> <li>2018 USP 23 NF 18 1995 - Excerpts (1955)</li> <li>2019 Patrick, Human Psychopharmacology, 12:527-546 (1997)</li> <li>2020 Spencer, Arch Gen Psych, 58:775-78 (2001 Aug)</li> <li>2021 Lehninger, Principles of Biochemistry, Excerpt (1993)</li> <li>2022 Benet, Toxicologic Pathology, 23:115-123 (1995)</li> <li>2023 Shargel, Applied Bio &amp; Pharmacokinetics, Ch. 2, 10 (1999)</li> <li>2024 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.1 (1991)</li> <li>2025 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.5 (1991)</li> <li>2026 Chiao, Remington, Ch. 94 – Sustained Release (1995)</li> <li>2027 Hinsvark, J. Pharmacokin. Biopharm., 1:319-328 (1973)</li> <li>2028 Benet, Transplantation Proc., 31 (Suppl 3A), 7S-9S (1999)</li> <li>2029 Winters, Basic Clinical Pharmacokinetics (1994)</li> </ul>	2015	Malinowsi, Remington, Ch. 53 – Bioequivalence (2000)			
<ul> <li>2018 USP 23 NF 18 1995 - Excerpts (1955)</li> <li>2019 Patrick, Human Psychopharmacology, 12:527-546 (1997)</li> <li>2020 Spencer, Arch Gen Psych, 58:775-78 (2001 Aug)</li> <li>2021 Lehninger, Principles of Biochemistry, Excerpt (1993)</li> <li>2022 Benet, Toxicologic Pathology, 23:115-123 (1995)</li> <li>2023 Shargel, Applied Bio &amp; Pharmacokinetics, Ch. 2, 10 (1999)</li> <li>2024 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.1 (1991)</li> <li>2025 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.5 (1991)</li> <li>2026 Chiao, Remington, Ch. 94 – Sustained Release (1995)</li> <li>2027 Hinsvark, J. Pharmacokin. Biopharm., 1:319-328 (1973)</li> <li>2028 Benet, Transplantation Proc., 31 (Suppl 3A), 7S-9S (1999)</li> <li>2029 Winters, Basic Clinical Pharmacokinetics (1994)</li> </ul>	2016	Stempel, 7th Ed Dispensing of Medication (1971)			
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<ul> <li>2023 Shargel, Applied Bio &amp; Pharmacokinetics, Ch. 2, 10 (1999)</li> <li>2024 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.1 (1991)</li> <li>2025 Gibaldi, Biopharmaceutics &amp; Clinical Pharmacokinetics, Ch.5 (1991)</li> <li>2026 Chiao, Remington, Ch. 94 – Sustained Release (1995)</li> <li>2027 Hinsvark, J. Pharmacokin. Biopharm., 1:319-328 (1973)</li> <li>2028 Benet, Transplantation Proc., 31 (Suppl 3A), 7S-9S (1999)</li> <li>2029 Winters, Basic Clinical Pharmacokinetics (1994)</li> </ul>	2021	Lehninger, Principles of Biochemistry, Excerpt (1993)			
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2029 Winters, Basic Clinical Pharmacokinetics (1994)	2027	Hinsvark, J. Pharmacokin. Biopharm., 1:319-328 (1973)			
	2028	Benet, Transplantation Proc., 31 (Suppl 3A), 7S-9S (1999)			
2030 Rowland, Clinical Pharmacokinetics 2d (1989)	2029	Winters, Basic Clinical Pharmacokinetics (1994)			
	2030	Rowland, Clinical Pharmacokinetics 2d (1989)			

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