

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner

v.

ALKERMES PHARMA IRELAND LIMITED,
Patent Owner

Case IPR2018-00943
Patent 7,919,499

Patent Owner's Current List of Exhibits

LIST OF EXHIBITS

| Exhibit No. | Description | Previously Submitted |
|--------------------|--|-----------------------------|
| 2001 | April 13, 2006 Vivitrol® Approval Letter for NDA No. 21897 (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021897_toc_Vivitrol.cfm) | X |
| 2002 | October 12, 2010 Vivitrol® Approval Letter (New Indication) for NDA No. 21897 (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021897_toc_Vivitrol.cfm) | X |
| 2003 | Vivitrol® Prescribing Information, revised 12/2015 (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021897s029lbl.pdf) | X |
| 2004 | “Drug Facts: Treatment Approaches for Drug Addiction” published by the National Institute on Drug Abuse (https://www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction (revised January 2018)) | X |
| 2005 | “Overdose Death Rates,” published by the National Institute on Drug Abuse (https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates) | X |
| 2006 | “Principles of Drug Abuse Treatment for Criminal Justice Populations A Research Guide,” published by the National Institute on Drug Abuse, NIH Publication No. 11-5316, (revised April 2014) (https://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/principles) | X |
| 2007 | November 21, 2005 Clinical Pharmacology and Biopharmaceutics Review for NDA No. 21897 (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021897_toc_Vivitrol.cfm) | X |

LIST OF EXHIBITS

(continued)

| Exhibit No. | Description | Previously Submitted |
|--------------------|---|-----------------------------|
| 2008 | “Incorporating Alcohol Pharmacotherapies Into Medical Practice, Treatment Improvement Protocol (TIP) Series 49 (2009) (‘TIP 49’),” published by Center for Substance Abuse Treatment (https://store.samhsa.gov/shin/content/SMA13-4380/SMA13-4380.pdf) | X |
| 2009 | Leavitt, S.B., “Evidence for the Efficacy of Naltrexone in the Treatment of Alcohol Dependence (Alcoholism),” published by Addiction Treatment Forum, March 2002, (https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone) | X |
| 2010 | Bartus et al., “Vivitrex [®] , in Injectable, Extended-Release Formulation of Naltrexone, Provides Pharmacokinetic and Pharmacodynamic Evidence of Efficacy for 1 Month in Rats,” <i>Neuropsychopharmacology</i> , 28, 1973-1982 (2003) | X |
| 2011 | July 11, 2011 Alkermes Comment to Docket No. FDA-2007-D-0369, Draft Guidance for Industry Describing Product-Specific Bioequivalence Recommendations for Naltrexone Extended Release Suspension/Intramuscular (https://www.regulations.gov/document?D=FDA-2007-D-0369-0061) | X |
| 2012 | U.S. Patent No. 7,919,499 | X |
| 2013 | June 2, 2014 Alkermes Comment to Docket No. FDA-2007-D-0369, Draft Guidance for Industry Describing Product-Specific Bioequivalence Recommendations for Naltrexone Extended Release Suspension/Intramuscular (https://www.regulations.gov/document?D=FDA-2007-D-0369-0291) | X |

LIST OF EXHIBITS

(continued)

| Exhibit No. | Description | Previously Submitted |
|--------------------|--|-----------------------------|
| 2014 | Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Patent Listing for Vivitrol [®] (https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=021897&Appl_type=N) | X |
| 2015 | “Practice Guidelines for the Pharmacological Treatment of Patients with Alcohol Use Disorder,” published by The American Psychiatric Association (January 2018) (https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9781615371969) | X |
| 2016 | December 23, 2005 Division Director Approvable Memo for NDA No. 21897 (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021897_toc_Vivitrol.cfm) | X |
| 2017 | Vereby et al., “Naltrexone: disposition, metabolism, and effects after acute and chronic dosing,” <i>Clinical Pharmacology & Therapeutics</i> , 20:315-329 (1976) | X |
| 2018 | “Medication for the Treatment of Alcohol Use Disorder: A Brief Guide,” published by National Institute on Alcohol Abuse and Alcoholism, Substance Abuse and Mental Health Services Administration (SAMHSA) (2015) (https://store.samhsa.gov/shin/content/SMA15-4907/SMA15-4907.pdf) | X |
| 2019 | American Psychiatric Association, “DSM-5 Frequently Asked Questions,” (https://www.psychiatry.org/psychiatrists/practice/dsm/feedback-and-questions/frequently-asked-questions) | X |

LIST OF EXHIBITS

(continued)

| Exhibit No. | Description | Previously Submitted |
|--------------------|---|-----------------------------|
| 2020 | “An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People with Opioid Dependence,” published by the Substance Abuse and Mental Health Services Administration (SAMHSA) (2012) (https://www.integration.samhsa.gov/Intro_To_Injectable_Naltrexone.pdf) | X |
| 2021 | Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for Alkermes PLC, Form 10-K, for the fiscal year ended December 31, 2017 (http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkzNjEzfnNoaWxkSUQ9NDA0ODMwfFR5cGU9MQ==&t=1) | X |
| 2022 | Declaration of J. M. O’Malley | X |
| 2023 | Yun et al., “Controlled Drug Delivery: Historical perspective for the next generation,” <i>Journal of Controlled Release</i> , 219 2–7 (2015) | |
| 2024 | Kleber et al., “Nontolerance to the Opioid Antagonism of Naltrexone,” <i>Biological Psychiatry</i> , 20:66–72 (1985) | |
| 2025 | Transcription of January 23, 2019 Deposition of Kinam Park, Ph.D. | |
| 2026 | Guidance for Industry. Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA. FDA CDER (December 2013) | |
| 2027 | Reserved | |
| 2028 | Meyer et al., “Bioequivalence, Dose-Proportionality, and Pharmacokinetics of Naltrexone after Oral Administration,” <i>Journal of Clinical Psychiatry</i> , 45:9 (Sept. 1984) | |
| 2029 | Reserved | |

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