Paper No. _____
Filed: June 21, 2019

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

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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

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LIST OF EXHIBITS
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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 Parmacokinetic and Pharmacodynamic Evidence of Efficacy for 1 Month in Rats," Neuropsychopharmacology, 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

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LIST OF EXHIBITS
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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," Clinical Pharmacology & Therapeutics, 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

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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=UGFyZW50SUQ9NjkzNjEzfENoaWxkSUQ9NDA0ODMwfFR5cGU9MQ==&t=1)	X
2022	Declaration of J. M. O'Malley	X
2023	Yun et al., "Controlled Drug Delivery: Historical perspective for the next generation," Journal of Controlled Release, 219 2–7 (2015)	X
2024	Kleber et al., "Nontolerance to the Opioid Antagonism of Naltrexone," Biological Psychiatry, 20:66–72 (1985)	X
2025	Transcription of January 23, 2019 Deposition of Kinam Park, Ph.D.	X
2026	Guidance for Industry. Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA. FDA CDER (December 2013)	X
2027	Reserved	
2028	Meyer et al., "Bioequivalence, Dose-Proportionality, and Pharmacokinetics of Naltrexone after Oral Administration," Journal of Clinical Psychiatry, 45:9 (Sept. 1984)	X
2029	Reserved	

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