

Filed on behalf of Petitioner

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.
Petitioner

v.

ALKERMES PHARMA IRELAND LIMITED
Patent Owner

Case No. IPR2025-00514
Patent 7,919,499

PETITIONER'S EXHIBIT LIST

Pursuant to 37 C.F.R. §42.63(e), below is a current listing of Petitioner's exhibits.

EXHIBIT	DESCRIPTION
1001	U.S. Patent No. 7,919,499, issued on April 5, 2011 to E. Ehrich ("the '499 Patent")
1002	File History of U.S. Patent Application No. 11/083,167, filed on March 17, 2005 ("the '167 Application")
1003	U.S. Provisional Application No. 60/564,542, filed on April 22, 2004
1004	Sandra D. Comer <i>et al.</i> , <i>Depot naltrexone: long-lasting antagonism of the effects of heroin in humans</i> , 159(4) <i>Psychopharmacology</i> (Feb. 2002), at 351-360
1005	U.S. Patent No. 7,157,102, issued on January 2, 2007 to E. Nuwayser ("the '102 Patent" or "Nuwayser")
1006	G. Rubio <i>et al.</i> , <i>Naltrexone Versus Acamprosate: One Year Follow-Up of Alcohol Dependence Treatment</i> , 36(5) <i>Alcohol & Alcoholism</i> (2001), at 419-425
1007	U.S. Patent No. 6,264,987, issued on July 24, 2001 to S. Wright <i>et al.</i> ("the '987 Patent" or "Wright")
1008	Henry R. Kranzler <i>et al.</i> , <i>Sustained-Release Naltrexone for Alcoholism Treatment: A Preliminary Study</i> , 22(5) <i>Alcoholism: Clinical and Experimental Research</i> (Aug. 1998), at 1074-79
1009	U.S. Patent No. 6,306,425, issued on October 23, 2001 to T. Tice <i>et al.</i> ("Tice")
1010	C.N. Chiang <i>et al.</i> , <i>Clinical Evaluation of A Naltrexone Sustained-Release Preparation</i> , 16 <i>Drug & Alcohol Dependence</i> (1985), at 1-8

EXHIBIT	DESCRIPTION
1011	T.N. Alim <i>et al.</i> , <i>Tolerability Study of A Depot Form of Naltrexone Substance Abusers</i> , Problems of Drug Dependence, 1994: Proceedings of the 56th Annual Scientific Meeting, The College on Problems of Drug Dependence, Inc., Vol. II: Abstracts, National Institute on Drug Abuse Research Monograph 153 (1995), at 253
1012	U.S. Securities and Exchange Commission, <i>FORM 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended March 31, 2002</i> . Alkermes, Inc. (July 2002)
1013	U.S. Trademark Application Serial Number 76/271,990, Allegation of Use of a Mark & specimen of the mark as used in commerce, Aug. 15, 2002 (“Vivitrex Specimen” or “Specimen”)
1014	S.J. Heishman <i>et al.</i> , <i>Safety And Pharmacokinetics of a New Formulation of Depot Naltrexone</i> , Problems of Drug Dependence, 1993: Proceedings of the 55th Annual Scientific Meeting, The College on Problems of Drug Dependence, Inc., Volume II: Abstracts, National Institute on Drug Abuse Research Monograph 141 (1994)
1015	U.S. Patent and Trademark Office, 1265(2) <i>Official Gazette of the United States Patent and Trademark Office</i> , Trademarks, Dec. 10, 2002
1016	Stewart B. Leavitt, PhD, ed., <i>Evidence for the Efficacy of Naltrexone in the Treatment of Alcohol Dependence (Alcoholism)</i> , Addition Treatment Forum Naltrexone Clinical Update (2002 Clinco Communications, Inc.), at 1-8
1017	ReVia, <i>Physicians’ Desk Reference</i> 936-938 (53rd ed. 1999) (“PDR”)
1018	U.S. Patent No. 4,882,335, issued on November 21, 1989 to J. Sinclair (“Sinclair”)

EXHIBIT	DESCRIPTION
1019	<i>Chiang et al., Kinetics of a naltrexone sustained-release preparation</i> , 36(5) Clin. Pharmacol. Ther. (Nov. 1984), at 704-08 “Kinetic of a naltrexone sustained-release preparation.”
1020	<i>Reuning et al., Pharmacokinetic Quantitation of Naltrexone Release From Several Sustained-Release Delivery Systems</i> , Naltrexone: Research Monograph 28 (R. E. Willette and G. Barnett, eds. National Institute on Drug Abuse 1980)
1021	Appeal Brief, Application No. 13/871,534, Oct. 19, 2015
1022	<i>Not assigned</i>
1023	<i>Not assigned</i>
1024	<i>Not assigned</i>
1025	<i>Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations</i> , Product Details for NDA 018932, REVIA (NALTREXONE HYDROCHLORIDE) 50MG
1026	<i>Not assigned</i>
1027	<i>Not assigned</i>
1028	<i>Not assigned</i>
1029	TREXAN™, <i>Physicians’ Desk Reference</i> 936-938 (46 ed. 1992) (“PDR”), at 937-939
1030	<i>Trademark Manual of Examining Procedure (TMEP)</i> (3rd ed. Jan. 2002), at 100-5 to 100-11
1031	<i>Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations</i> , NALTREXONE (VIVITROL) FOR SUSPENSION, EXTENDED RELEASE 380MG/VIAL
1032	<i>Not assigned</i>

EXHIBIT	DESCRIPTION
1033	Bertil Abrahamsson and Anna-Lena Ungell, <i>Biopharmaceutical support in formulation development: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form</i> , Pharmaceutical Preformulation and Formulation (Mark Gibson ed., Interpharm/CRC) (2004), 239-291, at 262
1034	Guidance for Industry. Bioavailability and Bioequivalence Studies for Orally Administered Products—General Considerations. FDA CDER (March 2003)
1035	Riddle <i>et al.</i> , <i>Anxiolytics, adrenergic agents, and naltrexone</i> , 38(5) J. Am. Acad. Child. Adolesc. Psychiatry, 546-556 (May 1999)
1036	<i>Not assigned</i>
1037	Rothenberg <i>et al.</i> , <i>Behavioral naltrexone therapy: an integrated treatment for opiate dependence</i> , 23 J. of Substance Abuse Treatment (2002), at 351-360
1038	B.A. Johnson, <i>Naltrexone long-acting formulation in the treatment of alcohol dependence</i> , 3(5) Ther. Clin. Risk Manag., 741-749 (2007), at 742.
1039	Food and Drug Administration, Guidance for Industry, <i>Exposure-response relationships – study design, data analysis, and regulatory applications</i> , FDA CDER (April 2003)
1040	Food and Drug Administration, Guidance for Industry, <i>Statistical approaches to establishing bioequivalence</i> , FDA CDER (April 2003)
1041	Schenker <i>et al.</i> , <i>Antecedent liver disease and drug toxicity</i> , 31 J. of Hepatology 1098-1105 (1999)
1042	U.S. Patent No. 3,332,950, issued on July 25, 1997 to H. Blumberg
1043	<i>Not assigned</i>

EXHIBIT	DESCRIPTION
1044	<i>Not assigned</i>
1045	<i>Not assigned</i>
1046	Declaration of Thomas Dowling
1047	<i>Curriculum Vitae</i> of Thomas Dowling
1048	Declaration of Jason Schiffman
1049	<i>Curriculum Vitae</i> of Jason Schiffman
1050	Declaration of June Munford
1051	<i>Curriculum Vitae</i> of June Munford
1052	Resume of Mike Ramstack, as obtained from LinkedIn
1053	Resume of Richard Reuning, as obtained from LinkedIn
1054	Resume of Steve Wright, as obtained from LinkedIn
1055	Declaration Under 37 C.F.R. §1.132 of Elliot Ehrich filed in Application No. Serial No. 11/083,167
1056	S. Hamilton <i>et al.</i> , <i>Pharmacokinetics and Pharmacodynamics of Hyaluronan Infused Healthy Human Volunteers</i> , 3 The Open Drug Metabolism Journal 43-55 (2009)
1057	Trademark Registration No. 2,443,435 (Depotrex)
1058	Institution Decision entered November 7, 2018 (Paper 8) in IPR2018-00943
1059	Termination Decision entered July 31, 2019 (Paper 29) in IPR2018-00943
1060	Patent Owner's Response, filed February 7, 2019 (Paper 14) in IPR2018-00943

EXHIBIT	DESCRIPTION
1061	U.S. Patent No. 5,210,083, issued on May 11, 1993 to R. Pfirrmann
1062	U.S. Patent No. 5,234,906, issued on August 10, 1993 to A. Young and G. Cooper
1063	U.S. Patent No. 6,677,320, issued on January 13, 2004 to A. Diederich <i>et al.</i>
1064	U.S. Patent No. 6,120,787, issued on September 19, 2000 to N.O. Gustafsson <i>et al.</i>
1065	U.S. Patent Publication No. 2003/0211167, published on November 13, 2003
1066	U.S. Patent No. 6,455,526, issued on September 24, 2002 to R. Kohn <i>et al.</i>
1067	Petition for Inter Partes Review of U.S. Patent No. 7,919,499, IPR2018-00943, filed on April 20, 2018
1068	Stipulated Consent Judgment and Injunction, filed August 30, 2023 in <i>Alkermes v. Teva Pharmaceuticals</i> , Civ. Action No. 2:20-cv-12470 (DNJ)
1069	United States Patent and Trademark Office – <i>Ex Parte</i> Reexamination Filing Data available at https://www.uspto.gov/sites/default/files/documents/ex_parte_historical_stats_.pdf (retrieved June 6, 2025)
1070	United States Patent and Trademark Office – Appeal Statistics (April 30, 2025) available at https://www.uspto.gov/sites/default/files/documents/fy2025_appeal_stats_april2025.pdf (retrieved June 6, 2025)

Date: June 6, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 6th day of June, 2025, a true and correct copy of the foregoing **PETITIONER'S EXHIBIT LIST (June 6, 2025) and EXHIBITS 1069-1070** are being served by electronic mail on counsel for Patent Owner as follows:

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