

Filed On Behalf Of:

Alkermes Pharma Ireland Limited and
Alkermes Controlled Therapeutics, Inc.

By:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**LUYE PHARMA GROUP LTD., LUYE PHARMA(USA) LTD.,
SHANDONG LUYE PHARMACEUTICAL CO., LTD., and NANJING
LUYE PHARMACEUTICAL CO., LTD.,**

Petitioners,

v.

**ALKERMES PHARMA IRELAND LTD and ALKERMES CONTROLLED
THERAPEUTICS, INC.,
Patent Owners.**

Case IPR2016-01096
U.S. Patent No. 6,667,061

PATENT OWNERS' EXHIBIT LIST 4

EXHIBIT LIST 4

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner Alkermes Pharma Ireland Limited (“Alkermes”) respectfully submits the following current exhibit list.

Alkermes Exhibit No.	Description
2001	Patrick P. DeLuca & James C. Boylan, <i>Chapter 5: Formulation of Small Volume Parenterals</i> , in PHARMACEUTICAL DOSAGE FORMS: PARENTERAL MEDICATIONS 173-248 (Kenneth E. Avis et al. eds., 2 nd ed. 1992).
2002	U.S. PHARMACOPEIA xxii-xxx (1995 ed.).
2003	EUROPEAN PHARMACOPEIA iii-vi, 1-10 (3rd ed. 1997).
2004	Intentionally Left Blank
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2008	S.L. Phillips et al., <i>Viscosity of NaCl and other solutions up to 350°C and 50 MPa pressures</i> , U.S. DEPT. ENERGY (1980).
2009	J. R. Nixon & B. P. S. Chawla, <i>Viscosity and stability relations of the system ascorbic acid: water: polysorbate 20</i> , 17 J. PHARMACY & PHARMACOLOGY 558-65 (1965).
2010	February 2, 2017 Declaration in Support of Patent Owners’ Motion for Pro Hac Vice Admission of Ha Kung Wong
2011	February 2, 2017 Declaration in Support of Patent Owners’ Motion for Pro Hac Vice Admission of Christina Schwarz
2012	February 2, 2017 Declaration in Support of Patent Owners’ Motion for Pro Hac Vice Admission of Melinda R. Roberts
2013	February 2, 2017 Declaration in Support of Patent Owners’ Motion for Pro Hac Vice Admission of Una Fan

Alkermes Exhibit No.	Description
2014	March 8, 2017 Declaration of Dr. Cory Berkland.
2015	Curriculum Vitae of Dr. Cory Berkland.
2016	February 22, 2017 Deposition Testimony of Dr. Patrick DeLuca.
2017	K.E. Avis, <i>Chapter 21: Particle Phenomena and Coarse Dispersions</i> , in REMINGTON'S PHARM. SCI. 301-329 (A.R. Gennaro et al. eds., 17 th ed. 1985).
2018	K.E. Avis, <i>Chapter 68: Particle Phenomena and Coarse Dispersions</i> , in REMINGTON'S PHARM. SCI. 1306 (A.R. Gennaro et al. eds., 17 th ed. 1985).
2019	U.S. FOOD AND DRUG ADMIN., Medical Review, Risperdal [®] Consta [®] Long-Acting Injection NDA No. 21-346, approved Oct. 29, 2003.
2020	S. D'Souza, J.A. Faraj, S. Giovagnoli, & P.P. DeLuca, <i>Dev. of Risperidone PLGA Microspheres</i> , 2014 J. DRUG DELIVERY Art. ID 420624 (2014).
2021	Y. Capan, G. Jiang, S. Giovagnoli, K.H. Na, & P.P. DeLuca, <i>Preparation and Characterization of Poly(D,L-lactide-co-glycolide) Microspheres for Controlled Release of Human Growth Hormone</i> , 4(2) AAPS PHARMSciTECH Art. 28 (2003).
2022	K.W. Burton, M. Shameem, B.C. Thanoo, & P.P. DeLuca, <i>Extended release peptide delivery systems through the use of PLGA microsphere combinations</i> , 11(7) J. BIOMATERIALS SCI. POLYMER ED. 715-29 (2000).
2023	H.B. Ravivarapu, H. Lee, & P.P. DeLuca, <i>Enhancing Initial Release of Peptide from Poly(d,l-lactide-co-glycolide) (PLGA) Microspheres by Addition of a Porosigen and Increasing Drug Load</i> , 5(2) PHARM. DEV. & TECH. 287-96 (2000).
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2025	J.W. Kostanski, B.A. Dani, G.A. Reynolds, C.Y. Bowers, & P.P. DeLuca, <i>Evaluation of Orntide Microspheres in a Rat Animal Model and Correlation to In Vitro Release Profiles</i> , 1(4) AAPS PHARMSciTECH Art. 27 (2000).

Alkermes Exhibit No.	Description
2026	B.H. Woo, J.W. Kostanski, S. Gebrekidan, B.A. Dani, B.C. Thanoo, & P.P. DeLuca, <i>Preparation, characterization and in vivo evaluation of 120-day poly(D,L-lactide) leuprolide microspheres</i> , 75 J. CONTROLLED RELEASE 307-15 (2001).
2027	B.A. Dani & P.P. DeLuca, <i>Preparation, Characterization, and In Vivo Evaluation of Salmon Calcitonin Microspheres</i> , 2(4) AAPS PHARMSciTECH Art. 22 (2001).
2028	B.H. Woo, K.H. Na, B.A. Dani, G. Jiang, B.C. Thanoo, & P.P. DeLuca, <i>In Vitro Characterization and in Vivo Testosterone Suppression of 6-Month Release Poly(D,L-Lactide) Leuprolide Microspheres</i> , 19(4) PHARM. RES. 546-50 (2002).
2029	G. Jiang, W. Qiu, & P.P. DeLuca, <i>Preparation and in Vitro/in Vivo Evaluation of Insulin-Loaded Poly(Acryloyl-Hydroxyethyl Starch)-PLGA Composite Microspheres</i> , 20(3) PHARM. RES. 452-59 (2003).
2030	P.P. DeLuca et al., Patent App. Pub. No. US 2007/0122487.
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2033	P.P. DeLuca, <i>Chapter 32: Parenteral Products: Design and Optimization, Including Freeze Drying</i> , in TOPICS IN PHARM. SCI. 471-91 (D.J.A. Crommelin et al. eds., 1994).
2034	<i>Aqualon Sodium Carboxymethylcellulose: Physical and Chemical Properties</i> , AQUALON (1999).
2035	X.H. Yang & W.L. Zhu, <i>Viscosity properties of sodium carboxymethylcellulose solutions</i> , CELLULOSE 14(5):409-17 (2007).
2036	<i>Carboxymethylcellulose</i> , DOW CHEMICAL, available at http://www.dow.com/dowwolff/en/industrial_solutions/polymers/carboxymethylcellulose/ (last visited March 1, 2017).
2037	U. Florjancic et al., <i>Rheological Characterization of Aqueous Polysaccharide Mixtures Undergoing Shear</i> , CHEM. BIOCHEM. ENG. Q. 16(3): 105-18 (2002).

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2038	<i>Performance Specialties Reference Guide</i> , ASHLAND, available at http://www.brenntag.com/media/documents/bsi/product_data_sheets/material_science/ashland_polymers/performance_specialties_reference_guide.pdf (last visited Mar. 1, 2017).
2039	Specification Sheet-Sodium carboxymethyl cellulose-ultra low viscosity, SIGMA-ALDRICH, available at http://www.sigmaaldrich.com/catalog/DataSheetPage.do?brandKey=ALDRICH&symbol=360384 (last visited March 1, 2017).
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2044	S.I. Conceicao et al., <i>Influence of deagglomeration and carboxymethyl cellulose binders on rheological behaviour of kaolin suspensions</i> , APPLIED CLAY SCI. 23: 257-64 (2003).
2045	M. Bonferoni et al., <i>Influence of medium on dissolution-erosion behavior of Na carboxymethylcellulose and on viscoelastic properties of gels</i> , INT'L J. PHARM. 117: 41-48 (1995).
2046	P. Sebert et al., <i>Gamma irradiation of carboxymethylcellulose: technological and pharmaceutical aspects</i> , INT'L J. PHARM. 106: 103-08 (1994).
2047	J. Wang & P. Somasundaran, <i>Adsorption and conformation of carboxymethylcellulose at solid-liquid interfaces using spectroscopic, AFM and allied techniques</i> , J. COLLOID & INTERFACE SCI. 291: 75-83 (2005).
2048	Y.C.J. Wang, <i>Chapter 7: Parenteral Products of Peptides and Proteins</i> , in 1 PHARM. DOSAGE FORMS: PARENTERAL MEDICATIONS

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