Paper No. <u>34</u> Date Filed: March 8, 2017

#### Filed On Behalf Of:

Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc.

By:

DOCKET

Scott K. Reed sreed@fchs.com 212-218-2100

## 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 3

## EXHIBIT LIST 3

Pursuant to 37 C.F.R. § 42.63(e), Patent Owners Alkermes Pharma Ireland

Limited and Alkermes Controlled Therapeutics, Inc. ("Alkermes") respectfully

submit the following current exhibit list.

DOCKE.

RM

Δ

Alkermes	Description
No.	
2001	Patrick P. DeLuca & James C. Boylan, <i>Chapter 5: Formulation of</i> <i>Small Volume Parenterals</i> , <i>in</i> PHARMACEUTICAL DOSAGE FORMS:
	PARENTERAL MEDICATIONS 173-248 (Kenneth E. Avis et al. eds., 2 <sup>nd</sup> ed. 1992).
2002	U.S. PHARMACOPEIA xxii-xxx (1995 ed.).
2003	EUROPEAN PHARMACOPEIA iii-vi, 1-10 (3rd ed. 1997).
2004	Intentionally Left Blank
2005	Intentionally Left Blank
2006	Intentionally Left Blank
2007	Intentionally Left Blank
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

Alkermes	Description
Exhibit	
No.	
2013	February 2, 2017 Declaration in Support of Patent Owners' Motion for
	Pro Hac Vice Admission of Una Fan
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
2010	reordary 22, 2017 Deposition resumony of Dr. ratter Delaca.
2017	K.E. Avis, Chapter 21: Particle Phenomena and Coarse Dispersions,
	<i>in</i> REMINGTON'S PHARM. SCI. 301-329 (A.R. Gennaro et al. eds., 17 <sup>th</sup>
	ed. 1985).
2018	K.E. Avis, Chapter 68: Particle Phenomena and Coarse Dispersions,
	<i>in</i> REMINGTON'S PHARM. SCI. 1306 (A.R. Gennaro et al. eds., 17 <sup>th</sup> ed.
	1985).
2019	U.S. FOOD AND DRUG ADMIN., Medical Review, Risperdal <sup>®</sup> Consta <sup>®</sup>
	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</i>
	Risperidone PLGA Microspheres, 2014 J. DRUG DELIVERY Art. ID
2021	420024 (2014).
2021	Y. Capan, G. Jiang, S. Giovagnoli, K.H. Na, & P.P. DeLuca,
	Preparation and Characterization of Poly(D,L-lactide-co-glycollae)
	Microspheres for Controlled Release of Human Growin Hormone,
2022	4(2) AAFS FHARMSCITECH AIL 26 (2003). K W Purton M Shamaam P.C. Thanaa & P.P. Dal yaa <i>Ertandad</i>
2022	K. W. Durton, W. Shameeni, D.C. Thanoo, & F.F. DeLuca, Extended
	combinations 11(7) I BIOMATERIALS SCI POLYMER ED 715-29
	(2000)
2023	H B Ravivarapu H Lee & P P DeLuca Enhancing Initial Release of
	Peptide from Polv(d.l-lactide-co-glvcolide) (PLGA) Microspheres by
	Addition of a Porosigen and Increasing Drug Load, 5(2) PHARM. DEV.
	& ТЕСН. 287-96 (2000).
2024	H.B. Ravivarapu, K. Burton, & P.P. DeLuca, Polymer and
	microsphere blending to alter the release of a peptide from PLGA
	microspheres, 50 Eur. J. PHARM. & BIOPHARM. 263-70 (2000).
2025	J.W. Kostanski, B.A. Dani, G.A. Reynolds, C.Y. Bowers, & P.P.
	DeLuca, Evaluation of Orntide Microspheres in a Rat Animal Model

Alkermes	Description
Exhibit	
No.	
	and Correlation to In Vitro Release Profiles, 1(4) AAPS
	PHARMSCITECH Art. 27 (2000).
2026	B.H. Woo, J.W. Kostanski, S. Gebrekidan, B.A. Dani, B.C. Thanoo, &
	P.P. DeLuca, Preparation, characterization and in vivo evaluation of
	120-day poly(D,L-lactide) leuprolide microspheres, 75 J. CONTROLLED
	Release 307-15 (2001).
2027	B.A. Dani & P.P. DeLuca, Preparation, Characterization, and In Vivo
	Evaluation of Salmon Calcitonin Microspheres, 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, In Vitro Characterization and in Vivo Testosterone
	Suppression of 6-Month Release Poly(D,L-Lactide) Leuprolide
	<i>Microspheres</i> , 19(4) PHARM. RES. 546-50 (2002).
2029	G. Jiang, W. Qiu, & P.P. DeLuca, Preparation and in Vitro/in Vivo
	Evaluation of Insulin-Loaded Poly(Acryloyl-Hydroxyethyl Starch)-
2020	PLGA Composite Microspheres, 20(3) PHARM. RES. 452-59 (2003).
2030	P.P. DeLuca et al., Patent App. Pub. No. US 2007/0122487.
2021	S Dugginala & D.D. Dol was Phaslogical Changetonization of
2031	S. Duggilaia & F.F. DeLuca, <i>Kneologicul Churacierization of</i> Collulosic and Alginate Polymers, DDA I DUADM SCI & TECH 50(5):
	Centrosic una Alginale Folymers, FDA J. FHARM. SCI. & TECH. $50(5)$ .
2032	A R Hurwitz P P Del uca & H R Kostenbauder <i>Binding of Organic</i>
2032	Flectrolytes by a Nonionic Surface-Active Agent I PHARM SCI 52(9).
	893-97 (1963)
2033	P.P. DeLuca Chapter 32: Parenteral Products: Design and
2033	Optimization Including Freeze Drving in TOPICS IN PHARM SCI 471-
	91 (D.J.A. Crommelin et al. eds., 1994).
2034	Aqualon Sodium Carboxymethylcelluose: Physical and Chemical
	Properties, AOUALON (1999).
2035	X.H. Yang & W.L. Zhu, Viscosity properties of sodium
	carboxymethylcellulose solutions, CELLULOSE 14(5):409-17 (2007).
2036	Carboxymethylcellulose, DOW CHEMICAL, available at
	http://www.dow.com/dowwolff/en/industrial solutions/polymers/carb
	oxymethylcellulose/ (last visited March 1, 2017).
2037	U. Florjancic et al., Rheological Characterization of Aqueous
	Polysaccharide Mixtures Undergoing Shear, CHEM. BIOCHEM. ENG. Q.

Alkermes	Description
Exhibit	
N0.	$16(3) \cdot 105-18(2002)$
2038	Parformance Specialties Reference Guide ASHI AND available at
2030	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=A
	LDRICH&symbol=360384 (last visited March 1, 2017).
2040	Specification Sheet-Carboxymethylcellulose sodium-low viscosity,
	SPECTRUM CHEMICAL, available at
	https://www.spectrumchemical.com/MSDS/CA193-AGHS.pdf (last
0.11	visited March 1, 2017).
2041	U.S. FOOD AND DRUG ADMIN., Clinical Pharm. and Biopharm. Review,
	Risperdal <sup>®</sup> Consta <sup>®</sup> Long-Acting Injection NDA No. 21-346, approved
2042	Oct. 29, 2003. A Denchahana & K. Dakkour, Pheological properties of
2042	A. Benchavane & K. Bekkoul, <i>Kneological properties of</i>
	(CMC) solutions, 280 COLLOID FOLYMER SCI.
2043	I H Guo et al Pharmaceutical applications of naturally occurring
2045	water-soluble polymers PHARM SCI & TECH TODAY 1(6): 254-61
	(1998).
2044	S.I. Conceicao et al., <i>Influence of deagglomeration and carboxymethyl</i>
	cellulose binders on rheological behaviour of kaolin suspensions,
	APPLIED CLAY SCI. 23: 257-64 (2003).
2045	M. Bonferoni et al., Influence of medium on dissolution-erosion
	behavior of Na carboxymethylcellulose and on viscoelastic properties
	<i>of gels</i> , INT'L J. PHARM. 117: 41-48 (1995).
2046	P. Sebert et al., Gamma irradiation of carboxymethylcellulose:
	technological and pharmaceutical aspects, INT'L J. PHARM. 106: 103-
	08 (1994).
2047	J. Wang & P. Somasundaran, Adsorption and conformation of
	carboxymethylcellulose at solid-liquid interfaces using spectroscopic,
	AFM and allied techniques, J. COLLOID & INTERFACE SCI. 291: 75-83
	(2005).

# DOCKET



## Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

#### **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

