Paper No. 11

Date Filed: September 1, 2016

Filed On Behalf Of:

Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc.

By:

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 Patent 6,667,061

PATENT OWNERS' PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.107



TABLE OF CONTENTS

I.	INT	RODUCTION					
II.	BACKGROUND OF THE INVENTION						
	A.	The	Development of the '061 Patent	5			
	B.	The '061 Prosecution History					
III.	THE	E PERS	PERSON OF ORDINARY SKILL IN THE ART				
IV.	CLAIM CONSTRUCTION						
	A.	"Suspension" and "Fluid Phase of Said Suspension"					
	B.	"Viscosity"		10			
V.	LEC	AL STANDARDS					
VI.	PETITIONERS' ALLEGED UNPATENTABILITY GROUNDS ARE FATALLY FLAWED			14			
	A.	14					
		1.	The Teachings in Johnson and Gustafsson that Petitioners Rely On Do Not Relate to the Fluid Phase of a Suspension	15			
		2.	Neither Johnson nor Gustafsson Specify the Viscosity or the Temperature at which Viscosity Should be Measured	16			
		3.	Petitioners' Reliance on the Tracy Declaration is Flawed	19			
	B.	Gustafsson Does Not Disclose or Teach Claimed Microparticle Limitation		2.2			



Petitioners Have Failed to Show a POSA Would Have Combined Johnson and Kino With a Reasonable Expectation of Success	
•	25
a. Petitioners Offer Only Conclusory and Vague Statements About Motivation to Combine and Likelihood of Success	
b. A POSA Would Not Have Combined Johnson and Kino	28
c. A POSA Would Not Have Had a Reasonable Expectation of Success at Arriving at the Claimed Invention by Combining Johnson and Kino	31
2. Petitioners Have Failed to Show a POSA Would Have Combined Gustafsson, Ramstack and the Handbook with a Reasonable Expectation of Success	32
a. Petitioners Offer Only Conclusory and Vague Statements About Motivation to Combine and Likelihood of Success	33
b. A POSA Would Not Have Combined Gustafsson, Ramstack and the Handbook	35
c. A POSA Would Not Have Had a Reasonable Expectation of Success in Combining Gustafsson, Ramstack and the Handbook	38
VII. PETITIONERS FAIL TO REBUT THE OBJECTIVE EVIDENCE OF NONOBVIOUSNESS	40
VIII. CONCLUSION	42



TABLE OF AUTHORITIES

Cases

Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341 (Fed. Cir. 2010)	22
Apple, Inc. v. Int'l Trade Comm'n, 725 F.3d 1356 (Fed. Cir. 2013)	41
Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech., 709 F.3d 1348 (Fed. Cir. 2013)	11
Continental Can Co. U.S.A. v. Monsanto Co., 948 F.2d 1264 (Fed. Cir. 1991)	17
Crocs v. U.S. Int'l Trade Comm'n, 598 F.3d 1294 (Fed. Cir. 2010)	31, 39
In re GPAC Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995)	42
<i>In re Montgomery</i> , 677 F.3d 1375 (Fed. Cir. 2012)	13, 18
<i>In re Soni</i> , 554 F.3d 746 (Fed. Cir. 1995)	13
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)	12, 13, 23
Leo Pharm. Prods., Ltd. v. Rea, 726 F.3d 1346 (Fed. Cir. 2013)	passim
Mformation Techs., Inc. v. Research in Motion Ltd., 764 F.3d 1392 (Fed. Cir. 2014)	11
Par Pharmaceutical, Inc. v. TWi Pharmaceuticals, Inc., 773 F.3d 1186 (Fed. Cir. 2014)	13
Phillips v. AWH Corp., 415 F 3d 1303 (Fed. Cir. 2005)	11



Procter & Gamble Co. v. Teva Pharms. USA, Inc., 566 F.3d 989 (Fed. Cir. 2009)	13, 23
Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340 (Fed. Cir. 2012)	41
Statutes	
35 U.S.C. § 103	12, 14
35 U.S.C. § 311(b)	12, 20, 21
35 U.S.C. § 314(a)	12
35 C.F.R. § 42.65(a)	26
P.T.A.B.	
Coalition for Affordable Drugs VII LLC v. Pozen Inc., IPR No. 2015-01680, Paper 18 (P.T.A.B. Feb. 11, 2016)	21
Conopco v. Procter & Gamble, IPR No. 2013-00510, Paper 9 (P.T.A.B. Feb. 12, 2014)	24
E.I. du Pont de Nemours & Co. v. Monsanto Tech. LLC, IPR No. 2014-00333, Paper 14 (P.T.A.B. July 11, 2014)	24
Fontaine Engineered Prods., Inc. v. Raildecks, Inc., IPR No. 2013-00361, Paper 8 (P.T.A.B. Dec. 13, 2013)	15, 24
Johns Manville Corp. v. Knauf Insulation, Inc., IPR No. 2015-01633, Paper 10 (P.T.A.B. Jan. 4, 2016)	26, 28
Merial Ltd. v. Virbac, IPR No. 2014-01279, Paper 13 (P.T.A.B. Jan. 22, 2015)	41
Oxford Nanopore Techs. Ltd. v. Univ. of Wash., IPR No. 2014-00512, Paper 12 (P.T.A.B. Sept. 15, 2014)	passim
Phigenix, Inc. v. Immunogen, Inc., IPR No. 2014-00676, Paper 39 (P.T.A.B. Oct. 27, 2015)	42



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.

