

Case IPR2016-01096
Patent No. 6,667,061
Petitioners' Reply
Attorney Docket No. 9LUYE 7.1R-004

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.

Patent No. 6,667,061 to Ramstack *et al.*
Issue Date: December 23, 2003
Title: PREPARATION OF INJECTABLE
SUSPENSIONS HAVING IMPROVED INJECTABILITY

Inter Partes Review No. IPR2016-01096

**PETITIONERS' REPLY TO
PATENT OWNER'S RESPONSE**

Mail Stop: Patent Board
Patent Trial and Appeal Board
U.S. Patent And Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iii
EXHIBIT LIST	iv
I. INTRODUCTION	1
II. BACKGROUND	2
A. The Patent	2
B. Person Of Skill In The Art (“POSA”)	3
III. INJECTION VEHICLES WITH A VISCOSITY OVER 20 CP WERE KNOWN.....	3
IV. INJECTABILITY AND SUSPENDABILITY	4
V. MICROPARTICLES OF THE PATENT	6
VI. COMMERCIALY-AVAILABLE CMC.....	8
VII. THE TRACY DECLARATION	9
VIII. ALKERMES’S FLAWED TESTING.....	10
IX. THE CHALLENGED CLAIMS ARE UNPATENTABLE.....	11
A. Ground 1: Johnson (Ex.1009) In View Of Kino (Ex.1010)	11
1. Johnson’s Viscosity Is Within The Claimed Range	12
a. Alkermes’s Testing Was Flawed.....	12
b. CMC Is The Viscosity-Controlling Component	14
c. Commercially-Available CMC.....	14
d. Other Viscosity Factors	14

2.	The Challenged Claims Are Obvious	16
a.	Claims 1-3, 6-9, 12-13, And 22-23.....	16
b.	Claims 4, 5, 10, And 11	17
B.	Ground 2: Gustafsson (Ex.1011) In View Of Ramstack (Ex.1005), And The Handbook (Ex.1008)	17
1.	Gustafsson's Viscosity Is Within The Claimed Range.....	18
a.	Alkermes's Testing Was Flawed.....	18
2.	Gustafsson Teaches The Claims And Does Not Teach Away	19
3.	The Challenged Claims Are Obvious	21
a.	Claims 1-3, 6-7, 17, And 22-23	21
b.	Claims 8-9 And 12-13	22
c.	Claims 18-19.....	23
d.	Claims 20-21.....	23
X.	SECONDARY CONSIDERATIONS CAN'T SAVE THE PATENT	27
XI.	CONCLUSION.....	29

Case IPR2016- 01096
Petitioners' Reply
Patent No. 6,667,061
Attorney Docket No. 9LUYE 7.1R-004

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Asyst Techs., Inc. v. Emtrak, Inc.</i> , 544 F.3d 1310 (Fed. Cir. 2008)	29
<i>In re DBC</i> , 545 F.3d 1373 (Fed. Cir. 2008)	28
<i>J.T. Eaton & Co. v. Atl. Paste & Glue Co.</i> , 106 F.3d 1563 (Fed. Cir. 1997)	29

...

Case IPR2016- 01096

Petitioners' Reply

Patent No. 6,667,061

Attorney Docket No. 9LUYE 7.1R-004

EXHIBIT LIST

Exhibit #	Reference
1001	U.S. Patent No. 6,667,061 (“the Patent”)
1002	Declaration of Dr. Patrick P. DeLuca
1003	<i>Curriculum Vitae</i> of Dr. Patrick P. DeLuca
1004	Intentionally Left Blank
1005	International Publication No. WO 95/13799 (“Ramstack”)
1006	U.S. Pharmacopeia Entry re: CMC, viscosity pp.274-75, 1840 (1994)
1007	EP Pharmacopoeia Entry re: CMC, pp.547-48(3d ed. 1997)
1008	Handbook of Pharmaceutical Excipients pp.78-81, 135-38, 294-95, 329-330, 375-78, 420-21, 439-42, 477-80, 481-82 (2nd ed. 1994)
1009	U.S. Patent No. 5,654,010 (“Johnson”)
1010	U.S. Patent No. 5,656,299 (“Kino”)
1011	International Publication No. WO199714408 (“Gustafsson”)
1012	Intentionally Left Blank
1013	Intentionally Left Blank
1014	Herbert A. Lieberman <i>et al.</i> (eds.), <i>Pharmaceutical Dosage Forms: Disperse Systems</i> , Vol.2, pp.26-35, 40, 43-46, 261, 285-318 (2nd ed. rev. expanded 1996)
1015	U.S. Patent No. 6,495,164 (“the ’164 Patent”)
1016	Serial No. 10/259,949, Office Action, Apr. 9, 2003
1017	Serial No. 10/259,949, Applicants’ Resp., May 14, 2003
1018	Serial No. 09/577,875, Declaration of Mark A. Tracy, May 17, 2002
1019	Serial No. 10/259,949, Notice of Allowability, July 24, 2003
1020	Kenneth E. Avis <i>et al.</i> (eds.), 1 (Chs.2, 4, 5) <i>Pharmaceutical Dosage Forms: Parenteral Medications</i> 17-25, 115-16, 140-43, 150-51, 173-75, 190-212 (2nd ed. rev. expanded Marcel Dekker, Inc. 1992)
1021	Leon Lachman, PhD <i>et al.</i> , <i>The Theory and Practice of Industrial Pharmacy</i> 642-44, 783-84 (Lea & Febiger 3rd ed. 1986)
1022	Herbert A. Lieberman <i>et al.</i> , <i>Pharmaceutical Dosage Forms: Disperse Systems</i> , Vol.1, pp.287-313 (2nd ed. rev. expanded 1996)
1023	Orange Book entries for RISPERDAL [®]
1024	Supplemental Declaration of Dr. Patrick P. DeLuca, June 9, 2017
1025	Intentionally left blank
1026	Stedman’s Medical Dictionary (26th ed. 1995)

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.