

Case IPR2016-01096
Patent No. 6,667,061
Petition for *Inter Partes* Review
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
Patent Owner

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

(Exhibit 1002)

**DECLARATION OF PATRICK P. DeLUCA, Ph.D. IN
SUPPORT OF PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 1-13 AND 17-23 OF U.S. PATENT NO. 6,667,061**

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TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. MY BACKGROUND AND QUALIFICATIONS	1
III. A PERSON OF ORDINARY SKILL IN THE ART	3
IV. BACKGROUND	6
A. Introduction.....	6
B. Improving Injectability	7
C. Risperidone	9
D. The Role Of Viscosity In Injectable Formulations.....	9
E. The Prior Art Taught Microparticle Suspensions With The Claimed Concentration and Viscosity.....	11
V. THE '061 PATENT.....	15
A. The Claims.....	15
B. The Family History Of The '061 Patent.....	16
C. The Specification	17
D. The May 14, 2003 Response And The Tracy Declaration	18
VI. CLAIM CONSTRUCTION	20
A. "Suitable For Injection"	21
B. "Microparticles".....	21
C. "Injection Vehicle"	21
D. "Suspension".....	21
E. "Fluid Phase Of Said Suspension"	22
F. "Viscosity Greater Than About 20 cp And Less Than About 600 cp"	22
VII. THE PRIOR ART.....	23

A.	Johnson	23
B.	Kino.....	24
C.	Gustafsson.....	24
D.	Ramstack.....	24
VIII.	GROUND 1: CLAIMS 1-13 AND 17-23 ARE OBVIOUS OVER JOHNSON (EX.1009) IN VIEW OF KINO (EX.1010).....	25
A.	Claims 1-3	25
B.	Claims 4, 5, 10, And 11	27
C.	Claims 6-9 And 12-13.....	28
D.	Claims 17-21	28
E.	Claims 22-23	29
IX.	GROUND 2: CLAIMS 1-13 AND 17-23 ARE OBVIOUS OVER GUSTAFSSON (EX.1011) IN VIEW OF RAMSTACK (EX.1008 AND THE HANDBOOK (EX.1008).....	31
A.	Claim 1	31
B.	Claims 2-3	32
C.	Claims 4, 5, 10, And 11	32
D.	Claims 6 And 7	33
E.	Claims 8 And 9	34
F.	Claims 12 And 13	34
G.	Claims 17-21	34
H.	Claims 22-23	36
X.	CONCLUSION.....	37

I, PATRICK P. DeLUCA, hereby declare and state as follows:

I. INTRODUCTION

1. I am a U.S. citizen and a resident of the State of Kentucky.

2. I am a Professor Emeritus in the Department of Pharmaceutical Sciences, College of Pharmacy, at the University of Kentucky. I received a B.S. and M.S. in Pharmacy from Temple University in 1957 and 1960, respectively. I received my Ph.D. in Pharmaceutical Sciences from Temple University in 1963.

3. I have been retained by Lerner, David, Littenberg, Krumholz & Mentlik, LLP (“counsel”) to provide my opinions in the fields of pharmaceutical formulation for purposes of this IPR. I have read and understood U.S. Patent No. 6,667,061 (“the ’061 Patent”) (Exh. 1001) as well as all other references discussed in this declaration. I am being compensated for my time in an amount consistent with my customary consulting fee and my compensation is not contingent on my opinion or the outcome of this proceeding.

II. MY BACKGROUND AND QUALIFICATIONS

4. During my career of over 50 years, my research and teaching interests in pharmaceutical science and technology have been in various areas, including parenteral and intravenous pharmaceutical formulations and drug product stability. I have published over 225 research articles and authored or co-authored chapters in

several textbooks pertaining to physical pharmacy and pharmaceutical research focusing on the above principles.

5. I have received numerous awards and honors for my research and teaching achievements. I am a founding member and Fellow of the American Association of Pharmaceutical Scientists (“AAPS”) and served as its President between 2008 and 2009. I was the first Editor-in-Chief of the international journal *Pharmaceutical Development and Technology* between 1995 and 1999, the first Editor-in-Chief of the AAPS online journal *PharmSciTech* between 2000 and 2007, and also served on the editorial boards of several other scientific journals in the broad field of pharmaceutical sciences with special focus on pharmaceutical technology and drug product development.

6. In addition to my research and teaching, I have consulted over the years for both brand and generic pharmaceutical companies on matters related to pharmaceutical formulation and development. Additional details of my education, experience, and credentials are set forth in my *curriculum vitae*. (Ex.1003.)

7. Noteworthy is my expertise and pioneering efforts in the research, development, processing and *in vitro* and *in vivo* evaluation of injectable microparticulate dosage forms including risperidone microspheres. I have published extensively on the processing effects on the morphology and degradation of the polylactide-co-glycolide polymers and have correlated in-vivo blood levels

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