

Case IPR2016-01095  
Patent No. 6,667,061  
Petition for *Inter Partes* Review  
Attorney Docket No. 9LUYE 7.1R-001

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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

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*Inter Partes* Review No. IPR2016- 01095

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(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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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

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