

**Filed On Behalf Of:**

Alkermes Pharma Ireland Limited and  
Alkermes Controlled Therapeutics, Inc.

**By:**

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212-218-2100

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. and  
ALKERMES CONTROLLED THERAPEUTICS, INC.,  
Patent Owner.

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Case IPR2016-01096  
Patent 6,667,061

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**DECLARATION OF ROBSON F. STOREY, Ph.D.**

ALKERMES EXH. 2054  
Luye v. Alkermes  
IPR2016-01096

## **I. Background and Qualifications**

1. I, Robson F. Storey, offer this declaration at the request of counsel for Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc. (hereinafter, collectively “Alkermes”), and in response to the declaration submitted by Dr. Patrick P. DeLuca (Exh. 1002).

2. I am a Professor of Polymer Science and Engineering in the School of Polymers and High-Performance Materials at The University of Southern Mississippi, where I have been employed since 1983. My research has focused on polymers and their properties, and especially upon biodegradable/biomedical polymers, including their applications in drug delivery systems.

3. Prior to joining the faculty of The University of Southern Mississippi, from 1982-1983, I was a research chemist with American Cyanamid Company where my research focused on polymers, and especially biodegradable/biomedical/veterinary polymers. At American Cyanamid, I worked on the development of microparticle-based drug delivery systems using poly(lactic-co-glycolic acid), also known as PLGA.

4. I received my Ph.D. in Polymer Science from the University of Akron, Akron, Ohio, in 1983. My Ph.D. thesis concerned synthesis and characterization of polyisobutylene polymers.

5. I have performed extensive research in the design, synthesis, and characterization of polymers, including biodegradable/biomedical polymers and their applications in drug delivery systems. I have published more than 160 refereed journal articles on polymers, including biodegradable/biomedical polymers. I am a named inventor on more than 30 U.S. Patents, all directed toward polymers and their applications.

6. I have supervised 41 Ph.D. students, including students whose doctoral research was directed to biodegradable/biomedical polymers. I have taught graduate courses regarding polymer synthesis and characterization.

7. I have served as a referee and reviewer of journal articles concerning polymers, including biodegradable/biomedical polymers. I have been a co-organizer and paper editor of the Waterborne, High-Solids, and Powder Coatings Symposium, a specialized polymer symposium, since 1985 and currently serve as its chairman.

8. I am knowledgeable regarding the level of skill of persons of ordinary skill in the art of polymers, including those engaged in the development of polymer-based drug delivery systems during and around the year 2000, when the provisional application for the U.S. Patent No. 6,667,061 (“the ’061 Patent”) was filed.

9. I am knowledgeable regarding the synthesis, properties, and applications of polymers, including biodegradable/biomedical polymers such as polylactide (“polylactic acid”), polyglycolide (“polyglycolic acid”), and poly(lactic-co-glycolic acid). I am also knowledgeable in the analytical tools used to study polymers, including, for example, size exclusion chromatography, light scattering, differential scanning calorimetry, and microscopy.

10. A copy of my current curriculum vitae is provided at Appendix 1.

11. I am being compensated at my standard rate of \$500 per hr.

12. I have reviewed the Petition, Paper 5, the decision of the Patent Trial and Appeal Board (“PTAB”) instituting *inter partes* review, Paper 13, the references at issue for trial, and the ’061 Patent, Exh. 1001. I have also reviewed the Declaration of Dr. Patrick P. DeLuca, Exh. 1002, the exhibits referenced in Appendix 2 to this Declaration, and Dr. DeLuca’s deposition transcript from February 22, 2017, Exh. 2016. I have formed my opinions in this matter based on my more than 30 years of experience and expertise with polymers and their applications in delivery systems as well as the materials that I have reviewed.

## **II. Scope and Summary of Opinions**

13. I have been asked by counsel for Alkermes to (i) provide my views as to whether claims 20-21 of the ’061 Patent would have been obvious on the ground on which the PTAB has instituted trial, and (ii) address the comments provided by

Dr. DeLuca in his declaration in support of the Petition for *inter partes* review (“IPR”) for these claims. I was also asked for my views as to the microparticle and polymeric issues for the claims of the ’061 Patent at issue in ground 2 of the IPR.

14. I understand that the PTAB rejected the Petition on the ground that claims 20-21 would have been obvious over Johnson (Exh. 1009) and Kino (Exh. 1010), but instituted IPR on the ground that they would have been obvious over Gustafsson (Exh. 1011), Ramstack (Exh. 1005) and the Handbook (Exh. 1008). I understand that the PTAB also instituted IPR of claims 8-9, 12-13, and 22-23 in view of Gustafsson combined with Ramstack and instituted IPR of claims 1-3, 6-7, and 17-19 in view of Gustafsson.

15. For the reasons set forth in detail below, it is my opinion that claims 20-21 of the ’061 Patent would not have been obvious over the combination of Gustafsson, Ramstack, and the Handbook at the time of the invention. My analysis also applies to the other claims at issue in ground 2. As discussed below, there would not have been any reason to combine Gustafsson and Ramstack (with or without the Handbook) at the time of the invention as Petitioner contends for claims 8-9, 12-13, and 22-23. In addition, Gustafsson has no teaching of “microparticles” as required by the claims of the ’061 Patent and Gustafsson’s special coated microparticles teach away from the invention claimed in the ’061 Patent.

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