

Case IPR2016-01096  
Patent No. 6,667,061  
Petitioners' Resp. to POs' Identification of Portions of Petitioners' Reply . . .  
Attorney Docket No. 9LUYE 7.1R-004

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 Owners.

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. IPR2016-01096

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**PETITIONERS' RESPONSE TO PATENT OWNERS' IDENTIFICATION  
OF PORTIONS OF PETITIONERS' REPLY ALLEGED TO EXCEED  
THE PROPER SCOPE OF REPLY OR RAISE NEW ARGUMENTS**

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Pursuant to the Board's conference call of June 30, 2017, and the parties' agreement (Ex.2080), Petitioners submit a responsive numbered list of citations to the record that provide support for where the arguments identified by Patent Owners were previously raised by Petitioners, or citations to arguments by Patent Owners to which the objected-to portions are properly responsive.

**I. PETITIONERS DID NOT NEWLY DEFINE THE INJECTION VEHICLE OF GUSTAFSSON OR JOHNSON**

**1. Patent Owners:**

Reply at 8-11, 18-19; Exs.1024 at ¶¶ 31-35, 40-45, 50-52, 86-89. Petitioners attempt to newly define the Gustafsson injection vehicle and make new arguments about how a POSA would have allegedly understood the disclosure.

**Petitioners' Response:**

Petitioners asserted in the Petition that Gustafsson's vehicle uses 3% CMC and referred to the Tracy Declaration to support the assertion that Gustafsson's vehicle provides the same viscosity as the '061 Patent (Pet. 39-40; Ex.1002 ¶70). In response to Patent Owners' arguments to the contrary, *e.g.*, that Gustafsson "does not mention viscosity, specify viscosity of the injection vehicle or the particular grade or type of CMC used, and does not describe how the injection vehicle or CMC is prepared" (POR 36) and statements regarding the testing data

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included in Exhibit 2059, which only used ultra-low and extra-low viscosity CMC (POR 37-38, Exs.2014 ¶¶40-41, 112-124; 2059 ¶¶5-12), Petitioners replied with the arguments now challenged by Patent Owners (Reply 8-11, 18-19; Ex.1024 ¶¶31-35, 40-45, 50-52, 86-89).

**2. Patent Owners:**

Reply at 8-14; Exs.1024 at ¶¶ 31-35, 40-45, 50-54, 57-60, 65. Petitioners attempt to newly define the Johnson injection vehicle and make new arguments about how a POSA would have allegedly understood the disclosure.

**Petitioners' Response:**

Petitioners asserted in the Petition that Johnson's vehicle uses low viscosity CMC (Pet. 24; Ex.1002 ¶59) and referred to the Tracy Declaration to support the assertion that Johnson's vehicle provides the same viscosity as the '061 Patent (Pet. 17-18; Ex.1002 ¶44). In response to Patent Owners' arguments to the contrary, *e.g.*, that "Johnson does not indicate the grade or type of CMC" (POR 21; Ex.2014 ¶¶51-56), that Petitioners "failed to show that . . . the vehicle would inherently have a viscosity within the claimed range," (POR 21-24; Ex.2014 ¶¶60-61) and statements regarding the testing data included in Exhibit 2059, which only used ultra-low and extra-low viscosity CMC (POR 16-24; Exs.2014 ¶¶47-50,

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77-81, 87; 2059 ¶¶5-12), Petitioners replied with the arguments now challenged by Patent Owners (Reply 8-14; Exs.1024 ¶¶31-35, 40-45, 50-54, 57-60, 65).

## **II. PETITIONERS DID NOT PROVIDE NEW THEORIES REGARDING THE MICROPARTICLE AND POLYMERIC BINDER LIMITATIONS**

### **3. Patent Owners:**

Reply at 6-8, 17-22; Exs.1024 at ¶¶ 25-30, 91-97, 100-102, 104; 1036, 1037; 1043. Petitioners assert new theories as to how Gustafsson allegedly satisfies the microparticle and polymeric binder limitations of the claims of the '061 patent, including newly arguing that starch satisfies the limitations.

### **Petitioners' Response:**

Petitioners asserted in the Petition that Gustafsson teaches that PLGA is a useful polymeric binder (Pet. 45; Ex.1002 ¶78), teaches any active may be used in its formulation, which includes an injection vehicle that aids in suspension of microparticles, and that a POSA would use Ramstack's microparticles in Gustafsson's vehicle (Pet. 39, 45-47; Ex.1002 ¶¶78, 80). The Board agreed (Institution Decision 30), and in response to Patent Owners' arguments to the contrary, *e.g.*, that the active agent of Gustafsson is not entrapped in a polymer (POR 40) and that "starches are not polymers" (POR 42), Petitioners replied with

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the arguments now challenged by Patent Owners (Reply 6-8, 17-22; Exs.1024 ¶¶25-30, 91-97, 100-102, 104; 1036, 1037; 1043).

**4. Patent Owners:**

Reply at 7-8, 19, 21-24; Exs.1024 at ¶¶ 30, 91, 93-94, 96, 100, 104; 1036.

Petitioners assert new theories that the PLGA coating of Gustafsson satisfies the microparticle and/or polymeric binder limitations for claims 1-3, 6-9, 12-13, 20-21, and 22-23.

**Petitioners' Response:**

Petitioners asserted in the Petition that microparticles are particles that include “an active agent or other substance dispersed or dissolved within a polymer (Pet. 20, Exs.1001, at 5:15-18; 1002 ¶48) and that Gustafsson teaches that PLGA is a useful polymeric binder (Pet. 45; Ex.1002 ¶78). In response to Patent Owners' arguments to the contrary, *e.g.*, that Gustafsson taught away from using a microparticle comprising a polymeric binder (POR 39-42), Petitioners replied with the arguments now challenged by Patent Owners (Reply 7-8, 19, 21-24; Exs.1024 ¶¶ 30, 91, 93-94, 96, 100, 104; 1036).

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