Paper No. 44
Date Filed: July 14, 2017

Filed On Behalf Of:

Alkermes Pharma Ireland Limited and
Alkermes Controlled Therapeutics, Inc.

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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.

Case IPR2016-01096
U.S. Patent No. 6,667,061

PATENT OWNERS' IDENTIFICATION OF PORTIONS OF PETITIONERS' REPLY THAT EXCEED THE PROPER SCOPE OF REPLY OR RAISE NEW ARGUMENTS

Pursuant to the Board's conference call of June 30, 2017 and the parties' agreement (Exh. 2080)[1], Patent Owners submit the following list setting forth the portions of Petitioners' Reply (Paper 40) that exceed the proper scope of reply and/or raise new arguments and evidence that could and should have been raised as part of their *prima facie* case, but were not included in the Petition, along with a brief explanation. These improper, new arguments by Petitioners should not be considered.

I. Petitioners' Late Attempts to Newly Define the Injection Vehicles Disclosed by Gustafsson and Johnson

1. Reply at 8-11, 18-19; Exh. 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. In contrast, in the Petition, Petitioners argued only that "a POSA would reasonably expect the injection vehicle of Gustafsson – having 3% CMC – to have a viscosity greater than 27cp at 20°C and certainly within the claimed range of 20-600cp at 20°C" (Petition at 39-40; *see also id.* at 11, 49; Exh. 1002 at ¶ 70; *see also id.* at ¶¶ 28, 57) and did not specify, for instance, that low viscosity, pharmaceutical

[1] Exh. 2080 is the transcript of the conference call with the Board.

grade and/or commercially available CMC would have been used in the Gustafsson vehicle.[1]

2. Reply at 8-14; Exh. 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. In contrast, in the Petition, Petitioners argued only that "a POSA would reasonably expect the injection vehicle of Johnson – having 3% CMC – to have a viscosity greater than 27cp at 20°C and certainly within the claimed range of 20-600cp at 20°C" (Petition at 25-26; *see also id.* at 10, 32-33; Exh. 1002 at ¶60; *see also id.* at ¶¶ 27, 59) and did not specify, for instance, that pharmaceutical and/or commercially available CMC would have been used in the Johnson vehicle or explain why a POSA would have understood the same CMC was used throughout the examples of Johnson.

II. Petitioners' Late Attempts to Satisfy the Microparticle and Polymeric Binder Limitations

3. Reply at 6-8, 17-22; Exh. 1024 at ¶¶ 25-30, 91-97, 100-102, 104; Exh. 1036, Exh. 1037; Exh. 1043. Petitioners assert new theories as to how Gustafsson

[1] Petitioners also fail to explain, in both the Petition and Reply, what "pharmaceutical grade," "low viscosity" and/or "commercially available" means with respect to CMC.

allegedly satisfies the microparticle and polymeric binder limitations of the claims of the '061 patent, including newly arguing that starch satisfies the limitations. In contrast, in the Petition, Petitioners argued only that the PLGA coating of Gustafsson satisfied the limitations for claims 17-19 (Petition at 10-11, 45-46, 49, 53-54; Exh. 1002 at ¶¶ 78-79; *see also id.* at ¶ 28 (failing to identify with specificity how Gustafsson satisfied the microparticle limitation, which requires a polymer that serves as a matrix or binder, and polymeric binder limitations for claims 1-16, 22-23)), Petitioners made no mention of starch, and, at deposition, Petitioners' expert expressly testified that the starch of Gustafsson's microparticles was not a polymer (Exh. 2016 at 243:7-12).

4. Reply at 7-8, 19, 21-24; Exh. 1024 at ¶¶ 30, 91, 93-94, 96, 100, 104; Exh. 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. In contrast, in the Petition, Petitioners relied on the PLGA coating of Gustafsson to meet these limitations only for claims 17-19. (Petition at 10-11, 45-46, 49, 53; Exh. 1002 at ¶¶ 28, 78-79).

III. Petitioners' Late Attempts to Argue New Combinations

5. Exh. 1024 at ¶ 101. Petitioners assert a new theory that a POSA would have combined the microparticles of Ramstack with the injection vehicle of Gustafsson to arrive at claims 17-19. In contrast, in the Petition, Petitioners argued

that Gustafsson alone met every limitation of claims 17-19. (Petition at 45-46, 49, 53; Exh. 1002 at ¶¶ 78, 79).

6. Reply at 20; Exh. 1024 at ¶¶ 95, 102; Exh. 1043; Exh. 1011 at 3:31-36. Petitioners assert a new theory that a POSA would have combined the microparticles of WO 90/13780 (Exh. 1043), a newly asserted prior art reference, with the injection vehicle of Example 6 in Gustafsson to arrive at claims 17-19 and assert that a POSA would do so because Gustafsson allegedly "acknowledges that any microparticle can be used." Exh. 1024 at ¶ 102. In contrast, in the Petition, Petitioners argued that Gustafsson alone met every limitation of claims 17-19 and did not mention or rely upon WO 90/13780. (Petition at 45-46, 49, 53; Exh. 1002 at ¶¶ 78, 79).

7. Reply at 23-26; Exh. 1024 at ¶¶ 106-112. Petitioners assert a new theory that a POSA could combine the risperidone active of Ramstack with the microparticles and injection vehicle of Gustafsson to arrive at claims 20-21. In contrast, in the Petition, Petitioners argued that a POSA could combine the risperidone microparticles of Ramstack with the injection vehicle of Gustafsson. (Petition at 45-47, 53-54; Exh. 1002 at ¶ 80).

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