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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' MOTION FOR OBSERVATIONS ON CROSS-EXAMINATION OF PATRICK DELUCA, PH.D.

I. The Viscosity Limitation is Not Inherent in Johnson or Gustafsson

In Exh. 2081 at page 121, line 22 to page 124, line 5, Dr. DeLuca testified that "it's possible" for a POSA to use a medium or high viscosity grade CMC in an injection vehicle. This is relevant to Petitioners' assertions that the Johnson and Gustafsson vehicles would comprise only low viscosity CMC. (Reply at 11-13, 18-19; Exh. 1024 at ¶¶ 54, 57-60, 65, 86-87.) This is relevant because it confirms that Petitioners should have accounted for all viscosity grades of CMCs to prove inherency.

In Exh. 2081 at page 135, line 4 to page 137, line 4; *see also* Exh. 2073, Dr. DeLuca confirmed that "viscosity [of a CMC solution] doesn't change between food grade, pharma grade and industrial grade." This is relevant to Petitioners' assertion that Patent Owners' testing is flawed because it did not use pharmaceutical grade CMC. (Reply at 8, 10-13, 18-19; Exh. 1024 at 41-45, 57-58, 86.) This is relevant because it contradicts Petitioners' testing criticism and establishes that use of a non-pharmaceutical grade CMC does not impact viscosity.

In Exh. 2081 at page 133, line 19 to page 135, line 3, *see also* Exhs. 2031, 2073, Dr. DeLuca confirmed that "in looking for an appropriate vehicle for drug delivery," he has used high and low viscosity, food grade CMCs. This is relevant to Petitioners' assertions that the Johnson and Gustafsson vehicles would comprise only low viscosity, pharmaceutical grade CMC. (Reply at 8, 10-13, 18-19; Exh.

1024 at ¶¶ 41-45, 54, 57-60, 65, 86-87.) This is relevant because it confirms that Petitioners should have accounted for all viscosity grades CMC to prove inherency and it contradicts Petitioners' testing criticism.

In Exh. 2081 at page 167, lines 21-25; *see also id.* at 158:4-167:20, 167:25-170:9; Exhs. 2074-2077, Dr. DeLuca confirmed that "Blanose 7UL® and 7EL® were commercially available as of the time of the invention." This is relevant to Petitioners' assertion that Patent Owners' testing is flawed because it did not use commercially available CMC. (Reply at 8-11, 13-14, 18; Exh. 1024 at ¶¶ 31-36, 40-41, 43-45, 65, 86-87.) This is relevant because it contradicts Petitioners' testing criticism and establishes that the tested CMCs were commercially available at the time of the invention.

In Exh. 2081 at page 176, lines 18-25; *see also id.* at 170:14-176:17; Exhs. 2039, 2078-2079, Dr. DeLuca confirmed the "use of an ultra low viscosity [non-pharmaceutical] grade CMC for a pharmaceutical application." This is relevant to Petitioners' assertions that Patent Owners' testing is flawed because it did not use low viscosity pharmaceutical grade CMC. (Reply at 10-13, 18; Exh. 1024 at ¶¶ 41-45, 57-58, 86-87.) This is relevant because it contradicts Petitioners' testing criticism and establishes that comparable CMCs to those tested are used in pharmaceutical applications.

In Exh. 2081 at page 208, lines 11-14; *see also* Exh. 2038, Dr. DeLuca confirmed that Ashland classifies its "CMC 7UL® and 7EL® as low viscosity grade CMC." This is relevant to Petitioners' assertion that Patent Owners' testing was flawed because it did not use low viscosity CMCs. (Reply at 8, 10-13, 18-19; Exh. 1024 at ¶¶ 54, 57-60, 65, 86-87.) This is relevant because it contradicts Petitioners' testing criticism and establishes that 7UL and 7EL CMCs are considered low viscosity CMCs.

In Exh. 2081 at page 166, lines 3-6; *see also* Exh. 2075, Dr. DeLuca confirmed that a third party "refers to Blanose 7ULC® as a low viscosity grade CMC." This is relevant to Petitioners' assertion that Patent Owners' testing was flawed because it did not use low viscosity CMCs. (Reply at 8, 10-13, 18-19; Exh. 1024 at ¶¶ 54, 57-60, 65, 86-87.) This is relevant because it contradicts Petitioners' testing criticism and establishes that 7UL CMC is considered low viscosity CMC.

In Exh. 2081 at page 48, line 18 to page 49, line 16, Dr. DeLuca confirmed that Gustafsson does not "state the source of the CMC," "say anything about pharmaceutical grade CMC," "say anything about whether it's a low viscosity CMC," and "say anything about the commercial availability of the CMC." This is relevant to Petitioners' assertions that Gustafsson's vehicle would inherently have a viscosity within the claimed range and that Patent Owners' testing is flawed

because it did not use a particular subcategory of CMCs. (Reply at 8-11, 13-14, 18-19; Exh. 1024 at ¶¶ 31-36, 40-45, 86-89.) This is relevant because it confirms the generic nature of Gustafsson's disclosure and it undermines Petitioners' claim that a POSA would only use a particular subcategory.

In Exh. 2081 at page 104, lines 4 to 16; *see also id.* at 76:5-8, 117:13-125:5, Dr. DeLuca confirmed that Johnson Example 7 does not state low viscosity CMC and that Johnson "didn't specify the supplier" of CMC. This is relevant to Petitioners' assertions that Johnson's vehicle would inherently have a viscosity within the claimed range and that Patent Owners' testing is flawed because it did not use a particular subcategory of CMCs. (Reply at 10-14, 16-17; Exh. 1024 at ¶¶ 31-36, 40-45, 56-60.) This is relevant because it confirms the generic nature of Johnson's disclosure and it undermines Petitioners' claim that a POSA would only use a particular subcategory of CMC.

In Exh. 2081 at page 196, line 25 to page 197, line 8; *see also id.* at 184:17-185:8, Dr. DeLuca confirmed that whether the CMC is added "before or after the sodium chloride" could impact viscosity. This is relevant to Petitioners' assertions that the Johnson and Gustafsson vehicles would inherently have viscosities within the claimed range. (Reply at 8-14, 16-19; Exh. 1024 at ¶¶ 31-36, 40-45, 56-60, 86-89.) This is relevant because it confirms that order of addition of ingredients can

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