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.

Patent No. 6,667,061 to Ramstack *et al*.
Issue Date: December 23, 2003
Title: PREPARATION OF INJECTABLE SUSPENSIONS HAVING IMPROVED INJECTABILITY

Inter Partes Review No. IPR2016-01096

RESPONSE TO PATENT OWNERS' OBSERVATIONS ON CROSS-EXAMINATION OF PATRICK DeLUCA, PH.D.

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I. Johnson And Gustafsson Inherently Teach The Viscosity Limitation

1: The cited testimony is irrelevant, incomplete, and does not confirm that Petitioners should have accounted for all grades of CMC to prove inherency. The testimony was given with respect to Example 7 of the Johnson vehicle. DeLuca testified that although Example 7 did not explicitly state low CMC, Johnson stated "low . . . 3 percent" CMC for all of the other examples, thus, it "would be unlikely that he would use a high in one case and low in another." (Ex.2081, 122:8-19; *see also* 119:21-24, 154:17-19, 123:24-124:5.) DeLuca testified that the low CMC in the Handbook (Ex.1008) "would be more appropriate for parenteral suspensions" (Ex.2081, 121:16-21), and that a POSA "for a parenteral suspension would have picked the low grade [CMC]" (*id.* 195:14-19).

2: The cited testimony is irrelevant, incomplete, and does not contradict Petitioner's argument. DeLuca's testimony only sets forth his understanding as to what Ex.2073 states on its face. Despite listing "all the different CMCs from Aqualon" (Ex.2081, 132: 2-9), DeLuca's testimony is only related to one specific CMC, "Aqualon CMC 7HF" (*id.* 135:4-137:4). DeLuca testified that a POSA "for a parenteral suspension would have picked the low grade [pharmaceutical CMC]." (Ex.2081, 194:20-195:19.)

3: The cited testimony is irrelevant, incomplete, and does not "confirm" POs' assertion. DeLuca testified that whether he used high and low grade CMCs in his study, "may be irrelevant . . . [b]ecause we are not talking about parenteral use." (Ex.2081, 130:5-10.) Similarly, with respect to Ex.2031, DeLuca testified that the work did not involve the injectable suspension of microparticles (Ex.2081, 240:11-241:25) and that matrices were "solid" and "certainly not injectable" (*id.* 242:2-18). The Tracy Declaration did not consider anything other than the amount of CMC used by Kino. (Ex.1018.) DeLuca utilized the Tracy Declaration in the exact same manner as the POs in obtaining the '061 Patent. (Pet. 17-18; Ex.1002 ¶44.)

4: The cited testimony is irrelevant, incomplete, lacks foundation, and does not contradict Petitioners' testing criticism. DeLuca's testimony only sets forth his understanding as to what Exs.2074-2077 state on their face. DeLuca testified that the disclosure "may not be accurate." (Ex.2081, 166:21-167:3.) Exs.2074-2077 are nonanalogous art. DeLuca testified that ultra low Blanose 7UL® and extra low Blanose 7EL® are not low viscosity CMCs as taught in the Handbook for low CMCs (*Id.* 121:16-21; Ex.1008, 79).

5: The cited testimony is irrelevant, incomplete, and does not contradict Petitioner's testing criticism. DeLuca's testimony only sets forth his understanding

as to what Exs.2039, 2078, and 2079 state on their face. None of these references is prior art.

6: The cited testimony is irrelevant, incomplete, does not contradict Petitioners' testing criticism. DeLuca's testimony only sets forth his understanding as to what Ex.2038 states on its face. DeLuca testified that ultra low Blanose 7UL® and extra low Blanose 7EL® are not low viscosity CMCs (Ex.2081, 121:16-21; 1008, 79).

7: The cited testimony is irrelevant, incomplete, lacks foundation, does not contradict Petitioners' testing criticism. DeLuca's testimony only sets forth his understanding as to what Ex.2076 states on its face. Ultra low Blanose 7UL® is not a low viscosity CMC. (Ex.2081, 121:16-22; Ex.1008, 79.)

8: The cited testimony is irrelevant, incomplete, and does not "confirm[] the generic nature of Gustafsson's disclosure." DeLuca's prior testimony explained that Gustafsson's vehicle would have a viscosity in the claimed range of the '061 Patent based on the Tracy Declaration. (Pet. 39; Ex.1002 ¶70.) The Tracy Declaration did not consider anything other than the amount of CMC used by Kino. (Ex.1018.)

9: The cited testimony is irrelevant, incomplete, and does not "confirm[] the generic nature of Johnson's disclosure." DeLuca testified that the CMC in Johnson's Example 7 is low viscosity CMC. (Ex.2081, 76:9-12, 122:14-19.) DeLuca's prior testimony explained that Johnson's vehicle would have

substantially a viscosity in the claimed range as of the '061 Patent. (Pet. 25-26; Ex.1002 ¶¶44, 60-61.)

10: The cited testimony is mischaracterized, irrelevant, incomplete, does not "confirm[] that order of addition of ingredients can impact viscosity," nor does it "support[] that Petitioners should have accounted for this factor in proving inherency." DeLuca testified that sodium chloride does not impact viscosity in any significant way when it is used for the isotonic concentration of a preparation. (Ex.2081, 190:4-9.) DeLuca testified that a POSA would dissolve CMC in the water and then add the sodium chloride (*id.* 191:3-192:22, 195:20-196:24) and that "Dr. Gehrke prepared his solutions using a method that would not be used by a POSA by adding the CMC after sodium chloride" (*id.* 191:7-10; *see also id.* 196:25-197:25). When asked if his concern was "that the order of addition of sodium chloride could impact viscosity," he testified that "[He has] no concern with viscosity." (*Id.* 197:14-25.)

11: The cited testimony is irrelevant, incomplete, and does not undermine Petitioners' assertion. DeLuca testified that the injection vehicle used in the animal model could be optimized in the human model. (Ex.2081, 58:15-59:11.) Both Johnson's Examples 6 and 7 are administered by subcutaneous injection into animals. (*Id.* 77:8-79:7) DeLuca testified that CMC in Johnson's Example 6 is the

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