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. PATENT OWNERS' OBSERVATIONS ARE AN UNAUTHORIZED SUR-REPLY

The Office Patent Trial Practice Guide ("Practice Guide") explains that the purpose of observations on cross-examination is to draw the Board's attention to relevant cross-examination testimony that "occurs *after* a party has filed its last substantive paper on an issue." *Chums, Inc. v. Cablz, Inc.*, IPR2014-01240, Paper 32, at 2 (Aug. 6, 2015); Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48768 (Aug. 14, 2012.). The Practice Guide makes clear that "[a]n observation . . . is not an opportunity to raise new issues, re-argue issues, or pursue objections." Office Patent Trial Practice Guide, 77 Fed. Reg. at 48768. Rather than following the Practice Guide, Alkermes instead filed Observations that raise new issues or re-argue issues. Thus, Petitioners' request that the Board use its discretion and dismiss Alkermes' Motion for Observations on Cross-Examination of Dr. DeLuca. *Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-00506, Paper 37, at 3-4 (Oct. 15, 2014.)

II. JOHNSON AND GUSTAFSSON INHERENTLY TEACH THE VISCOSITY LIMITATION

Response To Observation 1:

The cited testimony of Dr. DeLuca is irrelevant, incomplete, and does not confirm that Petitioners should have accounted for all grades of carboxymethylcellulose ("CMC") to prove inherency. (Mot. 1.) The testimony was given with respect to Example 7 of the Johnson vehicle. Dr. 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, at 122:8-19.) Although Dr. DeLuca testified that it was *possible* to use a medium grade viscosity CMC, he explained "3 percent of the medium would probably be too high or higher than necessary" (*id.* 119:21-24) and "a lower concentration" would be needed (*id.* 154:17-19). Dr. DeLuca also testified that although possible it was "unlikely" for high viscosity grade CMC to be used as an injection vehicle. (*Id.* 123:24-124:5.) Dr. DeLuca testified that out of all of the grades of CMC shown in the Handbook (Ex.1008), the low CMC "would be more appropriate for parenteral suspensions" (Ex.2081, at 121:16-21), and that a POSA "for a parenteral suspension would have picked the low grade [CMC]" (*id.* 195:14-19).

Response To Observation 2:

The cited testimony of Dr. DeLuca is irrelevant, incomplete, and does not contradict Petitioner's testing criticism and does not "establish that use of a non-pharmaceutical grade CMC does not impact viscosity." (Mot. 1) Dr. DeLuca's testimony only sets forth his understanding as to what Exhibit 2073 states on its face. Despite listing "all the different CMCs from Aqualon" (Ex.2081, at 132: 2-9), Dr. DeLuca's testimony is only related to one specific CMC, "Aqualon CMC 7HF" (*id.* 135:4-137:4). Although Dr. DeLuca testified that "viscosity of CMC doesn't change between food grade, pharma grade, and industry grade" (*id.* at 136:20-23), in Exhibit 2073, Dr. DeLuca did not testify that a POSA would use non-pharmaceutical grade CMC in an injectable suspension. To the contrary, Dr. DeLuca testified that the Handbook teaches pharmaceutical grade high, medium and low CMC and that a POSA "for a parenteral suspension would have picked the low grade [CMC]." (Ex.2081, at 194:20-195:19.)

Response To Observation 3:

The cited testimony of Dr. DeLuca is irrelevant, incomplete, and does not "confirm" Patent Owners' assertion that all grades of carboxymethylcellulose ("CMC") should be accounted for to prove inherency and does not contradict Petitioners' testing criticism. Dr. 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, at 130:5-10.) Similarly, with respect to Exhibit 2031, Dr. DeLuca testified that the work did not involve the injectable suspension of microspheres or microparticles (Ex.2081, at 240:11-241:25) and that matrices were "solid" and "certainly not injectable" (*id.* 242:2-18). Further, the Tracy Declaration did not consider anything (such as grade of CMC) other than the amount of CMC used by Kino in estimating patentability of the '061 invention. (Ex.1018.) Dr. DeLuca utilized the Tracy Declaration in the exact same manner as the Patent Owners, *i.e.*, to support the assertion that the Johnson vehicle has a viscosity within the range claimed in the '061 Patent (Pet. 17-18; Ex.1002 ¶44.)

Response To Observation 4:

The cited testimony of Dr. DeLuca is irrelevant, incomplete, lacks foundation, and does not contradict Petitioners' testing criticism, nor does it "establish[] that the tested CMCs were commercially available at the time of the invention." (Mot. 2.) Dr. DeLuca's testimony only sets forth his understanding as to what Exhibits 2074-2077 state on their face. Dr. DeLuca testified that the disclosure "may not be accurate." (Ex.2081, at 166:21-167:3.) Exhibits 2074 and 2075, titled "Dispersions for Producing Paint For Concrete Roof Tiles, Paint for Concrete Roof Tiles and Concrete Roof Tiles Coated with Such Paint" are

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