Paper No. <u>51</u>

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Filed On Behalf Of:

Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc.

By:

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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 TO EXCLUDE EVIDENCE



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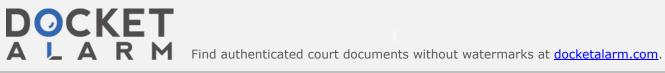
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I. <u>INTRODUCTION</u>

Patent Owners Alkermes Pharma Ireland LTD and Alkermes Controlled Therapeutics, Inc., move to exclude the following evidence:

- Petitioners' Reply (Paper 40). Petitioners' Reply far exceeds the proper scope of a reply by going above and beyond responding to arguments made in the Patent Owners' Response. 37 C.F.R. § 42.23(b). In addition, significant portions of Petitioners' Reply are based on exhibits that were improperly introduced with the Reply in violation of 37 C.F.R. § 42.123(b). The Board should not attempt to parse the Reply and should reject it in its entirety. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,767 ("[A] reply that raises a new issue or belatedly presents evidence will not be considered and may be returned.").
- The Supplemental Declaration of Dr. DeLuca (Exh. 1024). Exhibit 1024 constitutes supplemental information that was improperly submitted more than one month after the date the trial was instituted. 37 C.F.R. § 42.123(b). It is also rife with new opinions supporting new theories found in Petitioners' Reply.
- Exhibits 1027, 1028, 1030, 1032, 1034, 1036, 1037, and 1043. These exhibits were introduced to support new and improper sections of the Petitioners' Reply and Dr. DeLuca's Supplemental Declaration.
- At a minimum, all portions of Exh. 1024 and Petitioners' Reply that

 (1) exceed the proper scope of a reply and/or (2) rely on improperly introduced



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