

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' OPPOSITION TO PETITIONERS' MOTION TO
EXCLUDE EVIDENCE**

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I. INTRODUCTION

In accordance with 37 C.F.R. § 42.64, Patent Owners Alkermes Pharma Ireland LTD and Alkermes Controlled Therapeutics, Inc., respectfully oppose the Motion to Exclude filed by Petitioners Luye Pharma Group Limited, Luye Pharma (USA) Limited, Shandong Luye Pharmaceutical Company, Limited and Nanjing Luye Pharmaceutical Co., Limited (Paper 47).

II. ARGUMENT

A. The CMC Exhibits, Dr. Berkland’s Declaration (Exh. 2014), and Dr. Gehrke’s Declaration (Exh. 2059) should not be excluded.

1. Neither the CMC Exhibits (Exhs. 2034, 2036, 2038–2040, and 2052), nor Declarations which rely on them, should be excluded as hearsay.

Petitioners challenge the so-called “CMC Exhibits” as inadmissible hearsay. (Paper 47 at 2–3.) These exhibits are offered for their truth, but they fall within the hearsay exception set forth in F.R.E. 803(17). Under this exception, various commercial publications are admissible because a profession relies upon the accuracy of the data compiled, giving the compiler an incentive to be accurate. F.R.E. 803 Notes of Advisory Committee on Proposed Rules. Each of the “CMC Exhibits” is a commercial publication relied upon by professionals in fields such as materials science or biochemistry. As such, they fall within this hearsay exception,

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