

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' OPPOSITION TO PETITIONERS' SECOND
MOTION TO EXCLUDE**

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I. INTRODUCTION

Patent Owners respectfully oppose Petitioners' Second Motion to Exclude, which should be denied for the following reasons.

II. ARGUMENT

A. Exhibits 2073, 2075, 2077-2079, and 2081 Should Not Be Excluded Under 37 C.F.R. § 42.64(a), F.R.E. 402, or F.R.E. 403.

Petitioners argue that these exhibits should be excluded under grounds referred to by Petitioners' counsel in Dr. Patrick DeLuca's Deposition (Exh. 2081). The passages Petitioners cite are ambiguous, but they hint that the actual basis for the objection is that the exhibits might not be prior art, and in their view, irrelevant. (*Id.* at 132:24–133:11.) These exhibits were properly presented in response to arguments first made in Dr. DeLuca's Supplemental Declaration (Exh. 1024) and the Petitioners' Reply (Paper 40). Petitioners make a similar argument in II.E (Paper 70 at 4) regarding Exhs. 2073, 2078, and 2079, which we address here.

As Patent Owners have pointed out before (Paper 56 at 8–10), inherency does not require recognition in the prior art. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); M.P.E.P. § 2112. An exhibit need not be prior art to be relevant evidence. M.P.E.P. § 2124 (“[R]eferences cited to show a universal fact need not be available as prior art.”).

Exh. 2073, an excerpt from the *Rheology Modifiers Handbook*, compares Aqualon CMCs offered at different purities (food, pharmaceutical, and industrial)

and finds their viscosities identical (Table 2.7). Exh. 2073 was filed in the Library of Congress Catalog with a Card Number (LCCN) of 99-32076, indicating that it was filed in 1999. *See* The LCCN Namespace, U.S. LIBR. OF CONG. (Nov. 2003), <https://web.archive.org/web/20170819205149/http://www.loc.gov/marc/lccn-namespace.html> (explaining that the first two digits of the LCCN signify the year the reference was catalogued). Exh. 2073 rebuts Petitioners' argument that Patent Owners' tests were flawed for using CMCs that were not identified as pharmaceutical grade (Paper 40 at 10–11), and is relevant.

Exh. 2075, WO99/48841, is a German PCT application published on September 30, 1999, showing the use of Blanose 7UL, 7EL, and 7ULC. (*Id.* at 3, 10, 11.) Exh. 2077, WO98/02486, is a French PCT application published on January 22, 1998, showing the use of Blanose 7ULC. (*Id.* at 15, 22.) Both are prior art. *See Mazzari v. Rogan*, 323 F.3d 1000, 1005-06 (Fed. Cir. 2003) (holding that a printed publication need not be in English to be prior art). Both rebut Petitioners' argument that Patent Owners' tests were flawed by the use of CMCs that were not commercially available at the time of the invention and are relevant.

Exhs. 2078 and 2079 are not prior art, but disclose the use of another ultra-low CMC, Sigma 360384 (Exh. 2039; Exh. 2014 at ¶ 58), used in microneedles and medical adhesives. Both rebut Petitioners' argument that Patent Owners' tests were flawed for using CMCs that Petitioners allege would not be used in a

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