

Case IPR2016-01096
Patent No. 6,667,061
Opposition to Patent Owners' Motion to Exclude
Attorney Docket No. 9LUYE 7.1R-004

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

**REPLY TO PATENT OWNERS'
OPPOSITION TO MOTION TO EXCLUDE**

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I. INTRODUCTION

Petitioners (“Luye”) respectfully submit this reply to Patent Owners’ (“Alkermes”) Opposition to Petitioners’ motion to exclude certain evidence.

I. ARGUMENT

A. CMC Exhibits And 2049 Do Not Fall Within The Exception Under FRE 803(17)

Alkermes alleges that certain CMC Exhibits fall within the hearsay exception set forth in 803(17), which includes “[m]arket quotations, lists, directories, or other compilations that are generally relied on by the public or by persons in particular occupations.” In support, Alkermes relies on *Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2016-00130, Paper 35 (P.T.A.B. May 8, 2017), wherein the Patent Owner sought to exclude the dates on advertising brochures as hearsay. *Id.* at 16. Petitioners in that case submitted corroborating testimony from two of its employees who testified that the dates on the brochures were print dates and it was standard practice to disseminate the brochures to customers shortly thereafter. *Id.* at 18. The Board found the brochures admissible under FRE 803(17) based on the witnesses’ sworn testimony. *Id.* at 19.

Here, Alkermes seeks to rely on the brochures as showing that the products were available before the priority date. *Id.* at 17. Unlike in *Johns Manville*, Alkermes, however, has failed to provide any corroborating testimony or evidence that the dates on the CMC Exhibits are the publication dates, and thus, available

before the priority date. Exhibits 2034, 2036, 2038, 2039, and 2040 all have multiple dates and at least one of the dates on each document is *after* the priority date. *See TRW Auto. U.S. LLC v. Magna Elecs. Inc.*, IPR2014-01348, Paper 25, at 8 (P.T.A.B. Jan. 15, 2016) (a copyright is not probative that an article was published). Moreover, Alkermes failed to provide any evidence that CMC Exhibits are “generally relied on by the public or by persons in particular occupations” as required by FRE 803(17). Exhibits 2036, 2039, and 2052 are web pages, not product brochures. *See Google, Inc. v. Michael Meiresonne*, IPR2014-01188, Paper 38, at 9-10 (P.T.A.B. Jan. 20, 2016.) Thus, these exhibits are inadmissible hearsay under FRE 802 and do not fall with the exception under FRE 803(17).

Exhibit 2049 is similarly inadmissible. Exhibit 2049 is a press release posted on Johnson & Johnson's own web page. Alkermes has offered no evidence that a press release would be relied on by the public or persons in particular occupations or that Johnson & Johnson had “incentive to compile this information accurately.” (Opp'n 12.) As such, Exhibit 2049 is inadmissible hearsay under FRE 802 and does not fall within the exception under FRE 803(17).

**B. The CMC Exhibits Have Not Been Authenticated
As Documents Available Before The Priority Date**

Alkermes alleges that it is not relying on the CMC Exhibits “solely as evidence of commercial availability” prior to the date of invention. (Opp'n 4.) To the extent Alkermes does rely on them for that purpose, such as in Dr. Berkland's

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