Paper No. 16
Date Filed: December 14, 2016

Filed On Behalf Of:

Alkermes Pharma Ireland Limited and
Alkermes Controlled Therapeutics, Inc.

By:

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212-218-2100

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' OBJECTIONS UNDER 37 C.F.R. § 42.64 TO EVIDENCE SUBMITTED BY PETITIONERS DURING A PRELIMINARY PROCEEDING

Pursuant to 37 C.F.R. § 42.64(b)(1), Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc. ("Patent Owners") object to the admissibility of the following exhibits on the grounds set forth below. All evidence objected to below was submitted by Petitioners Luye Pharma Group Limited, Luye Pharma (USA) Limited, Shandong Luye Pharmaceutical Company, Limited, and Nanjing Luye Pharmaceutical Co., Limited, ("Petitioners" or "Luye") with their Petition seeking *inter parties* review of U.S. Patent No. 6,667,061 ("the '061 patent"). The Board partially instituted review of the '061 patent on November 30, 2016. *See* Paper 13. Therefore, these objections are timely.

In this paper, a reference to "F.R.E." means the Federal Rules of Evidence, and a reference to "C.F.R." means the Code of Federal Regulations. All objections under F.R.E. 802 (hearsay) apply to the extent Petitioners rely on the exhibits identified in connection with that objection for the truth of the matters asserted therein.

Patent Owners object as follows:

Exhibit 1001: '061 Patent

Patent Owners object to Exhibit 1001 under F.R.E. 802 and 37 C.F.R § 42.61(c) (hearsay).

Exhibit 1002: Declaration of Dr. Patrick P. DeLuca

Patent Owners object to Exhibit 1002 under F.R.E. 802 (hearsay), 702 (improper expert testimony) and 703 (bases for expert opinion) as the testimony is not based on sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case.

Patent Owners object to Exhibit 1002 under 35 U.S.C. § 312(a)(3); 37 C.F.R. §§ 42.65(a) and 42.104(b)(5); and F.R.E. 702 (improper expert testimony), 402 (relevance), and 403 (confusing, waste of time) for failing to identify with particularity the underlying facts and data on which the opinion is based: ¶¶ 9-13, 25, 33, 34, 39, 46, 48, 50-52, 60-62, 66-68, 71, 74-75, 78, 80-86 fail to cite any support at all, or include at least one statement that does not cite any support; and ¶¶ 20, 36, 40, 42, 44 cite or refer to entire exhibits without identifying which aspects of those references are relied upon.

Patent Owners also object to Exhibit 1002 ¶¶ 1-3, 17, 23, 31, 33, 45-46, 83-91 under F.R.E. 402 (relevance) and 403 (confusing, waste of time) as these paragraphs are not cited in the Petition.

Patent Owners further object to Exhibit 1002 ¶¶ 32, 64-66, 72-74 under F.R.E. 402 (relevance) and 403 (confusing, waste of time) as these paragraphs are

not cited in the Petition with respect to grounds for which *inter partes* review was instituted.

Patent Owners also object to Exhibit 1002 ¶¶ 10, 14-32, 34-44, 47-65, 67-73, 75-82 under F.R.E. 702 (improper expert testimony), 703 (bases of an expert opinion), 402 (relevance), and 403 (confusing, waste of time) as these paragraphs include expert opinion based on documents that are inadmissible under at least F.R.E. 802 (hearsay), 702 (improper expert testimony), 703 (bases of an expert opinion), 402 (relevance), or 403 (confusing, waste of time). Patent Owners further object to Exhibit 1002 ¶ 25 because it cites to an exhibit number that does not exist in the Petitioners' exhibit list.

Patent Owners also object to Exhibit 1002 ¶¶ 36, 55, 66, 68, 74-77, 80, 82-86 under F.R.E. 702 (improper expert testimony), 703 (bases of an expert opinion), 402 (relevance), and 403 (confusing, waste of time). The declarant is not stated to have expertise with respect to legal patent analysis. The exhibit does not include a section discussing the legal framework upon which his invalidity opinions are based. Additionally, the declarant does not specify the basis for his arguments or conclusions on invalidity, including at least obviousness. Thus, the declarant has not based the opinions in this exhibit on proper legal standards.

Exhibit 1005: WO 95/13799 ("Ramstack")

Patent Owners object to Exhibit 1005 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time). Patent Owners also object to Exhibit 1005 to the extent Petitioners seek to rely on it to establish the presence of any claim limitation in a ground upon which Exhibit 1005 was not instituted.

Exhibit 1006: Select Entries from U.S. Pharmacopeia

Patent Owners object to Exhibit 1006 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time). Patent Owners also object to Exhibit 1006, which was not cited in the grounds upon which review was instituted, to the extent Petitioners seek to rely on it to establish the presence of any claim limitation.

Exhibit 1007: Select Entries from European Pharmacopoeia Entries

Patent Owners object to Exhibit 1007 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time). Patent Owners also object to Exhibit 1007, which was not cited in the grounds upon which review was instituted, to the extent Petitioners seek to rely on it to establish the presence of any claim limitation.

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