

Filed On Behalf Of:

Alkermes Pharma Ireland Limited and
Alkermes Controlled Therapeutics, Inc.

By:

Scott K. Reed
sreed@fchs.com
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

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 Petitioners’ Reply (Paper 40) filed on June 9, 2017. 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 1024: “Supplemental Declaration of Dr. Patrick P. DeLuca, June 9, 2017”

Patent Owners object to Exhibit 1024 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 1024 under 37 C.F.R. §§ 42.65(a), 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: ¶¶ 5, 11, 15-17, 19, 21-24, 26, 28, 30-31, 37-39, 41-44, 46, 48-52, 54, 57-64, 66-67, 69-71, 73-80, 86-88, 90-91, 93, 101, 104-105, 110-112, 114, 116-119 fail to cite any support at all, or include at least one statement that does not cite any support; and ¶¶ 9, 18, 34-36, 42, 68, 95, 102 cite or refer to entire exhibits without identifying which aspects of those references are relied upon.

Patent Owners also object to Exhibit 1024 ¶¶ 1-3, 6, 31, 33-42, 45, 53, 72, 77-78, 81, 84-85, 98, 101, 109-112, 121 under F.R.E. 402 (relevance) and 403 (confusing, waste of time) as these paragraphs are not cited in Petitioners' Reply.

Patent Owners also object to Exhibit 1024 ¶¶ 7-18, 20, 22, 24-30, 32, 35, 43, 47-48, 54-56, 58, 63-65, 68-70, 76, 82-87, 91, 94-95, 100-102, 105-107, 109, 115-116 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).

Exhibit 1026: “Stedman’s Medical Dictionary (26th ed. 1995)”

Patent Owners object to Exhibit 1026 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1027: “Decapetyl components sheet”

Patent Owners object to Exhibit 1027 under F.R.E. 901 (authenticity), 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1028: “International Publication No. WO 97/44039 (“Francois”)

Patent Owners object to Exhibit 1028 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1030: “Nutropin Label (December 1999)”

Patent Owners object to Exhibit 1030 under F.R.E. 901 (authenticity), 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1031: “Deposition Transcript of Cory J. Berkland, Ph.D., May 26, 2017”

Patent Owners object to Exhibit 1031 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1032: “Macket et al., Tolerability of intramuscular injections of testosterone ester in oil vehicle, PubMed-NCBI, 10(4) Hum. Reprod. 862-5 (April 1995)”

Patent Owners object to Exhibit 1032 under F.R.E. 901 (authenticity), 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1034: “USP 23 NF 18, Suspensions, The U.S. Pharmacopeia, The Nat’l Formulary, Jan. 1, 1995”

Patent Owners object to Exhibit 1034 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1036: “Hawley’s Condensed Chemical Dictionary (12th ed. 1993)”

Patent Owners object to Exhibit 1036 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1037: “(Ch.19) Organic Chemistry (2nd ed. 1998)”

Patent Owners object to Exhibit 1037 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 1038: “U.S. Patent No. 5,417,982”

Patent Owners object to Exhibit 1038 under F.R.E. 802 and 37 C.F.R. § 42.61(c) (hearsay), F.R.E. 901 (authenticity), 402 (relevance), and 403 (confusing, waste of time).

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