Trials@uspto.gov
571.272.7822

Paper No. 13
Entered: November 30, 2016

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.,
Petitioner,

v.

ALKERMES PHARMA IRELAND LTD. and
ALKERMES CONTROLLED THERAPEUTICS, INC.,
Patent Owner.

Case IPR2016-01096
Patent 6,667,061 B2

Before LORA M. GREEN, ROBERT A. POLLOCK, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Shandong Luye Pharmaceutical Co., Ltd., and Nanjing Luye Pharmaceutical Co., Ltd. (collectively "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–13 and 17–23 of U.S. Patent No. 6,667,061 B2 (Ex. 1001, "the '061 patent"). Paper 5 ("Pet."). Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc. (collectively, "Patent Owner") filed a Preliminary Response to the Petition. Paper 11 ("Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–13 and 17–23. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Petitioner states that it has filed a second request for *inter partes* review seeking cancellation of claims 1–13 and 17–23 of the '061 patent on other grounds. Pet. 1; Prelim. Resp. 1 n.1. That petition for *inter partes* review, IPR2016-01095, is being decided concurrently with the instant proceeding.

B. The '061 Patent (Ex. 1001)

The '061 patent issued on December 23, 2003, with J. Michael Ramstack, M. Gary I. Riley, Stephen E. Zale, Joyce M. Hotz, and Olufunmi

L. Johnson as the listed co-inventors. Ex. 1001. According to the '061 patent, it is drawn "to injectable suspensions having improved injectability." *Id.* at 1:12–14.

The '061 patent discloses:

> Injectable suspensions are heterogeneous systems that typically consist of a solid phase dispersed in a liquid phase, the liquid phase being aqueous or nonaqueous. To be effective and pharmaceutically acceptable, injectable suspensions should preferably be: sterile; stable; resuspendable; syringeable; injectable; isotonic; and nonirritating. The foregoing characteristics result in manufacturing, storage, and usage requirements that make injectable suspensions one of the most difficult dosage forms to develop.

Id. at 1:17–25.

The '061 patent teaches that viscosity enhancers are added to injection vehicles to prevent settling of particles, but notes that viscosity is kept low to facilitate mixing and make the suspension easier to inject. *Id.* at 2:25–30. According to the '061 patent, it was "unexpectedly discovered that injectability is improved, and in vivo injectability failures significantly and unexpectedly reduced, by increasing the viscosity of the fluid phase of an injectable suspension." *Id.* at 4:57–60. The '061 patent teaches that "is in contrast to conventional teachings that an increase in the viscosity hinders injectability and syringeability." *Id.* at 4:60–62.

The '061 patent specifically teaches that "microparticles" and "microspheres" refer to "particles that contain an active agent or other substance dispersed or dissolved within a polymer that serves as a matrix or binder of the particle," wherein the "polymer is preferably biodegradable and biocompatible." *Id.* at 5:14–19.

The '061 patent specifically teaches the following injection vehicles: Vehicle A: 0.9% saline and 0.1% Tween 20; Vehicle B: 1.5% CMC, 30% sorbitol, and 0.2% Tween 20; and Vehicle C: 3% CMC, 0.1% Tween 20, and 0.9% saline. *Id.* at 9:38–46. According to the '061 patent, Vehicle A had a viscosity of 1.0 cp, Vehicle B had a viscosity of 24 cp, and Vehicle C had a viscosity of 56 cp. *Id.* at 10:Table 4. The '061 patent specifically teaches that CMC is a viscosity enhancing agent. *Id.* at 12:14–20.

C. Challenged Claims

Petitioner challenges claims 1–13 and 17–23 of the '061 patent. Claim 1, the only independent claim of the '061 patent, is representative:

> 1. A composition suitable for injection through a needle into a host, comprising:
>
> microparticles comprising a polymeric binder; and
>
> an injection vehicle, wherein said microparticles are suspended in said injection vehicle at a concentration of greater than about 30 mg/ml to form a suspension, *wherein a fluid phase of said suspension has a viscosity greater than about 20 cp and less than about 600 cp at 20° C.*, wherein the viscosity of said fluid phase of said suspension provides injectability of the composition through a needle ranging in diameter from 18–22 gauge.

Ex. 1001, 18:6–16 (emphasis added).

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–13 and 17–23 of the '061 patent on the following grounds (Pet. 4):

References	Basis	Claims Challenged
Johnson[1] and Kino[2]	§ 103	1–13 and 17–23
Gustafsson,[3] Ramstack,[4] and the Handbook[5]	§ 103	1–13 and 17–23

Petitioner relies also on the Declaration of Patrick Deluca, Ph.D. (Ex. 1002).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–45 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, we presume that a claim term carries its "ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question" at the time of the invention.

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[1] Johnson et al., U.S. Patent No. 5,654,010, issued August 5, 1997 (Ex. 1009) ("Johnson").

[2] Kino et al., U.S. Patent No. 5,656,299, issued August 12, 1997 (Ex. 1010) ("Kino").

[3] Gustafsson et al., WO 97/14408, published April 24, 1997 (Ex. 1011) ("Gustafsson").

[4] Ramstack et al., WO 95/13799, published May 26, 1995 (Ex. 1005) ("Ramstack").

[5] HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, 78–81, 135–138, 294–298, 329–330, 375–378, 420–421, 439–442, 477–482 (Ainley Wade and Paul J Weller, ed., Am. Pharm. Ass'n & Pharm. Press 2nd ed. 1994) (Ex. 1008) ("the Handbook").

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