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Paper No. 74
Filed: November 28, 2017

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 Judge*.

GREEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Determining That Claims 1–13 and 17–23 Have Not Been Shown to Be Unpatentable
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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."). We determined that the information presented in the Petition and the Preliminary Response demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1–13 and 17–23 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, we instituted trial on November 30, 2016, as to those claims of the '061 patent. Paper 13 ("Institution Decision" or "Dec. Inst.").

Patent Owner filed a Response (Paper 33, "PO Resp."), to which Petitioner filed a Reply (Paper 40). Patent Owner filed Observations on the Cross-Examination of Patrick DeLuca (Paper 50), to which Petitioner filed a Response (Paper 59). Patent Owner was authorized to file a paper identifying what it considered to be new and improper arguments in Petitioner's Reply (Paper 44), to which Petitioner was allowed a response (Paper 46). Patent Owner filed a Motion to Exclude (Paper 51), to which Petitioner filed an Opposition (Paper 57), and Patent Owner filed a Reply (Paper 62). Petitioner also filed a Motion to Exclude (Paper 47), to which Patent Owner filed an Opposition (Paper 56), and Petitioner filed a Reply (Paper 61). With authorization from the Board, Petitioner filed a second Motion to Exclude (Paper 70), to which Patent Owner filed an Opposition

(Paper 71), and Petitioner filed a Reply (Paper 72). Oral hearing was held on August 28, 2017, and a transcript of that hearing has been entered into the record. Paper 73 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Based on the record before us, we conclude that Petitioner has failed to demonstrate by a preponderance of the evidence that claims 1–13 and 17–23 of the '061 patent are unpatentable. Moreover, we *dismiss* Patent Owner's Motion to Exclude as improper. We also deny Petitioner's Motions to Exclude in part, and dismiss in part.

A. Related Proceedings

Petitioner 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, was *denied*. IPR2016-01095, Paper 13.

B. The '061 Patent

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 1:13–14.

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 carboxymethyl cellulose (“CMC”) is a viscosity enhancing agent. *Id.* at 12:14–20.

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.

C. Illustrative Claim

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 20º 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, 18:6–17 (emphasis added).

D. Instituted Challenges

We instituted trial on the following grounds (Pet. 33):

References	Basis	Claims Challenged
Johnson[1] and Kino[2]	§ 103	1–13, 22, and 23
Gustafsson,[3] Ramstack,[4] and the Handbook[5]	§ 103	1–3, 6–9, 12, 13, and 17–23

[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

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