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Paper No. 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

ALKERMES PHARMA IRELAND LIMITED,
Patent Owner.

Case IPR2018-00943
Patent 7,919,499 B2

Before CHRISTOPHER M. KAISER, JACQUELINE T. HARLOW, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Amneal Pharmaceuticals LLC ("Petitioner") requests an *inter partes* review of claims 1–13 of U.S. Patent No. 7,919,499 B2 ("the '499 patent," Ex. 1001). Paper 1 ("Pet."). Alkermes Pharma Ireland Limited ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review "unless . . . 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(a). On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314(b) may not institute review on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018). Moreover, in accordance with USPTO Guidance, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial) ("USPTO Guidance").

Applying those standards, and upon consideration of the information presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '499 patent is unpatentable. Accordingly, we institute an *inter partes* review of all challenged claims (1–13) of the '499 patent, based on all grounds raised in the Petition.

II. BACKGROUND

A. Related Matters

The parties state that there are no pending judicial proceedings involving the '499 patent. Pet. 61; Paper 6, 1. Patent Owner states that U.S. Patent Application No. 15/486,869 claims priority to the '499 patent and is currently pending before the Office. Paper 6, 1.

B. The '499 Patent

The '499 patent, titled "Naltrexone Long Acting Formulations and Methods of Use," issued on April 5, 2011. Ex. 1001, at [45]. The '499 patent relates to "a method for treating an individual in need of naltrexone comprising the step of parenterally administering a long-acting formulation comprising naltrexone." *Id.*, at [57].

According to the '499 patent, "[a]lcohol dependence is a chronic disorder that results from a variety of genetic, psychological and environmental factors." *Id.* at 1:13–14. The '499 patent states that, "[i]n the past, most rehabilitative treatments have been psychosocial." *Id.* at 1:18–19. But, "[w]ith advances in neurobiology, there is increasing interest in drug therapy for alcohol dependence," such as naltrexone therapy. *Id*. at 1:19–27.

The '499 patent states that "[t]he inventions described herein arose from unexpected discoveries made during clinical trials with a long acting formulation of naltrexone." *Id.* at 1:31–33. Specifically, "[t]his invention arose from the unexpected discovery that substantially improved serum levels of naltrexone can be achieved by administering long acting formulations of naltrexone, such as the Alkermes, Inc. formulation, Vivitrex® injectable suspension, made employing its Medisorb® delivery system." *Id.* at 2:29–34.

In one embodiment, the "invention includes a method for treating an individual in need of naltrexone comprising the step of parenterally administering a long acting formulation comprising naltrexone." *Id.* at 2:22–25. The formulation dosage preferably ranges from about 310 to about 480 mg of naltrexone. *Id.* at 1:45–46. The '499 patent states that the long acting formulation "may be achieved through the use of polymers (preferably poly-lactide or poly-lactide-co-glycolide polymers) to entrap or encapsulate the naltrexone." *Id.* at 3:11–16. The '499 patent identifies a preferred polylactide-co-glycolide ("PLGA") polymer as MEDISORB® 7525 DL polymer. *Id.* at 5:43–46; 6:44–51.

The '499 patent states that the disclosed method unexpectedly achieves a serum AUC of naltrexone that is "preferably at least about three times" that achieved by 50 mg/day oral administration of naltrexone. *Id.* at 2:22–28. The '499 patent provides a "semi-quantitative comparison" of the efficacy of long-acting naltrexone with oral naltrexone. *See id.* at 18:4–19:34 (Example 3). The '499 patent states that "oral naltrexone significantly decreased the relapse rate by 36% relative to placebo," whereas "Vivitrex suspension 380 mg significantly decreased the relapse rate by 45% relative to placebo." *Id.* at 18:57–67.

C. Illustrative Claim

Petitioner challenges the patentability of claims 1–13, but not claims 14 and 15, of the '499 patent. Of the challenged claims, claim 1 is independent and illustrative of the claimed subject matter. Claim 1 recites:

> 1. A method for treating an individual in need of naltrexone comprising the step of parenterally administering a long acting formulation comprising about 310 mg to about 480 mg of naltrexone and a biocompatible polymer to the individual wherein the serum AUC of naltrexone is about three times

> greater than that achieved by 50 mg/day oral administration and wherein the biocompatible polymer is a polylactide-co-glycolide polymer.

Ex. 1001, 21:2–9.

D. The Prior Art

Petitioner advances the following references as prior art on which it relies for the asserted grounds challenging the claims of the '499 patent:

1. Sandra D. Comer et al., *Depot naltrexone: long-lasting antagonism of the effects of heroin in humans*, 159(4) PSYCHOPHARMACOLOGY 351–30 (2002) ("Comer," Ex. 1010);

2. Elie S. Nuwayser, U.S. Patent No. 7,157,102 B1 (issued Jan. 2, 2007) ("Nuwayser," Ex. 1014);

3. G. Rubio et al., *Naltrexone versus acamprosate: one year follow-up of alcohol dependence treatment*, 36(5) ALCOHOL & ALCOHOLISM 419–25 (2001) ("Rubio," Ex. 1028);

4. Steven G. Wright et al., U.S. Patent No. 6,264,987 B1 (issued July 24, 2001) ("Wright," Ex. 1018);

5. Henry R. Kranzler et al., *Sustained-Release Naltrexone for Alcoholism Treatment: A Preliminary Study*, 22(5) ALCOHOLISM CLINICAL & EXPERIMENTAL RES. 1074–79 (1998) ("Kranzler," Ex. 1011);

6. Alkermes, Inc., *Form 10-K: Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934* (July 2002) ("Alkermes 10-K," Ex. 1016); and

7. U.S. Trademark Application No. 76/271,990 for Vivitrex (Aug. 2002) ("Vivitrex Specimen," Ex. 1017).

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