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Paper No. 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KVK-TECH, INC.
Petitioner,

v.

SHIRE PLC
Patent Owner.

Case IPR2018-00293
Patent 9,173,857 B2

Before RAMA G. ELLURU, SHERIDAN K. SNEDDEN, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

KVK-Tech, Inc. ("Petitioner") filed a corrected Petition requesting an *inter partes* review of claims 1–29 of U.S. Patent No. 9,173,857 B2 (Ex. 1001, "the '857 patent"). Paper 7 ("Pet."). Shire PLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9[1] ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "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 may not institute on fewer than all the claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Upon considering the Petition and Preliminary Response, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least claim 1 of the '857 patent. Accordingly, we institute an *inter partes* review of all challenged claims and grounds asserted in the Petition. *See* "Guidance on the impact of *SAS* on AIA trial proceedings" (April 26, 2018) (https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial).

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[1] Shire first filed a confidential version of the Patent Owner's Preliminary Response. Paper 8.

A. Related Proceedings

Petitioner identifies a concurrently filed petition for *inter partes* review of claims 1–31 of the parent patent to the '857 patent, U.S. Patent No. 8,846,100 (the "'100 patent") based on similar grounds, which has been assigned Case No. IPR2018-00290. Pet. 3. Patent Owner asserts that the '857 patent is being asserted in *Shire Development LLC et al v. Teva Pharmaceuticals USA, Inc. et al*, 1:17-cv-01696-RGA (D. Del). Paper 3, 1.

B. The '857 Patent

The '857 patent relates to a "long-acting amphetamine pharmaceutical composition, which includes an immediate release component, a delayed pulsed release component and a sustained release component, to meet the therapeutic needs for [Attention Deficit Hyperactivity Disorder "ADHD"] patients with longer-day demands." Ex. 1001, 3:61–65.

ADDERALL is the immediate release ("IR") formulation of a mixture of four amphetamine salts indicated for the treatment of ADHD in children. *Id.* at 1:59– 3:19. The '857 patent describes multiple solutions known in the art for lengthening the release of orally consumed drugs, including ADDERALL XR, which extended the release profile of ADDERALL. Ex. 1003 at 4. However, the '857 patent indicates that some patients require an additional dosage of medication to extend the short-acting effect even further, such that "clinicians have augmented the morning long-acting formulation, typically at 8-10 hours post-dose [of ADDERALL XR], with a dose of the same immediate-release (IR) medication." *Id.* at 3:42–51. Consequently, the '857 patent states that a need exists for a "once-daily, long-acting oral composition that provides effective treatment of ADHD,

without supplementation, for patients with longer day demands (e.g., 14-16 awake hours)." *Id.* at 3:54–57.

The disclosed long-acting amphetamine pharmaceutical composition includes "an immediate release component, a delayed pulsed release component and a sustained release component, to meet the therapeutic needs for ADHD patients with longer-day demands." *Id.* at 3:61–65. The '857 patent states that the composition is "bioequivalent to an equal dosage of ADDERALL XR® followed by an IR amphetamine composition 8 hours later." *Id.* at 3:65–43; 4:9–11.

C. Illustrative Claim

Petitioner challenges claims 1–29 of the '857 patent, of which claim 1 is the only independent claim. Claim 1 is representative and is reproduced below:

> 1. A method for treating attention deficit hyperactivity disorder (ADHD) which comprises:
>
> administering to a patient in need thereof, a pharmaceutical composition comprising:
>
> (a) an immediate release bead comprising at least one amphetamine salt;
> (b) a first delayed release bead comprising at least one amphetamine salt; and
> (c) a second delayed release bead comprising at least one amphetamine salt; wherein the first delayed release bead provides pulsed release of the at least one amphetamine salt and the second delayed release bead provides sustained release of the at least one amphetamine salt;
>
> wherein the second delayed release bead comprises at least one amphetamine salt layered onto or incorporated into a core; a delayed release coating layered onto the amphetamine core; and a sustained release coating layered onto the delayed release coating,

wherein the sustained release coating is pH-independent; and wherein the first delayed release bead and the second delayed release bead comprise an enteric coating.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–29 of the '857 patent on the following grounds:

Reference(s)	Basis	Claims challenged
Burnside[2]	§ 102(a)	1–19, 29
Burnside	§ 103	1–29
Adderall XR[3,4] and Burnside	§ 103	1–29

Petitioner also relies on the following declarations:

Exhibit	Reference
1004	Declaration of Diane J. Burgess, Ph.D.
1006	Declaration of William J. Jusko, Ph.D.

II. ANALYSIS

A. Discretionary Denial

35 U.S.C. § 325(d) provides, in relevant part: "In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or

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[2] Burnside, Beth A. et al., US 6,605,300 B1, issued August 12, 2003 ("Burnside," Ex. 1002).
[3] PHYSICIANS' DESK REFERENCE, entry for Adderall XR, 3144–3146 (58th ed. 2004) ("ADDERALL XR," Ex. 1003).
[4] FDA ADDERALL XR Label, 2004 (Published August 2004) ("ADDERALL XR," Ex. 1031).

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