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Paper No. 56
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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*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–29 of U.S. Patent No. 9,173,857 B2 (Ex. 1001, "the '857 patent"). We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Having reviewed the arguments of the parties and the supporting evidence, we determine that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims are unpatentable.

A. Procedural History

KVK-Tech, Inc. ("Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1–29 of the '857 patent. Paper 7 ("Pet."). Shire PLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9[1] ("Prelim. Resp."). We instituted an *inter partes* review of all challenged claims on all grounds, pursuant to 35 U.S.C. § 314. Paper 13 ("Inst. Dec."), 35.

Patent Owner filed a Response (Paper 19, "PO Resp."). Petitioner filed a Reply (Paper 31, "Reply"). With our permission (*see* Paper 36, authorizing additional briefing), Patent Owner filed a Sur-Reply (Paper 40, "PO Sur-Reply"), and Petitioner filed a Response to Patent Owner's Sur-Reply. (Paper 46, "Pet. Resp. to PO Sur-Reply").

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[1] Patent Owner first filed a confidential version of the Patent Owner's Preliminary Response. Paper 8. We refer to the public version of the Preliminary Response.

Petitioner and Patent Owner both filed Motions to Exclude Evidence. Papers 41 and 44, respectively. Petitioner and Patent Owner both filed respective Oppositions to Motions to Exclude Evidence. Papers 45 and 47, respectively. Petitioner and Patent Owner both filed Replies in Support of the Motion to Exclude Evidence. Papers 50 and 49, respectively.

An oral hearing was held on April 4, 2019, and a transcript of the hearing is included in the record. Paper 53 ("Tr.").

B. Related Proceedings

Petitioner states that another petitioner previously petitioned for *inter partes* review of claims 1–31 of U.S. Patent No. 8,846,100 (the "'100 patent"), the application of which is the parent to the '857 patent (Case IPR2017-00665), but withdrew its Petition prior to the deadline for Patent Owner's Preliminary Response. Pet. 3; Paper 3, 1. Petitioner also identifies a concurrently filed petition for *inter partes* review of the '100 patent, which was instituted as case 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.*, 1:17-cv-01696-RGA (D. Del). Paper 3.

C. The '857 Patent

The '857 patent relates to a "method for treating attention deficit hyperactivity disorder (ADHD)" comprising administering a "long-acting amphetamine pharmaceutical composition, which includes an immediate release component, a delayed pulsed[2] release component and a sustained

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[2] U.S. Patent No. 6,555,136 (Apr. 29, 2003) (Ex. 1018, "Midha") at 1:30–35 explains that "[f]or some types of drugs, it is preferred to release the drug in 'pulses,' wherein a single dosage form provides for an initial dose of drug followed by a release-free interval, after which a second dose of drug is

release component, to meet the therapeutic needs for [Attention Deficit Hyperactivity Disorder "ADHD"] patients with longer-day demands." Ex. 1001, 3:61–65, claim 1. "The present invention fills the need for once-daily longer-day treatment of ADHD by providing an amphetamine pharmaceutical composition that is bioequivalent to an equal dosage of ADDERALL XR® followed by an IR amphetamine composition 8 hours later." *Id*. at 3:65–4:3.

Adderall is the immediate release ("IR") formulation of a mixture of four amphetamine salts indicated for the treatment of ADHD in children. *Id*. at 3:13–19. According to the '857 patent, one disadvantage of IR-only treatments for children is that two separate doses are required to be administered, one in the morning and one approximately 4–6 hours later. *Id*. at 3:20–27. "ADDERALL XR® met the need for a dosage form, which can be administered once, in place of the two oral doses which are needed using the conventional drug delivery formulations of the prior art." *Id*. at 3:27–30. Adderall XR is designed to provide a duration effect up to 12 hours. *Id*. at 3:39–42.

The '857 patent indicates that some patients, however, require additional treatment with a short-acting stimulant to extend the daily therapeutic effect. *Id*. at 3:34–37. "For patients taking long-acting stimulant formulations who require duration of clinical benefit beyond 10-12 hours, clinicians have augmented the morning long-acting formulation [of Adderall XR], typically at 8-10 hours post-dose, with a dose of the same immediate-release (IR) medication." *Id*. at 3:45–49. Thus, the '857 patent recognizes

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released, followed by one or more additional release-free intervals and drug release 'pulses.'"

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.

D. 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.

Ex. 1001, 31:56–32:36.

Dependent claims 2–29 recite additional, or more restricted, limitations with respect to those in claim 1, including specifying

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