

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 9¹ (“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”).

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 pulsed² release component and a sustained

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

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

coating characteristics or components (claims 2–4, 13–16, and 29), pharmaceutical parameters (claims 5–12), amphetamine salts and amounts in the composition (claims 17, 18, and 20–28). *Id.* at 32:39–34:24. Claim 19 recites that “the composition does not include a food effect. *Id.* at 34:1–2.

E. Challenged Claims and Reviewed Grounds of Unpatentability

We instituted a trial to consider Petitioner’s challenges to the patentability of claims 1–29 of the ’857 patent on the following grounds (Ins. Dec. 34):

Reference(s)	Basis	Claims challenged
Burnside ³	§ 102(a)	1–19, 29
Burnside	§ 103	1–29
Adderall XR ^{4,5} and Burnside	§ 103	1–29

Petitioner relies on the Declarations of Dr. Diane Burgess (Ex. 1004, “Burgess Decl.”), Dr. William Jusko (Ex. 1006, “Jusko Decl.”), and Dr. James McCracken (Ex. 1045, “McCracken Decl.”).

³ Burnside, Beth A. et al., US 6,605,300 B1, issued August 12, 2003 (“Burnside,” Ex. 1002).

⁴ PHYSICIAN’S DESK REFERENCE, entry for Adderall XR, 3144–3146 (58th ed. 2004) (“Adderall XR,” Ex. 1003).

⁵ FDA Adderall XR Label, 2004 (published August 2004) (“Adderall XR,” Ex. 1031).

Patent Owner relies on the Declarations of Dr. Bernhardt Trout (Ex. 2001, “Trout Decl.”), Dr. Sara Rosenbaum (Ex. 2002, “Rosenbaum Decl.”), and Dr. James Polli (Ex. 2060, “Polli Decl.”).

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (internal quotation and citation omitted). In addition, the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required where “the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

Petitioner proposes that the person of ordinary skill would have had “at least a Bachelor of Science Degree in Pharmacy, Chemistry, or Chemical Engineering, or similar field, and experience in the field of pharmaceuticals (including pharmaceutical formulation or pharmacokinetics or a similar technical field of study).” Pet. 16 (emphasis added); Ex. 1004 ¶ 21. Petitioner further asserts that a person of ordinary skill in the art would have had “access to and may consult with a pharmacologist with experience in pharmacokinetics and/or an M.D. with experience with ADHD and pharmacological treatments for ADHD.” Pet. 16; *see also* Tr. 67:11–68:8.

Patent Owner proposes that a person of ordinary skill in the art at the time of the invention would have had “a Bachelor of Science Degree in Pharmacy, Chemistry, or Chemical Engineering, or similar field, and three years of experience in the field of pharmaceuticals (including pharmaceutical formulation or pharmacokinetics or a similar technical field of study).” PO Resp. 17 (emphasis omitted). Patent Owner notes that Petitioner proposes “at least” a certain identified skill level, whereas Patent Owner proposes “three years” of experience. *Id.* at 15. According to Patent Owner, “[i]f Petitioner’s ‘at least’ imputes a *higher* skill, as by osmosis from others on a team, *Okajima*’s reasoning could ‘bridge over gaps’ in Petitioner’s case, and disfavor Patent Owner via hindsight.” *Id.* at 16.

To the extent Petitioner’s proposed “at least” interjects ambiguity in the level of ordinary skill, we do not adopt that part of Petitioner’s proposed definition. Otherwise, we find it is not necessary to resolve any perceived differences in the parties’ definitions of the level of ordinary skill in the art for purposes of this Final Written Decision. With the deletion of the “at least” in Petitioner’s proposed definition of the level of ordinary skill, our determination regarding the patentability of the challenged claims does not turn on any remaining differences between the parties’ definitions; our conclusions would be the same under either assessment.

B. Claim Interpretation

In an *inter partes* review filed before November 13, 2018, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which

they appear.⁶ 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

In our Decision on Institution, we construed “about” and “no food effect” consistent with their definitions in the specification of the ’857 patent. Inst. Dec. 11–13. In particular, the ’857 patent specification defines “food effect” as “a significant difference in the bioavailability of a drug in a patient when the drug is administered in a fasted state compared to a fed state.” Ex. 1001, 12:4–9. Thus, we construe no “food effect” precisely as defined by the specification—no “significant difference in the bioavailability of a drug in a patient when the drug is administered in a fasted state compared to a fed state.” Neither party contested our construction of these

⁶ The Office recently changed the claim construction standard applicable to an *inter partes* review. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018). The rule changing the claim construction standard, however, does not apply to this proceeding because Petitioner filed its Petition before the effective date of the final rule, i.e., November 13, 2018. *Id.* at 51,340 (rule effective date and applicability date), 51,344 (explaining how the Office will implement the rule).

terms and we see no reason to modify that construction in light of the record developed at trial.

We have not identified any other terms that require construction for purposes of determining whether Petitioner has demonstrated unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); *Nidec Motor Corp. v. Zhongshan Borad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (*quoting Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)))

E. Overview of the Prior Art

1. Burnside (Ex. 1002)

Burnside relates to “a multiple unit dosage form delivery system comprising one or more amphetamine salts for administering the amphetamine salts to a recipient.” Ex. 1002, 1:9–11.

Burnside discloses examples in which amphetamine salts are layered onto sugar spheres for drug delivery and examples in which the amphetamine salts are further coated with a “protective layer” (enteric coating) to delay the drug release. *Id.* at 10:35–12:26. Burnside states that “suitable materials for the protective layer include cellulose derivatives such as hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, polyvinylpyrrolidone/vinyl acetate copolymer, ethyl cellulose aqueous dispersions (AQUACOAT[®], SURELEASE[®]), EUDRAGIT[®] RL 30D, OPADRY[®] and the like.” *Id.* at 8:20–29.

Example 1 of Burnside discloses immediate release beads containing mixed amphetamine salts.⁷ *Id.* at 10:30–57.

Example 2 of Burnside discloses the coating of mixed amphetamine salts with EUDRAGIT L. *Id.* at 10:60–11:8. “[T]he enteric coating delayed the drug release from the coated pellets until after exposure to pH 6 or higher.” *Id.* at 11:9–10. Figure 4 of Burnside is depicted below:

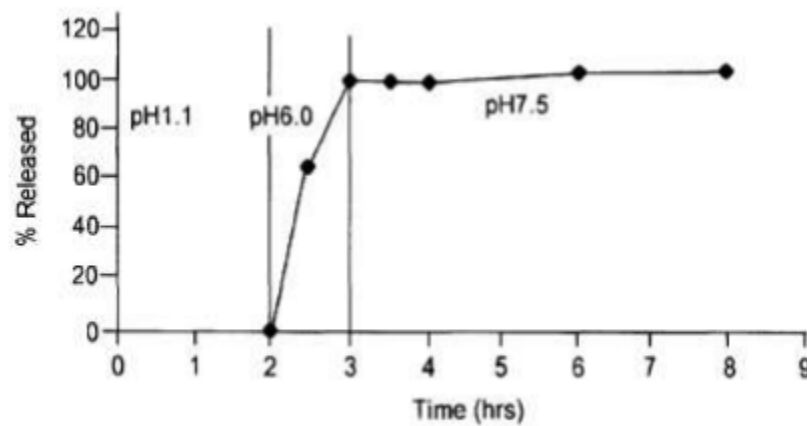


FIG. 4

Figure 4 illustrates the drug release profile of the coated pellets in Example 2. *Id.* at 11:23–24.

Example 3 discloses coating of mixed amphetamine salts with EUDRAGIT 4110D.⁸ *Id.* at 11:26–11:41. “[T]he enteric coating delayed the drug release from the coated pellets until the pH value reached 6.8 or higher.” *Id.* at 11:41–43. Figure 5 of Burnside is depicted below:

⁷ The immediate release beads from Burnside’s Example 1 will be referred to as “Burnside’s Example 1 IR” beads.

⁸ The delayed pulsed beads from Burnside’s Examples 2 and 3 are referred to as “Burnside’s Example 2 DPR beads” or “Burnside’s Example 3 DPR beads.”

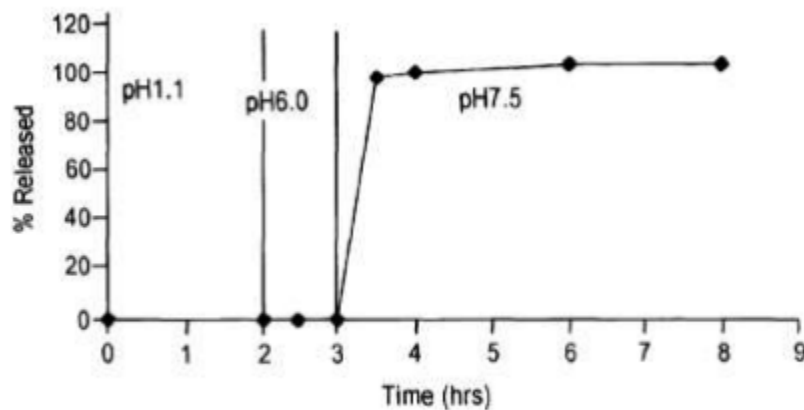


FIG. 5

Figure 5 illustrates the drug release profile of the coated pellets in Example 3. *Id.* at 11:56–57.

Example 4 discloses applying an additional coating to the coated pellets from Example 2 or Example 3 by spraying SURELEASE coating on the outer surfaces of the coated pellets.⁹ *Id.* at 11:59–12:9. Burnside states that the “SURELEASE coating slightly sustained the drug release from EUDRAGIT® L 30D-55 coated pellets at pH 7.5 buffer, while the SURELEASE® coating delayed the drug release up to 2 hours after the buffer switched from pH 1 to pH 7.5.” *Id.* at 12:9–14. Figure 6 of Burnside is depicted below:

⁹ The sustained release beads from Burnside’s Example 4 are referred to as “Burnside’s Example 4 SR” beads.

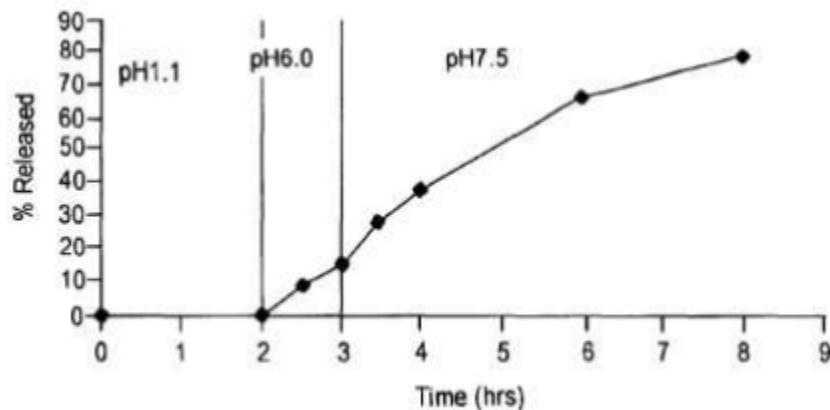


FIG. 6

Figure 6 illustrates the drug release profile of the coated pellets in Example 4. *Id.* at 12:25–26.

Example 5 of Burnside discloses a “pulsatile delivery system” achieved by combining Burnside’s Example 1 IR pellets with Burnside’s Example 2 DPR beads or Burnside’s Example 3 DPR beads.¹⁰ *Id.* at 12:29–31. Burnside discloses that pellets of both types equivalent to half of the total dose are “filled into a hard gelatin capsule to produce the oral pulsed dose delivery system. The delayed-release portion releases the amphetamine salts rapidly and completely, after a specified lag time.” *Id.* at 12:31–36. Figure 8 of Burnside is depicted below:

¹⁰ The beads from Burnside’s Example 5, containing both IR and DPR beads, will be referred as “Burnside’s Example 5 two-bead system.”

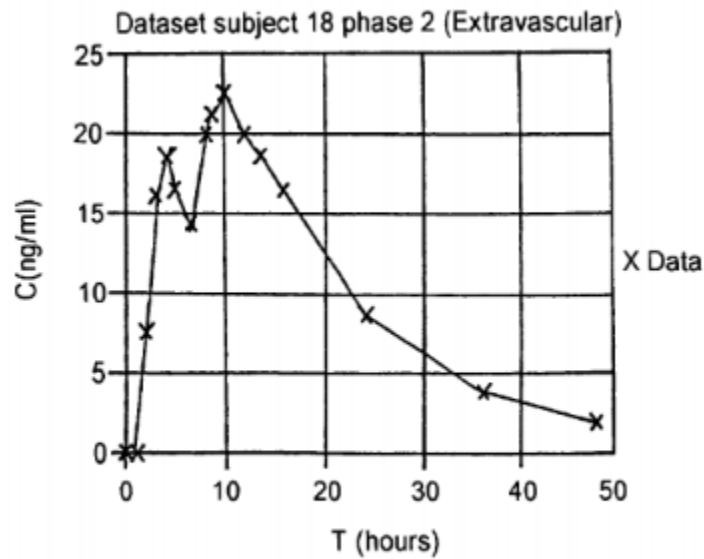


FIG. 8

Figure 8 is the *in vivo* drug release profile of the coated pellets in Example 5. *Id.* at 12:40–41.

2. *Adderall XR (Ex. 1003, 1031)*

Adderall XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Ex. 1031, 34. Adderall XR is administered as a capsule containing “two types of drug-containing beads designed to give a double-pulsed delivery of amphetamines, which prolongs the release of amphetamine” as compared to the Adderall IR formulation.¹¹ Ex. 1031, 14. In addition, food does not affect the extent of absorption of Adderall XR. Ex. 1031, 2.

¹¹ Petitioner’s declarant explains that Adderall XR is “a drug product comprising the same [drug] as Adderall IR®, but within immediate release and delayed pulsed beads with an enteric coating.” Ex. 1004 ¶ 32.

F. Anticipation by Burnside

Petitioner asserts that claims 1–19 and 29 of the '857 patent are anticipated by Burnside under 35 U.S.C. § 102(a). Pet. 4, 17–34.

A prior art reference that expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates. *See, e.g., EMI Group N. Am., Inc., v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001) (“A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim.”). As discussed below, Petitioner has not carried its burden of establishing that Burnside anticipates claim 1 or any of the dependent claims. We focus our analysis on independent claim 1.

Independent claim 1 recites a method for treating ADHD comprising administering to a patient in need thereof, a pharmaceutical composition comprising: (1) an immediate release bead (“the claimed IR bead”) comprising at least one amphetamine salt; (2) a first delayed release bead (“the claimed first DR bead”) comprising at least one amphetamine salt; and (3) a second delayed release bead (“the claimed second DR 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. Thus, the claimed method comprises administering a composition comprising three types of beads, each of which contains a core of amphetamine salt. The claimed first DR bead provides a pulsed release of the salt and comprises an enteric coating. The claimed second DR bead provides a sustained release of the salt, comprises a delayed release coating layered onto the core, and a sustained release coating layered onto the delayed release coating, wherein the sustained release coating is pH-independent and wherein the claimed second DR bead also comprises an enteric coating.

Petitioner refers to Burnside's Examples 1–5 in arguing that Burnside teaches each of the three beads in the composition claimed by claim 1. Pet. 19–25. Petitioner also argues that Burnside teaches the combination of the beads disclosed in Examples 1–4 in the same way as in claim 1. *Id.* at 25–29 (citing *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016)). In support, Petitioner refers to Burnside's statements that “the drug delivery system of the present invention preferably comprises one or a number of beads or beadlets in a dosage form” and “the present invention provides an oral multiple unit pulsed dose delivery system for amphetamine salts.” *Id.* (citing Ex. 1002, 6:33–35, 3:33–35, 1:9–11 (emphasis omitted)). In addition, Petitioner refers to Burnside's Example 5 two-bead system and acknowledges that Example 5 teaches combining pellets from Example 1 with those of either Examples 2 or 3. *Id.* at 24.

Patent Owner argues that because Burnside's Example 4 and 5 beads were never combined and arranged as in claim 1, Burnside does not anticipate the claim. PO Resp. 19–21, 25–26. With supporting testimony of its declarant, Dr. Trout, Patent Owner argues that Burnside's disclosure of

“one or a number of beads in a dosage form” does not teach using more than two types of beads, but rather “means a plurality of IR beads and a plurality of DPR beads. This provides multiple (i.e., two) pulses.” Prelim. Resp. 33 (citing Ex. 2001 ¶¶ 66–71); PO Resp. 26.

In our Decision on Institution, we indicated that we are not sufficiently persuaded by Petitioner’s argument and evidence that Burnside discloses the claimed composition of claim 1—a composition comprising the claimed IR bead, the claimed first DR bead, and the claimed second DR bead. Inst. Dec. 32–34. In particular, we determined that “[w]ithout an express disclosure of the claimed composition or a disclosure within Burnside to combine the three types of claimed beads, Burnside does not disclose all elements of claim 1 within the four corners of the document as arranged in the claim.” *Id.* at 34. Without the composition of claim 1, a skilled artisan could not practice the method of claim 1. Petitioner did not further argue anticipation in its Reply or Response to Patent Owner’s Sur-Reply. Accordingly, we find that Petitioner has not shown by a preponderance of the evidence that Burnside anticipates claim 1, or any dependent claim.

G. Obviousness over Burnside

Petitioner asserts that claims 1–29 are unpatentable under 35 U.S.C. § 103 as obvious over Burnside. Pet. 4, 35–36; 52–57; Pet. Reply 1–17; Pet Resp. to Sur-Reply 1–15.

Obviousness is a question of law based on subsidiary findings of fact. *In re Van Os*, 844 F.3d 1359, 1360 (Fed. Cir. 2017). An obviousness determination requires finding both “that a skilled artisan would have been motivated to combine the teachings of the prior art . . . , and that the skilled

artisan would have had a reasonable expectation of success in doing so.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016). Whether a skilled artisan would have been motivated to modify or combine teachings in the prior art, and whether she would have had a reasonable expectation of success, are questions of fact. *Id.* at 1366. Moreover, Petitioner has the burden to show a motivation to combine and a reasonable expectation of success. *See Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015) (“When asserting that a claimed invention would have been obvious, that party ‘must demonstrate . . . that a skilled artisan would have had reason to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.’” (quoting *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014))); *see also* 35 U.S.C. § 316(e) (“In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.”). As discussed below, Petitioner has not carried its burden of establishing a motivation to combine the teachings of the prior art to achieve the claimed composition¹² that would enable a skilled artisan to practice the method of claim 1, and that a skilled artisan would have had a reasonable expectation of success in doing so.

¹² Although claim 1 is directed at a method of treatment, both parties focus their arguments on the composition recited in claim 1 that is administered in the method of treatment and claimed in the ’100 patent. We adopt this focus with the understanding that the method of treatment cannot be practiced without the recited composition. In addition, we do not analyze the dependent claims due to our finding that Petitioner has not established that independent claim 1 is unpatentable as challenged.

Petitioner argues that Burnside alone renders claim 1 obvious because Burnside Example 5 “teaches each and every limitation associated with the immediate and first delayed release beads of claim 1, and Example 4 teaches the second delayed release beads of claim 1.” Pet. 36. In other words, Petitioner argues that a skilled artisan would have combined Burnside’s Example 4 SR beads with Burnside’s Example 5 two-bead system to arrive at the claimed invention. Patent Owner does not contest that Burnside teaches the three types of beads required by claim 1. *See* PO Resp., generally. Patent Owner, however, argues that a skilled artisan would not have been motivated to combine Burnside’s Example 4 SR beads with Burnside’s Example 5 two-bead system to arrive at the composition of claim 1 and would not have had a reasonable expectation of success in doing so. PO Resp. 29–59. Accordingly, we focus our analysis on these issues.

As an initial matter, Petitioner’s position that a skilled artisan would have been motivated to make the claimed composition and would have had a reasonable expectation of success in doing so rests on Burnside’s disclosure of separate *in vitro* release profiles for the immediate release, delayed pulsed release, and sustained release beads, and *in vivo* results solely for the combination of immediate release and delayed pulsed release beads (i.e., Example 5). *See* Ex. 1004, Example 4, Figs. 6, 7, 8. Burnside does not disclose *in vivo* data for Burnside’s Example 4 SR beads or, more importantly, for a combination that includes Example 4’s SR beads. Yet, relying on the testimony of Drs. Burgess and Jusko, Petitioner contends that the skilled artisan would have been motivated to combine as proposed, because Burnside’s Example 4 SR beads are “capable of releasing additional amphetamine in [a] patient *after* release of [the] amphetamine active in the

two-bead systems of Example 5” and because a skilled artisan “would understand that such later release of amphetamine is necessary to provide prolonged therapeutic efficacy.” Pet. 53 (citing Ex. 1004 ¶¶ 160, 161; Ex. 1006 ¶¶ 19, 34–41, 48). Petitioner’s argument is unavailing.

We are not sufficiently persuaded that a skilled artisan’s knowledge of the individual *in vitro* release profile of Burnside’s Example 4 SR beads (i.e., alleged claimed second DR bead) and the *in vivo* release profile of Burnside’s Example 5 two-bead system (alleged claimed IR and first DR bead) would have led a skilled artisan to the claimed composition. See Ex. 1024, 26 (“[C]urrent *in vitro* methods of evaluating enteric coatings may not accurately predict *in vivo* performance. It is, therefore, important that enteric coated dosage forms be subjected to *in vivo* evaluations.”). It is not disputed that the formulation of Burnside’s Example 4 SR beads is different than Burnside’s Example 5 two-bead system, and that there was no *in vivo* data for Burnside’s Example 4 SR beads. “[W]hether the skilled artisan can extrapolate *in vivo* success from *in vitro* results is highly fact specific.” *Nantkwest, Inc. v. Lee*, 686 F. App’x 864, 870 (Fed. Cir. 2017).

Petitioner’s contention that *in vitro* release profiles translate to *in vivo* release profiles is based on Drs. Jusko’s and Burgess’s opinions. See Tr. 8:21–9:7. However, we give little weight to these opinions because they are not sufficiently factually supported. Dr. Jusko opines that a skilled artisan “would understand that adding the delayed sustained release beads of Example 4 to Adderall XR®, or to Example 5 of Burnside, would release significant additional amphetamine active after all the active in the immediate and delayed pulsed beads has been released.” Ex. 1006 ¶ 37. Dr. Jusko’s opinion, however, is based solely on Burnside’s *in vitro* data.

Id. (citing Ex. 1002, Fig. 6). Dr. Jusko's opinion is conclusory because, for example, he does not sufficiently explain how the *in vitro* release environment disclosed in Burnside's examples would translate to *in vivo* conditions. In *Nantkwest*, "there were specific studies undertaken to determine whether the [cell line at issue] would be useful for *in vivo* therapy." 686 F. App'x at 869. Petitioner does not cite to any such studies here relating to whether the *in vitro* data for Example's 4 SR beads would correlate to *in vivo* results. Indeed, Dr. Jusko testified that such studies are necessary when asked how one would establish whether there is a correlation between an *in vitro* dissolution profile and *in vivo* release of the drug: "In part, it is a well-accepted expectation between *in vitro* dissolution and *in vivo* behavior, but, in part, it needs to be established by an actual study in human subjects." Ex. 2070, 17:3–10.

Dr. Burgess's testimony that "[o]ne *possibly could predict* [*in vivo* pharmacokinetics of an amphetamine drug formulation from *in vitro*]" and "the point of those *in vitro* release tests is to [] give *an idea* of the performance of the drug in the body" is likewise summarily unconvincing. Ex. 2071, 72:6–22 (emphases added). For example, Dr. Burgess does not explain how *in vivo* pH values would affect amphetamine release despite disclosure that dissolution of the delayed release coatings of the beads in Burnside's Examples 4 and 5 is pH-dependent. See PO Resp. 44 (Patent Owner arguing that the *in vitro* releases described in Figures 4–6 of Burnside are "after a pH change at artificial time points," not at a certain time "'after administration' *in vivo*").

In addition, even assuming a skilled artisan would have realized a correlation between *in vitro* and *in vivo* release profiles, Petitioner has not

sufficiently persuaded us that a skilled artisan would translate later *in vivo* release of amphetamine to therapeutic effect. For example, without *in vivo* data for Burnside's Example 4 SR beads, either separately or in a formulation, a skilled artisan would not have sufficiently appreciated the proposed combination's bioavailability, pharmacokinetics, and performance in the body. See PO Resp. 11–14, 50–52; Ex. 2081, 9 (as of 2006, “the design of a unique dissolution test to be used reliably as a prognostic tool of oral drug absorption will not appear in the near future”).

We acknowledge Dr. Jusko's testimony that the skilled artisan would have understood the pharmacokinetics principle of “superposition,” which he explains as follows:

The superposition principle provides that, under linear conditions (i.e., a constant rate of clearance of drug from the body), the total concentration of drug in the body is the sum of the remaining concentrations from each administered dose at the time of measurement plus newly absorbed drug.

Ex. 1006 ¶ 40. However, as explained above, Petitioner does not provide sufficient data to confirm that linear conditions exist such that the superposition principle would apply. In particular, Patent Owner's declarant, Dr. Trout, testifies that “[l]inearity is formulation specific” and “can only be reasonably determined for the same drug in the same dosage form at different doses of that drug, based on known data about that drug and dosage form, including the same structure for the dosage form.”

Ex. 2001 ¶ 134. Indeed, Dr. Burgess testifies that a skilled artisan would perform *in vivo* studies “to find that the formulation, not just the drug, is effective in the body.” Ex. 2071, 39:16–24. In addition, Dr. Burgess, when testifying as to whether different pharmaceutical products containing the same kind and amount of drug may differ in efficacy, admitted that “[i]f you

release [a drug] too slowly, it may not be effective at all because you never got the right level of drug in the body.” *Id.* at 163:13–164:22. And Dr. Jusko states that “therapeutic efficacy is *generally* related to the concentration of active amphetamine in the blood plasma” (Ex. 1006 ¶ 41), but Burnside does not provide any information about what the blood plasma concentration would be for a patient dosed with Example 4’s SR beads. *See* 1002, Fig. 6.

Rather, as Patent Owner’s evidence shows, the art recognized that *in vivo* confirmation of *in vitro* results is important to creating formulations that would achieve the desired treatment in patients. In particular, Patent Owner argues that because various controlled release products of the same drug show differences in performance in varying conditions, without relevant information regarding how a pharmaceutical was metabolized *in vivo*, the skilled artisan would be speculating as to its bioavailability. PO Resp. 3–4, 12–14, 50–52; Ex. 2038, 5 (FDA presentation stating that it is hoped that in the future, *in vitro* testing could be predictive of *in vivo* testing to reduce human studies and accelerate drug development); Ex. 2077, 3 (describing need for and benefits of developing a verified *in vitro/in vivo* correlation (IVIVC) to for use in accurately predicting *in vivo* performance of drugs based on their *in vitro* performance). Ex. 2001 ¶¶ 134–135 (Dr. Trout explaining that there are differences between Burnside’s beads and those in Adderall XR, and thus, the skilled artisan “would not have extrapolated from one to the other and then further have extrapolated to a three bead IR-DPR-SR composition”, certainly not without *in vivo* data to extrapolate from; “[d]rug absorption is complex and unpredictable,” and, thus, the “pharmacokinetics and pharmacodynamics, including plasma concentration

profiles, are often difficult to determine from *in vitro* dissolution or release testing and *vice versa*” (*id.*) and “[i]n *vitro* and *in vivo* systems must be compared ‘for every formulation type’ to develop an IVIVC (*in vitro/in vivo* correlation).”). *Id.* As Dr. Polli explains,

IVIVC is the development of a predictive mathematical model that describes the relationship between the *in vitro* property of a dosage form (i.e., dissolution) and the *in vivo* PK response. . . . Absent a validated IVIVC correlation, it is not possible to predict one from the other (*in vitro* $\leftrightarrow$ *in vivo*) for any drug development, for any meaningful degree of clinical or therapeutic success.

Ex. 2060 ¶¶ 51–52.

Petitioner has provided no evidence of an IVIVC, or sufficient evidence from which one could be constructed. In contrast, Dr. Polli explains that a skilled artisan would have known that the data in Burnside was insufficient for use in making qualitative or quantitative predictions because the pH changes that the compositions were subjected to were artificial and at selected times, and the *in vitro* dissolution profile would not show any of: “*in vivo* release, *in vivo* pharmacodynamics (PK), *in vivo* pharmacodynamics (PD), and *in vivo* therapeutic results.” *Id.* ¶¶ 60–66; *id.* ¶¶ 91, 109 (Dr. Polli opining that the AUC for a drug “cannot be reasonably predicted to any useful degree from dissolution data, absent a validated IVIVC model” and that no IVIVC model could be constructed and validated on the information available in Burnside). In sum, Petitioner has not provided sufficient evidence that a skilled artisan could reasonably extrapolate the *in vivo* activity of Burnside’s Example 4 SR beads, alone or in a formulation, from Burnside’s *in vitro* data. The facts of this case are in contrast to those in *Nantkwest*, 686 F. App’x at 870, where the Federal Circuit determined “there is over-whelming specific evidence that a skilled

artisan could reasonably extrapolate from the *in vitro* data with respect to TALL-104 and NK-92 that would reasonably teach their successful substitution *in vivo*.” The lack of *in vivo* data for Burnside’s Example 4 SR beads, either alone or in a formulation, undermines Petitioner’s motivation to combine and reasonable expectation arguments, as discussed further below.

a. Motivation to Combine

Petitioner makes several arguments with regard to a skilled artisan’s motivation to combine Burnside’s Example 4 SR beads with Burnside’s Example 5 two-bead system. Pet. 52–57. Patent Owner disputes that a skilled artisan would have been motivated to combine the beads disclosed in Burnside’s Example 4 with those disclosed in Example 5. PO Resp. 29–39. Having considered the parties’ positions and evidence of record, we determine that a skilled artisan would not have been motivated to combine the beads disclosed in Burnside’s Example 4 and Example 5, for the following reasons, and we address each of Petitioner’s motivation to combine arguments in turn.

Petitioner argues that a skilled artisan would have been motivated to “prolong the therapeutic efficacy provided by the two-bead system[] of Example 5 and/or Adderall XR®.” Pet. 52. According to Petitioner, despite the extended benefit of treatment for ADHD offered by Adderall XR, clinicians recognized that a proportion of patients “still required additional treatment to extend the daily therapeutic effect [and i]n many cases,

clinicians instructed those patients to augment Adderall XR[®] with a later dose of Adderall IR[®].” Pet. 7–8 (citing Ex. 1001, 3:26–45; Ex. 1010, 2).

In support, Petitioner refers to Kratochvil, which “teaches administration of a second Adderall IR[®] dose at 6:00pm.” Pet. at 53 (citing Ex. 1010, 2); see Pet. Reply 2 (referring to the ’100 patent’s statement at Ex. 1001, 3:39–49 that “[f]or patients . . . who require duration of clinical benefit beyond 10–12 hours, clinicians have augmented the morning long-acting formulation, typically 8–10 hours post-dose; with a dose of the same immediate (IR) medication”). Kratochvil teaches administering this second dose to those patients for whom treatment for only 10–12 hours is insufficient. Ex. 1010, 2. Petitioner, thus, contends that a skilled artisan would have been motivated “to create a once-daily oral composition to meet the demand for a longer duration of efficacy than provided by Adderall XR[®],” and that to do so, the artisan “would add the sustained release beads taught by Example 4 of Burnside to Example 5 of Burnside and/or Adderall XR[®].” Pet. 53. Petitioner’s argument is unavailing.

As Patent Owner argues, Kratochvil “identified a problem and guided no solution.” PO Resp. 22. In particular, Patent Owner contends that Kratochvil’s “XR plus IR delivers three pulses from two dosage forms 10–12 hours apart” and “[t]here was no hint that SR dosing might work.” *Id.* (citing Ex. 2001 ¶ 106). Patent Owner further argues that “Kratochvil’s second IR dose releases in the stomach” and “[a] later and longer SR release risks poor absorption in the distal GI tract.” *Id.* (citing Ex. 2001 ¶ 165). Given the differences between Kratochvil’s disclosure of administering a second *immediate release* dose, and the composition of claim 1, which requires *sustained release* beads, we are not sufficiently persuaded that

Kratochvil would have motivated a skilled artisan to combine Burnside's Example 4 SR beads with those of Example 5.

Similarly, Petitioner argues that a skilled artisan "would have expected that the addition of SR beads from Burnside's Example 4 to the IR and DR beads of Adderall XR would prolong therapeutic efficacy. This is in part because a [skilled artisan] would understand that the SR beads release a third dose of amphetamine after the initial IR and DR pulsed doses of Adderall XR are released." Pet. Reply 3 (citing Ex. 1006 ¶¶ 34–41, 48; Ex. 1004 ¶ 66). Dr. Burgess states that "[s]ome patients taking Adderall XR[®], however, still required additional treatment to further extend the daily therapeutic effect," and, therefore, "clinicians would instruct these patients to take a once daily dose of Adderall XR[®], augmented with a dose of Adderall IR[®] 8–10 hours after the Adderall XR[®] dose." Ex. 1004 ¶ 39. However, Petitioner's evidence does not support Petitioner's argument. As noted above, the prior art's disclosure would have been deficient to motivate a skilled artisan to arrive at the claimed composition based on Burnside's disclosures because Burnside lacks *in vivo* data for the Example 4 SR beads. Moreover, Burnside lacks drug release data for Example 4 SR beads beyond 8 hours following administration, and Petitioner has provided no other data to show what would happen after this time, or any data reflecting absorption of the drug before or after 8 hours.

Petitioner also refers to Couch¹³ in support of its argument that a skilled artisan would have been motivated to arrive at the claimed composition. This argument is similar to Petitioner's previous argument.

¹³ US 2004/0059002 A1, published March 25, 2004 (Ex. 1023, "Couch").

According to Petitioner, Couch teaches “formulations containing immediate and sustained release beads of mixed amphetamine salts,” one of which employs a sustained release coating used in the same configuration as Burnside Example 4. Pet. 54 (citing Ex. 1004 ¶¶ 162–163; Ex. 1023 ¶¶ 8, 10, 20, claim 11). Petitioner further refers to Couch’s teaching that “sustained release bead systems with an immediate release component can provide an *in vivo* plasma concentration profile ‘substantially equivalent’ to that achieved by Adderall XR®.” *Id.* (citations omitted). Petitioner contends that “[b]y extension then, addition of a sustained bead to Adderall XR® would mimic Adderall XR® plus a separate immediate release dose late in the day, per Kratovchil.” *Id.* at 55 (citing Ex. 1004 ¶1644). With this knowledge, Petitioner argues, the skilled artisan would have been motivated to add Burnside’s Example SR beads to Burnside’s Example 5 two-bead system to prolong the efficacy of the prior art two-bead systems. *Id.* at 55 (citing Ex. 1004 at ¶164; Ex. 1023 at ¶3, 8.) Petitioner’s argument is unavailing.

As Patent Owner argues, Couch does not provide “release profiles, PK data, IVIVC, PK/PD analysis, or therapeutic efficacy studies for the [disclosed] SR formulations; the data are for Adderall XR.” PO Resp. 24 (citing Ex. 2060 ¶¶ 84, 163, 168–175). Petitioner’s counsel admitted as much at trial. *See* Tr. 12:6–8:

JUDGE ELLURU: Does Couch disclose *in vivo* data for the SR bead?

MR. Roth: No, it doesn’t.

Petitioner’s counsel further stated that “[t]here’s no clinical efficacy data in Burnside and Couch on the sustained release beads.” *Id.* at 18–20; *id.* at 38:9–14 (Patent Owner’s counsel stating that Couch did not have data for a

formulation containing sustained release and immediate release beads, but only disclosed “data from Adderall XR, which was IR plus DPR”). Thus, Petitioner’s argument, based on Couch, fails for the same reasons discussed above.

Specifically, the prior art does not provide *in vivo* data to support the alleged motivation and, as noted above, Burnside lacks drug release data for Example 4 SR beads beyond 8 hours following administration. In addition, Couch indicates that the “[p]referred” “*in vivo* plasma concentration profiles of amphetamine salts” could be accomplished by providing a formulation of amphetamine salts “which is capable of providing a sustained release of the one or more amphetamine salts over a time period of, for example, from 8-12 hours, or longer preferably 10-12 hours.” Ex. 1023 ¶ 8. Hence, as Patent Owner argues, Couch is directed at “replacing either all of 12-hour Adderall XR or its pulsed bead with an SR bead, and [does] not indicate a different combination for a different goal.” PO Resp. 35–36 (emphasis omitted). We, thus, agree with Patent Owner that a skilled artisan “would not have add[ed] back a DPR bead that Couch removed and expect[ed] SR beads to work at a later time.” PO Resp. 24.

Petitioner further argues that “[a]dditional prior art also supports” addition of Burnside’s Example 4 and Example 5 beads. Pet. 55. Specifically, Petitioner alleges that, according to Mehta¹⁴, a skilled artisan “can eliminate multiple dosing and achieve full-day therapeutic efficacy with a once-daily dosage form comprising (i) ‘uncoated’ immediate release beads, (ii) pulsed beads ‘coated with a pH sensitive coat’ and (iii) beads

¹⁴ U.S. Patent No. 4,728,512 (Mar. 1 1988) (Ex. 1015, “Mehta”).

‘coated with a pH independent coat’ (sustained release beads).” *Id.* (citing Ex. 1015, ¶ 57). Patent Owner does not dispute that Mehta discloses three beads, but contends that Mehta does not disclose any teachings relevant to the proposed combination. PO Resp. 22–23. As Patent Owner contends, Mehta “used ‘timed disintegration,’ not IR or DPR pulses, for long releases of propranolol and other drugs, not amphetamine (Examples 1-10).” *Id.* at 22 (citations omitted). Indeed, Dr. Burgess, Petitioner’s declarant, testifies that she did not see the relevance of the “[p]harmacology of propranolol,” or an example of a propranolol formulation in which three beads are used, to this case. Ex. 2071, 191:9–25.

Petitioner also refers to Midha as a bead containing amphetamine and capable of satisfying the need to prolong the therapeutic efficacy of Adderall XR. Pet. 56 (citing Ex. 1004 ¶ 158). But, as Petitioner admits, Midha “teaches a triple pulsed bead system for treating ADHD.” *Id.* at n.12. Midha describes “sustained release” as a “substantially continuous release” and does not use sustained release as contemplated in the ’857 patent. Ex. 1018, 1:20–29. Moreover, Midha explains that pulsatile drug delivery is useful with active agents that must be administered two or three times daily, with active agents that lose the desired therapeutic effect when constant blood levels are maintained, and for drugs for which tolerance can be problematic. Ex. 1018, 1:20–46, 2:43–44. Given the differences between Midha and the proposed composition based on Burnside—for example, that Midha discloses using pulsatile delivery as opposed to sustained release—

we are not persuaded that Midha would have motivated a skilled artisan to arrive at the claimed composition.¹⁵

Petitioner next argues that a skilled artisan would have added a sustained release bead to Burnside's Example 5 two-bead system, as opposed to a pulsed release bead, to avoid release of amphetamine active in the colon, where absorption is reduced. Pet 55–56 (citing Ex. 1004 ¶ 168; Ex. 1038, 5, 7–8; Ex. 1039, 185–88; Ex. 1040, 212–213). In support, Petitioner refers to the '857 patent's acknowledgement that a delayed pulsed formulation with a lag time of about 8 hours would be unsuitable for this reason. Pet. 55 (citing Ex. 1001, 4:3–8). As an initial matter, Petitioner's reference to the challenged patent suggests hindsight reconstruction. *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) ("Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper."). Moreover, the lack of *in vivo* data for Burnside's Example 4 SR beads undermines Petitioner's argument. Petitioner has not supported its argument with pharmacokinetic or bioavailability data. Thus, Petitioner has not shown that a skilled artisan would have appreciated where in the body Burnside's sustained release

¹⁵ Patent Owner also identifies other formulations disclosed in the prior art that were directed to different drugs and combinations. PO Resp. 25.

beads would have released amphetamine or where it would have been absorbed.

In its Reply, Petitioner refers to the testimony of Dr. Polli, Patent Owner's declarant, stating that "[t]he SR beads are releasing later and further along the GI tract than the IR and DPR beads." Pet. Reply 3 (quoting Ex. 2060 ¶ 204). Dr. Polli's testimony is not based on the prior art, however. In fact, he testifies that "[n]o other prior art I have reviewed specifies a dose for a third SR bead" and "[n]o prior art did." Ex. 2060 ¶ 197. Petitioner also alleges, "Dr. Polli admitted that the SR bead was added with the 'intent' to allow later day treatment of ADHD." Pet. Reply 3 (citing Ex. 1046, 20). Here, again, Dr. Polli's testimony is not relying on the prior art, but rather refers to the challenged patent's disclosure. Ex. 1046, 20 ("I am thinking about the '100 patent, and the SR bead did have that intent to allow for treatment of ADHD for later day to prong the duration of therapy via the SR bead."). Dr. Polli's testimony, based on the disclosure in the '100 patent, does not support Petitioner's argument regarding a motivation to combine. *See In re Dow Chemical*, 837 F.2d 469, 473 (Fed. Cir. 1988) ("There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure."). Thus, we are not persuaded that a skilled artisan would have been motivated to add Burnside's Example 4 SR bead to Example 5's two-bead system "to prolong therapeutic efficacy, because the SR bead provides a later release of a third dose of amphetamine into the gastro-intestinal tract." Pet. Reply 4.

Lastly, Petitioner argues that the claimed composition would have been "obvious to try." Pet. 56. Petitioner contends that "[t]he prior art

identified a design need with respect to Adderall XR[®], namely to prolong its therapeutic efficacy” and “[t]he only beads containing amphetamine and capable of satisfying this need appear in Burnside, Couch and Midha.” *Id.* (citing Ex. 1004 ¶¶ 158, 160). Petitioner concludes that a skilled artisan “could” have evaluated this “finite universe of beads” and added sustained release beads to existing dosage forms to prolong therapeutic efficacy. *Id.* at 56 (citing Ex. 1004 ¶¶ 162–173). Petitioner adds:

Couch expressly teaches the predicted *in vivo* behavior of these sustained release beads and Burnside provides *in vitro* data for the Example 4 sustained release beads making them the beads a [skilled artisan] would zero in on for adding to the two-bead composition of Adderall XR[®] or Burnside Example 5.

Id. at 57. Patent Owner disagrees that Burnside’s Example 4 SR bead was “within a predictable ‘finite universe’ for prolonging amphetamine treatment.” PO Resp. 38 (citing *KSR, Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); *Eurand, Inc. v. Mylan Pharms., Inc. (In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.)*, 676 F.3d 1063, 1072 (Fed. Cir. 2012)). Petitioner has not shown that Burnside’s Example 4 SR bead was obvious to try in the claimed composition.

As an initial matter, Burnside itself cautions against using Burnside’s Example 4 SR beads. Burnside states “sustained release delivery is not suitable, for various reasons,” including variable absorption in the GI tract and biological tolerance. Ex. 1002, 1:21–63. In addition, as Patent Owner points out, Couch discloses “‘bi-phasic’ SR coatings, matrices, and osmotic systems, with no ‘tri-phasic’ suggestion, and many water-soluble and water-insoluble polymers;” “[m]any bead constructions;” “along with [a genera] of SR polymers and dispersions;” and “[e]nteric polymers.” PO Resp. 39

(citing Ex. 1023 ¶¶ 9–19, 22, 33–34; Ex. 2060 ¶ 171; Ex. 2071, 149:6–12). Patent Owner also points out that Midha “disclose[s] a universe of pulsatile options based on coatings and matrices comprising many diverse polymers,” “plus unlimited ‘combinations of different coating materials’” and that “[t]he Examples use[] different amounts of particular coatings for methylphenidate, none suggesting finite options for amphetamine.” *Id.* at 39 (citing Ex. 1018, 5:52–6:8, 6:24–25). Given the myriad potential options for a skilled artisan and the lack of guidance in the identified prior art, we are not persuaded by Petitioner’s argument that adding Burnside’s Example 4 beads to Example 5’s two-bead system was obvious to try.

Therefore, we determine that Petitioner has not shown that a skilled artisan would have been motivated to add Burnside’s Example 4 SR beads to Burnside’s Example 5 two-bead system (IR and DPR beads) to arrive at the composition recited in claim 1 in order to practice the method of claim 1.

b. Reasonable Expectation of Success

To determine whether a skilled artisan would have had a reasonable expectation of success in practicing claim 1, we must consider the degree of unpredictability in the art as well as the guidance provided by the art. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007); *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (the prior art must provide more than “general guidance as to the particular form of the claimed invention or how to achieve it”). “To the extent an art is unpredictable, as the chemical arts often are, *KSR*’s focus on [] ‘identified, predictable solutions’ may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.” *Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (*quoting KSR*, 550 U.S. at 402). Researchers can only

“vary all parameters or try each of numerous possible choices until one possibly arrive[s] at a successful result, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful.” *In re O’Farrell*, 853 F.2d at 903. In such cases, “courts should not succumb to hindsight claims of obviousness.” *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009).

Petitioner further argues that a skilled artisan would have had a reasonable expectation of success in making the composition of the challenged claims because “Burnside demonstrate[s] that each of the three claimed beads could be successfully made, and provided *in vitro* release-profile data for each of the beads.” Pet. 60. Petitioner further contends that “[m]ethods for making each were straightforward and clearly taught in Burnside’s experimental examples.” *Id.* (citing Ex. 1004 ¶ 141). In addition, Petitioner avers that there is nothing “unusual or challenging about a triple-bead system,” and cites examples of three-bead systems in the prior art. *Id.* (citing Ex. 1015, [57]; Ex. 1016; Ex. 1017; Ex. 1019; Ex. 1002).

Moreover, Petitioner argues the skilled artisan would have reasonably expected that the addition of Burnside’s SR beads would “prolong the therapeutic efficacy of the mixed amphetamines salts for hours beyond that of Adderall XR®.” Pet. 60 (citing Ex. 1006 ¶¶ 19, 34–41, 48); Pet. Reply 4 (Petitioner arguing that “the reason to combine the SR beads with the IR + DR beads was to prolong treatment of ADHD over that provided by [] the IR and DR beads alone (Adderall XR)” and “[t]he evidence demonstrates that a [skilled artisan] would have reasonably expected that the SR bead would achieve that goal”). According to Petitioner, a skilled artisan would have understood that Burnside’s Example 4 SR beads would “release active

amphetamine both during and for at least 5 to 6 hours after the release of active amphetamine from the delayed pulsed release beads.” Pet. 60 (citing Ex. 1006 ¶ 39). Again relying on the “superposition principle,” Petitioner contends that a skilled artisan would have “known that this additional amphetamine would be additive to the amphetamine released by the immediate and delayed pulsed release beads.” *Id.* (citing Ex. 1006 ¶ 40). Petitioner concludes that a skilled artisan would have thus reasonably expected that the addition of Burnside’s Example SR beads would provide “a plasma concentration profile with a higher maximum plasma concentration and sustained higher blood levels for at least 5 or 6 hours after the two-bead system of Adderall XR[®]” and “provide hours of additional therapeutic efficacy compared to Adderall XR[®].” *Id.* at 61 (citing Ex. 1006 ¶ 41). In support, Petitioner refers to Mehta and Couch. *Id.* (citations omitted).

Patent Owner argues that “[t]here could not have been a reasonable expectation of success without *in vivo* pharmacokinetic, pharmacodynamic, and therapeutic data for the unfamiliar inside-out SR bead¹⁶ alone, or in combination with IR and DPR beads.” PO Resp. 41 (citing Ex. 2060 ¶¶ 46, 49–52, 58, 62–68). In particular, Patent Owner argues that a skilled artisan would have been aware of the unpredictability of amphetamine absorption in the GI tract and the potential for a patient to develop acute tolerance¹⁷ to the

¹⁶ Patent Owner refers to the SR bead, which has “a pH-independent coating layered over an enteric coating” as an “inside-out” configuration. *See, e.g.*, PO Resp. 1.

¹⁷ Tolerance is “a process that results in a reduction in the response to a specific drug concentration following repeated drug exposure.” Ex. 2001 ¶ 153 (citing Ex. 1018, 1:42–46, 2:43–47 (tolerance is the loss of clinical efficacy when constant blood levels are maintained)).

drug. PO Resp. 40–49. Thus, concludes Patent Owner, a skilled artisan would not have had a reasonable expectation of therapeutic success. We agree with Patent Owner.

Petitioner’s reasonable expectation of success arguments suffer from the same infirmities as its motivation to combine arguments. Petitioner argues that a skilled artisan would have had a reasonable expectation of success based solely on *in vitro* results of Burnside’s Example 4 SR bead. As noted above, the prior art did not disclose *in vivo* data for Burnside Example 4 SR beads, by themselves or in a multi-bead formulation. Thus, as Patent Owner notes, there was no pharmacokinetic, pharmacodynamic, or therapeutic data for these beads. For the same reasons discussed above in detail, Petitioner has not established that a skilled artisan would have reasonably predicted the proposed combination’s *in vivo* drug release, bioavailability, and therapeutic effect based on the *in vitro* release profile disclosed for Burnside’s Example 4 SR beads. In addition, the record includes ample evidence that a skilled artisan would not have reasonably expected success given a patient’s potential to develop acute tolerance to amphetamine.

The lack of *in vivo* data would have been a significant obstacle to a reasonable expectation of success given a skilled artisan would have been aware that GI barriers to drug absorption introduced variability and unpredictability. Burnside itself recognizes that one reason “sustained release delivery” is not suitable for some drugs was that there are “[d]rug absorption differences in various gastrointestinal segments.” Ex. 1002, 1:20–55. Patent Owner argues that “[a]nother problem was that effects of amphetamine on the gastrointestinal tract are unpredictable.” PO Resp. 31.

Patent Owner's expert, Dr. Polli, describes the complexity of digestion of an oral dosage form along the GI tract. Ex. 2060 ¶¶ 43–50. Conditions such as pH, transit time, half-life, and dosage form can each influence bioavailability. *Id.* ¶ 43. Relevant here, long-acting drugs may be severely limited due to a “short GI-transit time” and are “variable and unpredictable.” Ex. 2034, 47 (“the length of *in vivo* delivery by oral [continued release] products is severely limited due to a short GI-transit time,” “mak[ing] drug delivery both variable and unpredictable,” and as a result “most oral dosage form[s] are limited to a 12-hour period”). *See also* Ex. 2039, 4 (predicting “expected bioavailability characteristics for an [extended release] product from dissolution profile characteristics is a long sought after goal”). Dr. Polli also explains that the unpredictability of GI tract bioavailability is the reason *in vitro/in vivo* correlation analyses (“IVIVC”) are necessary in drug formulation. Ex. 2060 ¶¶ 51–69.

Petitioner, in Reply, cites to testimony from witnesses on both sides that amphetamine from Burnside's Example 4 SR beads would be released and absorbed in the intestines and colon. Reply 5–6 (citing Dr. Trout, Ex. 2001 ¶ 165; Dr. Polli, Ex. 2060, ¶ 202; and Dr. McCracken, Ex. 1045 ¶¶ 107–108). This testimony does not advance Petitioner's case. In the cited testimony, Dr. Trout states that a skilled artisan “would not reasonably have predicted the same [absorption results as Adderall IR], because the SR component would be releasing amphetamine at an entirely different rate (slower and constant v. immediate and pulsatile); at a different time . . . and at a different place (the intestine v. the stomach).” Ex. 2001 ¶ 165. Dr. Trout's current observation that “the SR component” would release amphetamine in the intestine versus the stomach is not based on prior art

disclosure, and, therefore does not bear on what a skilled artisan would have known at the time of the invention. Dr. Polli testifies that “[a] possible reason to use more SR than IR or DPR amphetamine would be to . . . assure that an appropriate amount of amphetamine is absorbed in from the SR dose when it releases some or all of its dose in the lower small intestine and in the colon, where absorption is more difficult.” Ex. 2060 ¶ 202. Dr. Polli’s testimony likewise does not speak to prior art teachings with respect to amphetamine absorption in the GI tract. Dr. McCracken testifies that a skilled artisan “would further understand that a majority of the SR beads’ amphetamine would be released into the small intestine.” Ex. 1045 ¶ 108. Dr. McCracken’s observation is based on the ’857 patent, not disclosure in the prior art. *Id.* None of the cited testimony speaks to whether a skilled artisan would have reasonably believed, at the time of the invention, that amphetamine from Burnside’s Example 4 SR beads would be released and absorbed in the intestines and colon. Thus, Petitioner’s cited evidence does not persuade us that a skilled artisan would have reasonably predicted the location or timing of the amphetamine absorption of the proposed combination.

In addition, Petitioner’s reliance on Mehta and Couch to establish a reasonable expectation of success (Pet. 61) is unavailing. Petitioner refers to Mehta for its alleged teaching that “three-bead systems containing immediate, pulsed and sustained release components can provide full-day therapeutic efficacy.” *Id.* (citing Ex. 1015). But, as Patent Owner argues, “Mehta’s beads are different, are arranged differently, and only suggest broad experimentation with ‘time disintegration.’” PO Resp. 34 (citing Ex. 1015, 2:29–33, Figs. 3–4). In addition, Petitioner argues that Couch “by

extension, teaches a [skilled artisan] that the right combination of pulsed release components plus sustained release beads may be employed to mimic the plasma concentration profile of Adderall XR[®] plus a separate immediate release dose late in the day.” Pet. 61 (citing Ex. 1004 ¶ 164; Ex. 1023 ¶¶ 8, 11, 19–21). As Petitioner itself recognizes, however, Couch was directed to treating ADHD in the same manner as Adderall XR (Pet. Reply 6–7 (citing Ex. 1023 ¶6), and “did not validate an IR-DPR-SR combination” nor “suggest Burnside’s [Example 4 SR] bead as a predictable therapeutic success,” as Patent Owner argues (PO Resp. 42 (citing Ex. 2060 ¶¶ 169–71)).

Furthermore, the record contains ample evidence that a skilled artisan would not have had a reasonable expectation of success because she would have been aware of the possibility that a patient might develop acute tolerance (also “hysteresis” or “tachyphylaxis”) to amphetamine delivered in a sustained release dose, as opposed to a pulsed delivery. See PO Resp. 9–10, 53–57. Patent Owner’s expert, Dr. Polli, explains that “acute tolerance [to amphetamine] is the rapid dissipation of the clinical effects of amphetamines after the drug produces its initial effects, even though plasma concentration is level.” Ex. 2060 ¶ 156; Ex. 2053, 2–3 (acute tolerance to amphetamine can cause dissociation between the time course of plasma levels and drug effects).

Petitioner disagrees that sustained release formulations of amphetamine were known to cause acute tolerance. Pet. Reply 9–14. In particular, Petitioner argues that “sustained release amphetamine formulations [in the prior art] were known to extend efficacy without acute tolerance,” referring to Couch as an example, and distinguishes the prior art

cited by Patent Owner as having “no relation to alleged amphetamine acute tolerance issues.” *Id.* at 10–14. According to Petitioner, a skilled artisan “would not expect an acute tolerance issue from a mixed ‘IR-DR-SR’ amphetamine formulation that employs two pulsatile doses.” *Id.* at 11. In addition, Petitioner points to a 2003 study by Dr. McCracken disclosing that “even though amphetamine blood levels for Adderall XR peaked between 5 and 7 hours, efficacy continued for at least another 5 to 7 hours for a total of 12 hours of efficacy.” *Id.* (citing Ex. 1045 ¶ 27). Petitioner’s arguments are unavailing.

The prior art recognizes that sustained release drug formulations and amphetamine presents acute tolerance issues. Burnside itself acknowledges that “[c]ontinuous release drug plasma profiles are often accompanied by a decline in the pharmacotherapeutic effect of the drug,” identifying “transdermal nitroglycerin” as *an example*, and explaining that “[b]iological tolerance” is one of the reasons “sustained release delivery is not suitable.” Ex. 1002, 1:21–34. The prior art also recognizes that amphetamine results in declining therapeutic effect despite elevated amphetamine levels. *See* Ex. 1014, 4, 11 (“[c]linical behavioral effects are most apparent during the absorption phase and decrease after peak plasma concentrations are reached,” “pharmacokinetic and pharmacodynamics effects of amphetamine . . . show[] little correlation between serum levels and behavioral effects,” and “effects on behavior and learning performance were greatest during the absorption phase and declined slowly thereafter despite substantial amphetamine levels”); Ex. 2053, 3 (“[t]he results of this study indicate that the time course of plasma levels and drug effects of *d*-amphetamine are dissociable” and “although plasma levels peaked 4 hours after drug

administration . . . subjective effects peaked at approximately 2 hours and declined within 6 hours,” “suggest[ing] tolerance to the subjective effects of *d*-amphetamine”). Moreover, the prior art also teaches that acute tolerance is addressed by pulsed formulations. For example, the prior art teaches that “[p]ulsatile drug delivery is useful . . . with active agents which lose the desired therapeutic effect when constant blood levels are maintained” and drugs for which tolerance can be problematic. Ex. 1018, 1:35–46; *see* Ex. 2061, 6 (“One way to overcome this mechanism of tolerance is to provide a medication-free interval; when synaptic dopamine concentrations return to baseline levels, the receptors re-emerge from the cell membrane, reverting to their normal sensitive states.”); Ex. 1018, 2:43–44 (Midha teaches away from SR by using pulses to conquer “loss of clinical efficacy when constant blood levels are maintained,” i.e. tolerance); Ex. 1010, 2 (Kratochvil teaches away by disclosing a “drug burst” to attack “tachyphylaxis [that] occurs with steady blood levels of stimulant drugs”).

Petitioner’s reference to Couch and other prior art references that do not indicate an acute tolerance problem likewise does not persuade us that a skilled artisan would have predicted success in making the pharmacological composition of claim 1. *See* Reply 4–11. Petitioner argues that Couch discloses that sustained release formulations do not display acute tolerance issues. Reply 10 (citing Ex. 1023, ¶ 6). However, as discussed above and as explained by Petitioner’s expert Dr. Burgess, Couch discloses formulations that replicate the effect of Adderall XR. Ex. 1004 ¶¶ 162–163; *see also* Ex. 2001 ¶ 130 (Patent Owner’s expert, Dr. Trout, explaining “Couch disclosed replacing a relatively early pulsed release with a similarly early sustained release to provide the same duration of effect as ADDERALL XR. EX1023,

claim 1. Couch's data is for the targeted ADDERALL XR product, which repeats Burnside (EX1002), the [Physician's Desk Reference for Adderall XR] (EX1003), and the ADDERALL XR Label (EX1031)."). Couch does not provide release or pharmacokinetic data for amphetamine and the *in vivo* data disclosed is from patients treated with Adderall XR, not with the compositions disclosed in Couch nor the three-bead combination proposed by Petitioner. Ex. 2001 ¶ 130. Moreover, Petitioner does not provide data comparing Burnside's formulations to those in Adderall XR, referenced by Couch, despite their differences. *Id.* ¶ 134. Thus, Couch would not have informed a skilled artisan whether adding a third sustained release amphetamine bead to a composition comprising immediate release and delayed release amphetamine beads that deliver in a pulsed manner would have led to acute tolerance. In sum, the prior art acknowledges acute tolerance of amphetamine with *in vivo* data supporting the conclusions reached by skilled artisans regarding their belief in acute tolerance.

We acknowledge Dr. McCracken's testimony on behalf of Petitioner, opining that "it was well-known prior to 2006 that acute tolerance had little to no effect on the therapeutic efficacy of amphetamine-containing drug products like Adderall® and Adderall XR®" and that it would have been obvious to add the delayed release bead of Example 4 to extend the duration of therapeutic efficacy of Adderall XR. Ex. 1058 ¶¶ 20, 24–67. We further acknowledge Dr. McCracken's testimony that a skilled artisan would not have expected acute tolerance to affect an amphetamine formulation comprising both pulsatile and sustained release compositions based on his evaluation of the prior art. *Id.* ¶¶ 68–78. Dr. McCracken's testimony, however, provides a current reinterpretation of data obtained from a study he

performed on administration of amphetamine compositions to children, which he summarized in a 2003 publication. *Id.* ¶¶ 30–44 (citing Ex. 1037, publication). Dr. McCracken testifies that his *current analysis of his earlier study data* shows that the observed patterns of amphetamine metabolism, a decrease of effectiveness over time, were not the result of acute tolerance, but instead reflected that the subjects experienced “normal common fatigue and decreased afternoon arousal, which occurs regardless of the presence of amphetamine plasma concentrations and ADHD.” *Id.* ¶¶ 39–42 (emphasis added). We give more weight to Dr. McCracken’s conclusions provided at the time of his study. Indeed, his contemporaneous conclusions are more consistent with other prior art publications identified above noting that acute tolerance/ hysteresis/ tachyphylaxis was a factor to consider in developing an amphetamine pharmaceutical composition. *See* Ex. 1014, 11;¹⁸ Ex. 2046, 8; Ex. 2045, 2; Ex. 2044, 7; Ex. 2061, 1–2.

We note that Dr. McCracken’s publication concludes:

Our data suggest new drug delivery systems such as SL1381 (Adderall XR) represent a successful strategy to extend the benefits of psychostimulant treatment of ADHD without incurring added side effects, thereby avoiding some of the compliance issues raised by shorter-acting stimulant preparations . . . [O]ur initial data suggest that extending drug exposure over a 12-hour period sufficient to yield clinical improvement does not markedly increase reported side effects.

Ex. 1037, 682.

This conclusion discloses that amphetamine treatment of up to 12 hours without side effects is possible, but, relevant here, the study does not teach a

¹⁸ The cited pages refer to the numbered pages of the parties’ exhibits and not the original publication pages, for consistency with the citations in the briefing.

skilled artisan about effects after that time period. Thus, without *in vivo* data or a IV/IVC teaching a skilled artisan that amphetamine tolerance would not result from an “‘IR-DR-SR’ amphetamine formulation” (Pet. Reply 11), we are persuaded that a skilled artisan’s appreciation of potential acute tolerance problems would have been a significant obstacle to developing the method of treatment of ADHD of claim 1. In addition, we do not find Dr. McCracken’s testimony (Ex. 1058 ¶¶ 24–67) regarding the prior art cited by Petitioner to be sufficiently persuasive that the skilled artisan viewing these references at the time would not have believed potential acute tolerance could be an issue in developing an amphetamine pharmaceutical composition for use in treating ADHD.

After consideration of the evidence on this point, we are not persuaded that Petitioner has established by a preponderance of the evidence that a skilled artisan would have had a reasonable expectation of success in arriving at the composition of claim 1 for use in a method of treating ADHD. We, thus, determine that Petitioner has not shown that a skilled artisan would have had a motivation to combine Burnside’s Example 4 SR beads with Burnside’s Example 5 two-bead system and would have had a reasonable expectation of success in doing so. Having so concluded, we do not reach the issue of whether Patent Owner’s objective evidence of non-obviousness outweighs Petitioner’s case for obviousness. Accordingly, we determine that Petitioner has not carried its burden of establishing that claim 1 of the ’857 patent would have been obvious based on Burnside alone. For

the same reasons, Petitioner has not established the unpatentability of dependent claims 2–29 of the '857 patent based on Burnside alone.

H. Obviousness over Burnside and Adderall XR

Petitioner asserts that claims 1–29 are obvious under 35 U.S.C. § 103 over the combination of Burnside and Adderall XR. Pet. 5, 39–61; Pet. Reply 18–27; Pet Resp. to Sur-Reply 1–15.

With respect to the claimed composition recited in independent claim 1, Petitioner argues that Adderall XR includes the claimed IR beads and the claimed first DR beads of claim 1 to be administered to patients for the treatment of ADHD, and Burnside teaches the claimed second DR beads for the same purpose. Pet. 39–42. Petitioner refers specifically to its arguments with respect to obviousness based solely on Burnside. Pet. 44. Patent Owner does not contest that the combination of Adderall XR and Burnside teaches the three types of beads recited in claim 1, but argues the skilled artisan would not have been motivated to or had reasonable success in making the composition of claim 1 for use in treating ADHD. See PO Resp. 29–39.

Petitioner's arguments with respect to a skilled artisan's motivations to combine and reasonable expectation of success are the same for Petitioner's challenges based on Burnside alone and Adderall XR and Burnside. See Pet. 52–61. Petitioner does not identify any aspect of these arguments that is different for the obviousness challenge based on Adderall XR and Burnside. For the same reasons discussed above with respect to Petitioner's obviousness challenge based on Burnside alone, we are not persuaded that a skilled artisan would have been motivated to combine the teachings of Adderall XR and Burnside to arrive at the composition of claim

1 for use in treating ADHD or would have had a reasonable expectation of success in doing so.

We, thus, determine that Petitioner has not shown that a skilled artisan would have been motivated to add Burnside's Example 4 SR beads to Adderall XR to arrive at the composition recited in claim 1 in order to practice the method of claim 1 and would have had a reasonable expectation of success in doing so. Having so concluded, we do not reach the issue of whether Patent Owner's objective evidence of non-obviousness outweighs Petitioner's case for obviousness. Accordingly, we determine that Petitioner has not carried its burden of establishing that claim 1 of the '857 patent would have been obvious based on the combination of Adderall XR and Burnside. For the same reasons, Petitioner has not established the unpatentability of dependent claims 2–29 of the '857 patent based on the combination of Adderall XR and Burnside.

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moves to exclude Exhibits 1047, 1049, 1051, and 1054–1056 filed by Petitioner in support of Petitioner's Reply (Paper 31). Paper 41, 1. We do not consider the merits of Patent Owner's Motion to Exclude because our Final Written Decision does not rely on any of these exhibits. Accordingly, we dismiss Patent Owner's Motion to Exclude as moot.

IV. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Patent Owner's Exhibit 2083 and a portion of Exhibit 2082 as "improper new evidence submitted on March 7, 2019 with its sur-reply brief." Paper 44, 2. We do not reach the merits of Petitioner's Motion to Exclude because our Decision does not rely on

Exhibit 2082 or Exhibit 2083. Accordingly, we dismiss Petitioner's Motion to Exclude as moot.

V. CONCLUSION

After reviewing the record and weighing the evidence offered by both parties, we determine that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–19 and 29 are unpatentable as anticipated by Burnside, claims 1–29 are unpatentable as obvious over Burnside, and claims 1–29 are unpatentable as obvious over the combination of Adderall XR and Burnside.

I. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not shown by a preponderance of the evidence that claims 1–29 of the '857 patent are unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 42) is dismissed as moot; and

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 44) is dismissed as moot;

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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