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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS (ADROCA) LLC,
Petitioner,

v.

ACORDA THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-01850 (Patent 8,440,703 B2)
Case IPR2015-01853 (Patent 8,007,826 B2)
Case IPR2015-01857 (Patent 8,663,685 B2)
Case IPR2015-01858 (Patent 8,354,437 B2)[1]

Before JACQUELINE WRIGHT BONILLA, *Vice Chief Administrative Patent Judge*,
LORA M. GREEN and SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. § 42.73

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[1] Because resolution of issues common to all four *inter partes* reviews resolves the outstanding disputes between the parties with respect to all challenged claims of the four patents at issue, we exercise our discretion to issue a single Final Written Decision to be entered in each case.

I. INTRODUCTION

This is a Final Written Decision in four *inter partes* reviews IPR2015-01850, IPR2015-01853, IPR2015-01857, and IPR2015-01858. IPR2015-01850 involves review of claims 1–52 of U.S. Patent No. 8,440,703 B2 (Ex. 1001, "the '703 patent). As this case is representative of the dispositive issues in all four *inter partes* reviews, we will refer to the papers in IPR2015-01850 unless otherwise indicated.

Coalition for Affordable Drugs (ADROCA), LLC ("Petitioner"), filed a Petition (Paper 2, "Pet.") on September 2, 2015, requesting an *inter partes* review of claims 1–52 of the '703 patent. Patent Owner, Acorda Therapeutics, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp.") on December 14, 2015. On March 11, 2015, we instituted trial on the following grounds:

Reference(s)	Basis	Claims Challenged
S-1[2]	§ 103	1–7, 10, 11, 26–33, 44–46, 52
S-1 and Hayes[3]	§ 103	8, 9, 12–21, 34–41, 47–49

[2] Acorda Therapeutics, Inc., Registration Statement under the Securities Act of 1933 (Form S-1) (Sept. 26, 2003) ("S-1") (Ex. 1003).
[3] Keith C. Hayes et al., *Pharmacokinetic Studies of Single and Multiple Oral Doses of Fampridine-SR (Sustained-Release 4-Aminopyridine) in Patients With Chronic Spinal Cord Injury*, 26 CLIN. NEUROPHARMACOLCOY 185–92 (2003) ("Hayes") (Ex. 1005).

Reference(s)	Basis	Claims Challenged
S-1 and Juarez[4]	§ 103	22–25, 42, 43, 50, 51

Paper 14 ("Dec. Instit."), 21. As discussed in more detail below, every instituted ground in all four *inter partes* reviews relies on S-1, either alone or in combination with other references.

Subsequently, Patent Owner filed a Response (Paper 34, "PO Resp."), and Petitioner filed a Reply (Paper 43, "Reply").[5]

Petitioner filed a Motion to Exclude (Paper 56) certain of Patent Owner's exhibits and testimony by Dr. Gregory K. Bell. Paper 56, 1, 15. Patent Owner filed an Opposition to the Motion to Exclude (Paper 60), and Petitioner filed a Reply (Paper 64).[6]

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[4] Haydee Juárez et al., *Influence of Admixed Carboxymethylcellulose on Release of 4-Aminopyridine from Hydroxypropyl Methylcellulose Matrix Tablets*, 216 INT'L J. PHARM., 115–25 (2001) ("Juarez") (Ex. 1006).

[5] Both Patent Owner and Petitioner filed the Response and Reply, respectively, as confidential with accompanying motions to seal. *See* Papers 28, 29, 44, 45. Because we do not need to refer to any confidential information in our Final Written Decision, we will reference the public versions of the Response and Reply.

[6] Petitioner and Patent Owner filed Objections to Evidence, *see* Papers 35, 47, and Patent Owner filed Observations regarding the Cross-Examination of Dr. Fairweather, Dr. Pleasure, and Ms. Distler, to which Petitioner filed a response, *see* Papers 58, 63, respectively (public versions). We have reviewed these papers and will give the evidence the appropriate weight in light of these observations and objections. We do not need to refer to any confidential information in our Final Written Decision.

A final hearing was conducted on January 19, 2016. Paper 68 ("Tr."). We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–52 ("the challenged claims") are unpatentable on the instituted grounds.

A. Related Proceedings

The parties identify a number of judicial matters involving the patents in the four *inter partes* proceedings at issue in this Final Written Decision, including, among others, *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 1:14-cv-00935 (D. Del); *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 1:14-cv-00139 (N.D. W. Va.); *Acorda Therapeutics, Inc. v. Accord Healthcare Inc.*, No. 1:14-cv-00932 (D. Del.); and *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, Case 15-124 (Fed. Cir.). Pet. 2–3; Paper 5, 3–5. The parties also identify Case No. IPR2015-00817, previously denying *inter partes* review of U.S. Patent No. 8,007,826 patent, as well as Case No.

IPR2015-00720, previously denying *inter partes* review of U.S. Patent No. 8,663,685. Pet. 3; Paper 5, 2–3.

B. The '703 Patent (Ex. 1001)

The '703 is directed to a sustained release oral dosage of an aminopyridine pharmaceutical composition that can be used to treat individuals affected with neurological disorders. Ex. 1001, 1:14–16. The most preferred aminopyridine is 4-aminopyridine ("4-AP" or "fampridine"). *Id*. at 1:35–41, 2:29–32. According to the '703 patent, its pharmaceutical composition can be used to treat spinal cord injury, multiple sclerosis ("MS"), Alzheimer's disease, and amyotrophic lateral sclerosis ("ALS"). *Id*. at 2:23–27. The composition is said to maximize therapeutic effects while minimizing side effects. *Id*. at 1:17–18.

In one embodiment of the '703 patent, the composition is administered to patients with MS to increase their walking speed. *Id*. at 3:65–4:3. The composition is administered twice daily in an amount of less than about 15 milligrams of aminopyridine, preferably about 10 to 15 milligrams of aminopyridine. *Id*. at 4:1–5. In other embodiments, the composition is said to improve lower extremity muscle tone and lower extremity muscle strength in patients with MS. *Id*. at 4:6–19. The '703 states that in responsive patients (approximately 37%), "treatment with fampridine at doses of 10–20 mg produced a substantial and persistent improvement in walking." *Id*. at 29:23–26.

D. Illustrative Claim

The '703 patent contains fifty-two claims, all of which are challenged by Petitioner. All fifty-two claims are directed to methods of improving lower extremity function in an MS patient in need thereof. Claims 1 and 2 are the only independent claims. Claims 1 and 2 are illustrative of the challenged claims and are reproduced below:

> 1. A method of improving lower extremity function in a human multiple sclerosis patient in need thereof comprising orally administering to said patient a sustained release composition of less than 15 milligrams of 4-aminopyridine twice daily for a time period of at least two weeks, wherein the amount of said 4-aminopyridine administered to said patient in each said administering step is the same over said time period.
>
> 2. A method of improving lower extremity function in a human multiple sclerosis patient in need thereof comprising orally administering to said patient a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a time period of at least two weeks.

Id. at 29:55–67.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016)

(concluding that 37 C.F.R. § 42.100(b) "represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office"). Under that standard, claim terms generally are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner asserts constructions for the following claim terms, "less than 15 milligrams," "release profile," "matrix," "improving walking," and "initiating treatment." Pet. 18–19. Patent Owner contends that Petitioner has failed to provide an explanation as to why the identified claim terms require construction and why the Board should depart from the plain and ordinary meaning of the terms. Prelim. Resp. 17, n.4.

In the Institution Decision, we agreed with Patent Owner and determined that it was unnecessary to construe explicitly the claim terms for purposes of the Institution Decision. S*ee* Dec. Instit. 6 *(citing Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed '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))). We also determine here that we need not construe expressly any claim term in order to issue a Final Written Decision regarding the patentability of the challenged claims.

B. The Asserted References

1. S-1 (Ex. 1003)

S-1 is an Acorda prospectus SEC filing that describes Acorda's initial public offering of common stock and Acorda's desire to list their common stock on the Nasdaq National Market. Ex. 1003, 2[7]. S-1 describes Acorda as a late-stage biopharmaceutical company dedicated to identification, development and commercialization of therapies that improve neurological function. *Id*. at 5. Acorda's therapies are focused on treating people suffering from spinal cord injury, multiple sclerosis and related disorders of the nervous system. *Id*. S-1 states that Fampridine-SR is Acorda's lead product candidate and that laboratory studies have shown that fampridine improves impulse conduction in nerve fibers that have been damaged, such as in the case of MS. *Id*. at 6. Fampridine-SR was developed by and manufactured for Acorda by Elan. *Id*. at 34.

Fampridine-SR is described as suitable for twice daily dosing for both SCI (spinal cord injury) and MS. *Id*. at 34. S-1 states that it is believed that Fampridine-SR represents a "fundamental shift in the treatment of both SCI and MS because it may improve neurological function rather than only treating the symptoms or slowing the progression of these diseases." *Id*.

[7] We cite exhibit page numbers as indicated by Petitioner on the bottom right of Exhibit 1003, rather than page numbers designed in S-1 itself.

Specifically, S-1 teaches that fampridine is able to block exposed myelin potassium channels in MS patients, thereby permitting the axons in nerve fibers to transmit nerve impulses again. *Id*.

S-1 states that clinical trials of Fampridine-SR have demonstrated improved neurological function in people with chronic SCI or MS. *Id*. at 6. S-1 states that eight clinical trials have been conducted with Fampridine-SR for SCI and six clinical trials for MS. *Id*. S-1 further states that in Phase 2 clinical trials, treatment with Fampridine-SR has been associated with a variety of neurological benefits in people with SCI or MS. *Id*. S-1 also states that Acorda was conducting a late Phase 2 clinical trial in people with MS for the improvement of walking speed. *Id*. According to S-1, Acorda has performed clinical trials of Fampridine-SR in chronic SCI and MS to establish the "pharmacokinetics, safety, and optimal dosing of the drug, as well as to assess its efficacy." *Id*. at 34. S-1 states that clinical trials of Fampridine-SR therapy have shown "a statistically significant improvement in walking speed and leg strength" in MS patients. *Id*. at 35.

S-1 describes the design and results of a clinical trial designated "MSF201" as follows:

> In 2001, we completed a double-blind Phase 2 clinical trial of Fampridine-SR in Multiple Sclerosis, MS-F201. The clinical trial was designed to determine the optimal dose level of Fampridine-SR and to evaluate possible ways in which to measure the effect of the drug on symptoms of the disease, including motor strength, timed walking, and self-reported

> fatigue. The clinical trial involved a total of 36 MS subjects in four major academic MS research centers. A total of 25 subjects received Fampridine-SR in doses increasing from 10 mg to 40 mg twice per day over eight weeks of treatment, and 11 subjects were given placebo over the same period. This treatment period was preceded by a series of baseline evaluations over the course of four weeks to allow the subjects to become adjusted to the clinic visits and allow the various measurements to stabilize. A one week blinded treatment with placebo preceded the first drug administration to look for potential placebo effects on the various outcome measures.
>
> The clinical trial demonstrated that doses up to 25 mg twice a day were well tolerated, and were associated with statistically significant improvements in walking speed and leg muscle strength. Most of the improvement in strength and walking speed was apparent within the first three weeks of the Fampridine-SR treatment, at doses from 10 to 25 mg twice a day.

Id. at 37.

S-1 also describes a current late Phase 2 clinical trial, "MS-F202," that was designed, based on extensive consultations with expert MS neurologists and the FDA, to provide support for an NDA for the use of Fampridine-SR in MS. *Id*. The MS-F202 trial was designed to "compare three doses of 10, 15 and 20 mg, twice per day, and assess their relative safety and efficacy over a treatment period of 12 weeks." *Id*. at 37. The primary endpoint of the MS-F202 trial involved timing subjects completing a 25 foot walk. *Id*. The trial enrolled approximately 200 subjects in 24

major MS centers in July 2003 and was to conclude by the end of March 2004. *Id*.

2. Hayes (Ex. 1005)

Hayes is entitled "Pharmacokinetic Studies of Single and Multiple Oral Doses of Fampridine-SR (Sustained-Release 4-Aminopyridine) in Patients With Chronic Spinal Cord Injury." Ex. 1005, 1. Hayes states that "[t]wo studies were conducted to determine the pharmacokinetics and safety profile of an oral, sustained-release (SR) formulation of fampridine (fampridine-SR, 10–25 mg) administered as a single dose (n = 14) and twice daily for 1 week (n = 16) in patients with chronic, incomplete SCI," i.e., spinal cord injury. *Id*. at 1, Abstract.

Hayes discloses that "[c]linical trials have confirmed that administration of fampridine results in symptomatic improvements in patients with SCI and multiple sclerosis." *Id*. at 1 (citations omitted). Hayes discusses its "first study [that] evaluated single oral doses of fampridine-SR (10 mg, 15 mg, 20 mg, and 25 mg) in 14 patients with SCI," and its "second study [that] examined multiple oral doses (10 mg, 15 mg, 20 mg, and 25 mg, twice daily, each given for 1 week) of fampridine-SR in 16 patients with SCI." *Id*. at 2.

In relation to the second study, Hayes discloses that 16 patients "received doses of orally administered fampridine-SR tablets at each dose level (10, 15, 20, and 25 mg) twice daily for 6 consecutive days and then

once daily on the seventh day," and "[d]osing at each level was performed in an ascending manner over 4 weeks with no intervening washout period." *Id*. Thus, at one point, patients received 10 mg of Fampridine-SR tablets twice daily for six days as part of this study.

In relation to a number of measured pharmacokinetic parameters in the second study, as presented in Figure 1B and Table 3, Hayes states that "[s]teady state was achieved by day 5 (4 days of fampridine-SR dosing) after twice-daily administration of fampridine-SR." *Id*. at 4. Figure 1B presents the mean fampridine plasma concentration versus time over 24 hours for each dosage, including 10 mg, given twice daily. *Id*. at 5. Table 3 presents the "Mean (±standard deviation) pharmacokinetic parameters of fampridine-SR after multiple-dose administration" for each dosage, including 10 mg given twice daily. *Id*. at 7. Such parameters for the 10 mg dosage twice daily dosage include: C_{maxss}, ng/mL of 32.2 ± 8.9, C_{minss}, ng/mL of 14.0 ± 4.4, C_{avss}, ng/mL of 20.8 ± 5.7, and t_{max}, h of 2.7 ± 1.0. *Id*.

3. Juarez (Ex. 1006)

Juarez describes the use of mixtures of polymers to achieve a variety of release properties. Ex. 1006, 1. In particular, Juarez describes testing the matrix release behavior of tablets of 4-aminopyridine with hydroxypropyl methylcellulose ("HPMC"). *Id*. at 2. Juarez states that the purpose of the HPMC matrix is to "prolong delivery with zero-order kinetics to maintain a

constant in vivo plasma drug concentration, and with this to maintain a constant pharmacological effect." *Id*. at 2.

C. Asserted Obviousness over S-1

Petitioner challenges claims 1–52 of the '703 patent as rendered obvious over S-1, either alone or in combination with Hayes or Juarez. Pet. 20. In support, Petitioner provides a detailed explanation, as well as a claim chart, as to how each claim limitation is taught. *Id.* at 30–60. Petitioner also relies on the Declarations of Scott Bennett (Ex. 1016), an academic librarian, and Dr. Samuel J. Pleasure, a Professor of Neurology (Ex. 1023), and James Polli, a Professor of Pharmaceutical Sciences (Ex. 1044). *See generally*, Pet. 11–56.

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In that regard, an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see Translogic*, 504 F.3d at 1259.

1. Level of Skill

Petitioner's declarants, Drs. Pleasure and Polli, testify that a person of ordinary skill in connection with the '703 patent would have had an M.D. or Ph.D. in neuroscience or a related field with an understanding of pharmacokinetics and at least some experience in providing drug therapy to MS patients. Ex. 1023 ¶ 16, Ex. 1044 ¶ 13. Additionally, Drs. Pleasure and Polli testify that a person of ordinary skill in the art would have had access to a person having an advanced degree in pharmaceutics or pharmaceutical formulation, specifically oral sustained release formulations, or at least five years of experience in formulating sustained oral release drug products and may work as part of a multi-disciplinary team. Ex. 1023 ¶¶ 16–17; Ex. 1044 ¶¶ 13–14. Patent Owner does not dispute this recitation of the level of ordinary skill in the art. *See* Ex. 2042 ¶ 68 n.5. We adopt the level of ordinary skill in the art identified by Drs. Pleasure and Polli as it is consistent with the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (stating level of ordinary skill in the art may be reflected by the prior art of record); *In re GPAC Inc.*,

57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

2. Decision on Institution

In our Decision on Institution, we determined that S-1 is a printed publication based on the evidence of record at the institution stage. Specifically, we stated that there was sufficient evidence of record before us "to demonstrate that a person of ordinary skill in the art would have been aware of Acorda's clinical trials and would have monitored and sought information about such studies by looking for and accessing statements and publications by Acorda and its researchers." Dec. Instit. 14. We also noted that Acorda would have an opportunity at trial to provide further evidence concerning its S-1document. *Id*.

Turning to the merits of the asserted challenges based on the record at the institution stage, we determined that, based on the teachings of S-1 in light of Dr. Pleasure's testimony, that "one of ordinary skill in the art would have combined the known elements 10 mg dosage, twice daily for more than 2 weeks, in an MS patient for the stated purpose of improving lower extremity function, including improvement in walking speed and muscle strength." *Id*. at 17. As to the challenges combining the teachings of S-1 and Hayes or Juarez, we concluded on the record at institution that

> Petitioner has provided sufficient and credible evidence to demonstrate that one skilled in the art would have combined the

> references for the purpose of forming a polymeric delayed release tablet with 4-AP to maintain *in vivo* plasma concentrations (S-1 and Juarez) and the purpose of achieving Hayes' extended release profile with 4-AP (S-1 and Hayes).

Id. at 20.

We also specifically stated that "[f]or purpose[s] of this Decision we need not determine whether the '703 patent is entitled to priority benefit of the provisional application as the S-1 prospectus is statutory prior art under either effective filing date." *Id*. at 12, n.2.

During trial after institution, Patent Owner presented evidence that S-1 could potentially qualify as prior art only under 35 U.S.C. § 102(a), but not § 102(b), and because S-1 corresponds to the inventors' own work, S-1 does not qualify as prior art against the '703 patent under § 102(a) either. *See* PO Resp. 1–22. In this Final Written Decision, we will first address the status of S-1 as prior art under § 102(a) or (b).

3. Petitioner's Arguments Regarding Prior Art Status of S-1

Petitioner asserts that at least claims 1–30 and 32–52 are not entitled to the benefit of the filing date of the provisional application to which the '703 claims priority. Pet. 10. The '703 patent claims the benefit of provisional application No. 60/560,894, filed on April 9, 2004 ("the Provisional"). Ex. 1001 ¶ 60.

Petitioner offers three reasons why the Provisional does not provide support for claims 1–30 and 32–52. Pet. 10–17. First, Petitioner asserts that

claims 1–30 and 32–52 all require that 10 mg or less than 15 mg of 4-AP be administered twice daily, and that the claimed time period for administration for all of these claims is "at least two weeks" or "more than two weeks" (i.e., the so-called "two-week limitations"). Pet. 11. Petitioner refers to Example 11, including a graphically depicted Study Design, presented in the Provisional and concludes "the disclosure of a ***12-week*** 'treatment period' to improve lower extremity function in MS patients does not adequately disclose to a POSA that the challenged claims' two-week limitations were necessarily present from the Provisional's disclosure." *Id.*

Petitioner notes that graphically depicted Example 11 Study Design has five time periods that include a "2-week ***upward titration*** (10/15 mg bid or placebo)" followed by a "12-week stable ***treatment period***." Pet. 11–12. Petitioner further explains that there is no disclosure of "*any* data for the first two weeks of the 12-week treatment period" because data is provided only for Visit 4 at the end of the upward titration period and not again until Visit 7, which appears to take place no earlier than week 4 of the 12-week treatment period. *Id*. at 12 (citing Ex. 1023 ¶¶ 41–42). Petitioner concludes that "[a]s a result, this disclosure is not a full, clear, concise, and exact disclosure of the challenged claims' two-week limitations—and 'a POSA would not immediately discern that the Provisional necessarily disclosed the two-week limitations based on reviewing the Provisional.'" *Id*. (citing Ex. 1023 ¶¶ 43, 36).

Petitioner asserts also that the two-week limitations are not met during the two-week upward titration period. Pet. 12–14. Noting that the current explanation for the upward titration period in the '703 patent is absent from the Provisional, Petitioner's declarant states: "At best, a POSA would have understood this disclosure to mean that the '2-week upward titration' period involved administering SR 4-AP BID at a dose of 10 mg for some portion of the 2-week period, follow[ed] by an upward dose of 15 mg for the remaining portion of the 2-week period, to ensure patients do not have an adverse reaction." Pet. 13 (quoting Ex. 1023 ¶ 47). Therefore, Petitioner concludes that the "two-week limitations" were not necessarily present in the Provisional's disclosure because the claims require administering *the same dose* of 4-AP for at least two weeks or more than two weeks, not for some portion of the two weeks. *Id.* at 14.

Regarding Petitioner's second reason as to why the Provisional does not provide support for claims 1–30 and 32–52, Petitioner asserts that the Provisional's single data point other than the 15 mg dosing data point in the 12-week period, *i.e.*, a 10 mg dosing, is insufficient to disclose the full scope of the claimed range of "less than 15 milligrams," which would encompass from "between 0 and 15 mg." Pet. 15.

Finally, for claims 14–15 and 35–36 that require a C_{avSS} range of 15 ng/ml to 35 ng/ml in MS patients receiving 10 mg (or less than 15 mg) 4-AP BID, Petitioner asserts the Provisional does not provide adequate support for

the full scope of claimed range because it only discloses C_{avSS} ranges of 15.1 ng/ml to 26.5 ng/ml in Table 7. *Id*. at 16 (citing Ex. 1007, 45). Petitioner again notes that the description for the claimed C_{avSS} ranges in the '703 patent are absent from the Provisional. *Id*.

Based on this analysis, Petitioner posits that:

> The S-1 constitutes prior art under 35 U.S.C. §§ 102(a) and (b) because it was printed and made publicly available at least as early as September 30, 2003—more than one year before the earliest effective filing date of April 8, 2005 (for claims without provisional priority). (Ex. 1004-9; *see generally*, Ex. 1003). Even assuming *arguendo* that the priority date is April 9, 2004, the S-1 would still qualify as prior art against *all* claims under 35 U.S.C. § 102(a).

Pet. 23.

Petitioner asserts further that S-1 was publicly available as early as 2000 because a person of skill would have known that Acorda was investigating 4-AP for treating multiple sclerosis and would have been motivated to monitor and seek information about Acorda's studies, such as Acorda's publically available S-1 filing. *Id*. 24–26.

4. Patent Owner's Arguments Regarding Prior art Status of S-1

Patent Owner asserts that Petitioner's challenges fail because S-1 cannot be asserted against the claims of the '703 patent. The claims of the '703 patent, Patent Owner argues, are entitled to the benefit of the Provisional's filing date, which disqualifies S-1 as prior art under § 102(b)

against the ’703 patent. PO Resp. 1. In addition, according to Patent Owner, because S-1 is the work of the named inventors of the ’703 patent, and not “by others,” it cannot be asserted against the claims of the ’703 patent as prior art under § 102(a). *Id*. Also, Patent Owner asserts that S-1 does not qualify as a printed publication. *Id*.

As to Patent Owner’s argument that the ’703 patent is entitled to the benefit of the Provisional’s filing date, Patent Owner refers to Example 11 of the Provisional, asserting

> Because patients in the ‘10 mg bid’ dosing arm received the 10 mg big dose throughout the ‘2-week upward titration (10/15 mg bid or placebo)’ phase of the study, the reported ‘significant difference . . . at up-titration’ shows that the inventors possessed therapeutically effective abbreviated treatment periods comprising, for example, two weeks of 4-AP dosing at 10 mg bid.

Id. at 5–6.

Patent Owner also asserts that Table 7 of the Provisional discloses C_{avSS} ranges for patients receiving “10 mg BID” as “Mean $\pm$ SD” data referring to a standard deviation or the measure of the spread of data within a sample, not as an accounting for error as Petitioner assumes. *Id*. at 7. Thus, Patent Owner states that “a POSA with an understanding of the term ‘standard deviation’ would have appreciated that, by definition, only ‘around 66 or 67 percent’ of measured data falls within one SD from the mean, and approximately 95% of the measured values fall within two SDs from the

mean." *Id*. at 8 (citing Ex. 2039, 76:20–23, 78:25–79:3; Ex. 2041 ¶¶ 20, 22, 24 (Hayes Declaration); Ex. 2038, 43:25–45:2).

Therefore, Table 7 as properly interpreted, Patent Owner asserts, discloses a C_{avSS} from about 3.7 ng/ml to about 37.8 ng/ml at three standard deviations encompassing greater than 99 percent of measured values. *Id*. at 9. The Provisional, therefore, discloses the C_{avSS} range of "about 15 ng/ml to about 35 ng/ml" recited in the challenged claims. *Id.* at 9–10 (citing Ex. 2041 ¶¶ 25–26).

Finally, Patent Owner asserts that S-1 cannot qualify as § 102(a) art because it is the inventors' own work. *Id*. at 10. Petitioner, Patent Owner asserts, relies on two clinical trials, MS-F201 and MS-F202 mentioned in S-1 to support its assertion of obviousness. *Id*. at 11. Patent Owner states that:

> There is, in fact, overwhelming evidence that the relied-upon portions of the S-1 describe the work of, and were authored by, Andrew R. Blight, Ph.D., and Ron Cohen, M.D., the named inventors on the '703 Patent, who were responsible for the design and analysis of those clinical trials, which yielded the claimed inventions. The accompanying unequivocal declarations of Drs. Blight (Ex. 2044) and Cohen (Ex. 2045) and five noninventors whom the inventors directed and supervised in preparing the relied-upon portions of the S-1 (Mary M. Fisher (Ex. 2052), Dr. Mitchell A. Katz (Ex. 2046), David Lawrence (Ex. 2047), Tierney Saccavino (Ex. 2056), and Fran M. Stoller (Ex. 2048)), together with contemporaneous documents that summarize the design and results of the MS-F201 clinical trial

> (Ex. 2049 and Ex. 2051, respectively) and the results of the MS-F202 clinical trial (Ex. 2050), leave no room for doubt.

PO Resp. 12–13.

5. Petitioner's Reply Regarding Prior Art Status of S-1

Petitioner counters that statements in S-1 belie Drs. Blight and Cohen's declaratory statements that they were the only inventors of the claimed inventions in the '703 patent. *See* Reply 1–4. Petitioner points to the following statement in S-1: "The current late Phase 2 clinical trial, MS-F202, was designed, ***after extensive consultation with a panel of expert MS neurologists and with the FDA***." *Id*. 2 (quoting Ex. 1003, 37). Petitioner asserts that because neither inventor recalls the content of their discussions with the panel of experts and FDA individuals, except using them as a "sounding board," neither can claim that the MS-F202 protocol described in S-1 was the work of the named inventors alone. *Id.* at 2–3 (citing Ex. 1064, 64:18–65:14; Ex. 1063, 76:20–77:20, 80:9–81:14, 110:13–111:2).

Petitioner also takes issue with Patent Owner's statement that in "early 2002," Drs. Blight and Cohen drafted descriptions of the design and results of the MS-F201 trial and of the design of the MS-F202 trial in anticipation of an initial public offering of stock that year. Petitioner points us to version 1.0 of the MS-F202 protocol, which is dated October 2002, too late to be "early 2002." *Id*. at 2. Petitioner also points to different

publications describing the MS-F201 trial and the MS-F202 trial that do not consistently list Drs. Blight and Cohen as authors or as the sole authors. *Id*. at 3–4.

Petitioner concludes that because the Patent Owner "has not 'provided a satisfactory showing which would lead to a reasonable conclusion' that the S-1's description of at least the design of the MS-F202 trial is the work of Drs. Blight and Cohen *alone*, the Board should consider the S-1 to be § 102(a) prior art against the '703 patent." *Id*. at 4 (citing *In re Katz*, 687 F.2d 450, 455 (CCPA 1982)).

Petitioner also asserts that, as to claims 1–30 and 32–52, S-1 qualifies as § 102(b) prior art because these claims are not entitled to the benefit of the Provisional's filing date. *Id*. at 4–5. Petitioner submits that the evidence of record shows that a person of ordinary skill would have understood that during the upward titration period of Example 11 that all dosing arms were upwardly titrated because of the potential psychoactive effects of 4-AP and not that 10 mg bid was given consistently through the upward titration period. *Id*. at 6–7 (citing Ex. 2038, 58:3–59:9, 60:22–61:10, 64:25–65:17, 55:25–56:13, 60:2–60:21). Due to the shorthand nature of the description of the 2-week upward titration period in Example 11 of the Provisional, Petitioner asserts that because "a POSA would not know, based on the information presented in the '894 Provisional, that patients in the '10 mg bid' arm *necessarily* received 10 mg bid throughout the '2-week upward

titration,' the '703 patent claims containing the two-week limitations are not entitled to the '894 Provisional's priority date." *Id.* at 7.

Petitioner offers evidence that the full range of C_{avSS} from 15 ng/ml to 35 ng/ml resulting from 4-AP administration, as required for claims 14–15 and 35–36, also is not disclosed in the Provisional. *Id*. at 8–12. Petitioner asserts that Table 7, which reports a mean and standard deviation, does not disclose an actual range of *measured* data, but provide only *estimated* values based on descriptive statistics provided in the table. *Id*. at 9 (citing Ex. 1066 ¶¶ 35, 75; Ex. 1069, 52:2–19). Finally, Petitioner asserts that "[w]ithout information about the distribution of the data underlying Table 7—which the '894 Provisional does not provide—a POSA could not know whether to expect data points at two or three standard deviations from the mean," as Patent Owner assumes to achieve the claimed range. *Id*. at 12.

6. Analysis

We first must determine if S-1 qualifies prior art under only 35 U.S.C. § 102(a), or also under 35 U.S.C. § 102(b). As part of that analysis, we must determine the filing date to which each of challenged claims 1–30 and 32–52 of the '703 patent are entitled. If the claims of the '703 patent are not entitled to the effective filing date of its provisional application (i.e., the Provisional), S-1 qualifies as prior art under § 102(b), which acts as a statutory bar irrespective of whether S-1 presents the work of "others." Whereas if the '703 patent is entitled to the effective filing date of the

Provisional, S-1 qualifies as prior art only under § 102(a), and we must consider Patent Owner's evidence that S-1 was not the work of "others." *See In re Katz*, 687 F.2d 450, 454 (CCPA 1982).

In relation to the effective filing date of the '703 patent, Petitioner questions whether the Provisional to which the '703 claims priority provides adequate written description support for the so-called "two-week limitations" found in all challenged claims, as well as the specific C_{avSS} ranges found in claims 14–15 and 35–36.[8]

a. "Two-week limitations"

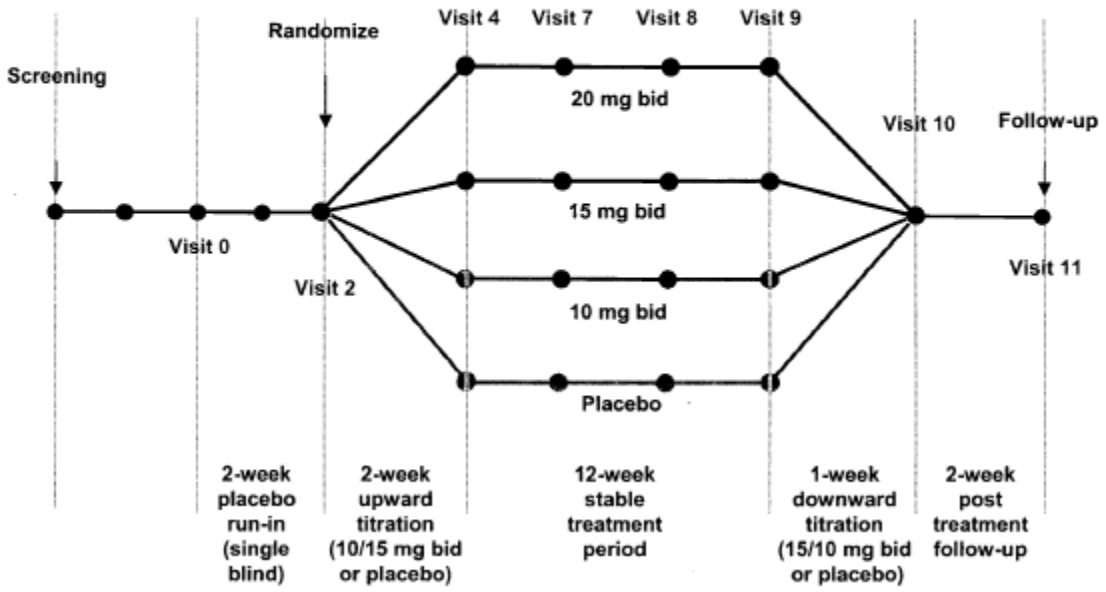
All challenged claims 1–30 and 32–52 require either a time period of "at least two weeks" or "more than two weeks" during which a multiple sclerosis patient is orally administered 4-AP to improve lower extremity function in a human multiple sclerosis patient in need thereof. *See generally*, Ex. 1001, 29:55–67, 31:7–10, 32:18–22. The amount of 4-AP administered differs per claim, but each claim requires that the same amount of 4-AP be administered throughout the time period. *Id*. at 29:55–62 (claiming in independent claim 1 an amount of 4-AP administered of less than 15 milligrams twice daily, but also requiring "wherein the amount of said 4-aminopyridine administered to said patient in each said administering

[8] Petitioner is not contesting that the Provisional provides written description support for claim 31 of the '703 patent. *See* Pet. 10, 17.

step is the same over said time period"); 29:63–67 (requiring in independent claim 2, "10 milligrams of 4-aminopyridine twice daily for a time period of at least two weeks").

The parties' dispute concerning whether the Provisional provides adequate written description support centers on Example 11 and what is conveyed to the ordinary artisan by the graphically depicted Example 11 Study Design, shown below.

Example 11 Study Design



The Example 11 Study Design depicted above "was a double-blind, placebo-controlled, 20 week, parallel-group study to evaluate safety, tolerability and activity of oral fampridine-SR in subjects with Multiple

Sclerosis." Ex. 1007 ¶ 115 (U.S. Provisional Patent Application No. 60/560,894 (filed Apr. 9, 2004)). The Example 11 Study Design depicted above shows administration of twice-daily Fampridine-SR for 15 weeks, including a two-week upward titration period, a 12-week stable treatment period, and a 1-week downward titration period. Pet. 11–12; PO Resp. 4. The parties' dispute focuses on the two-week, upward titration period between Visits 2 and 4 depicted in the Example 11 Study Design above.

In order for claims of the '703 patent to be entitled to benefit of the filing date of the Provisional, the Provisional must provide written description support for those claims. *See* 35 U.S.C. § 120. To satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, and provide support for the challenged claims of the '703 patent under 35 U.S.C. § 120, the Provisional must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See In re Wertheim*, 541 F.2d 257, 261, 262 (CCPA 1976); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991). The primary consideration in determining whether appropriate written description support exists "is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000).

Petitioner relies on testimony from Dr. Pleasure, who stated:

> At best, a POSA would have understood this disclosure to mean that the "2-week upward titration" period involved administering SR 4-AP BID at a dose of 10 mg for some portion of the 2-week period, following by an upward dose of 15 mg for the remaining portion of the 2-week period, to ensure patients do not have an adverse reaction [to 4-AP]. Nothing in Example 11 suggests that different treatment groups took different dosages during the upward titration period. And the applicant essentially acknowledges the Provisional's failure to disclose the upward titration method of Example 11 because it ***added at least 15 lines of text*** to the '703 Patent to explain the dosing parameters of the upward-titration period.

Pet. 13 (quoting Ex. 1023 ¶ 47).

Patent Owner offers the testimony of two declarants, Drs. Fred D. Lublin and Carl C. Peck, which provides a different interpretation of the Example 11 Study Design graphic, specifically for the upward titration period. *See* PO Resp. 5–6. Dr. Lublin, a Professor of Neurology, testified that:

> Patients in the clinical study described in Example 11 were divided into four "arms": placebo, 10 mg b.i.d., 15 mg b.i.d., and 20 mg b.i.d., which were administered during a "12-week stable treatment period." [Ex. 1007-00056] Prior to the 12-week stable treatment period, a "2-week upward titration (10/15 mg bid or placebo)" was implemented. An upward titration in a clinical study applies increasing doses until the treatment dose is reached. However, where the treatment dose is also the lowest available dose, a POSA would have understood that this dose would be applied throughout the titration period. Therefore, with regard to patients in the 10 mg b.i.d. arm of this study, a POSA would have

> understood the '894 provisional to be disclosing that these patients received 10 mg b.i.d. sustained release 4-aminopyridine for the entirety of the 2-week titration period. [Ex. 1007-00056]

Ex. 2042 ¶ 71. Dr. Lublin specifically disagrees with Dr. Pleasure's assumption that during the 2-week upward titration period a patient in the 10 mg bid arm of the study would be administered both 10 mg bid and 15 mg bid to ensure no adverse reaction because "a POSA would not upwardly titrate the dose to above the treatment dose for any period of time, as that may distort later measurements of efficacy at the lower dose and potentially affect any safety determinations." *Id*. ¶ 72.

Dr. Peck, a board-certified physician in internal medicine and clinical pharmacology, also testified that it is his opinion that the Provisional "adequately discloses consistent administration of 10 mg bid fampridine-SR for at least two weeks to improve lower extremity function and walking in MS patients." Ex. 2043 ¶¶ 5, 13; *see also id*. ¶ 72 (stating " the '894 Provisional Application dated April 9, 2004 describes and possesses administering to a human with multiple sclerosis a sustained release composition of 10 mg of 4-AP twice daily for a time period of ' at least two weeks' or 'greater than two weeks.'"). Specifically, Dr. Peck states that "Example 11 of the '894 Provisional teaches that a two week administration of Fampridine-SR in MS patients significantly improves walking in MS patients." Ex. 2043 ¶ 64 (citing Ex. 1007, 00050, 00055, 00061–64).

Dr. Peck describes Dr. Pleasure's testimony regarding patients in the 10 mg bid arm of the study receiving both 10 mg bid and 15 mg bid in the 2-week upward titration period as illogical. Ex. 2043 ¶ 68. Dr. Peck explains that it is illogical:

> because patients designated after randomization to receive 10 mg bid of fampridine-SR to determine the effect of 10 mg bid on the patients would never be administered a higher dose of the drug in a parallel clinical trial. A parallel trial like Example 11 observes the effect of different doses on different groups of patients and not on the same patients. Furthermore, the slash or virgule designated by the symbol "/" is punctuation shorthand for either "and" or "or" depending upon the context. A POSA would not have considered "10/15 mg bid" as precluding the option of only administering 10 mg bid.

Id. ¶ 68 (citation omitted). Dr. Peck also testifies that a POSA would not have administered a lower dose than 10 mg bid in the upward titration phase in Example 11 "and would have known from the MS-F201 study that 10 mg b.i.d. was an acceptable starting dose." *Id*. ¶ 69 (citations omitted).

We agree with Patent Owner that the Provisional provides adequate written description support for the challenged claims of the '703 patent. We agree with Drs. Lublin and Peck and credit their testimony that one of skill in art reading the Study Design schematic for Example 11 would have understood that a patient in the 10 mg b.i.d. arm of the study would have received 10 mg b.i.d. throughout the two-week upward titration period. As 10 mg b.i.d. is the lowest dose except for placebo, we find that it necessarily

follows that those patients in the 10 mg b.i.d. arm of the study do not need upward titration to the treatment dose because they start and finish at the lower 10 mg dose.

Dr. Pleasure's testimony that during the two-week upward titration period there must be some variation in the dosage between the 10 mg b.i.d. and the 15 mg b.i.d., as listed in Example 11, appears inconsistent with the four dosage, randomized study where patients are sorted into the different dosing arms of the study before the upward titration period begins. *See* Ex. 2038, 57:7–16 (Dr. Pleasure agreeing that patients randomized into one of the four dosage arms of the study in Example 11 of the Provisional at Visit 2); Ex. 2043 ¶ 66. Because Example 11 indicates two dosages during the upward titration period, 10 mg b.i.d. and 15 mg b.i.d., and a patient in the 10 mg b.i.d. arm would be receiving 10 mg b.i.d. during the treatment period, we find one of skill in the art would interpret Example 11 as providing a 10 mg b.i.d. dose during the 2-week upward titration period to those patients in the 10 mg b.i.d. arm of the study.

Also, Dr. Pleasure states that upward titration would be used to ensure patients have no adverse reaction to the drug. *See* Ex. 1023 ¶ 47. Providing a higher dose to a patient than the treatment dose, however, would not appear to be done to minimize adverse reactions at the lower treatment dose that the patient would be given during the study. *See* Ex. 2043 ¶ 69 (stating escalating dose study, such as the MS-F201 has a primary goal of

determining the tolerablity of the higher escalated doses with the starting dose of 10 mg b.i.d.). We also credit Dr. Lublin's testimony that changing the dose of a patient in the 10 mg b.i.d. arm of the study to 15 mg b.i.d. may distort later measurements of efficacy at the lower dose and potentially affect any safety determinations for the 10 mg b.i.d. dose.

In addition, we agree with Patent Owner that the Provisional provides adequate written description support for the claims of the '703 that require orally administered 4-AP for "at least two weeks" or "more than two weeks" to improve lower extremity function in a human multiple sclerosis patient. *See* Ex. 1007, 00050, 00061 (reporting that all doses, including the 10 mg b.i.d. dose, "showed a statistically significant difference" at up-titration); Ex. 2042 ¶ 71 n.6; 2043 ¶¶ 66 (describing Example 11 study as encompassing 15 weeks of treatment including a two week upward titration period, followed by a 12-week stable treatment period, and a one week downward titration period), 71 (discussing "statistical significant difference).

b. C_{avSS} ranges

The parties' dispute as to whether the Provisional supports the C_{avSS} ranges in claims 14–15 and 35–36 involves a determination of what Table 7 of the Provisional teaches one of skill in the art about C_{avSS} ranges for a 10 mg BID of 4-AP. Patent Owner offers persuasive evidence that a person of skill in the art would have understood the C_{avSS} in Table 7 to disclose a range from about 3.7 ng/mL to about 37.8 ng/ml to support the range of "about 15

ng/ml to about 35 ng/ml" in the challenged claims. PO Resp. 9–10 (citing Ex. 2041 ¶¶25–26). Specifically, Dr. Hayes states the standard deviation set forth in Table 7 of the Provisional refers to the spread of data within a sample, and the "SD" values represent one standard deviation from the mean, propositions to which two of Petitioner's experts agree. Ex. 2041 ¶¶ 18–19 (citing deposition testimony of Drs. Pleasure and Polli).

Dr. Hayes testifies that "a POSA would have known that about 95% of measured values are arranged within two standard deviations from the mean, and over 99% of the measured values are positioned within three standard deviations from the mean." *Id*. ¶ 22. Dr. Hayes noted testimony from Petitioner's declarants, Drs. Polli and Pleasure, that confirmed this understanding as well. *Id*. (citing Ex. 2039, 76:20–23; Ex. 2038, 43:25–45:2).

Dr. Hayes also states:

> In light of the fact that a POSA would immediately recognize that Table 7 of the '894 Provisional (Ex. 1007-00045) shows possession of measured data beyond even two standard deviations from its reported mean values, a more complete view of the information reported in Table 7 would consider data dispersed beyond two standard deviations from the mean. For example, considering only data within one standard deviation from the mean excludes nearly one-third of measured data.
>
> . . . .
>
> . . . [T]he information given in Table 7 of the '894 Provisional (Ex. 1007-00045) would have informed a POSA that the experimenters possessed a range of measured C_{avSS} data

> spanning from about 3.7 to about 37.8 ng/mL (i.e., three standard deviations from the mean).

Ex. 2041 ¶¶ 23, 25.

Thus, Dr. Hayes concludes that a POSA would have understood this C_{avSS} range of from about 3.7 to about 37.8 ng/ml to support the entire range of "about 15ng/ml to about 35 ng/ml" as required by the challenged claims. *Id*. ¶ 26.

In its Reply relying on testimony from Dr. William R. Fairweather, Petitioner questions whether the data in Table 7 in the Provisional has a normal distribution, as determining the ranges for the data in Table 7 for three standard deviations results in negative values, which are not possible. Reply 11–12 (citing Ex. 1066 ¶¶ 69–70, 72–74). Petitioner concludes that "[w]ithout information about the distribution of the data underlying Table 7—which the '894 Provisional does not provide—a POSA could not know whether to expect data points at two or three standard deviations from the mean." *Id*. at 12 (citing Ex. 1066 ¶¶ 75, 78). In its reply, Petitioner does not address the testimony of Drs. Pleasure and Polli that Dr. Hayes noted agrees with his understanding of how measured values are arranged within standard deviations from the mean.

We are persuaded by Dr. Hayes' testimony as confirmed by testimony from Drs. Pleasure and Polli, and conclude that the Provisional supports the C_{avSS} ranges in claims 14–15 and 35–36. Dr. Hayes offers credible

testimony concerning how one of skill in the art would interpret Table 7 of the Provisional, which depicts essentially the same data as Table 3 of Hayes. *See* Ex. 2041 ¶ 17. Dr. Hayes interpretation of the data in Table 7 is supported by testimony from Drs. Pleasure and Polli that about two thirds of the measured data fall within one standard deviation and approximately 95 percent of measured values are within two standard deviations from the mean. *Id*. at 20–22 (citing deposition testimony from Drs. Pleasure and Polli confirming such an understanding). We agree with Dr. Hayes that "[i]n light of the fact that a POSA would immediately recognize that Table 7 of the '894 Provisional (Ex. 1007-00045) shows possession of measured data beyond even two standard deviations from its reported mean values, a more complete view of the information reported in Table 7 would consider data dispersed beyond two standard deviations from the mean" to encompass a C_{avSS} range from 3.7–37.8 ng/ml. Ex. 2041 ¶ 23.

We are not persuaded by Dr. Fairweather's testimony that Table 7 supports a C_{avSS} of only 15.1 ng/ml to 26.5 ng.ml. *See* Ex. 1066 ¶ 21. Dr. Fairweather was asked if he could identify where "range" is defined as plus or minus one standard deviation, and he replied that he could not identify where he found such a definition, Ex. 2176, 44:13–22, but Dr. Fairweather confirmed such a definition is not how he would define "range" in his usual practice, *Id*. at 92:20–93:21. *See also id*. at 108:5–11 (conceding there may not be any document that defines "range" as one

standard deviation from the mean). When asked whether he could justify the range that he provided for C_{avSS} in his declaration, Dr. Fairweather stated that he could not. *Id*. at 104:25–105:2. He testified that he conceded the smallest range so as to avoid a discussion of what's the proper definition for range. *Id*. at 104:16–20. Dr. Fairweather stated twice that he was not a person of skill in the art and would not be able to answer what assumptions such a person would make when reviewing Table 7 of the Provisional. *Id*. 136:16–23, 138:14–139:7. Finally, Dr. Fairweather also testified that he could not rule out whether the C_{avSS} data for the 10 mg b.i.d. dose described in Table 7 of the Provisional had a range of at least 15 to 35 ng/ml. *Id*. at 90:9–92:19. In light of these statements, we do not credit Dr. Fairweather's testimony.

In its obviousness challenge for claims 14–15 and 35–36 requiring a C_{avSS} range of between about 15 ng/ml to about 35 ng/ml, Petitioner relies on data provided in Hayes to teach this claimed range, data that both parties agree provides reliable pharmokinetic data *in vivo* for SR4-AP. *See* Pet. 45–49; Ex. 1002, 151; Ex. 2041 ¶ 17. In his claim chart supporting Petitioner's obviousness challenge for claims 14, 15, 34, and 35, Dr. Pleasure states "Hayes discloses pharmacokinetics profile for SR 4-AP with C_{avSS} of about 15 ng/ml to about 35 ng/ml." Ex. 1043, 14–15, 22–23; *see* Ex. 1023 ¶ 154. Thus, the above cited evidence in fact also supports our conclusion that the

Provisional supports the supports the C_{avSS} ranges in claims 14–15 and 35–36.

Because the Provisional provides written description support for the challenged claims, S-1 potentially qualifies as prior art only under 35 U.S.C. § 102(a), but not § 102(b), because the S-1 publication date of September 26, 2003 is less than one year before the filing date of the Provisional of April 9, 2004. As discussed in more detail below, however, Patent Owner has provided evidence that S-1 is not prior art to the claims of the '703 patent under § 102(a) either because the pertinent portions of the S-1 are the original work of inventors Drs. Blight and Cohen. *See* 35 U.S.C. § 102(a); *Katz*, 687 F.2d at 454 (stating "one's own work is not prior art under sec. 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under [sec.] 102(a)").

c. Pertinent Portions of S-1 are Inventors Own Work not "By Others"

Patent Owner presented declarations from five declarants in addition to the inventors stating that the work described in S-1 relating to MS-F201 and MS-F202 were solely the work of the inventors Drs. Blight and Cohen. *See* Exs. 2046–48, 2052, 2056.

Petitioner and Patent Owner disagree as to who has the burden of persuasion on proving that S-1 is the work of the inventors of the '703 patent or the work of others. The United States Court of Appeals for the Federal Circuit ("Federal Circuit") has recently stated the following:

> In an *inter partes* review, the burden of persuasion is on the petitioner to prove "unpatentability by a preponderance of the evidence," 35 U.S.C. § 316(e), and that burden never shifts to the patentee. "Failure to prove the matter as required by the applicable standard means that the party with the burden of persuasion loses on that point—thus, if the fact trier of the issue is left uncertain, the party with the burden loses."

Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378–79 (Fed. Cir. 2015) (quoting *Tech. Licensing Corp. v. Videotek, Inc*. 545 F.3d 1316, 1327 (Fed. Cir. 2008)). Therefore, the burden of persuasion for unpatentability does not shift from Petitioner to prove unpatentability to Patent Owner to prove patentability of the challenged claims. Moreover, even if Patent Owner has the burden to prove that S-1 was the inventors own work, it has amply done so on the record before us.

Dr. Blight testified that he and Dr. Cohen alone are the inventors of the four patents subject to *inter partes* review at issue here. Ex. 2044 ¶ 7 ("The inventions claimed in the patents under review derive directly from the work of Dr. Cohen and me."). Dr. Blight also testified that

> Together, and without help from anyone other than individuals working under our direction and supervision, Dr. Cohen and I developed the protocols for clinical trials of Fampridine-SR, including MS-F201 and MS-F202. Dr. Cohen and I also worked together to analyze the results of those clinical trials. To the extent that others contributed to the design or analysis of those trials, they did so under the direction and supervision of Dr. Cohen and me.

Id. ¶ 8 (citations omitted). Dr. Blight concludes that "S-1 disclosures that Petitioner relies on, which concern Fampridine-SR and clinical trials MS-F201 and MS-F202, describe the original work of Dr. Cohen and me." *Id*. ¶ 17.

Dr. Cohen testifies similarly. *See* Ex. 2045 ¶ 6 ("Dr. Andrew R. Blight and I are the inventors of the patents under review. There are no other co-inventors."). Dr. Cohen specifically stated that "I note that portions of the S-1 describing Fampridine-SR clinical trials describe the original work of Dr. Blight and me. No one else was involved in that work, except under our direction and supervision." *Id*. ¶ 13.

Dr. Katz, who is not an inventor and now the Head of Clinical Research and Drug Safety Operations at Perdue Pharma L.P., confirmed Drs. Blight and Cohen's testimony. Ex. 2046 ¶ 3. Dr. Katz stated that he worked on the MS-F201 and MS202 studies under the direction and supervision of Drs. Blight and Cohen. Ex. 2046 ¶ 7. Dr. Katz further testified that he has personally reviewed and has knowledge of the preparation of the MS-F201 and MS-F202 protocols and the Integrated Clinical and Statistical Report, "all of which I understand to be the original work of Drs. Blight and Cohen." *Id*. Dr. Katz concludes that "[g]iven my experience working on the MS-F201 and MS-F202 trials under the direction and supervision of Drs. Blight and Cohen, I affirm that the disclosures in the S-1 that I understand are now being cited against the patents under review

were derived from Drs. Blight and Cohen, and no one else, and describe their work." *Id*. ¶ 8.

Four other fact witnesses, David Lawrence, Chief of Business Operations at Acorda; Fran M. Stoller, counsel for Acorda for the proposed initial public offering; Mary M. Fisher, current President, Chief Executive Officer, and Board Director at Colorescience and previous employee of Acorda; and Tierney E. Saccavino-Payne, Executive Vice President of Corporate Communications at Acorda, all confirm Drs. Blight and Cohen's sole inventorship role in the portions of S-1 relating to the clinical trials with 4-AP. *See* Ex. 2047 ¶ 7 (stating business section of S-1 "and other portions that describe Acorda's Fampridine-SR clinical studies originated with Drs. Blight and Cohen and describe their own work; this information was communicated by Drs. Blight and Cohen in confidence to the team that prepared the S-1, solely for the purpose of preparing the S-1"); Ex. 2048 ¶ 7 (stating "portions of the S-1 regarding Acorda's Fampridine-SR clinical trials (including MS-F201 and MS-F202) were derived from draft disclosure prepared by Drs. Blight and Cohen and others working under their direction and supervision"); Ex. 2052 ¶ 7 (stating draft of the "Business" section of S-1 "was created by Drs. Blight and Cohen and represented their own work" and "that draft became the foundation for portions of the S-1 that discuss clinical trials with Fampridine-SR in multiple sclerosis patients (e.g., the MS-F201 and MS-F202 trials)"; also stating "having closely served on the

team that prepared the S-1, I know that no other than Drs. Blight and Cohen provided original, substantive discussion of those trials"); Ex. 2056 ¶ 7 (stating Drs. Blight and Cohen created the draft "Business" section to the S-1 involving Acorda's 4-AP clinical trials and "Drs. Blight and Cohen were the sole source of original technical discussion describing Acorda's Fampridine-SR clinical trials (including MS-F201 and MS-F202)").

Although the burden of persuasion for unpatentability never shifts from Petitioner during the trial, the burden of production may shift. *See Dynamic Drinkware*, 800 F.2d at 1379. Petitioner adequately met its burden of production by presenting S-1 as prior art that on its face lists authors that differ from the inventors of the patents at issue. *See* Ex. 1003, 92. Patent Owner has responded with ample and persuasive evidence, however, that Drs. Blight and Cohen are the sole source of the disclosure of S-1. Thus, Patent Owner satisfies any burden of production to refute Petitioner's case that S-1 is prior art under 35 U.S.C. § 102(a). *See supra*. Petitioner's response to Patent Owner's evidence does not persuade us that the portions of S-1 upon which they rely are not solely attributable to Drs. Blight and Cohen.

Specifically, Petitioner offers evidence from the S-1 of a statement that the MS-F202 clinical trial was designed "after extensive consultation with a panel of expert MS neurologists and with the FDA," arguing that statement indicates that Drs. Blight and Cohen may not be the sole authors

of the protocol for this clinical trial. Reply 2. Petitioner further argues that Drs. Blight and Cohen's deposition testimony supports its contention that Drs. Blight and Cohen may not be the sole authors of the protocol for this clinical trial because they could not recall the details of that consultation. *Id*. at 3 (citing Ex. 1064, 64:18–65:14; Ex. 1063, 76:20–77:20, 80:9–81:14, 110:13–111:2). Petitioner also takes issue with another statement in S-1 indicating that in *early* 2002, Drs. Blight and Cohen drafted descriptions of the MS-F201 and MS-F202, although version 1.0 of the MS-F202 protocol is dated October 2002. *Id*. at 2 (citing Paper 28, 16; Ex. 2050, 6). Finally, Petitioner points to publications discussing MS-F201 and MS-F202 where Drs. Blight and Cohen are not consistently named as authors and other authors, such as Drs. Goodman and Katz, are listed. *Id*. at 3–4.

We find that Petitioner's evidence that allegedly casts doubt on the authorship of the relevant portions of S-1 is not sufficient to overcome the ample, unequivocal evidence presented by Patent Owner that supports our finding that the relevant portions of S-1 are the original work of Drs. Blight and Cohen alone. *See In re Katz*, 687 F.2d at 455. Both Drs. Cohen and Blight state that they alone are the inventors and sole originators of the work in S-1 upon which Petitioner relies. *See* Exs. 2044, 2045. Five other declarants, intimately involved in the development of S-1, two of which now work for entities other than Acorda, substantiate this testimony. *See* Exs. 2046–2048, 2052, 2056. Relying on statements that may, on their face,

indicate that others may have been involved without any evidence that others were, in fact, originators of the work in question or inventors is simply not enough to carry Petitioner's burden to show that the S-1 is prior art under 35 U.S.C. § 102(a).

For the reasons discussed above, we determine that S-1 does not qualify as prior art to the claims of the '703 patent under 35 U.S.C. § 102(a) or (b). Thus, all of Petitioner's challenges to the patentability of the claims of the '703 patent, which depend on S-1 alone or in combination with Hayes or Juarez, fail. Petitioner, therefore, has not carried its burden to prove unpatentability of claims 1–52 of the '703 patent by a preponderance of the evidence.[9]

D. IPR2015-01853; IPR2015-01857; and IPR2015-01858

Petitioner's patentability challenges to the claims of U.S. Patent No. 8,354,437 B2 ("the '437 patent"), U.S. Patent No. 8,007,826 B2 ("the '826 patent"), and U.S. Patent No. 8,354,437 B2 ("the '437 patent"), at issue in IPR2015-01853, IPR2015-01857, and IPR2015-01858, respectively, essentially raise the same issues presented in the patentability challenge to the claims of the '703 patent in IPR2015-01850. Therefore, we chose to

[9] Because we find that S-1 is not prior art under 35 U.S.C. § 102(a), we need not reach whether S-1 is a printed publication.

address the patentability of all challenged claims in these additional three *inter partes* reviews in this Final Written Decision as well.

1. *IPR2015-01853*[10]

In IPR2015-01853, Petitioner challenges the patentability of claims 1–3, 5–8, and 10–41 of the ’826 patent based on the combination of S-1 and Hayes. Pet. 21. We instituted *inter partes* review based on that challenge. Dec. Instit. 20.

The ’826 patent relates to methods of using a sustained release oral dosage form of an aminopyridine composition to treat a neurological disorder, such as multiple sclerosis (“MS”), by maximizing the therapeutic effect, while minimizing adverse side effects. Ex. 1001, 1:16–25.

Examples 4 and 5 in the ’826 patent present pharmacokinetic parameters of fampridine (4-aminopyridine) compositions administered to patients with MS. *Id*. at 19:56–22:32. In Example 8, the ’826 patent describes a clinical trial “to evaluate safety, tolerability and activity of oral fampridine-SR [sustained release] in subjects with Multiple Sclerosis.” *Id*. at 25:52–56. As stated in Example 8, “the Timed 25 Foot Walk is widely used to assess MS patients’ functional status.” *Id*. at 26:37–40. The trial “showed a strong positive trend across all three dose groups compared to

[10] Unless otherwise stated, all references in this section are to the Papers and Exhibits in *inter partes* review IPR2015-01853.

placebo in its primary endpoint, improvement in walking speed, as measured by a timed 25-foot walk as shown in FIG. 3." *Id*. at 26:29–32. In addition, the trial "showed a statistically significant improvement across dose groups in its secondary endpoint, the Lower Extremity Manual Muscle Test (LEMMT), as shown in FIG. 4." *Id*. at 26:32–35. The '826 patent further states that this study "confirms the safety profile of 4-aminopyridine and preferable dosing of 10 to 15 milligrams twice daily." *Id*. at 26:46–48.

Claims 1, 6, 11, 17, 31, 36, and 37 are independent claims in the '826 patent. Claims 1 and 31, reproduced below, are representative.

> 1. A method for maintaining a therapeutically effective concentration of 4-aminopyridine in order to improve walking in a human with multiple sclerosis in need thereof, said method comprising:
>
> orally administering to the human a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a day; and thereafter,
>
> maintaining administration of 4-aminopyridine by orally administering to said human a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a time period of at least two weeks, whereby an in vivo 4-aminopyridine C_{maxSS}:C_{minSS} ratio of 1.0 to 3.5 and a C_{avSS} of 15 ng/ml to 35 ng/ml are obtained in the human.
>
> 31. A method of increasing walking speed in a human multiple sclerosis patient in need thereof comprising orally administering

> to said patient a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a time period of greater than two weeks, wherein said sustained release composition provides a mean T_{max} in a range of about 1 to about 6 hours after administration of the sustained release composition to the patient.

Ex. 1001, 27:17–30, 29:16–23.

The ’826 patent claims priority to the same Provisional as the ’703 patent that has a filing date of April 9, 2004. *See* Ex. 1001 ¶ 60.[11] As Patent Owner notes, Petitioner does not challenge that claims 33 and 39 of the ’826 have the benefit of the filing date of the Provisional. *See* Pet. 11; PO Resp. 3. Petitioner does challenge, however, whether the Provisional provides adequate written description support for claims 1–3, 5–8, 10–32, 34–38, and 40–41 of the ’826 patent.

Petitioner’s arguments as to why these claims of the ’826 patent do not have adequate written description support is the same as for the claims of the ’703 as discussed above, namely, “[t]he ’894 Provisional nowhere discloses a method of improving walking, increasing walking speed, or improving lower extremity muscle strength by

[11] The ’826 patent also claims priority to three additional provisionals filed in 2003, but the priority benefit of these applications is not at issue here. *See* Ex. 1001 ¶ 60; Pet. 11–12; PO Resp. 2–3.

administering 10 mg 4-AP for a one or two-week treatment period" or for an unspecified period of time (more than a day) in which efficacy is demonstrated; "claims 1–3, 5–8, 10–30, and 36 all require the pharmacokinetic range of C_{avSS} of 15 ng/ml to 35 ng/ml in MS patients receiving 10 mg 4-AP BID," which is not supported by Table 7 of the Provisional; and claims 32 and 38 also require a C_{maxSS}:C_{minSS} ration of 1.0 to 3.5, which is also not supported by Table 7 of the Provisional. *See* Pet. 13–19.

For the same reasons discussed *supra* in Section C.6., we find that the Provisional provides adequate support for the challenged claims of the '826 patent.[12] Also, as we found above in the same section, because all challenged claims of the '826 are entitled to the benefit of the filing date of the Provisional, S-1 can only be prior art for these claims under 35 U.S.C. § 102(a), but not § 102(b). Because S-1 in relevant part corresponds to work by the inventors, not "by others," S-1 does not qualify as prior art to the claims of the '826 patent under §102(a). *See supra* Section C.6. Therefore, Petitioner's challenge to the patentability of the claims of the '826 patent, which depend on the combination of S-1 with Hayes, fails. Petitioner has

[12] The same analysis concerning "mean $\pm$ SD" that applies to how to determine the range for C_{avSS} also applies to how to determine the range for CmaxSS and CminSS ranges and ratio. *See* PO Resp. 8–11; Ex. 2041 ¶¶ 21–29.

not carried its burden to prove unpatentability of claims 1–3, 5–8, and 10–41 of the ’826 patent by a preponderance of the evidence.

2. IPR2015-01857[13]

In IPR2015-1857, Petitioner challenges the patentability of claims 1–8 of the ’685 patent. Pet. 22, 35–54. We instituted *inter partes* review based on the following challenges:

Reference(s)	Basis	Claims Challenged
S-1	§ 103	1 and 8
S-1 and Hayes	§ 103	2–5
S-1 and Juarez	§ 103	1, 6, 7

Dec. Instit. 24.

The ’685 and the ’826 patents share the same specification. *See* Ex. 1001 ¶ 63 (stating continuation application No. 11/010,828, filed on Dec. 13, 2004, now Pat. No. 8,007,826). The description of the ’826 patent applies to the ’685 patent.

Claim 1 is the only independent claim in the ’685 patent. Claims 1, 2, 5, and 6, reproduced below, are representative.

> 1. A method of improving walking in a human multiple sclerosis patient in need thereof comprising orally administering to said patient a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a time

[13] Unless otherwise stated, all references in this section are to the Papers and Exhibits in *inter partes* review IPR2015-01857.

period of at least two weeks, wherein the sustained release composition further comprises one or more pharmaceutically acceptable excipients.

2. The method of claim 1 wherein said sustained release composition provides a mean T_{max} in a range of about 2 to about 6 hours after administration of the sustained release composition to the patient.

5. The method of claim 1 wherein the sustained release composition provides an average plasma concentration at steady state in humans in the range of about 15 ng/ml to about 35 ng/ml.

6. The method of claim 1 wherein the 4-aminopyridine is dispersed in a rate of release controlling polymer.

Ex. 1001, 27:22–28:20.

Like the ’703 patent, the ’685 patent claims priority to the Provisional that has a filing date of April 9, 2004. *See* Ex. 1001 ¶ 60. Petitioner challenges whether the Provisional provides adequate written description support for challenged claims 1–8 of the ’685 patent. Pet. 14.

Petitioner’s arguments as to why these claims of the ’685 patent do not have adequate written description support are the same as for the claims of the ’703 as discussed above, namely, “[t]he ’894 Provisional nowhere discloses a method of improving walking by

administering 10 mg 4-AP for a two-week treatment period" as required by all challenged claims, and "[b]ecause the claimed range for claim 5 claims up to 35 ng/ml—while the '894 Provisional does not disclose at least the upper range of 26.6 ng/ml–35 ng/ml—claim 5 of the '685 Patent cannot claim priority to the '894 Provisional." *See* Pet. 14–19.

For the same reasons discussed *supra* in Section C.6., we find that the Provisional provides adequate support for the challenged claims of the '685 patent. Also, as we found above in the same section, because all challenged claims of the '685 are entitled to the benefit of the filing date of the Provisional, S-1 could only be prior art for these claims under 35 U.S.C. § 102(a), but not § 102(b). Because S-1 in relevant part corresponds to work by the inventors, not "by others," however, S-1 does not qualify as prior art to the claims of the '685 patent under § 102(a). *See supra* Section C.6. Therefore, all of Petitioner's challenges to the patentability of the claims of the '685 patent, which depend on the S-1 alone or in combination with Hayes or Juarez, fail. Petitioner has not carried its burden to prove unpatentability of claims 1–8 of the '685 patent by a preponderance of the evidence.

3. IPR2015-01858[14]

In IPR2015-01858, Petitioner challenges the patentability of claims 1–40 of the '437 patent based on S-1 alone, or in combination with Hayes. Pet. 20–21. We instituted *inter partes* review based on the following challenges:

Reference(s)	Basis	Claims Challenged
S-1	§ 103	1–21 and 26–40
S-1 and Hayes	§ 103	13–25, 32–35, and 39

Dec. Instit. 20.

Independent claims 1 and 32 of the '437 patent are directed to methods of increasing walking speed in an MS patient and independent claims 2 and 33 are directed to improving walking in an MS patient. *See* Ex. 1001, 27:55–67, 29:10–24. Independent claims 3, 4, 34, and 35 are directed to methods of improving lower extremity muscle strength (claims 4 and 35) and tone (claims 3 and 34) in an MS patient. *See id*. at 28:1–16, 29:25–30:10. Additionally, independent claim 38 is directed to a method of treating walking disability in a MS patient in need thereof. *Id*. at 30:15–21. Similar to the claims of the '703 patent, each of the independent claims requires administering to the patient a sustained release composition of 10 mg of 4-aminopyridine twice daily for a time period of at least two weeks with claims 32–35 requiring administering at about every 12 hours.

[14] Unless otherwise stated, all references in this section are to the Papers and Exhibits in *inter partes* review IPR2015-01858.

Claims 1 and 32 are illustrative of the challenged claims and are reproduced below:

> 1. A method of increasing walking speed in a human multiple sclerosis patient in need thereof comprising orally administering to said patient a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a time period of at least two weeks, wherein said 10 milligrams of 4-aminopyridine twice daily are the only doses of 4-aminopyridine administered to said patient during said time period.
>
> 32. A method of increasing walking speed in a human multiple sclerosis patient in need thereof comprising orally administering to said patient a sustained release tablet of 10 milligrams of 4-aminopyridine at about every 12 hours for a time period of at least two weeks, wherein said 10 milligrams of 4-aminopyridine at about every 12 hours are the only doses of 4-aminopyridine administered to said patient during said time period.

Id. at 27:55–61, 29:11–18.

Like the ’703 patent, the ’437 patent claims priority to the Provisional that has a filing date of April 9, 2004. *See* Ex. 1001 ¶ 60. As Patent Owner notes, Petitioner does not challenge that claims 5–8, 17, 36, 37, and 40 of the ’437 have the benefit of the filing date of the Provisional. *See* Pet. 11; PO Resp. 3. Petitioner does challenge, however, whether the Provisional provides adequate written

description support for claims 1–4, 9–16, 18–35, 38, and 39 of the '437 patent.

Petitioner's arguments as to why these claims of the '437 patent do not have adequate written description support is the same as for the claims of the '703 as discussed above, namely, "[t]he Provisional nowhere discloses a method of improving any lower extremity function by administering 10 mg 4-AP for 'at least two weeks'" as required by all challenged claims, and "claims 22–25 are not supported by the Provisional because they require a C_{avSS} range of 15 ng/ml to 35 ng/ml in MS patients receiving 10 mg 4-AP BID." *See* Pet. 12–17.

For the same reasons discussed *supra* in Section C.6., we find that the Provisional provides adequate support for the challenged claims of the '437 patent. Also, as we found above in the same section, because all challenged claims of the '437 are entitled to the benefit of the filing date of the Provisional, S-1 could only be prior art for these claims under 35 U.S.C. § 102(a), but not § 102(a). Because S-1 in relevant part corresponds to work by the inventors, not "by others," S-1 does not qualify as prior art to the claims of the '437 patent under § 102(a). *See supra* Section C.6. Therefore, all of Petitioner's challenges to the patentability of the claims of the '437 patent, which depend on the S-1 alone or in combination with Hayes,

fail. Petitioner has not carried its burden to prove unpatentability of claims 1–40 of the '437 patent by a preponderance of the evidence.

D. Petitioner's Motions to Exclude

In all four *inter partes* reviews at issue in this Final Written Decision, Petitioner moves to exclude Exhibits 2025, 2027–2030, 2032, 2033, 2036, 2053, 2094, 2109, and 2169–2173. Paper 56. Patent Owner filed an opposition (Paper 60), and Petitioner filed a reply (Paper 64).

Our Final Written Decision does not rely on evidence contained in any of the objected-to exhibits. Accordingly, Petitioner's Motions to Exclude are dismissed as moot.

III. CONCLUSION

For the foregoing reasons, we are not persuaded that Petitioner has shown by a preponderance of the evidence that any claim at issue in the four *inter partes* reviews, IPR2015-01850, IPR2015-01853, IPR2015-01857, and IPR2015-01858, are unpatentable based on grounds asserted by Petitioner under 35 U.S.C. § 103(a).

IV. ORDER

Accordingly, it is

ORDERED that claims 1–52 of the '703 patent have not been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that claims 1–3, 5–8, and 10–41 of the ’826 patent have not been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that claims 1–8 of the ’685 patent have not been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that claims 1–40 of the ’437 patent have not been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Petitioner’s Motions to Exclude are *dismissed* as moot; and

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.

Case IPR2015-01850 (Patent 8,440,703 B2)
Case IPR2015-01853 (Patent 8,007,826 B2)
Case IPR2015-01857 (Patent 8,663,685 B2)
Case IPR2015-01858 (Patent 8,354,437 B2)

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