Paper No. _____
Filed: May 26, 2015

Filed on behalf of: Acorda Therapeutics, Inc.

By: Gerald J. Flattmann (acorda-685patent@paulhastings.com)
Naveen Modi (acorda-685patent@paulhastings.com)

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 IPR2015-00720
Patent 8,663,685

Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 8,663,685

Table of Contents

Table of Authorities

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

I. Introduction

U.S. Patent No. 8,663,685 ("the '685 patent") is one of five U.S. patents that protect Ampyra®, a novel treatment for multiple sclerosis ("MS") developed by Patent Owner Acorda Therapeutics, Inc. ("Patent Owner" or "Acorda") that is now a standard of care for improving walking in MS.[1] (Ex. 2001, Orange Book at 49.) Petitioner Coalition For Affordable Drugs (ADROCA) LLC ("Petitioner"), a wholly-owned subsidiary of a hedge fund managed by Kyle Bass, commenced this proceeding, filing the Petition for *Inter Partes* Review ("the Original Petition") and then the Corrected Petition for *Inter Partes* Review ("the Corrected Petition" or "the Petition") in an attempt to profit in the stock markets merely from the public's reaction. As explained in this Preliminary Response, submitted in accordance with 35 U.S.C. § 313 and 37 C.F.R. § 42.107, the Board should not institute *inter partes* review for several reasons.

The Original Petition was the first in what has become a rapidly expanding series of highly controversial filings aimed at using the U.S. Patent and Trademark Office and the *inter partes* review process itself to move stock prices and reap

[1] U.S. Patent No. 8,007,826, at issue in IPR2015-00817, as well as U.S. Patent Nos. 5,540,938, 8,354,437, and 8,440,703, not at issue in any PTAB proceedings, also protect Ampyra. (Ex. 2001, Orange Book at 49.)

profits. To date, entities controlled by Kyle Bass' hedge fund have filed fifteen petitions for *inter partes* review against eight publicly traded biopharmaceutical companies. Use of the *inter partes* review process as a tool to manipulate markets is not what Congress intended. Moreover, such filings are a costly drain on the Office's resources. In order to preserve the Office's resources for proper petitions and stem the sort of filings involved here, the Board should exercise its discretion under 35 U.S.C. § 314(a) to deny institution of this *inter partes* review petition. The Board should also deny institution because of Petitioner's failure to name its investors and identify them as real parties-in-interest.

Even if the Office considers the Petition in its discretion, the Petition should still be denied because it is fatally flawed. Each of Petitioner's three grounds for rejecting the '685 patent relies on at least one reference that Petitioner has failed to show is a "printed publication," as required under 35 U.S.C. § 311(b). Thus, Petitioner has not satisfied its burden of establishing that it is relying on statutory prior art.

Moreover, the Petition contains nothing new. The Petition's proposed grounds of rejection are all based on information that was "previously . . . presented to the Office" during prosecution of the '685 patent and/or its parent, U.S. Patent No. 8,007,826 ("the '826 patent"). As such, the Board should exercise its discretion under 35 U.S.C. § 325(d) and deny the Petition in its entirety.

In addition, the obviousness arguments presented in the Petition's three proposed grounds of rejection are facially deficient. For example, the proposed grounds are ambiguous and inconsistent with respect to the combinations of references relied upon, are conclusory, and fail to specify how or why the cited references should be combined. In addition, the Petition fails to respond to most of the evidence of secondary considerations that was presented to the Office during prosecution. The Petition also relies improperly on substantive material that was added for the first time in the Corrected Petition.

Finally, the Petition sheds no light on any distinctions among the proposed grounds of rejection. The Board should decline to consider the Petition's redundant grounds.

In sum, Petitioner has failed to establish a reasonable likelihood that at least one of the challenged claims in the '685 patent is unpatentable. Petitioner's filing—designed to use the *inter partes* review process itself as a tool for driving down Patent Owner's stock price—is riddled with critical deficiencies. Patent Owner respectfully submits that the Board should deny the Petition and decline to institute a trial.

II. Background – Development of Ampyra

Treating MS is fundamentally difficult. MS is a complex neurological disease that involves both the central nervous system and the immune system. (Ex.

2027, Declaration of Rossella Medori, filed in the prosecution of the ’826 patent (“Medori Decl.”) at ¶¶4-5; *see also id.* at 37-63 (Declaration Exhibit B).) Drug development in each of these fields is extremely unpredictable; the challenge is magnified in developing drugs for conditions that involve both systems. (Ex. 2027, Medori Decl. at ¶¶ 5, 15-17; *see also id.* at 275-287 (Declaration Exhibit L); Ex. 2018 at 1, 5, 17.) The high degree of variability among MS patients further confounds work in this area. There are multiple forms of MS and substantial variation within each disease type. (Ex. 2027, Medori Decl. at ¶¶ 5; Ex. 2019 at 1-5.) Moreover, the symptoms experienced by individual patients may change significantly from day-to-day (good days and bad days), which complicates assessment of a patient’s condition and treatment. (Ex. 2020 at 1-5.)

The discovery and bringing to market of a new MS drug are precisely the sort of endeavors patent laws ought to incentivize by giving the public confidence in the grant of a patent. The invention claimed in the ’685 patent and the underlying work by inventors Ron Cohen and Andrew Blight on the use of 4-aminopyridine (“4-AP”)[2] represented a “milestone” in the treatment of MS. (Ex. 2011, Sustained-Release Fampridine for Multiple Sclerosis at 1.) Patent Owner’s 4-AP product, Ampyra, was developed after years of research into 4-AP – years

[2] 4-AP is also known as fampridine or dalfampridine. (Ex. 2004 at 6.)

characterized by false starts, promising leads that failed, and inconsistent results within studies. (*See generally id.*) Ampyra received priority review and approval by the FDA.[3] (Ex. 2027, Medori Decl. at ¶ 8.) Such priority review is reserved for drugs that "offer major advances in treatment, or provide a treatment where no adequate therapy exists." (*See* Ex. 2027 at 316 (Declaration Exhibit O); *see also id.* at ¶ 8.)

Ampyra is the first drug approved by the United States Food and Drug Administration ("FDA") for improving walking in MS patients, the first FDA-approved drug not limited by MS subtype, the first FDA-approved drug covering Primary Progressive MS, and the first FDA-approved MS drug for oral administration. (Ex. 2027, Medori Decl. at ¶¶ 8-10; Ex. 2028, Declaration of Lauren Sabella, filed in the prosecution of the '826 patent ("Sabella Decl.") at ¶¶ 5-7; *see also* Ex. 2003, FDA News Release at 1.) Since FDA approval, Ampyra has helped thousands of MS patients and has generated $1.37 billion in sales. (Ex. 2021 at 7; Ex. 2022 at 7; Ex. 2023 at 9; Ex. 2024 at 7; Ex. 2025 at 7; Ex. 2026 at 22.)

[3] Ampyra is a sustained release composition of 4-aminopyridine, administered orally in twice daily 10 mg doses. (*See* Ex. 2004.)

III. The Board Should Deny the Petition Because It Was Filed for an Improper Purpose and Fails to Name All of the Real Parties-in-Interest

Petitioner is a wholly owned subsidiary of a hedge fund managed by Kyle Bass. (Corr. Pet. at 1-2.) Petitioner is not involved in the pharmaceutical industry, so as to potentially be impacted by the patents in suit, has of course not been sued by Patent Owner, and apparently has no purpose or existence outside of the IPR arena. The much-publicized filing at issue here has been widely described as part of a strategy devised by Mr. Bass to profit by using the IPR process to drive down the price of Patent Owner's stock in which he or his investment funds held short positions. (Ex. 2005 at 1; Ex. 2006 at 1 ("A well-known hedge fund manager is taking a novel approach to making money: filing and publicizing patent challenges against pharmaceutical companies while also betting against their shares."); Ex. 2008 at 1 ("The founder of Hayman Capital has filed an *inter partes review* (IPR) petition with the U.S. Patent and Trademark Office challenging Acorda Therapeutics' patent of its flagship drug Ampyra. . . . Shares of Acorda . . . fell 9.65%. In early January, it was leaked . . . that Bass has a 'short activist strategy' against the U.S. pharmaceutical industry and its 'BS patents.'").)[4] On the day the

[4] As part of this strategy, Kyle Bass is utilizing the paid consulting services of Erich Spangenberg and his company IPNav, which have notoriously been involved in thousands of patent litigations. (Ex. 2007 at 2.)

Original Petition was filed, before anyone could possibly have assessed its merits, Patent Owner Acorda's stock price plunged nearly 10%. (Ex. 2009 at 1 ("Kyle Bass, a hedge fund manager . . . is aiming at pharmaceutical companies. . . . A new method of challenging patents gives him a tool. . . . Mr. Bass . . . has already drawn blood. Acorda Therapeutics stock fell almost 10 percent on news of his challenge.").)

The standard for institution of an *inter partes* review under 35 U.S.C. § 314(a) "is written in permissive terms. . . . Thus, Congress has given the office discretion whether to institute a review or not institute a review." *Zetec, Inc. v. Westinghouse Elec. Co.*, IPR2014-00384, Paper No. 10 at 5 (July 23, 2014); *see also Heckler v. Chaney*, 470 U.S. 821, 831 (1985). Congress also stated that, in prescribing regulations under 35 U.S.C. § 316, the Director shall consider the effect of any such regulation on things such as "the economy" and "the integrity of the patent system." 35 U.S.C. § 316(b). Congress' aim in establishing the IPR process was to "provid[e] quick and cost effective alternatives to litigation[,] . . . not . . . [a] tool[] for harassment." *See* H.R. Rep. No. 112-98, pt. 1, at 48.

There can be no dispute that allowing hedge funds to use the IPR process to manipulate financial markets is inconsistent with Congressional intent and the directives given to the Office discussed above. Instituting *inter partes* review here will only encourage more such filings, which will burden additional patent owners,

their industries, and the Office. At least two other investment funds, Ferrum Ferro Capital LLC (IPR2015-00858) and The Mangrove Partners Master Fund, Ltd. (IPR2015-01046 and IPR2015-01047), have already followed Mr. Bass' lead. The Board should, therefore, exercise its discretion under § 314(a) and refuse to institute this IPR.[5]

Moreover, the Petition should also be denied because it fails to name all of the real parties-in-interest (RPIs). The funding of an IPR is an important factor that the Board must consider in determining whether a party is an RPI. Office Patent Trial Practice Guide, 77 Fed. Reg. 157 at 48760 (Aug. 14, 2012). Yet Petitioner, a hedge fund, does not name the investors funding the Petition. Petitioner identifies Hayman Capital Management, L.P. ("Hayman Capital") as an RPI. Hayman Capital "manages assets of privately offered pooled investment vehicles" and only accepts investors that provide millions of dollars of funding. (*See* Ex. 2002 ("The minimum investment with Hayman is $5 million"; Ex. 2006 at 3-4 ("Mr. Bass was pitching wealthy individuals and institutions to invest in a dedicated fund that would bet against, or short, the shares of companies whose

[5] As evidenced in each of the petitions, Kyle Bass' hedge fund has controlled the filing of IPR2015-00720, -00817, -00988, -00990, -01018, -01076, -01086, -01092, -01093, -01096, -01102, -01103, -01136, -01169, and -01241.

patents Mr. Bass believed to be specious, and wager on rivals that could benefit . . . . The fund requires a minimum $1 million investment, and Mr. Bass's firm will keep 20% of all profits earned, according to a person familiar with the matter. The trades also will be part of Hayman Capital's main fund.").) The undisclosed investors that provided substantial funding for the Petition are the parties that stand to gain or lose, and, therefore, are RPIs. *See RPX Corp. v. VirnetX, Inc.*, IPR2014-00171, Paper No. 52 at 9 (June 23, 2014) (finding the petitioner to be "at most, a 'nominal plaintiff' with 'no substantial interest' in these IPR challenges apart from those of its client," which was held to be an RPI).

In addition, Hayman Capital has a self-described fiduciary duty to its investors. (*See* Ex. 2010, Hayman Capital Brochure at 16.) The fiduciary relationship between the unnamed investors and Hayman Capital further compels a finding that the investors are RPIs. *See Taylor v. Sturgell*, 553 U.S. 880, 894 (2008) (finding "fiduciaries" to be part of the third of six categories that create an exception to the common law rule that normally forbids nonparty preclusion in litigation); *see also RPX Corp.*, IPR2014-00171, Paper No. 52 at 6 (relying on the six categories in *Taylor* to determine the scope of RPI).

IV. The Petitioner Improperly Relies on Material That It Fails to Establish Is Statutory Prior Art

A petitioner in an *inter partes* review may rely only on "a ground that could be raised under section 102 or 103 and *only on the basis of prior art consisting of*

patents or printed publications." 35 U.S.C. § 311(b) (emphasis added). In order to qualify as a "printed publication" within the meaning of § 102, a reference "must have been sufficiently accessible to the public interested in the art." *In re Klopfenstein*, 380 F.3d 1345, 1348 (Fed. Cir. 2004); *see also L-3 Comm. Holdings, Inc. v. Power Survey, LLC*, IPR2014-00832, Paper No. 9 at 11-12 (Nov. 14, 2014). A petitioner bears the burden of establishing that a reference is a printed publication. *See, e.g.*, *Actavis, Inc. v. Research Corp. Techs., Inc.*, IPR2014-01126, Paper No. 22 at 9-13 (Jan. 9, 2015) (finding that "Petitioner has not satisfied its burden to prove that [a] thesis is a printed publication under § 102(b)"); *A.R.M., Inc. v. Cottingham Agencies Ltd.*, IPR2014-00671, Paper No. 10 at 7 (Oct. 3, 2014) (denying institution where the petitioner had "not provided sufficient evidence to support a threshold showing that [the purported prior art] is a printed publication"). "The party seeking to introduce the reference 'should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents.'" *L-3 Comm. Holdings*, IPR2014-00832, Paper No. 9 at 12. The determination of whether a given reference constitutes a prior art "printed publication" involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public. *Klopfenstein*, 380 F.3d at 1350; *see also Dell, Inc. v.*

Selene Comm. Techs., LLC, IPR2014-01411, Paper No. 23 at 21 (Feb. 26, 2015); *Actavis*, IPR2014-01126, Paper No. 22 at 9-13; *Cisco Sys., Inc. v. Constellation Techs. LLC*, IPR2014-00871, Paper No. 12 at 8-9 (Dec. 19, 2014); *A.R.M.*, IPR2014-00671, Paper No. 10 at 7.

Here, Petitioner fails to establish that the cornerstone of each of its proposed grounds of rejection—a "poster" titled "Placebo-controlled double-blinded dose ranging study of fampridine-SR in multiple sclerosis" by Goodman et al. (Ex. 1008, "the Goodman Poster")—qualifies as a "printed publication." Petitioner likewise fails to show that the "poster" titled "Open-label, multiple-dose study to determine the pharmacokinetics and safety of fampridine-SR (sustained-release 4-aminopyridine) in patients with chronic spinal cord injury" by Hayes et al. (Ex. 1009, "the Hayes Poster"), relied on in Petitioner's proposed Ground 1, is a printed publication.

A. Petitioner Fails to Establish that the Goodman Poster and the Hayes Poster Are Statutory Prior Art Under *In re Klopfenstein*

The Information Disclosure Statements (IDSs) that Petitioner cites state that the Goodman and the Hayes Posters were "presented." (*See* Corr. Pet. at 18-19; *see also* Ex. 2033, IDS filed October 1, 2012, at 3; Ex. 2031, IDS filed October 31,

2011, at 12.)[6] But even if Petitioner claims that the posters were displayed at meetings, this does not establish that the posters are printed publications. *See, e.g.*, *Klopfenstein*, 380 F.3d at 1349 n.4 (finding that "a presentation that includes a transient display of slides is . . . not necessarily a 'printed publication'").

The Federal Circuit has explained that if a reference "was never distributed to the public and was never indexed"—in other words, was displayed only temporarily—"several factors" bear on whether the reference qualifies as a "printed publication":

1. "the length of time the display was exhibited";
2. "the expertise of the target audience";
3. "the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied"; and

[6] Petitioner incorrectly cites to Ex. 1043 for the IDS referencing the Goodman Poster and Ex. 1033 for the IDS referencing the Hayes Poster. A reference to the Goodman Poster can be found at page 1 of Ex. 1008, and a reference to the Hayes Poster can be found in Ex. 1043. Because Petitioner filed incomplete copies of the IDSs, as discussed in more detail in Part IV.C, Patent Owner has submitted complete versions of the IDSs as Exhibits 2033 (for the IDS citing the Goodman Poster) and 2031 (for the IDS citing the Hayes Poster).

4. "the simplicity or ease with which the material displayed could have been copied."

Klopfenstein, 380 F.3d at 1350. "Only after considering and balancing these factors can we determine whether or not" a temporarily displayed reference is a printed publication. *Id.*; *see also Dell, Inc., LLC,* IPR2014-01411, Paper No. 23 at 21; *Cisco Sys., Inc.*, IPR2014-00871, Paper No. 12 at 8-9; *A.R.M.*, IPR2014-00671, Paper No. 10 at 7; *Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.*, CBM2013-00009, Paper No. 68 at 18 (Feb. 11, 2014).

Petitioner does not demonstrate or even allege that either the Goodman Poster or the Hayes Poster was distributed to the public or indexed (*e.g.*, in a library or database) in any way. Petitioner also presents no evidence that the *Klopfenstein* factors compel a finding that the Goodman and Hayes Posters qualify as printed publications. This failure of proof is fatal to the Petition. Petitioner has thus failed to make the showing necessary to demonstrate that the Goodman and Hayes Posters are statutory prior art.

1. Petitioner Cites No Evidence Regarding the Length of Time the Posters Were Presented

As set forth in *In re Klopfenstein*, one factor that bears on whether the Goodman and Hayes Posters qualify as printed publications is the length of time that they were exhibited. *Klopfenstein*, 380 F.3d at 1350. However, the IDSs that Petitioner cites provide only the names and dates of the conferences/meetings at

which the posters were presented. (*See* Ex. 2033, IDS filed October 1, 2012, at 3; Ex. 2031, IDS filed October 31, 2011, at 12.) Petitioner submits no evidence at all regarding the length of time the posters were presented. Petitioner's failure of proof is key because "[t]he more transient the display, the less likely it is to be considered a 'printed publication.'" *See Klopfenstein*, 380 F.3d at 1350-51 (citing *Regents of the Univ. of Cal. v. Howmedica, Inc.*, 530 F.Supp. 846, 860 (D.N.J. 1981), which held that slides presented during a conference lecture did not constitute "printed publications" under § 102(b)).

2. Petitioner Advances No Evidence Regarding the Expertise of the Target Audience

Another factor which impacts whether the Goodman and Hayes Posters qualify as printed publications is the expertise of the audience to which the posters were exhibited. *Klopfenstein*, 380 F.3d at 1350. Petitioner fails to analyze this factor. In particular, Petitioner provides no evidence regarding the expertise of the target audience for "the 7th Annual Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and 18th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS/ECTRIMS)," at which the Goodman Poster was "presented" (Ex. 2033, IDS filed October 1, 2012, at 3), or the "American Neurological Association," to which the Hayes Poster was "presented" (Ex. 2031, IDS filed October 31, 2011, at 12).

3. Petitioner Presents No Evidence Regarding Any Reasonable Expectation That the Posters Would Be Copied

A further factor to be considered in determining whether the Goodman and Hayes Posters qualify as printed publications is the likelihood that the posters would be copied. *Klopfenstein*, 380 F.3d at 1350. As the Federal Circuit has explained:

> Where professional and behavioral norms entitle a party to a reasonable expectation that the information displayed will not be copied, we are more reluctant to find something a "printed publication." This reluctance helps preserve the incentive for inventors to participate in academic presentations or discussions.

Id. at 1351. Nonetheless, Petitioner provides no evidence as to whether there was a reasonable expectation that the Goodman and Hayes Posters would or would not be copied at the time that they were "presented" over a decade ago (*e.g.*, prior to common use of smartphones). (*See* Corr. Pet. at 18-19; *see also* Ex. 2033, IDS filed October 1, 2012, at 3; Ex. 2031, IDS filed October 31, 2011, at 12.)

4. Petitioner Presents No Evidence Regarding the Simplicity or Ease with which the Posters Could Have Been Copied

The simplicity or ease with which the Goodman and Hayes Posters could have been copied is an additional factor to be considered in assessing whether they qualify as printed publications. *Klopfenstein*, 380 F.3d at 1350. Again, however, Petitioner presents no information on the subject.

In sum, Petitioner has failed to meet its burden. It does not even mention the *Klopfenstein* factors, much less show how they bear on whether the Goodman and Hayes Posters should be deemed printed publications. Because all of the grounds of rejection advanced by Petitioner are predicated on the Goodman Poster as a primary reference (and Ground 1 further relies on the Hayes Poster), the Board should reject the Corrected Petition in its entirety and deny institution.

B. Petitioner Fails to Establish That the Goodman and Hayes Posters Are Statutory Prior Art Under Board Precedent

Consistent with the *Klopfenstein* factors, the Board has frequently found that references were not statutory prior art where a petitioner failed to provide evidence regarding the group to which a reference was allegedly made available. For example, in *Samsung Elecs. Co. v. Rembrandt Wireless Techs., LP*, IPR2014-00514, Paper No. 18 at 5, 7 (Sep. 9, 2014), the petitioner relied on a "Draft Standard" of the Institute of Electrical and Electronics Engineers ("IEEE"). The Board found that the petitioner had failed to provide evidence as to whether the reference was made available to persons outside of the IEEE "Working Group" responsible for the Draft Standard and how members of the public would have known about the reference. *See id.* at 7-8. Similarly, in *Elec. Frontier Found. v. Pers. Audio, LLC*, IPR2014-00070, Paper No. 21 at 22-24 (Apr. 18, 2014), the Board found that a reference was not a printed publication where a "Petitioner

fail[ed] to provide any information regarding [a reference] posting, the group [to which the reference was posted], who is in the group, or the size of the group."

As in *Samsung Elecs. Co.* and *Elec. Frontier Found.*, Petitioner has failed to establish that the Goodman and Hayes Posters are printed publications because Petitioner failed to provide evidence regarding the groups to which the posters were presented if any. For example, Petitioner fails to present evidence as to:

- whether the Goodman and Hayes Posters would have been available to anyone not attending the conferences/meetings (*see Samsung Elecs. Co.*, IPR2014-00514, Paper No. 18 at 7-8);
- whether the conferences/meetings were advertised or otherwise announced to the public (*id.*);
- whether anyone not attending the conferences/meetings would have known about the Goodman and Hayes Posters (*id.*);
- how posters such as the Goodman and Hayes Posters were "presented" at the conferences/meetings (*id.*); and
- the compositions and sizes of the groups organizing the conferences/meetings (*Elec. Frontier Found.*, IPR2014-00070, Paper No 21 at 22-24).

The Board has consistently held petitioners accountable—and denied institution—for failing to demonstrate that a cited reference qualified as a printed

publication. *See, e.g.*, *Dell, Inc.*, IPR2014-01411, Paper No. 23 at 22-24; *Cisco Sys., Inc.*, IPR2014-00871, Paper No. 12 at 9-11; *A.R.M.*, IPR2014-00671, Paper No. 10 at 7-8. Accordingly, the Board should deny all of Petitioner's proposed grounds of rejection, each of which rely on one or more of the Goodman and Hayes Posters.

C. Petitioner's Characterizations of the Information Disclosure Statements Are Incorrect

The entirety of Petitioner's effort to establish that the Goodman and Hayes Posters are printed publications is a reference to the IDSs that Patent Owner submitted during prosecution. (*See* Corr. Pet. at 18-19). According to Petitioner, the '685 patent applicants "admitted" in an October 1, 2012 IDS that the "Goodman reference constitutes prior art under 35 U.S.C. § 102(b) because it was published at least as early as September 18-21, 2002." (*Id.* at 18.) Petitioner similarly asserts that the '685 patent applicants "admitted" in an October 31, 2011 IDS that "Hayes constitutes prior art under 35 U.S.C. § 102(b) because it was published on Sept. 30–October 3, 2001." (*Id.* at 19.) Petitioner is wrong on both counts.

As discussed above, the IDSs to which Petitioner cites acknowledged only that the Goodman and Hayes Posters were "presented." (*See* Ex. 2033, IDS filed October 1, 2012, at 3; Ex. 2031, IDS filed October 31, 2011, at 12.) Nowhere did Patent Owner "admit" that either of the posters was "published," as Petitioner

incorrectly asserts. (*See* Ex. 2033, IDS filed October 1, 2012, at 3; Ex. 2031, IDS filed October 31, 2011, at 12.) In fact, as shown in the complete versions of the IDSs that Patent Owner is submitting with this Preliminary Response, Patent Owner explicitly stated that "[i]dentification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as 'prior art' against the subject application." (*See* Ex. 2033, IDS filed October 1, 2012, at 1; Ex. 2031, IDS filed October 31, 2011, at 2.) The Board recently rejected an argument regarding an applicant's alleged "admission" that a reference was a prior art printed publication at least in part because of such a statement. *See L-3 Comm. Holdings*, IPR2014-00832, Paper No. 9 at 16 ("The IDS expressly states that the submission of the IDS is not an admission that any item listed therein is prior art."). Tellingly, Petitioner did not include these portions of the IDSs in the Exhibits it submitted. (*See* Exs. 1008, 1033, and 1043.)

Petitioner's contention that the IDSs constitute an admission that the Goodman and Hayes Posters are prior art and/or printed publications is contrary to Federal Circuit precedent. The Board has recognized that "the Federal Circuit has repeatedly held that the submission of a reference on an IDS does not constitute an admission that a cited reference falls within the legal definition of prior art." *See L-3 Comm. Holdings*, IPR2014-00832, Paper No. 9 at 16 (citing *ResQNet.com v.*

Lansa Inc., 594 F.3d 860, 866 (Fed. Cir. 2010); *Abbott Labs. v. Baxter Pharm. Prod., Inc.*, 334 F.3d 1274, 1279 (Fed. Cir. 2003); *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003)); *see also ResQNet.com*, 594 F.3d at 866 (holding that the mere submission of a reference in an IDS "did not convert [the reference] into printed publication prior art"). At most, the statements in the IDSs are evidence that these posters were "presented" in some form. *See Stamps.com Inc. v. Endicia, Inc.*, 437 Fed. Appx. 897, 903 (Fed. Cir. 2011). But as explained in *Klopfenstein*, presentation does not equal publication.

For all of the reasons above, Petitioner has failed to establish that the Goodman and Hayes Posters qualify as statutory prior art. Accordingly, the Board should deny the Petition in its entirety.

V. The Board Should Exercise Its Discretion Under 35 U.S.C. § 325(d) Because the Petition Relies Entirely on References That Were Previously Considered

Under 35 U.S.C. § 325(d), "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." The Board has exercised that authority to deny institution of an IPR based on art or arguments that were previously considered by an examiner during prosecution. *See e.g., Hulu LLC v. Intertainer, Inc.*, IPR2014-01456, Paper No. 8 at 7-8 (Mar. 6, 2015); *Prism Pharma Co. v. Choogwae Pharma Corp.*, IPR2014-00315, Paper No. 14 at 12-13

(July 8, 2014); *Excelsior Med. Corp. v. Lake*, IPR2013-00494, Paper No. 10 at 20 (Feb. 6, 2014) ("The Board exercises its authority under 35 U.S.C. § 325(d) to deny this ground because the asserted prior art references and arguments were considered previously by the office.").

In making its determination under Section 325(d), the Board should take into account not only the references considered by the Office during prosecution of the '685 patent, but also the references considered by the Office during prosecution of the parent '826 patent. *See Prism Pharma Co.,* Paper No. 14 at 12-13. This is especially so because the '826 and '685 patents claim common subject matter that distinguishes the claims of both patents from the prior art, such as the common recitations of improving walking in a human with MS in need thereof by orally administering a sustained release composition of 10 mg of 4-aminopyridine twice daily for at least 2 weeks.[7] The Examiner of the application that issued as the '685 patent took the relationship between the patents into account in evaluating patentability and ultimately allowing the patent. In fact, the Examiner stated that the claims being allowed in the '685 patent were "methods of use claims, corresponding to the methods of use claims which [had] been found to be novel and unobvious and [had] been allowed and issued in U.S. Patent No. 8,007,826

[7] Claim 6 of the '826 patent specifies no titration in lieu of "at least 2 weeks."

(parent application 11/010,828 to the instant application)." (Ex. 2036, Notice of Allowance mailed April 25, 2013 at 7.) Along the same lines, the Examiner had rejected the claims of the application that issued as the '685 patent for obviousness-type double patenting over the claims of the '826 patent,[8] stating:

> The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows a method of improving walking in subjects with multiple sclerosis by orally administering a sustained release composition of 10 milligrams of 4-aminopyridine twice daily.

(Ex. 2034, Office Action mailed December 17, 2012 at 4.)[9]

[8] At the time of the obviousness-type double patenting rejection in the application that issued as the '685 patent, the pending claims were identical to those that issued, except that the "wherein" clause specifying "wherein the sustained release composition further comprises one or more pharmaceutically acceptable excipients" in the first claim had not yet been added, "maximum plasma concentration" in the fifth claim had not yet been revised to "plasma concentration at steady state," and then pending claims 32 and 33 had not yet been cancelled.

[9] Applicants overcame this rejection by filing a Terminal Disclaimer over the '826 patent on March 18, 2013. (Ex. 2035, Terminal Disclaimer filed March 18, 2013.)

All of the references asserted in the Petition were previously considered by the Office during prosecution of the ’685 patent. Moreover, either the references asserted in the Petition or references disclosing the same or substantially the same information were discussed with the Office during prosecution of the parent ’826 patent. As explained in detail below, and pursuant to 35 U.S.C. § 325(d), the Board should deny institution.

A. The Goodman Poster and the Information Contained Therein Were Previously Considered by the Office

Each of the grounds asserted by Petitioner relies on the Goodman Poster. (Corr. Pet. at 13-14.) However, applicants cited the Goodman Poster during the prosecution of the ’685 patent (as reference C416) in an IDS filed on October 1, 2012, and the Examiner considered it, as indicated in a paper mailed from the Office on December 17, 2012. (Ex. 2033, IDS filed October 1, 2012, at 3; Ex. 2034, Office Action mailed December 17, 2012 at 3, 17.)

Furthermore, during the prosecution of the ’685 patent, Applicants submitted IDSs on June 7, 2012 (Ex. 2032), October 2, 2013 (Ex. 2039), and January 13, 2014 (Ex. 2042), which included materials filed in opposition proceedings before the European Patent Office (“EPO”) involving related European patents. Those filings discussed the Goodman Poster and the information contained therein. The IDSs filed on October 2, 2013 and January 13, 2014 are of particular note because they were submitted together with Requests for Withdrawal from Issue and

Requests for Continued Examination filed specifically to permit consideration of the cited references, as expressly acknowledged by the Examiner in subsequent Notices of Allowability. (*See* Exs. 2037, 2038, 2041, 2043, 2044, 2045.)

References C420 and C422, cited in the October 2, 2013 IDS, discussed an abstract by Goodman *et al*. from 2003 (Goodman *et al*., 2003, "Placebo-controlled double-blinded dose ranging study of fampridine-SR in multiple sclerosis," Neurology, Suppl. 1, Vol. 60(5):A167, Abstract S21.001, "the Goodman 2003 Abstract" (Ex. 2012)).[10] The Goodman 2003 Abstract covers the same study as the Goodman Poster and contains substantially the same information as that relied on by Petitioner. (*See generally* Ex. 2012.) In an October 18, 2013 Notice of Allowability, the Examiner stated that the information contained in the October 2, 2013 IDS had "been considered as to the merits" and that the Examiner had "determined that the cited references do not teach nor provide adequate motivation to arrive at the instantly claimed methods. . . . [T]he instant claims are seen to be novel and non-obvious over the teachings of the prior art." (Ex. 2040 at 8-9.)

The January 13, 2014 IDS cited references C432 and C433 that discussed the Goodman 2003 Abstract, and reference C434 that discussed both the Goodman

[10] References C420 and C422 refer to the Goodman 2003 Abstract as "C10."

Poster and the Goodman 2003 Abstract.[11] In a January 22, 2014 Notice of Allowability, the Examiner stated that the information contained in the January 13, 2014 IDS had "been considered as to the merits" and that the Examiner had "determined that the cited references do not teach nor provide adequate motivation to arrive at the instantly claimed methods. . . . [T]he instant claims are seen to be novel and non-obvious over the teachings of the prior art." (Ex. 2045 at 3.)

During the '826 patent prosecution, in an Amendment filed on November 24, 2010, Applicants expressly addressed two abstracts, the Goodman 2003 Abstract mentioned above and Goodman *et al*., 2002, "Placebo-controlled double-blinded dose ranging study of fampridine-SR in multiple sclerosis," ACTRIMS 7th Annual Conference and ECTRIMS 18th Congress, Programme, Multiple Sclerosis, Suppl. 1, Vol. 8:S116-S117, Abstract P308 (the "Goodman 2002 Abstract") (Ex. 2013). (Ex. 2053, Amendment filed November 24, 2010 at 25-26, 50.) Like the Goodman 2003 Abstract, the Goodman 2002 Abstract describes the study that was the subject of the Goodman Poster and discloses substantially the same information as the Goodman Poster. At pages 25-26 of a November 24, 2010 Amendment,

[11] Reference C434 refers to the Goodman Poster as "S20," and references C432, C433 and C434 refer to the Goodman 2003 Abstract as "C10," "E1" and "S10," respectively.

Applicants described the Goodman 2002 and 2003 Abstracts as follows:

> Goodman 2002, discussing administration of SR 4-AP to MS patients in a dose escalation study, disclosed that "[d]ose response curves showed **increasing benefit** in both measures [functional measures of mobility (timed walking speed) and lower extremity strength (manual muscle testing)] in the 20 to 50 mg/day range" (emphasis added). It was also stated that "[d]oses above 50 mg added little benefit and increased adverse effects." [. . .] Goodman 2003 is to similar effect [. . .]. It stated that dose response curves showed increasing benefit with increasing dose, and "[d]oses above 50 mg added little benefit and increased adverse effects."

(Ex. 2053 at 25-26.)

Thus, in the November 24, 2010 Amendment, Applicants set forth the subject matter relied on here by Petitioner, in particular, increasing benefit in timed walking speed and lower extremity muscle strength in the 20 to 50 mg/day range,[12] and little benefit and increased adverse effects at doses above 50 mg/day. Accordingly, the Goodman Poster is cumulative to the Goodman 2002 and 2003 Abstracts that were discussed during the prosecution of the parent '826 patent.

[12] Petitioner refers to 20-40 mg/day (as opposed to 20-50 mg/day) range in the Goodman Poster.

B. The Hayes Poster and the Information Contained Therein Were Previously Considered by the Office

In addition to relying on the Goodman Poster, Ground 1 of the Petition relies on the Hayes Poster. (Corr. Pet. at 14.) However, Applicants cited the Hayes Poster during prosecution of the '685 patent (as reference C148) in an IDS filed on October 31, 2011, and the Examiner considered it, as indicated in a paper mailed from the Office on December 17, 2012. (Ex. 2031, IDS filed October 31, 2011, at 12; Corr. Pet. at 7; Ex. 2034, Office Action mailed December 17, 2012 at 3, 18.)

During the '826 patent prosecution, Applicants extensively discussed with the Examiner a related reference, Hayes *et al*., 2003, "Pharmacokinetic studies of single and multiple oral doses of fampridine-SR (sustained-release 4-aminopyridine) in patients with chronic spinal cord injury," Clin. Neuropharmacol. 26(4):185-192 ("Hayes 2003") (Ex. 2014), which discloses substantially the same information as the Hayes Poster. The study presented in the Hayes Poster is one of two studies discussed in Hayes 2003 (referred to as "Study 2" throughout Hayes 2003).

Hayes 2003 was the basis of an anticipation rejection during the '826 patent prosecution that was predicated on information upon which Petitioner relies here in citing to the Hayes Poster. In particular, the Examiner stated that Hayes 2003 "admit[s] that fampridine is potentially a valuable treatment for multiple sclerosis. . . ." (Ex. 2046, Office Action mailed June 6, 2008 at 6; *see also* Corr.

Pet. at 20.) The Examiner also pointed to the pharmacokinetic data in Table 3 of Hayes 2003, which reports (in different order) the very same pharmacokinetic values reported in Table 2 of the Hayes Poster, including the average plasma concentration (C_{avSS}) and T_{max} values relied on by Petitioner. (Ex. 2046, Office Action mailed June 6, 2008 at 5-6; Corr. Pet. at 20, 34, 39, 40.) Applicants successfully overcame the anticipation rejection over Hayes 2003, explaining in a December 8, 2008 Amendment:

> Hayes merely discloses the pharmacokinetic and safety profile of a particular fampridine formulation in spinal cord injury patients, and is silent as to the therapeutic efficacy or dosing requirements . . . .

(Ex. 2047, Amendment filed December 8, 2008 at 9.)

Later in the prosecution of the ’826 patent (after the anticipation rejection over Hayes 2003 was withdrawn), in the November 24, 2010 Amendment, Applicants discussed the pharmacokinetic data upon which the Petition relies. The Amendment addressed and partially reproduced the data in Table 3 of Hayes 2003 relating to the multiple-dose Study 2 presented in Hayes 2003 (and the Hayes Poster), including certain pharmacokinetic data for 4-AP at a dose of 10 mg BID. (Ex. 2053, Amendment filed November 24, 2010 at 25.) In addition, Figure 1 of the Hayes Poster, which the Petition also cites (Corr. Pet. at 20, 34-35, 40-41), is identical in substance to Figure 1B in Hayes 2003.

Furthermore, in the Reasons for Allowance section of the April 18, 2011 Notice of Allowability for the application that issued as the ’826 patent, the Examiner characterized Hayes 2003 as one of three publications constituting “the closest prior art” and referred to the data in Table 3 (which contains the same data as that in Table 2 of the Hayes Poster, relied on by the Petition). (Ex. 2055, Notice of Allowance mailed April 18, 2011 at 12-13.)

The data and information presented in the Hayes Poster are the same or substantially the same as the data and information presented regarding Study 2 in Hayes 2003. Accordingly, the Hayes Poster is cumulative to Hayes 2003 discussed during the prosecution of the parent ’826 patent.

C. The Polman Reference and the Information Contained Therein Were Previously Considered by the Office

Ground 1 of the Petition cites Polman *et al*., 1994, “4-Aminopyridine is superior to 3,4-diaminopyridine in the treatment of patients with multiple sclerosis,” Arch. Neurol. 51:1136-1139 (Ex. 1032) (“the Polman reference”) as evidence of the “knowledge of [a person of skill in the art] that a number of prior art studies and applications teach and disclose long-term administration of 4-AP for treatment of MS” and as teaching “a method of improving walking in a human

multiple sclerosis patient."[13] (Corr. Pet. at 21, 33.) However, Applicants disclosed the Polman reference in the October 31, 2011 IDS during prosecution of the '685 patent (as reference C288), and the Examiner considered it, as indicated in an Office Action mailed from the Office on December 17, 2012. (Ex. 2031, IDS filed October 31, 2011 at 19; Ex. 2034, Office Action mailed December 17, 2012 at 3, 25.)

During the '826 patent prosecution, Applicants discussed Polman *et al.*, "4-Aminopyridine in the treatment of patients with multiple sclerosis," Arch Neurol. 51: 292-296 (Ex. 2017) ("Polman 1994") in the November 24, 2010 Amendment. (Ex. 2053, Amendment filed November 24, 2010 at 27.) Polman 1994 discloses substantially the same information as that relied on here by Petitioner from the Polman reference. For example, in the November 24, 2010 Amendment, Applicants discussed the information presented in Polman 1994 as follows:

> [E]ven improvement in one neurologic function does not predict improvement in another. See e.g., Polman et al., Mar. 1994, Arch. Neurol. 51:292-296 at Table 1, with data on 23 patients regarding subjectively reported

[13] Petitioner fails to mention that the studies described in the Polman reference were conducted using immediate release compositions, whereas the claims of the '685 patent are directed to administration of a sustained release composition.

> improvements, only one improved in speech and 22 did not, one improved in spasticity and 22 did not, one improved in incontinence and 22 did not, while four improved in cognition and 19 did not, five improved in visual function and 18 did not, 13 improved in fatigue and 10 did not, and 13 *improved in ambulation* and 10 did not.

(Ex. 2053, Amendment filed November 24, 2010 at 27 (emphasis added).)

In addition, the long-term administration of 4-AP, for which Petitioner relies on the Polman reference, was discussed with the Office during the prosecution of the '826 patent in the context of a different reference co-authored by five of the seven authors of the Polman reference: van Diemen *et al*., 1993, "4-aminopyridine in patients with multiple sclerosis: dosage and serum level related to efficacy and safety," Clin. Neuropharmacol. 16(3):195-204 ("van Diemen 1993") (Ex. 2015). In an Office Action dated May 25, 2010 (Ex. 2051), the Examiner referred to van Diemen 1993 as follows:

> Van Diemen et al teach the administration of nonenteric-coated capsules for a period of 12 weeks each in a randomized sequence in patients with multiple sclerosis.

(Ex. 2051, Office Action mailed May 25, 2010 at 5.)

Thereafter, in the November 24, 2010 Amendment, Applicants noted the Examiner's view regarding the disclosure of long-term administration of 4-AP in

van Diemen 1993 as follows:

> The Examiner notes that Van Diemen involved the administration of non-enteric coated capsules for 12 weeks, and states that "Van Diemen teaches that 10-20 mg orally per day is given in 2-3 divided doses."

(Ex. 2053, Amendment filed November 24, 2010 at 41.)

Thus, in the November 24, 2010 Amendment, Applicants addressed both the Polman 1994 disclosure relating to improving walking in MS patients with 4-AP and the van Diemen 1993 disclosure of long-term administration of 4-AP to MS patients, which constitute the subject matter for which Petitioner relies on the Polman reference. The information relied on by Petitioner from the Polman reference is, therefore, the same or substantially the same as the information presented in Polman 1994 and van Diemen 1993 that Applicants discussed with the Office during the prosecution of the '826 patent.

D. The van Diemen Reference and the Information Contained Therein Were Previously Considered by the Office

Ground 1 of the Petition cites van Diemen *et al*., 1992, "The effect of 4-aminopyridine on the clinical signs in multiple sclerosis: a randomized, placebo-controlled, double-blind, cross-over study," Ann. Neurol. 32:123-30 (Ex. 1007) ("the van Diemen reference") as "[a]nother example of a POSA's knowledge concerning the length of 4-AP therapy to treat MS." (Corr. Pet. at 22-23.) The Petition relies on the van Diemen reference to show "administering 4-AP to treat

MS disability for at least 2 weeks and specifically for twelve weeks" with the starting dose of 10 mg/day or 15 mg/day "elevated by an additional 5 to 15 mg/day at weeks 2 and 6," and to show an "effect of 4-AP on the mean EDSS score." (*Id.* at 23, 33, 38.) The Petition characterizes the disclosure of dose administration in the van Diemen reference as "striking in its similarity to the '685 patent."[14] (*Id.* at 33).

During the '685 patent prosecution, Applicants cited the van Diemen reference (as reference C386) in the IDS dated October 31, 2011 (Ex. 2031, IDS filed October 31, 2011 at 24), and the Examiner considered it, as indicated in a paper mailed from the Office on December 17, 2012. (Ex. 2034, Office Action mailed December 17, 2012 at 3, 30.)

During the '826 patent prosecution, Applicants repeatedly discussed van Diemen 1993, which discloses the information relied on here by Petitioner from the van Diemen reference. The Examiner addressed van Diemen 1993 at length in a May 25, 2010 Office Action, citing the reference as the basis, alone and in

[14] As with the Polman reference, Petitioner fails to mention that the studies described in the van Diemen reference were conducted using immediate release compositions, whereas the claims of the '685 patent are directed to administration of a sustained release composition.

combination with other references, for three obviousness rejections. (Ex. 2051, Office Action mailed May 25, 2010 at 4-13.)

Applicants responded to the obviousness rejections in a November 24, 2010 Amendment, arguing, for example:

> The Examiner notes that Van Diemen involved the administration of non-enteric coated capsules for 12 weeks, and states that "Van Diemen teaches that 10-20 mg orally per day is given in 2-3 divided doses." Van Diemen 1993 is a study of the use of IR 4-AP in MS patients, not SR 4-AP (see e.g., Schwid *et al*., 1997, Neurology 48:817-821, at 819 col. 2, lines 4-12; Van Diemen 1993 p. 196, bot. para.)

(Ex. 2053, Amendment filed November 24, 2010 at 41.) Applicants further discussed Van Diemen 1993 with the Examiner during another interview on February 3, 2011, and ultimately overcame the rejection. (Ex. 2054 at 2, 4.)

In addition to the duration of treatment and dosing, van Diemen 1993 discloses the effect of 4-AP on EDSS for which Petitioner also relies on the van Diemen reference. (Corr. Pet. at 23, 33, 38.) Specifically, the van Diemen 1993 reference cites to the van Diemen reference and discloses that it "demonstrated that 4-AP may have a favorable effect on the disability of MS patients as measured by the Kurtzke expanded disability status scale (EDSS)." (Ex. 2015 at 196.)

Because van Diemen 1993 discloses the same or substantially the same information for which Petitioner relies here on the van Diemen reference, the van Diemen reference is cumulative to van Diemen 1993 which was discussed during the prosecution of the ’826 patent.

E. The Masterson Reference and the Information Contained Therein Were Previously Considered by the Office

Ground 2 of the Petition relies on U.S. Patent No. 5,540,938 (Ex. 1010) (“the Masterson reference”) for its disclosure of formulations for twice-daily administration, comprising 4-aminopyridine and “polymeric material,” that permit release of 4-AP “at a rate allowing controlled absorption thereof over … not less than a 12 hour period” and “which can maintain therapeutically effective blood plasma levels for over 12 hours with peak plasma levels (T_{max}) occurring between 1 and 10 hours, and especially between 2 and 8 hours.” (Corr. Pet. at 42-49.) Petitioner also points to the disclosure in the Masterson reference that “the active agent is preferably administered at a dose less than 15 mg/day until a tolerable state is reached, the dose administered is increased by amounts of at least 5-15 mg/day until said therapeutic dose is reached. The active agent is preferably 4-aminopyridine. . . .” (Corr. Pet. at 46.)

In prosecuting the ’685 patent, Applicants cited the Masterson reference (as reference A08) in the IDS filed on October 31, 2011 (Ex. 2031, IDS filed October 31, 2011 at 3), and the Examiner considered it, as indicated in an Office Action

mailed from the Office on December 17, 2012 (Ex. 2034, Office Action mailed December 17, 2012 at 3, 9). U.S. Patent No. 5,580,580 ("the Masterson '580 patent") (Ex. 2016), which issued from an application that was a divisional of the Masterson reference and which, therefore, has the *same specification* as the Masterson reference, figured prominently in the prosecution of the '826 patent. The information from the Masterson reference relied on by Petitioner is identical to information presented in the Masterson '580 patent.

During the '826 patent prosecution, the Examiner discussed the Masterson '580 patent extensively, relying on it, alone or in combination with other references, in every substantive office action, as a basis for obviousness rejections. (Ex. 2046, Office Action mailed June 6, 2008 at 7-9; Ex. 2049, Office Action mailed June 10, 2009 at 6-14; Ex. 2051, Office Action mailed May 25, 2010 at 8-13.) At one point, the Examiner characterized the Masterson '580 patent as the closest prior art. (Ex. 2049, Office Action mailed June 10, 2009 at 12.)

The Examiner's rejections over the Masterson '580 patent, which Applicants ultimately overcame, relied on the same or substantially the same information as Petitioner relies on here. The Examiner focused repeatedly on the Masterson '580 patent's teaching of a method of treating MS "comprising administering a controlled administration of 4-aminopyridine that can maintain therapeutically effective blood levels over a period of 12 hours." (Ex. 2046, Office Action mailed

June 6, 2008 at 7; *see also* Ex. 2049, Office Action mailed June 10, 2009 at 6; Corr. Pet. 44, 47-49.) The Examiner also noted Masterson's incorporation of polymeric material. (Ex. 2051, Office Action mailed May 25, 2010 at 12; *see also* Corr. Pet. 44, 49.) The Masterson '580 patent was the subject of interviews with the Examiner on February 3, 2009, October 14, 2009, July 20, 2010 and February 3, 2011. (Exs. 2048, 2050, 2052, 2054.)

Moreover, in a December 8, 2008 response, Applicants stated the following about the Masterson '580 patent:

> Masterson discloses *in vitro* dissolution profiles of pharmaceutical compositions containing fampridine and discloses that the pharmaceutical compositions for twice-daily administration can maintain therapeutically effective blood levels substantially over 12 hours, with peak plasma levels occurring between 1 and 10 hours.

(Ex. 2047, Amendment filed December 8, 2008 at 10; *see also* Corr. Pet. at 24, 43, 44.) In the November 24, 2010 Amendment, Applicants characterized the Masterson '580 patent as follows:

> Masterson, U.S. Patent No. 5,580,580, discloses oral and percutaneous administration of controlled release formulations of mono- and di-aminopyridines.

(Ex. 2053, Amendment filed November 24, 2010 at 31.) Applicants added:

> Masterson's twice daily administration form can also include a rapid release (IR) form of the active agent (col. 4, lines 16-20). The formulation can be for oral administration or percutaneous administration (col. 2, lines 53-57). . . . According to Masterson, one would need to start at some dose less than 15mg/day, a range that provides numerous choices for total daily dose. (Even if one considers only dose increments of 0.5 mg there are at least 29 choices from doses above zero and up to 14.5mg.) One then would need to decide whether to embark on a one daily or twice daily regimen. Then one or more days later, if a tolerable state were reached, additional drug would be administered in some amount within the range of 5-15 mg/day (as above, even if one considers only dose increments of 0.5 mg there are at least another 21 choices among the 10mg range of 5-15mg).

(*Id*. at 49.)

Because the disclosure of the Masterson reference relied on by Petitioner is identical to the disclosure in the Masterson '580 patent, the Masterson reference is cumulative to the Masterson '580 patent discussed during the prosecution of the '826 patent.

F. The Juarez Reference and the Information Contained Therein Were Previously Considered by the Office

Ground 3 of the Petition relies on Juarez *et al*., 2001, "Influence of admixed carboxymethylcellulose on release of 4-aminopyridine from hydroxypropyl methylcellulose matrix tablets," Int'l J. of Pharmaceutics 216:115-125 (Ex. 1018) ("the Juarez reference") for its disclosure of "matrices to control the release of the active ingredient in a tablet" and "the rate of release controlling polymer." (Corr. Pet. at 25, 50-52.)

Applicants cited the Juarez reference during prosecution of the '685 patent (as reference C177) in the October 31, 2011 IDS (Ex. 2031, IDS filed October 31, 2011 at 14), and the Examiner considered it, as indicated in a paper mailed from the Office on December 17, 2012. (Ex. 2034, Office Action mailed December 17, 2012 at 3, 20.)

G. The Petition Should Be Denied Because the Art Relied on by Petitioner Is Cumulative to the Art Considered by the Office

In sum, the Goodman Poster, the Hayes Poster, the Polman reference, the van Diemen reference, the Masterson reference, and the Juarez reference, were all presented to and considered by the Office during the prosecution of the '685 patent. Further, the essential data and information in those references were discussed with the Office during the prosecution of the parent '826 patent. The Petition fails to cite a single reference or provide any information that was not

already considered by the Office. Pursuant to 35 U.S.C. § 325(d), the Petition should, therefore, be denied.

VI. Petitioner Advances Incomplete and Flawed Obviousness Arguments

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented 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). Obviousness is a question of law based on underlying factual findings, including: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). All four *Graham* factors must be considered in considering an assertion of obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075, 1077, 1080 (Fed. Cir. 2012); *Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.*, IPR2014-00309, Paper No. 83 at 45-46 (Mar. 23, 2015).

A determination of unpatentability on the ground of obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The

obviousness analysis "should be made explicit" and it "can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 550 U.S. at 418.

Petitioner proposes three different grounds of rejection against the '685 patent claims, all under 35 U.S.C. § 103. In each instance, however, Petitioner relies on a defective obviousness analysis.

A. The Petition Does Not Clearly Articulate the Proposed Grounds

The Petition is unclear as to which combinations of references apply to which claims. As such, Petitioner has failed to "specify where each element of the claim is found in the prior art patents or printed publications relied upon[.]" 37 C.F.R. § 42.104(b)(4).

As Ground 1, the Petition alleges that the combination of the Goodman Poster, the Hayes Poster, and the knowledge of a person of ordinary skill in the art, as evidenced by the Polman reference and the van Diemen reference, renders obvious claims 1-8 of the '685 patent. (Corr. Pet. at 13-14.) Yet, in the Original Petition, Petitioner relied only on the Goodman Poster, the Polman reference and the van Diemen reference in the analysis of claim 1, listing the Hayes Poster only in the chart identifying the Grounds of challenge. (Orig. Pet. at 26-33, 35-39.)

Petitioner provides no explanation as to how or why the Hayes Poster is applicable with respect to claim 1.[15]

Similarly, for Ground 2, the Petition initially alleges that the combination of the Goodman Poster and the Masterson reference renders obvious claim 1-4 and 6-8 of the '685 patent. (Corr. Pet. at 14). Later, however, the Petition alleges that "Claims 1 and 8 are obvious in light of Goodman and a POSA's knowledge of the state of the art as evidenced by Polman and van Diemen." (Corr. Pet. at 42.) In other words, Petitioner first indicates that the combination of the Goodman Poster and the Masterson reference applies to all challenged claims in Ground 2, but later does not appear to rely on Masterson for either claim 1 or 8 and instead adds citations to Polman and van Diemen. The Petition creates the same confusion in Ground 3, which initially purports to rely only on the Goodman Poster and the Juarez reference (*see* Corr. Pet. at 14), yet later also relies on "a POSA's knowledge" (*see* Corr. Pet. at 50).

[15] Petitioner added citations to the Hayes Poster in the claim chart for claim 1 in its Corrected Petition, presumably to correct this deficiency. But as explained below, this change constituted a substantive change in violation of the Board's Order, and the Board should not consider these citations.

Neither Patent Owner nor the Board should be required to guess as to Petitioner's contentions. *See, e.g.*, 37 C.F.R. § 42.104(b)(4); *Zetec*, IPR2014-00384, Paper No. 10 at 14 (finding that petition failed to comply with Section 42.104(b)(4) and (5) and noting that "the Petition places a significant and unfair burden on the Patent Owner to respond adequately to underdeveloped arguments for numerous asserted grounds"). The Board should, therefore, deny the Petition in its entirety.

B. The Petition Lacks a Proper Obviousness Analysis for Ground 1

Each of the proposed grounds in the Petition alleges that the challenged claims are unpatentable as obvious. Although Petitioner cites to certain portions of various references, Petitioner does not explain how the teachings of the references would be arranged or combined by a person of ordinary skill in the art, or why a person of ordinary skill would have made such a combination.

The Corrected Petition includes, for example, a section titled "Overview of State of the Art Providing Motivation to Combine for All Grounds in the Petition." (Corr. Pet. at 15.) However, this section contains only a "history" of 4-AP and discussions of each of the references individually. There is no analysis of a supposed motivation to combine the Goodman Poster with any of the other references cited by Petitioner, and no explanation of why it would have been

obvious to a person of ordinary skill in the art to combine the features that Petitioner alleges are disclosed by the references. (*See id.* at 18-23.)

Similarly, with respect to claim 1, the body of the Petition does not mention how or why a person of ordinary skill in the art would have been motivated at the time of the invention to combine the Goodman Poster with any of the Hayes Poster, the Polman reference, or the van Diemen reference (*i.e.*, the four references Petitioner relies on in Ground 1). Nor do either of Petitioner's experts opine as to why it would have been obvious to a person of ordinary skill in the art to combine the Goodman Poster with any of the Hayes Poster, the Polman reference, or the van Diemen reference. (*See* Exs. 1013, 1035.)

The Board has repeatedly denied institution where a petition failed to demonstrate that it would have been obvious to combine references, holding that conclusory or general statements regarding the reasons to combine or modify references are insufficient. *See, e.g., Heart Failure Techs., LLC v. Cardiokinetix, Inc.*, IPR2013-00183, Paper No. 12 at 9 (July 31, 2013) ("Petitioner must show some *reason* why a person of ordinary skill in the art would have thought to combine *particular* available elements of knowledge, as evidenced by the prior art, to reach the claimed invention") (emphasis in original); *see also TRW Auto. US LLC v. Magna Elecs. Inc.*, IPR2014-00293, Paper No. 19 at 17 (July 1, 2014) ("[A]n analysis under 35 U.S.C. § 103(a) is objective and includes an explicit

analysis requiring more than 'mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'") (quoting *KSR*, 550 U.S. at 418); *Moses Lake Indus. v. Enthone, Inc.*, IPR2014-00243, Paper No. 6 at 20 (June 18, 2014) ("MLI must provide more than conclusory expert testimony…and conclusory rationales to combine the teachings, to present a prima facie case of obviousness").

For Ground 1, Petitioner does not even provide a conclusory statement as to the reasons for combining the cited references. Absent an articulated reasoning with a rational underpinning to support the legal conclusion of obviousness, Petitioner fails to establish a prima facie case of obviousness. *See, e.g., TRW Auto. US LLC v. Magna Elecs. Inc.*, IPR2014-00257, Paper No. 16 at 7, 12 (June 26, 2014) (denying petition in its entirety due to failure to show why one of ordinary skill in the art would have been prompted to combine the asserted references).

Further, in analyzing claim 1, Petitioner admits that "Goodman doesn't explicitly disclose a regimen for a time period of 'at least two weeks,'" but contends that "a POSA prior to December 2002 'would have had both a reason to continue the administration of SR 4-aminopyridine at the relatively low dose level noted previously (10 mg BID) over a course of multiple weeks, and more than a reasonable expectation that this dosage regimen would provide enhanced mobility in MS patients,' (*e.g.*, improved walking) over that same time period based on the

prior art clinical studies which demonstrated the efficacy of this regimen in those patients." (Corr. Pet. at 29, 32-33.) At best, Petitioner is seeking to make an "obvious to try" argument. (*See id.* at 29.) However, Petitioner fails to support the argument with the requisite showing that there were only a "finite number of identified, predictable solutions." *See KSR*, 550 U.S. at 421.

As claims 2-8 depend from claim 1, the obviousness analysis as to claims 2-8 is deficient for at least the same reasons. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("dependent claims are nonobvious if the independent claims from which they depend are nonobvious"); *Wright Med. Tech., Inc. v. Orthophoenix, LLC*, IPR2014-00912, Paper No. 9 at 12 n.4 (Dec. 16, 2014). Further, Petitioner's obviousness analysis as to claims 6 and 7 amounts to no more than a conclusory allegation. The narrative portion of the Corrected Petition does not substantively address claims 6 and 7. (*See* Corr. Pet. at 34-36.) In the claim chart provided for Ground 1, Petitioner cites the Hayes Poster and the Polli Declaration for claim 6, and the Goodman Poster, the Hayes Poster, and the Polli Declaration for claim 7, but fails to show that it would have been obvious to a person of ordinary skill in the art to modify what is disclosed in the Goodman Poster to include the supposed features of the Hayes Poster. (*See id.* at 40-41.) Petitioner merely concludes that "claims 2 through 7 would have been obvious to a person skilled in the art based on Goodman, in view of Hayes." (*Id.* at 36.)

Paragraph 32 of the Polli Declaration, which Petitioner cites with respect to claims 6 and 7, is likewise lacking. Dr. Polli states that "[i]t is additionally my view that it would have been obvious to one of ordinary skill in the art at the time of the invention to homogenously disperse 4-aminopyridine in a matrix of HPMC to control the release rate of the 4-aminopyridine—a technique well-known in the art—while practicing the method of Goodman for treating MS." (Ex. 1035, ¶ 32.) The Board has repeatedly rejected such conclusory assertions. *See, e.g., LG Display Co. v. Innovative Display Techs. LLC*, IPR2014-01362, Paper No. 12 at 13 (Mar. 2, 2015); *Valeo North America, Inc. v. Magna Elecs., Inc.*, IPR2014-01208, Paper No. 13 at 22 (Dec. 23, 2014) (finding that a petitioner had not established a reasonable likelihood of prevailing when it failed to explain "how the references are combined to reach the claimed subject matter" and only provided "conclusory assertions that the teachings are combined"); *Samsung Elecs. Co. v. Black Hills Media*, IPR2014-00737, Paper No. 7 at 22 (Nov. 4, 2014).

C. The Petition Lacks a Proper Obviousness Analysis for Ground 2

While Petitioner purports to rely on Masterson instead of the Hayes Poster in Ground 2 (*see* Corr. Pet. at 14), the only analysis of Masterson with respect to claim 1 appears in the claim chart on pages 45-47, where Petitioner merely lists disclosures that it alleges are present in the Goodman Poster and disclosures that it alleges are present in Masterson. (*See id.* at 45-47.) Petitioner fails to include any

analysis regarding the supposed obviousness of claim 1 over the Goodman Poster and Masterson. *See KSR*, 550 U.S. at 406; *Graham*, 383 U.S. at 17-18.

Notably, in the Original Petition, Petitioner admitted that both the Goodman Poster and Masterson failed to disclose "a time period of at least two weeks," as recited in claim 1. (*See* Orig. Pet. at 48; *see also infra* Part VII.) Petitioner deleted this admission in the Corrected Petition without explanation, but this does not serve to remove the effect of the admission previously made of record. (*See* Corr. Pet. at 46; *see also infra* Part VII (explaining why Petitioner should be held to the admission).)

D. The Petition Lacks a Proper Obviousness Analysis for Ground 3

Petitioner asserts as Ground 3 that the combination of the Goodman Poster and Juarez renders obvious claims 6 and 7. (Corr. Pet. at 14.) Claims 6 and 7 each depend from claim 1. (*See* Ex. 1001 at 28:18-23.) According to Petitioner, "Goodman and a POSA's knowledge render claim 1 obvious for the detailed reasons previously set forth." (Corr. Pet. at 50.) But Petitioner never showed that "Goodman and a POSA's knowledge render claim 1 obvious." Therefore, Petitioner's analysis of claims 6 and 7, which necessarily include the limitations of claim 1, is similarly deficient. *Fritch*, 972 F.2d at 1266 ("dependent claims are nonobvious if the independent claims from which they depend are nonobvious"); *Wright Med. Tech.*, IPR2014-00912, Paper No. 9 at 12 n.4.

E. Petitioner Fails to Adequately Address Evidence of Secondary Considerations

The Corrected Petition incorrectly characterizes the current state of the law regarding secondary considerations. According to the Petitioner, the Patent Owner "has the burden of establishing the existence and sufficiency of such secondary considerations." (Corr. Pet. at 53 (citing to an *ex parte* reexamination decision that is over two decades old).) However, the Federal Circuit has held that the "burden of persuasion" does not shift to the Patent Owner for secondary considerations, stating that a district court erred in "impos[ing] a burden-shifting frame-work in a context in which none exists." *See Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d at 1075, 1077, 1080. The burden of persuasion with respect to invalidity starts, and remains, with the Petitioner.

The Federal Circuit has made clear that evidence of secondary considerations must be considered in determining whether a patent is obvious. *Apple Inc. v. ITC*, 725 F.3d 1356, 1365 (Fed. Cir. 2013). As the Board recently explained, even if "the first three *Graham* factors favor a determination that the challenged claims are obvious," a "case for non-obviousness based on secondary considerations [that] is particularly strong [can] outweigh[] the other three factors." *Intri-Plex Techs.*, IPR2014-00309, Paper No. 83 at 45-46. Here, Patent Owner submitted evidence of secondary considerations during the prosecution of the parent '826 patent. While the Petition purports to address this evidence,

Petitioner's analysis is deficient.

Petitioner attempts to dispute the record evidence of unexpected results by reiterating its reliance on the Goodman Poster. (*See* Corr. Pet. at 54.) Petitioner fails to respond to, or even acknowledge, Patent Owner's evidence of commercial success, long-felt but unsolved needs, and failure of others, that was also submitted during the '826 patent prosecution. (*See* Ex. 2027, Medori Decl. at ¶¶ 4-17 (discussing long-felt but unsolved needs); Ex. 2030, Declaration of Andrew Blight, filed in the prosecution of '826 patent ("Blight Decl.") at ¶¶ 18-19 (discussing long-felt but unsolved needs), 20-21 (discussing unexpected results); Ex. 2028, Sabella Decl. at ¶¶ 9-56 (discussing commercial success).)

For example, in a declaration submitted during the '826 patent prosecution, Dr. Rossella Medori, a neurologist, explained that despite the fact that "MS affects approximately 400,000 people in the United States and 2.5 million worldwide," "as of the filing date of the [parent application to the '685 patent] in 2004, no treatment for MS [had] been approved for walking." (*See* Ex. 2027, Medori Decl. at ¶¶ 6, 8.) Dr. Medori also stated that Ampyra was "the first FDA-approved MS drug for oral administration" and represented "the first approval for an MS drug without any restriction on the subtype of MS for which it is indicated." (*Id.*, ¶¶ 9-10; *see also* Ex. 2028, Sabella Decl. at ¶¶ 5-7.) In fact, "the FDA gave Ampyra® 'Priority Review' status, a designation given to drugs that 'offer major advances in

treatment, or provide a treatment where no adequate therapy exists.'" (Ex. 2027, Medori Decl. at ¶ 8.) The prosecution history of the '826 patent also included a declaration of Lauren Sabella, Acorda's Executive Vice President, Commercial Development, which set out extensive evidence as to the commercial success of Ampyra. (Ex. 2028, Sabella Decl. at ¶¶ 9-56; Ex. 2029 at 2.) Petitioner does not address any of this evidence.

Petitioner's attempt at overcoming only a small portion of the substantial evidence of secondary considerations is insufficient to carry its burden of establishing a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. Since Petitioner fails to properly analyze these and other secondary considerations, Petitioner's obviousness analysis is legally deficient and should be rejected. *See Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d at 1075, 1077, 1080 (Fed. Cir. 2012).[16]

[16] Should this proceeding be instituted, Patent Owner would submit in its Patent Owner's Response additional evidence of secondary considerations further establishing the failure of Petitioner to prove invalidity of the claims of the '685 patent.

VII. The Board Should Not Consider the New Analysis Added to the Corrected Petition

The Board issued an order (Paper No. 3) on February 26, 2015, requiring the Petitioner to file a corrected petition because the Original Petition included improper claim charts. (Paper No. 3 at 2.) The Board stated that no substantive changes could be made to the Original Petition. (*Id.*) Indeed, the Board has previously held that it will not consider substantive changes when deciding institution. *Valeo, Inc. v. Magna Elecs., Inc.*, IPR2014-00223, Paper No. 13 at 10 (May 29, 2014).

Nonetheless, on March 5, 2015, Petitioner filed the Corrected Petition (Paper No. 7) which includes substantive changes, in violation of the Board's order.[17] The table below identifies examples of the substantive changes that Petitioner made in the Corrected Petition as to Ground 1 regarding claim 1:

[17] On March 9, 2015, the Patent Owner requested a conference call to discuss whether the Corrected Petitioner contains substantive changes. The Board indicated that the Patent Owner may raise any concerns/response in relation to the Corrected Petition in the Preliminary Response.

Claim Element	Substantive Changes for Ground 1, Claim 1
1. A method of improving walking in a human multiple sclerosis patient in need thereof	**Change 1**: Rather than alleging that "Goodman (Ex. 1008) teaches" this claim element (Orig. Pet. at 35), Petitioner now alleges that "Goodman (Ex. 1008) and Hayes (Ex. 1009) disclose this element" (Corr. Pet. at 36). **Change 2**: Petitioner added a citation to the Hayes Poster. (Corr. Pet. at 36 (citing "Hayes Ex. 1009 at Introduction").)
comprising orally administering to said patient a sustained release composition of 10 milligrams of 4-aminopyridine twice daily	**Change 3**: Rather than alleging that "Goodman teaches" this claim element (Orig. Pet. at 36), Petitioner now alleges that "Goodman (Ex. 1008) and Hayes (Ex. 1009) disclose this element" (Corr. Pet. at 36-37). **Change 4**: Petitioner added a citation to the Hayes Poster. (Corr. Pet. at 37 (citing "Hayes Ex. 1009 at Objective").)

Claim Element	Substantive Changes for Ground 1, Claim 1
for a time period of at least two weeks,	**Change 5**: Rather than alleging that "Goodman teaches" this claim element (Orig. Pet. at 37), Petitioner now alleges that "Goodman (Ex. 1008) and Hayes (Ex. 1009) disclose this element" (Corr. Pet. at 37). **Change 6**: Petitioner added a citation to the Hayes Poster. (Corr. Pet. at 37 (citing "Hayes Ex. 1009 at Introduction").)
wherein the sustained release composition further comprises one or more pharmaceutically acceptable excipients.	**Change 7**: Rather than alleging that "Goodman teaches" this claim element (Orig. Pet. at 39), Petitioner now alleges that "Goodman (Ex. 1008) and Hayes (Ex. 1009) disclose this element" (Corr. Pet. at 38). **Change 8**: Petitioner added a citation to the Hayes Poster. (Corr. Pet. at 39 (citing "Hayes Ex. 1009 at Abstract").)

The table below points out substantive changes that Petitioner made in the Corrected Petition as to Ground 2 regarding claim 1:

Claim Element	Substantive Changes for Ground 2, Claim 1
1. A method of improving walking in	

Claim Element	Substantive Changes for Ground 2, Claim 1
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	**Change 9**: Rather than alleging that "Goodman teaches" this claim element (Orig. Pet. at 47), Petitioner now alleges that "Goodman (Ex. 1008) and Masterson (Ex. 1010) disclose this element" (Corr. Pet. at 45).
for a time period of at least two weeks,	**Change 10**: Rather than alleging that "Goodman teaches" this claim element (Orig. Pet. at 48), Petitioner now alleges that "Goodman (Ex. 1008) and Masterson (Ex. 1010) disclose this element" (Corr. Pet. at 46). **Change 11**: Petitioner **deleted an admission** that the Goodman Poster and the Masterson reference each fail to teach this claim element. (*See* Orig. Pet. at 48 (providing that "Goodman does not specifically teach administering for a person of at least two weeks" and "Masterson does

Claim Element	Substantive Changes for Ground 2, Claim 1
	not specifically teach a time period of at least two weeks"); Corr. Pet. at 46.)
wherein the sustained release composition further comprises one or more pharmaceutically acceptable excipients.	

The changes made to Grounds 1 and 2 of the Petition violated the Board's February 26, 2015 Order. (Paper No. 3 at 2.) The Order merely provided Petitioner the opportunity to remove improper argument from the claim charts. The Board did not authorize Petitioner to change or edit its citations to the alleged prior art, or to change its position about whether a reference discloses a limitation or not. These changes alter the substance of the challenge, as well as the arguments to which Patent Owner must respond, for both Grounds 1 and 2. In fact, given that Petitioner had not previously relied on the Hayes Poster with respect to its substantive analysis of claim 1, Petitioner's added citations to that reference effectively constitute a new ground—a change that the Board explicitly forbade. *Id.* at 2 ("No substantive changes (e.g., new grounds) may be made to the

petition"). Therefore, the changes are substantive and violate the Board's Order. As in *Valeo Inc.*, the Board should not consider these new arguments. *See Valeo, Inc.*, IPR2014-00223, Paper No. 13 at 10; *see also id.* at 22 (denying institution).

VIII. The Board Should Not Institute Based on the Petition's Redundant Grounds

For the reasons discussed above, the Board should not institute a review based on any of Petitioner's three proposed grounds. The Petition is replete with legal deficiencies. However, if the Board were to institute a trial, it should be limited to only one of the redundant grounds proposed by Petitioner. The use of redundant references in an IPR petition contradicts regulatory and statutory mandates, and the Board has indicated that it will not consider such grounds. *See, e.g.*, *Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.*, CBM2012-00003, Paper No. 7 (Oct. 25, 2012). Redundant grounds impose a significant burden on both the Board and the patent owner, and they cause unnecessary delay that jeopardizes completing the *inter partes* review by the statutory deadline. *Id.*

Because "[t]he Board seeks to streamline and converge issues at all phases of the proceeding . . . at [the] time of institution the Board analyzes the petition on a claim-by-claim, ground-by-ground basis, to eliminate redundant grounds." *Idle Free Sys., Inc. v. Bergstrom, Inc.*, IPR2012-00027, Paper No. 26 at 4-5 (June 11, 2013). The redundancy inquiry does not focus on "whether the applied prior art disclosures have differences, for it is rarely the case that the disclosures of different

prior art references, will be literally identical." *EMC Corp. v. Personal Web Techs., LLC*, IPR2013-00087, Paper No. 25 at 3 (June 5, 2013). Instead, the redundancy inquiry focuses on "whether the petitioner articulated a meaningful distinction in terms of relative strengths and weaknesses with respect to application of the prior art disclosures to one or more claim limitations." *Id.* at 3-4. The burden is on the petitioner to articulate such a "meaningful distinction." *ScentAir Techs., Inc. v. Prolitec, Inc.*, IPR2013-00180, Paper No. 18 at 3 (Aug. 26, 2013).

Each of Grounds 1-3 is redundant with respect to claims 6-7 of the '685 patent. In Ground 1, Petitioner relies on the Hayes Poster as a secondary reference with respect to the limitations of claims 6 and 7. (Corr. Pet. at 40-41.) As distinct and separate alternatives, in Grounds 2 and 3, Petitioner relies on Masterson and Juarez, respectively, as secondary references with respect to the limitations of claims 6 and 7. (Corr. Pet. at 48-49, 52.) Petitioner's otherwise defective explanations of the alleged disclosures of these references as applied to claims 6-7 are nonetheless substantially the same. Similarly, each of Grounds 1 and 2 is redundant with respect to claims 1-4 and 6-8 of the '685 patent. While Petitioner relies on different secondary references, Petitioner's explanations of the alleged disclosures of the references in Ground 1 are substantially the same as Petitioner's explanations of the alleged disclosures of the references in Ground 2.

Each of Petitioner's proposed grounds relies on the same base reference, the

Goodman Poster, differing only as to the secondary references. Petitioner does not articulate any relative strengths or weaknesses of those grounds, shed light on how any of the proposed obviousness combinations improves on any of the other combinations, or explain why one secondary reference is better or worse than another. Petitioner has thus failed to identify a "meaningful distinction" among the alleged prior art combinations as applied to the claims. *See LaRose Indus., LLC v. Capriola Corp.*, IPR2013-00120, Paper No. 20 at 4 (July 22, 2013) ("Petitioner has not explained any such strengths and weaknesses . . . ."). The Board should thus not consider more than one alleged ground for invalidating each of the challenged claims in the event that a trial is instituted.

IX. Petitioner Advances Flawed Claim Constructions

Although Petitioner advances two claim construction positions, Petitioner does not explain how either of its proposed claim constructions is relevant to any of the proposed grounds. Nor does Petitioner explain why either of the limitations requires construction or why the Board should depart from the plain and ordinary meaning of those terms. Patent Owner submits that, for all of the reasons set forth above, there are sufficient reasons for the Board to deny the Petition in its entirety without even considering the claim terms Petitioner has proposed for construction.

If the Board considers claim construction issues, Patent Owner submits that the Board should apply the plain and ordinary meaning in light of the specification

of the ’685 patent. *See* 37 C.F.R. § 42.100(b). However, Patent Owner expressly reserves the right to argue for an alternative construction of any claim term in its Patent Owner’s Response should a trial be instituted.

X. Conclusion

For at least these reasons, the Original Petition and Corrected Petition do not comply with the rules and regulations regarding petitions. Petitioner has also not established a reasonable likelihood of success because it relies on material that it has not established as statutory prior art, is based on art that is cumulative to what the Office has already considered, and includes legally improper obviousness analysis. The Board also should exercise its discretion to deny a petition such as this filed by a hedge fund using the *inter partes* review process itself as a tool for financial gain. Therefore, the Board should deny institution.[18]

Respectfully submitted,

Dated: May 26, 2015

By: /Gerald J. Flattmann/
Gerald J. Flattmann
Registration No. 37,324

Counsel for Patent Owner

[18] If trial is instituted, Patent Owner reserves its rights to raise additional arguments as to why Petitioner has failed to carry its burden and why the claims should be confirmed.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that I caused to be served on the counsel for Petitioner a true and correct copy of the foregoing Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 8,663,685 and associated exhibits by electronic means on May 26, 2015 as follows:

Counsel for Petitioner:

Ki O (ki.o@skiermontpuckett.com)
Sarah E. Spires (sarah.spires@skiermontpuckett.com)
Parvathi Kota (parvathi.kota@skiermontpuckett.com)
Paul J. Skiermont (paul.skiermont@skiermontpuckett.com)
Skiermont Puckett LLP
2200 Ross Ave. Ste. 4800W
Dallas, Texas 75201

Dated: May 26, 2015

By: /Gerald J. Flattmann/
Gerald J. Flattmann
Registration No. 37,324

Counsel for Patent Owner