

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Avita Medical Limited
Petitioner

v.

RenovaCare Sciences Corp.
Patent Owner

Case IPR2017-01243
Patent 9,610,430

**PATENT OWNER RENOVACARE SCIENCES CORP.'S
PRELIMINARY RESPONSE**

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EXHIBIT LIST

- Ex. 2001 Declaration of Dr. Gary D. Shipley
- Ex. 2002 Resume of Dr. Gary D. Shipley
- Ex. 2003 U.S. Ser. No. 13/036,569 File History Portions: Declarations by Fiona M. Wood and Marie L. Stoner and Application Filing Receipt
- Ex. 2004 *Ex Parte Jorgen J. Moller*, Appeal No. 2010-012534 (BPAI Jan. 27, 2011)
- Ex. 2005 *GrowlerWerks, Inc. v. Drink Tanks Corporation*, IPR2016-01125, Paper No. 8 (PTAB Nov. 22, 2016)
- Ex. 2006 *Ex Parte Borgwardt*, Appeal 2012-009099 (PTAB, Oct. 14, 2014)

I. INTRODUCTION

U.S. Patent No. 9,610,430 (“the ’430 patent”) issued to RenovaCare Sciences Corp. (“RenovaCare” or Patent Owner) on April 4, 2017 after roughly 3 years of prosecution. The day the ’430 issued Avita Medical Limited (“Avita” or Petitioner) filed its IPR petition (“the Petition”), which came as a surprise to RenovaCare because, unlike most parties before the PTAB, it had no prior dispute with Avita.

The Petition alleges that claims 1-11 of the ’430 patent are obvious based on five challenges using five references, each challenge including at least U.S. Patent Application Publication No. 2002/0106353 to Wood et al. (“Wood” or Ex. 1002). The Petition acknowledges that Wood was considered in prosecution, but that the prosecution examiner “did not apprehend the full disclosure of Wood.” (Pet. at 4-5.) However, the examiner was right to grant the ’430 patent over Wood.

The Petition ignores the fact that the manual cell delivery approach used by Wood was recognized as a problem and solved by the ’430 patent. It ignores the spray flow controls offered by the ’430 patent to provide an even cell distribution. It purports to show that Wood provides a single cell suspension, but overlooks critical differences between the various methods of Wood, and it attempts to support its claim on flimsy science without the necessary and fundamental scientific testing.

And it was not just Wood, but *four of the five references* asserted in the Petition were considered in prosecution before the '430 patent was issued. Indeed, problems with the cell delivery approach of Navarro (Ex. 1003) were recognized in the Background of the Invention and remedied by the invention of the '430 patent. In essence, Avita seeks a “redo” of the '430 patent prosecution.

Ironically, even though the Petition was filed the day the '430 patent issued, it is still untimely for another reason and should be dismissed. At the time of filing its Petition, Avita “expressly denie[d]” that the '430 patent claims were entitled to priority. (Pet. at 15.) Thus, Avita effectively took the position that the '430 patent is a post-AIA patent, because it was filed after March 16, 2013. If Avita was of that belief, then the '430 patent would not be eligible for *inter partes* review until after nine months from issue, and Avita should not have certified its IPR petition for filing until after January 4, 2018. (35 U.S.C. § 311(c)(1), 37 C.F.R. § 42.102(a)(1).)

The Petition fails to meet its burden to establish a reasonable likelihood that any of the challenged claims are obvious in view of the cited prior art. Accordingly, the Petition fails to show that Petitioner will prevail on at least one claim, and *inter partes* review of the '430 patent should be denied.

II. THE '430 PATENT

Patent Owner RenovaCare Sciences Corp. filed a patent application on December 20, 2013, U.S. Ser. No. 14/136,681, which issued on April 4, 2017 as U.S. Patent 9,610,430 (“the ’430 patent” or Ex. 1001), the subject of the instant IPR Petition.

A. Prosecution Summary of the ’430 Patent

The application leading to the ’430 patent (Ex. 1009) was filed on December 20, 2013. (Ex. 1009, pp. 223-263.) The ’430 patent claims priority as a continuation application of 11/518,012 filed September 11, 2006. A Preliminary Amendment was filed on April 21, 2014, which canceled claims 1-14 and added claims 15-25. (Ex. 1009, pp. 208-218.) A first Office Action dated August 25, 2015 rejected claims 15-25 based on two references used in this IPR proceeding, Lyles (Ex. 1004) and Wood (Ex. 1002). The then-pending claims were rejected as being anticipated or obvious over Lyles, or obvious in view of Lyles and Wood, Lyles and Guirguis (US 5,139,031), or Lyles and Andree et al. (US 2005/0043007). (Ex. 1009, pp. 145-153.) A Response Under 37 C.F.R. § 1.111 dated February 23, 2016 was filed requesting reconsideration. (Ex. 1009, pp. 120-143.) A Final Office Action dated June 1, 2016 maintained the rejections. (Ex. 1009, pp. 101-111.) An Amendment and Response Under 37 C.F.R. § 1.116 were filed on November 1, 2016, amending claim 15 and arguing the rejections based on

Lyles, (Ex. 1009, pp. 82-99.) A first Notice of Allowability was mailed November 25, 2016. (Ex. 1009, pp. 57-67.) The Reasons For Allowance section states:

“The following is an examiner’s statement of reasons for allowance: Applicant’s arguments (as per Remarks, pages 7-8) are found persuasive. The closest prior art of record Lyles (US 20040219133), Wood et al. (US 2002/0106353), Guirguis (US 5,139,031) and Andree et al. (US 2004/0043007) fail to teach, suggest or render obvious the method, wherein the skin cells have not been subjected to ex vivo or in vitro expansion. The additional search provided under the After Final Consideration Program did not bring any reference teaching mentioned limitations as well.”

(Ex. 1009, p. 62.)

A Request For Continuing Examination and an Information Disclosure Statement identifying additional references for consideration were filed (Ex. 1009, 44-56), and a second Notice of Allowability was mailed on February 10, 2017. (Ex. 1009, 10-43.) The Reasons For Allowance section states:

“The following is an examiner’s statement of reasons for allowance: IDS submitted 01/18/2017 has been fully considered. Presented references alone or in combination do not constitute potential 102 or 103 rejections.”

(Ex. 1009, p. 15.)

U.S. Patent 9,610,430 issued on April 4, 2017 with claims 1-11. Claim 1 is the only independent claim:

1. A method to treat a wounded area of skin on a human subject, comprising:

providing a single cell-suspension of cells comprising progenitor skin cells in a serum-free physiological solution in a sterilizable container, wherein the cells are obtained from the subject's normal skin tissue that has been treated with enzymes so as to release the cells from the dermal-epithelial cell junction, wherein the skin cells have not been subjected to ex vivo or in vitro expansion;

contacting the single-cell suspension of cells with a gas flow at an outlet of the container to create droplets of the suspension at a flow-controlled spray head; and

spraying the droplets onto the wounded area of skin without forming a closed cell sheet so that the single cells are distributed directly and evenly and the cells regenerate normal skin by in situ multiplication to heal the wounded area in the absence of applying a preformed skin graft.

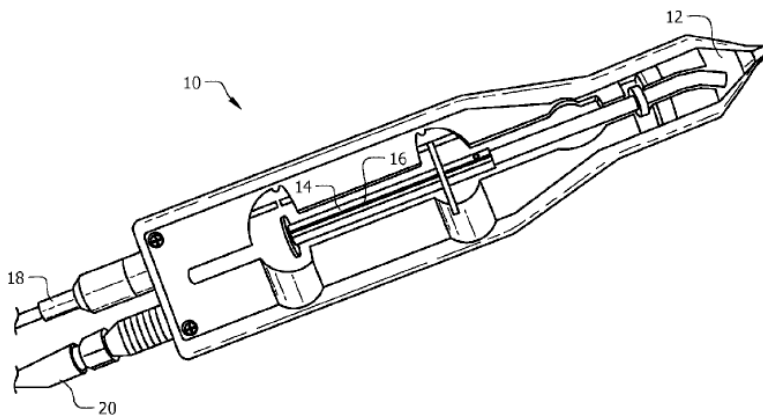
B. Summary of the '430 Patent

The '430 patent discloses apparatus and method for producing a sterile suspension of tissue regenerating cells from a subject's normal skin tissue, and using a flow controlled cell spraying medical device for the even distribution of the cells over a wound by creating droplets of the suspension and spraying the droplets containing the cells using a sterilizeable spray head, such that individually-sprayed cells are sprayed onto a wound without forming a closed sheet of cells and so the sprayed cells can regenerate skin on the wound by in situ multiplication to heal the

wounded area without requiring a skin graft. The resulting approach may avoid problems arising from such things as uneven application of cells and blister formation. (Ex. 1001, for example at FIG. 1; 3:5-4:60; 5:13-7:5; and 7:21-8:53.)

In various embodiments, the '430 patent teaches an electronically controlled medical device for distribution of tissue regenerating cells in a sterile suspension over a tissue surface via electronic controlled compressed gas and/or pump driven spraying through a sterilizeable spray head. In various embodiments, the apparatus is capable of providing continuous force application in a single shot and generating suspension drops containing cells. In various embodiments, the apparatus may provide means to measure and control parameters such as flow, pressure, and/or temperature. (Ex. 1001 at 3:16-33 and 7:25-47.)

FIG. 1 of Ex. 1001 shows an embodiment of a spray gun having a controlled spray head:



The apparatus may comprise a first member, not shown, and second member **10** wherein: the first member includes power supply, gas/air supply and electronic controls, and the second member **10** includes a sterilizeable spray head **12** and a container **14** with the cell suspension **16**. In that case both members may be connected through connectors **18, 20**. One connector may supply power and the other connector may supply gas/air from the power supply and gas/air supply within the first member, not shown, respectively. The suspension is transformed into small airborne droplets by mixing the suspension with air/gas within the second member **10** when the container **14** is actuated to release the solution **16**. (Ex. 1001 at 7:60-8:10.)

In various embodiments, the '430 patent discloses providing a cell suspension, where the cells in the suspension are preferably autologous cells or stem cells obtained by subjecting a tissue sample including cells suitable for grafting to a patient, to at least a physical and/or chemical dissociating means capable of dissociating cells in the tissue sample; taking the cells suitable for grafting on to a patient into a saline solution, and removing large cellular conglomerates to produce a cell suspension. (Ex. 1001 at 3:16-33.)

The '430 patent discloses the importance of controlling the spray of the cell suspension to achieve an even cell distribution over the region to be treated:

Embodiments of the invention also provide a sprayed aqueous cell suspension, highly suitable for tissue regeneration and grafting techniques, produced by the method described. An important advantage of the invention is an even cell distribution.

(Ex. 1001, 6:55-59, underlining added.) The '430 patent distinguishes uncontrolled hand driven sprays from the present controlled spray of the suspension because uncontrolled sprays result in an uneven cell distribution. (Ex. 1001, 4:33-60.) Such uncontrolled sprays include the mechanical hand driven sprays disclosed in Navarro et al. (Exhibit 1003) which were distinguished in the Background of the Invention:

Navarro et al. (2000) and Wood et al. (2003) describe the use of single cells suspended in Hartmans's solution and distributed over the wound, thus avoiding the sheets. The cell suspension may be delivered via a pipette, common "eye-droppers," syringe and needle, and/or other similar devices to place small quantities of cellular suspension on a graft site. As method of choice a mechanical hand driven spray technique is described (see references).

The spray technique addressed some aforementioned problems in the field. A hand driven spray method and subsequent distribution of the cells, however, is not performed in a controlled manner and thus results in uneven cell distribution.

Accordingly, what is needed is an improved device and technique for skin grafting.

(Ex. 1001 2:30-44.)

The '430 patent thereby distinguished the invention over the mechanical hand driven spray mechanisms which include: “pipette, common ‘eye-droppers,’ syringe and needle, and/or other similar devices to place small quantities of cellular suspension on a graft site.” The Navarro et al. (2000) paper is the same Navarro which is Ex. 1003 in the IPR Petition. Thus, Navarro Ex. 1003 was explicitly distinguished in the Background of the Invention of the '430 patent. Navarro used a spray apparatus having a hand operated plastic actuator or nozzle attached to a syringe. (Ex. 1003, p. 514.) Navarro demonstrates some problems with syringe and nozzle approaches: “[n]ozzles were eliminated if the droplets were too large and just dripped onto the wound or if the fluid emitted as a jet rather than a spray mist.” (Ex. 1003, p. 514.)

III. THE INSTANT IPR PETITION AND GROUNDS

The instant *inter partes* review petition (the “Petition”) was filed by Petitioner, Avita Medical Limited (“Avita”), the day the '430 patent issued to challenge the patentability of claims 1-11 of the '430 patent on these obviousness grounds:¹

¹ The grounds are listed in the order they are argued in the Petition, which is slightly different than the order listed in section **II. Identification of Claims Being Challenged**, on pp. 2-3 of the Petition.

- **Ground 1:** Claims 1-11 are obvious under 35 U.S.C. § 103 (pre-AIA) over U.S. Publication No. 2002/0106353 to Wood et al. (“Wood”) [Ex. 1002];
- **Ground 2:** Claims 1-11 are obvious under 35 U.S.C. § 103 (pre-AIA) over Wood in view of U.S. Publication No. 2004/0219133 to Lyles (“Lyles”) [Ex. 1004];
- **Ground 3:** Claims 1-11 are obvious under 35 U.S.C. § 103 (pre-AIA) over Wood in view of Navarro et al., “Sprayed Keratinocyte Suspensions Accelerate Epidermal Coverage in a Porcine Microwound Model,” *Journal of Burn Care & Rehabilitation*, November/December 2000, 21(6):513-518 (“Navarro”) [Ex. 1003];
- **Ground 4:** Claims 1-11 are obvious under 35 U.S.C. § 103 (pre-AIA) over Wood in view of U.S. Patent No. 7,833,522 to Dixon (“Dixon”) [Ex. 1005]; and
- **Ground 5:** Claims 1-11 are obvious under 35 U.S.C. § 103 (pre-AIA) over Wood in view of U.S. Patent No. 6,479,052 to Marshall (“Marshall”) [Ex. 1006].

(Pet., pp. 2-3.) The Petition also references a declaration by Petitioner’s expert, Dr. Jeffrey W. Shupp (“the Shupp Declaration” or “Shupp,”) [Ex. 1007].

As set forth in Section VI of this Preliminary Response, the Petition fails to establish a reasonable likelihood that the challenged claims are obvious in view of the cited prior art. Therefore, *inter partes* review should be denied.

IV. THE PERSON OF SKILL IN THE ART FOR THE '430 PATENT

The Petitioner states a person of ordinary skill in the art (“POSA”) for the ’430 patent would be a medical doctor specializing in skin injury, skin grafting and wound care. (Pet. at 4; Ex. 1007, ¶ 24.) Patent Owner submits that a POSA would have an advanced degree in cellular biology or biomedicine and about 5 years or more of experience with the isolation of cells from human tissue, and familiarity with the technologies used for wound care. (Ex. 2001, ¶ 6.) Patent Owner submits a Declaration of Dr. Gary D. Shipley with this Preliminary Response (Ex. 2001). Dr. Shipley has a Ph.D. in in Molecular, Cellular and Developmental Biology and has taught at the Mayo Medical School, the Mayo Graduate School, and Oregon Health Sciences University. Dr. Shipley also has over 25 years of experience in the life sciences industry relating to cell cultures, cell isolation from human and animal tissues, growth of human and animal cells in vitro, and the development of nutrient growth media to support the growth of these cells. He started a company specializing in the isolation of cells from human tissues and their in vitro expansion and cryopreservation. (Ex. 2001, ¶¶ 3-7.) Dr. Shipley’s resume is attached as Ex. 2002.

V. CLAIM CONSTRUCTIONS

When considering whether to institute a patent trial the Board has indicated that it will interpret the claims of a challenged patent using a "broadest reasonable construction" approach. (Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012).) The broadest reasonable interpretation of claims is made in light of the specification, but should not import limitations into the claims. Furthermore, unless there are indications to the contrary, a claim term is accorded its ordinary and customary meaning. (*Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005).)

Petitioner proposes claim constructions for “*single cell-suspension*,” “*progenitor skin cells*” / “*skin progenitor cell*,” “*ex vivo or in vitro expansion*,” “*a gas flow*,” “*flow-controlled spray head*,” “*closed cell sheet*,” “*preformed skin graft*,” “*comparable*,” “*morphology*,” “*similar*” “*large cellular congregates*” and “*continuous force application*.” (Pet., pp. 6-15.)

Patent Owner disagrees with many of Petitioner’s claim constructions and provides the following analysis of the claim constructions to the extent necessary to assist the Board in making its initial determination. In cases where Petitioner’s claim construction is not argued, Patent Owner does not admit that Petitioner’s claim constructions are correct and reserves the right to argue all of Petitioner’s claim constructions in the future. Patent Owner reserves the right to submit new

claim construction arguments and different claim constructions, using additional evidence where appropriate, at a future date if this IPR proceeding is instituted for trial. The present claim constructions are submitted under the broadest reasonable interpretation (BRI) standard, and not the narrower standard applied in claim constructions used for district court litigation.

A. “single cell-suspension” or “single-cell suspension”

Petitioner proposes an interpretation of the term “*single cell-suspension*” or “*single-cell suspension*” as “a suspension comprising individual cells that are not adhered to, or otherwise associated with, each other.” (Pet. pp. 6-8; Ex. 1007, ¶¶ 39-43.) Petitioner’s construction is misleading and overly broad because it would technically include any suspension that included individual cells, and a POSA would not understand a “single cell suspension” to be defined that broadly. Under Petitioner’s definition a suspension could include a very high percentage of large conglomerates of cells and would still fall within its definition provided the suspension included at least a few individual cells.² A POSA would not call such a

² In fact, Dr. Shupp states: “Consistent with dependent claims 6 and 7, this construction does not preclude the presence of some amount of agglomerated cells in the suspension, so long as there are also individual cells present.” (Ex. 1007, ¶43, underlining added.) Dr. Shupp’s definition does not rule out the case when

suspension a “single-cell suspension,” nor would that be the single-cell suspension used in the ’430 patent. Petitioner’s definition is unreasonably broad because it gives no sense of the composition of individual cells to ones that are not individual cells. A POSA would understand that a single-cell suspension would be a suspension of cells that included primarily single cells but may include a minor percentage of small conglomerates of cells, and may include relatively few or no large conglomerates of cells. (Ex. 2001, ¶ 19.)

Petitioner’s definition would improperly include a suspension of individual, nonviable cells, which would not work for the purposes of the ’430 patent.

Petitioner’s own expert, Dr. Shupp, recognized the need for viability of cells in the suspension in his discussion of cell morphology of the Shupp Declaration, Ex. 1007, ¶¶ 60-61. (Ex. 2001, ¶ 20.)

Patent Owner proposes the definition of “single-cell suspension” include a suspension of viable cells that includes primarily single cells or small conglomerates of cells, and which includes relatively few or no large conglomerates of cells. (Ex. 2001, ¶ 21.)

most of the cells are agglomerated, which a POSA would not call a “single cell suspension.” (Ex. 2001, ¶ 19.)

B. “ex vivo or in vitro expansion” and “wherein the skin cells have not been subjected to ex vivo or in vitro expansion”

Petitioner asserts that “*ex vivo* or *in vitro* expansion” would be understood by a POSA to mean “the multiplication of cells occurring outside of the human body or in an artificial environment.” (Pet. at 9-10; Ex. 1007, ¶¶ 46-48.)

Patent Owner submits that it is more helpful to interpret the phrase “wherein the skin cells have not been subjected to *ex vivo* or *in vitro* expansion.” A POSA would understand that some minor expansion of the cell population may occur during the process of cell isolation and while the cells are in suspension before being applied to a patient. For example, cells in certain phases of the cell cycle at the time they were isolated from the tissue may continue to complete the cell cycle and undergo mitosis while they are held in the serum-free nutrient solution provided and especially if the suspension of cells is held at 37°C. Thus, a minor amount of multiplication may be expected. However, in the absence of certain hormones or other molecules, cell growth is not promoted by the nutrient solution. (Ex. 2001, ¶ 26.)

Therefore, a POSA would understand cells in suspension which “have not been subjected to *ex vivo* or *in vitro* expansion” are cell suspensions where some minor multiplication of cells outside of the human body or in an artificial environment may occur, but such cell multiplication is not promoted. (*Id.*)

C. “a gas flow”

Petitioner proposes an interpretation of “a gas flow” to be “the flow of a propellant gas that forces the suspension through a flow-controlled spray head.” (Pet., p. 10.) However, Petitioner’s construction improperly imports limitations into “a gas flow,” such as “propellant gas,” “forcing the suspension,” and “through a flow-controlled spray head.”³ The phrase “a gas flow” has a plain an ordinary meaning to a POSA that does not require special interpretation and special construction of this phrase is not necessary. (Ex. 2001, ¶ 22.)

In ¶ 49 of the Shupp Declaration [Ex.1007], Dr. Shupp attempts to relate “a gas flow” to “a flow-controlled spray head,” citing Col. 7, lns. 34-36 of the ’430 patent. However, that excerpt from the ’430 patent does not use the term “flow-controlled spray head,” nor does it reference flow control. It merely states: “In this embodiment, the apparatus can be operated by producing a gas flow, for example air from a compressor, to engage the spray head, [].” (Ex. 1001, 7:34-36;

³ “Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.” *Superguide Corp. v. DirecTV Enters.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

underlining.) The excerpt refers to a “spray head” – it does not refer to a “flow-controlled spray head.” A POSA would understand that flow control may be performed by different components of the embodiments of the ’430 patent. (Ex. 2001, ¶ 23.)

For example, the ’430 patent states: “[a]n embodiment of the spray gun includes an electronically controlled apparatus used as a medical device to operate the spraying through a sterilizeable spray head. (Ex. 1001, 7:25-27.) It goes on to state: “The apparatus may provide means to measure and control parameters such as flow, pressure, and/or temperature.” (Ex. 1001, 7:46-47; underlining added.) An example of the spray gun is shown in FIG. 1; however, the ’430 specification makes it clear that the apparatus of FIG. 1 may comprise a first member (not shown) and a second member (10) wherein the first member includes “power supply, gas/air supply and electronic controls.” (Ex. 1001, 7:60-67; underlining added.) The first member and the second member can be connected through connectors 18 and 20. (Ex. 1001, 7:65-66.) And the first and second member can include “sensor/effector controls in the first and second member.” (Ex. 1001, 8:11-14; underlining added.) The ’430 patent also discloses an embodiment which is an “all-in-one device for hand-held operation.” (Ex. 1001, 8:15-18.) Therefore, a POSA would understand that “a gas flow” can be controlled in various components of various embodiments of the ’430 patent. (Ex. 2001, ¶ 24.)

Consequently, Petitioner's characterization of "a gas flow" is not accurate, not consistent with the '430 patent, and not necessary. (Ex. 2001, ¶ 25.)

D. "flow-controlled spray head"

Petitioner asserts that the term "flow-controlled spray head" has a plain and ordinary meaning to a POSA, "referring to a spray device which controls or regulates the flow of a fluid therethrough." Petitioner asserts "[t]he term would include, for example, a 'nozzle.'" (Pet. at 10-11; Ex. 1007, ¶ 50.)

Petitioner employs the phrase "would include," so it is not entirely clear if Petitioner is asserting that a nozzle is one component of a multiple component "flow-controlled spray head" or is by itself the "flow-controlled spray head." If Petitioner is asserting that a nozzle, by itself, is one example of a "flow-controlled spray head," a POSA would disagree with that interpretation based on reading and understanding the '430 patent. (Ex. 2001, ¶ 27.)

A POSA would understand that a nozzle receiving an unpressurized, weak, or highly varied stream of fluid may not control the fluid passing through it—in such cases the fluid source will control or regulate the flow of fluid. A POSA would also understand the same is true for a nozzle with an aperture that is large with respect to the volume of fluid being transferred. Thus, a POSA would understand that a spray head and the means for providing and controlling the fluid

to the spray head must be considered together to determine if the system provides a “flow-controlled spray head.” The ’430 patent describes various means for controlling fluid which were discussed above with relationship to the construction of “a gas flow” and which are discussed in the following paragraphs. (Ex. 2001, ¶ 28.)

Petitioner asserts that the specification of the ’430 patent supports its interpretation, and cites an excerpt from the ’430 patent specification: “[the] invention also contemplates an apparatus containing a spray head to distribute the cells. The suspension may be sprayed through *any type of nozzle* that transforms liquid into small airborne droplets.” (Pet. at 10-11; Ex. 1007, ¶ 51, citing Col. 7, lns. 21-24 of the ’430 patent [Ex. 1001].) However, the excerpt references a “spray head,” and not a “flow-controlled spray head.” A POSA would also understand that, as described above, the use of a nozzle does not in itself provide a flow-controlled spray head. The reference to Col. 7, lns. 21-24 of the ’430 patent supports Patent Owner’s interpretation, because the excerpt does not say that any type of nozzle can be used. It states that any type of nozzle that transforms liquid into small airborne droplets can be used. A POSA would understand the configuration of the means for controlling fluid to the nozzle with the nozzle determine if liquid is transformed into small airborne droplets. Thus, they work in conjunction and droplets will not come from just any nozzle. (Ex. 2001, ¶ 29.)

Petitioner conflates “spray head” with “flow-controlled spray head” to attempt to read statements about the spray head onto the flow-controlled spray head, despite a presumption that the drafter intended something other than the spray head. There is a “general presumption that different terms have different meanings.” *Chicago Bd. Options Exchange, Inc. v. Int’l Securities*, 677 F.3d 1361, 1369 (Fed.Cir. 2012). Moreover, “claims are interpreted with an eye toward giving effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed.Cir. 2006). Applying these rules, a proper interpretation of flow-controlled spray head should take into account the flow controls described by the ’430 patent.

The ’430 patent provides embodiments that can control the flow rate and pressure of a gas used to create droplets of the suspension at the flow-controlled spray head, such as the electronically controlled examples discussed in the section on “a gas flow,” above. In conjunction with these control examples, the ’430 patent states:

“The suspension is transformed into small airborne droplets by mixing the suspension with air/gas within the second member **10** when the container **14** is actuated to release the solution **16**. The apparatus may comprise a first and second member wherein both members are wirelessly connected for data exchange . . . to connect sensor/effector controls in the first and second member.”

(Ex. 1001, 8:7-14.) Therefore, the flow-controls exemplified by embodiments of the '430 patent can be distributed over the device and are more than a nozzle. (Ex. 2001, ¶ 30.)

Petitioner's expert, Dr. Shupp, concludes "a POSA would at once envisage that a "propellant fluid" includes a propellant gas." (Ex. 1007, ¶ 77.) Dr. Shupp offers no explanation for his conclusion, and yet he references it numerous times throughout his declaration. (Ex. 2001, ¶ 52.) Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. 37 C.F.R. § 42.65(a). Therefore, Petitioner's characterization of a nozzle itself being a "flow-controlled spray head" as understood from the '430 patent is inaccurate and an oversimplification of the "flow-controlled spray head" term. (Ex. 2001, ¶ 31.)

Patent Owner proposes that a "flow-controlled spray head" in the context of the '430 patent is an "electronically controlled spray device having controlled procuring of the cell suspension for even and repeatable cell spraying." (Ex. 1001, 4:33-40; Ex. 2001, ¶¶ 58-63.)

E. "closed cell sheet"

Petitioner asserts that "closed cell sheet" would be understood to refer to "a collection of adherent cells in the form of a sheet structure." (Pet. at 11; Ex. 1007, ¶ 53.) Petitioner cites col. 4, lns. 41-46 of the '430 patent and concludes with a

slightly different definition: “[a]ccordingly, a ‘closed cell sheet’ would be understood to encompass a continuous sheet of cells.” (Pet. at 11; Ex. 1007, ¶ 53.) Petitioner’s statements are confusing and it is not clear which definition is intended. A POSA would disagree with these definitions and would arrive at a different definition for at least the following reasons. (Ex. 2001, ¶ 32.)

Rather than attempt to interpret “closed cell sheet” as an isolated phrase to understand its meaning, a POSA would read at least the last element of claim 1, which recites:

“spraying the droplets onto the wounded area of skin without forming a closed cell sheet so that single cells are distributed directly and evenly and the cells regenerate normal skin by in situ multiplication to heal the wounded area in the absence of applying a preformed skin graft.”

(Ex. 1001, 10:5-10; Ex. 2001, ¶ 33.)

A POSA would understand that the “closed cell sheet” of claim 1 is set forth in the context of sprayed cells at the time they are sprayed onto an area, and not a grown sheet of cells. However, Petitioner’s definitions appear to include a grown sheet of cells, and therefore are incorrect and overly broad with regard to claim 1. (Ex. 2001, ¶ 34.)

While Petitioner asserts col. 4, lines 41-46 of the ’430 patent to attempt to support its definition, a POSA would interpret the statement of col. 4, lines 41-46

differently than Petitioner. A POSA would understand that statement to mean the tissue required to create the suspension of the '430 patent is a relatively small biopsy area because the suspension can be made from a relatively small number of cells, as contrasted with the number of cells needed for a grown sheet graft of the prior art that must cover the entire wound. (Ex. 2001, ¶ 35.)

Based on the claim language and the specification of the '430 patent, a POSA would understand that the “closed cell sheet” is an accumulation of cells sprayed onto a wounded area of skin so that the sprayed cells form a layer of cells with a sufficient density so as to cover and coat the area with sprayed cells. The POSA would further appreciate that the sprayed cells lack the cell-to-cell junctions of a grown sheet of cells at the time of spraying. (Ex. 2001, ¶ 36.)

Accordingly, a POSA would appreciate that “spraying the droplets onto the wounded area of skin without forming a closed cell sheet so that single cells are distributed directly and evenly and the cells regenerate normal skin” means that the cells sprayed “without forming a closed cell sheet” would be spread out evenly and would not completely cover the area. Such cells could grow over time to form a new layer of skin by *in situ* multiplication to create a sheet of cells with cell-to-cell junctions that create new skin and heal the wound. Blister formation is avoided by the use of single cells without forming a closed sheet. (Ex. 2001, ¶ 37; Ex.1001, 4:33-60.)

F. “preformed skin graft” and “in the absence of applying a preformed skin graft”

Petitioner interpreted “preformed skin graft” as “any skin graft, such as a split-thickness graft, full-thickness graft, mesh graft, micro-grafting, and cultured epithelial autografts, that is formed before spraying the droplets.” (Pet. at 11-12; Ex. 1007, ¶ 54.) Petitioner does not offer a reason for why its definition requires that the skin graft is formed “before spraying the droplets.” A POSA would not interpret the “preformed” in “preformed skin graft” as a reference to a time of spraying the droplets. A POSA would interpret a “preformed skin graft” to be a skin graft made of tissue having formed cell-to-cell junctions and capable of substantially covering the wound. Therefore, a POSA would interpret “in the absence of applying a preformed skin graft” as recited in claim 1 as meaning the sprayed cells regenerate normal skin by in situ multiplication to heal the wound without the application of a skin graft or a cultured epithelial graft during the wound healing process. (Ex. 2001, ¶ 38.)

G. “continuous force application”

Petitioner interprets “continuous force application,” to mean “the application of force, manually or otherwise, continuously for about 30 seconds to about 10 minutes.” (Pet. at 15; Ex. 1007, ¶¶ 64-65.) Petitioner’s claim construction is erroneous. First, a POSA would not specify a time range for the application of force in a “continuous force application.” Second, each time the ’430 patent

specification discusses a “continuous force application” it is in the context of an automated application—not a manual application—as discussed in the following paragraphs. (Ex. 2001, ¶ 39.)

The ’430 patent specification provides a first reference to “continuous force application” at Col. 3, lines 27-33:

“According to the invention an electronically controlled apparatus is provided as a medical device for distribution of tissue regenerating cells in a sterile suspension over a tissue surface via electronic controlled compressed gas and/or pump driven spraying through a sterilizeable spray head, providing continuous force application in a single shot and generating suspension drops containing cells.”

(Ex. 1001, 3:27-33, underlining added.) This excerpt from the specification does not specify a duration of the application, and makes it clear that the application is electronically controlled and automated. (Ex. 2001, ¶ 40.)

A second reference to “continuous force application” is found at Col. 7, lines 34-45 of the ’430 patent specification:

“In this embodiment, the apparatus can be operated by producing a gas flow, for example air from a compressor, to engage the spray head, or forcing the cell suspension pump driven through the nozzle, for example by motor operated pushing of a sterile Luer-lock syringe containing the cell suspension, the gas may flow through a sterile syringe. An alternative is to produce the spray without mixing with gas. The apparatus also may provide continuous force application over

a range of about 0.5 to about 10 ± 1.0 minutes for a single shot, or several shots, and generate suspension drops containing cells in the range of about 30 to about 500 ± 200 millimeters.”

(Ex. 1001, 7:34-45, underlining added.) This excerpt also emphasizes that the apparatus provides the “continuous force application” and that it is not a manual operation. The time duration range is suggested (“may provide”), but is not mandatory. (Ex. 2001, ¶ 41.)

Accordingly, a POSA would understand a “continuous force application” as used by the ’430 patent to be “an automated and controlled force.” (Ex. 2001, ¶ 42.)

VI. THE PETITION FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD THAT PETITIONER WOULD PREVAIL AS TO ANY CHALLENGED CLAIM

A. Wood Does Not Render Claims 1-11 Obvious

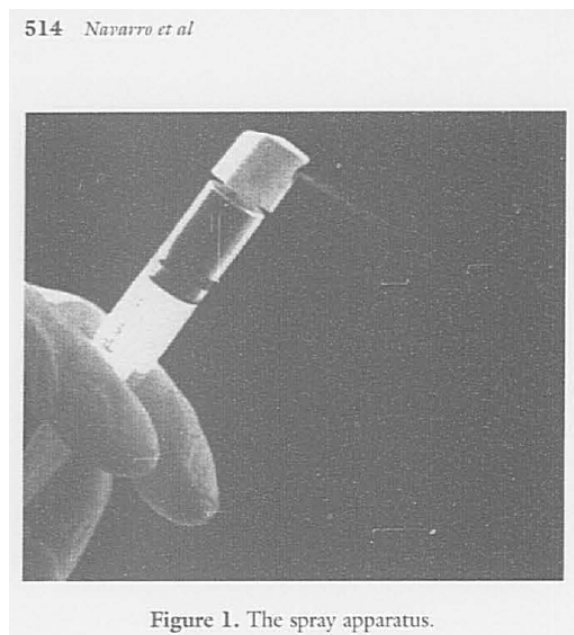
1. Wood [Ex. 1002] and Navarro [Ex. 1003]

The Wood and Navarro publications relate to work performed by the same team: Fiona M. Wood and Marie L. Stoner, the co-inventors of Wood. Even though Navarro lists many co-authors, it is the work directed by Ms. Wood and Ms. Stoner per § 132 declarations they filed in a continuation of Wood. The declarations state the other Navarro co-authors were “merely working under [their] direction” Ex. 2003 provides these declarations and a filing receipt from the

related application, U.S. Ser. No. 13/036,569, which claims priority to the Wood application.

Navarro published in the November/December 2000 *Journal of Burn Care & Rehabilitation*, about three months before the Australian provisional application filed Feb. 7, 2001, which Wood claims for priority.

Navarro relates to a porcine model to study the effect of sprayed cell suspensions delivered on small wounds within a meshed autograft. (Ex. 1003, p. 513.) Navarro used a spray apparatus having a hand operated plastic actuator or nozzle attached to a syringe:



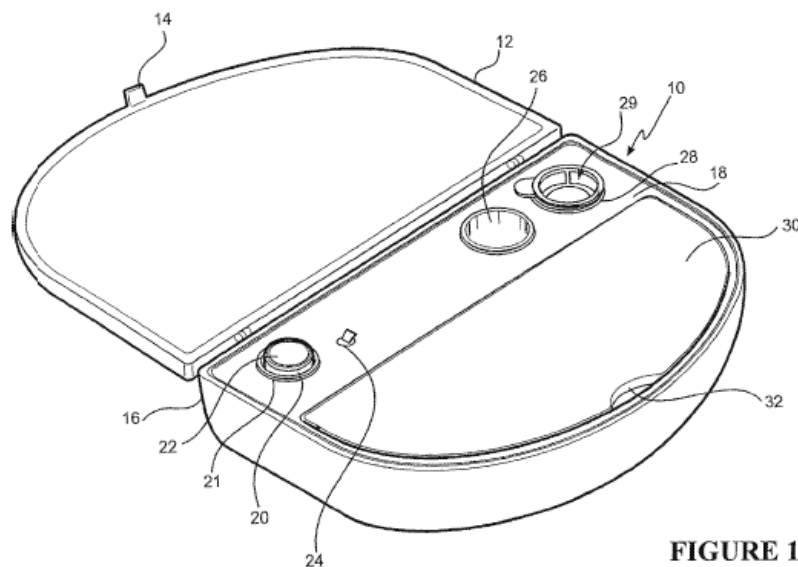
(Ex. 1003, p. 514.) Navarro tested syringe and nozzle combinations that failed to provide a spray: “[n]ozzles were eliminated if the droplets were too large and just

dripped onto the wound or if the fluid emitted as a jet rather than a spray mist.”

(Ex. 1003, p. 514.)

In the four months after Navarro, Drs. Wood and Stoner filed Australian and U.S. provisional applications and Wood was filed a year later, claiming priority to the provisional applications.

Wood relates to a cell suspension preparation technique and device. FIG. 1 shows an embodiment of a Re-Cell® Rapid Technique cell harvesting apparatus **10** including a closure lid **12** possessing a locking mechanism **14** adapted to releasably engage a base portion **16**.



Located within the base portion **16** is a first member **18** within which there is provided an aperture **20** in which there is located a vial **22** for the enzyme.

Adjacent the aperture there is provided an activation switch **24** capable of

activating the heating means (not shown). The first member also provides a fluid containment well **26** and a filter recess **28**. As presented in this illustration the filter **29** is shown located in the filter recess. (Ex. 1002, ¶ [0116].) The second member **30** forms a reservoir in which tissue manipulations may be performed. (Ex. 1002, ¶ [0118].)

Wood does not show a spray device, but discusses manually distributing cells and the types of nozzles that can be used:

A liquid suspension containing cells may be manually distributed onto the graft site by any of several techniques, which include spraying, spreading, pipetting and painting.

The suspension may be sprayed through any type of nozzle that transforms liquid into small airborne droplets. This embodiment is subject to two constraints. First, it must not subject the cells in solution to shearing forces or pressures that would damage or kill substantial numbers of cells. Second, it should not require that the cellular suspension be mixed with a propellant fluid that is toxic or detrimental to cells or wound beds. A variety of nozzles that are commonly available satisfy both constraints. Such nozzles may be connected in any conventional way to a reservoir that contains the cellular suspension.

Alternatively the suspension may be delivered via a pipette, common "eye-droppers," syringe and needle and or other similar devices to place small quantities of cellular suspension on a graft site. (Ex. 1002, ¶¶ [0063]-[0065].)

Similar to Navarro, Wood uses a syringe and nozzle approach to spraying or dripping cells in Example 1: “[t]he resulting suspension of cells collected in the conical recess was aspirated into a syringe and a nozzle was attached to the syringe for spraying or dripping on to the wound area.” (Ex. 1002, ¶ 112.)

Navarro and Wood are similar in that they both describe apparatus for manually spraying or dripping cells on a wound area. Navarro and Wood are also similar in that they were before the examiner in the *ex parte* prosecution of the ’430 patent.

**2. The ’430 Patent Recognized Problems Of Manual Spray Methods
And Invented A Controlled Spray Approach To Remedy Them**

The inventor of ’430 patent recognized problems with uneven cell distribution from uncontrolled hand driven sprays, including those experienced in Navarro et al. (Ex. 1003), as discussed in the Background of the Invention:

Navarro et al. (2000) and Wood et al. (2003) describe the use of single cells suspended in Hartmans’s solution and distributed over the wound, thus avoiding the sheets. The cell suspension may be delivered via a pipette, common “eye-droppers,” syringe and needle, and/or other similar devices to place small quantities of cellular suspension on a graft site. As method of choice a mechanical hand driven spray technique is described (see references).

The spray technique addressed some aforementioned problems in the field. A hand driven spray method and subsequent distribution

of the cells, however, is not performed in a controlled manner and thus results in uneven cell distribution.

Accordingly, what is needed is an improved device and technique for skin grafting.

(Ex. 1001 2:30-44; the underlined reference is to Navarro Ex. 1003.)

The '430 patent provides the needed improved device and technique using a single cell suspension delivered by a flow-controlled cell spray apparatus to spray suspension droplets evenly over a wound so as to avoid forming a closed sheet prone to blistering. (Ex. 1001, 4:33-60.) Thus, over time as the evenly sprayed cells regenerated and formed new skin, the wound could heal without applying a skin graft. Therefore, the '430 patent expressly addressed and remedied the manual spray approach of Navarro, which used a spray apparatus having a hand operated plastic actuator or nozzle attached to a syringe. (Ex. 1003, p. 514.)

Navarro was a precursor to Wood, and Example 1 of Wood (which Petitioner has attempted to reproduce in a laboratory) used substantially the same delivery approach as Navarro: a hand operated syringe and nozzle for spraying or dripping suspension. (Ex. 1002, [0112].)

Navarro was explicitly distinguished from the invention of the '430 patent in its Background of the Invention. Wood and Navarro were both considered in prosecution, and the '430 patent was issued over Wood and Navarro (in fact, the '430 patent was issued over 4 of the 5 references in the instant IPR petition). And

now, Petitioner seeks *inter partes* review to read the “flow-controlled spray head” of claim 1 on practically any nozzle; including the nozzles provided by Wood and by the combination of Wood and Navarro.

The Board may use its own precedent to deny Petitioner’s claim construction: “It is not reasonable to read the claims on a prior art configuration which was expressly addressed and remedied by the [] patent.” *Ex Parte Jorgen J. Moller*, Appeal No. 2010-012534, p.9 (BPAI Jan. 27, 2011) (Ex.2004). Accordingly, it is not reasonable now to read the ’430 claims on Wood or Navarro, and in particular, the “flow-controlled spray head” of claim 1 on a nozzle of Wood or Navarro.

3. Wood Does Not Teach A “Flow-Controlled Spray Head”

The second element of claim 1 recites:

contacting the single-cell suspension of cells with a gas flow at an outlet of the container to create droplets of the suspension at a flow-controlled spray head.

(Ex. 1001, 10:1-3.)

In the Claim Constructions section above, Patent Owner explained why Petitioner’s claim constructions relating to the term “*flow-controlled spray head*” were unclear and why its attempts to relate it to “*a gas flow*” and a “nozzle” are flawed.

Petitioner has not shown that “any type of nozzle that transforms liquid into small airborne droplets” can be a “flow-controlled spray head” within the meaning of the ’430 patent, and instead seeks to improperly interpret the claim terms as covering the prior art hand driven approaches despite the ’430 patent teachings. (Ex. 2001, ¶ 61; see prior section VI(A)(2) and *Ex Parte Jorgen J. Moller.*)

Petitioner admits that Wood does not expressly disclose a “gas flow” at an outlet of the container to create droplets. (Pet. at 27; Ex. 1007, ¶ 95.) Dr. Shupp failed to state a rationale for why a POSA would use a propellant gas to force a suspension through a nozzle. (Pet. 27-28; Ex. 1007, ¶¶ 95-96; Ex. 2001, ¶ 62.)

Patent Owner proposes that a “flow-controlled spray head” in the context of the ’430 patent is an “electronically controlled spray device having controlled procuring of the cell suspension for even and repeatable cell spraying.” (Ex. 1001, 4:33-40; Ex. 2001, ¶¶ 58-63.) Wood has no comparable teaching or suggestion. Indeed, Wood teaches uneven cell distribution practices, such as spraying or dripping using a syringe and nozzle. (Ex. 1002, ¶ [0112].) Patent Owner submits that Wood fails to teach or suggest a “flow-controlled spray head” as is used in the ’430 patent.

4. Wood Does Not Teach Skin Tissue Treated With Enzymes

Claim 1 recites “*wherein the cells are obtained from the subject’s normal skin tissue that has been treated with enzymes so as to release the cells . . .*.”

Petitioner and Dr. Shupp rely on Wood ¶ [0020] to assert that Wood discloses “subjecting a tissue sample including cells suitable for grafting to a patient, to an enzyme suitable for dissociating cohesive pieces of the tissue stratum in the sample.” (Ex. 1002, ¶ [0020], underlining added.) This portion of Wood refers to the use of a single enzyme and not “enzymes,” which is plural. (Pet. at 25-26; Ex. 1007, ¶ 92.) Dr. Shupp also references Wood ¶ [0051]⁴ which states: “dissociation of the tissue sample is achieved by placing the sample in a pre-warmed enzyme solution containing an amount of enzyme sufficient to dissociate cellular stratum in the tissue sample.” This excerpt of Wood also refers to a single enzyme and not “enzymes.” (Ex. 1007, ¶ 92; Ex. 2001, ¶ 55.)

Dr. Shupp concludes: “[t]hus, Wood discloses the limitation that the skin tissue can be ‘treated with enzymes so as to release the cells.’” Apparently, Dr. Shupp is relying upon a list of enzymes he references from Wood ¶ [0050] which lists chemical dissociation means that “might include, for example, digestion with enzymes such as trypsin, dispase, collagenase, trypsin-edta, thermolysin, pronase, hyaluronidase, elastase, papain and pancreatin.” (Ex. 1007, ¶ 92, underlining added.) However, this is a list of possible enzyme candidates and there is no

⁴ The Petition at p. 26 cites Wood, ¶ [0057] which does not refer to enzymes.

specific teaching of the why Dr. Shupp believes Wood teaches that multiple enzymes would be used.

Dr. Shupp also does not account for several references to use of a single enzyme in Wood (listed in Dr. Shipley's Declaration in ¶ 56.), which demonstrate Wood teaches a single enzyme is to be used. (Ex. 2001, ¶ 56.). Thus, a POSA who read Wood carefully would understand that it does not teach the use of multiple enzymes. When Wood uses the phrase "enzymes" it appears to do so with reference to different enzymes that may be employed singly, but does not disclose multiple enzymes being used. In fact, Wood appears to teach limiting exposure to enzyme to avoid decreases in viability of the cellular suspension. (See Ex. 1002, Wood, ¶¶ [0016] and [0062].)

Therefore, since Dr. Shupp has not provided any factual basis for his assertion of the application of enzymes in Wood, his testimony on this assertion should be given little or no weight. The numerous references to a single enzyme in Wood outweigh a conclusory statement by Dr. Shupp, and no additional proof of his conclusion was offered. Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. 37 C.F.R. § 42.65(a). Therefore, the Petition and Dr. Shupp do not show that Wood teaches "*skin tissue [] treated with enzymes,*" as recited in claim 1 of the '430 patent.

**5. Wood Does Not Teach Regenerating Normal Skin [] In The
Absence Of Applying A Preformed Skin Graft**

Claim 1 recites that “*the cells regenerate normal skin by in situ multiplication to heal the wounded area in the absence of applying a preformed skin graft.*” The Petitioner asserts Wood [0017]-[0019] and Example 1 of Wood ¶¶ [0100]-[0114] to support its assertion that “[t]he wound can be treated and healed without applying a preformed skin graft; that is, prior to spraying the droplets, no other skin graft was applied to the wound.” (Pet. 29-30; Ex. 1007, ¶ 100; Ex. 2001, ¶ 65.)

However, Wood [0017]-[0019] does not teach anything about “prior to spraying the droplets” or that “no other skin graft was applied to the wound.” It refers to “treating a patient in need of graft surgery” and “administering the suspension directly to a region on the patient that requires a cell graft in a manner that facilitates spreading of the cell suspension in a relatively even distribution over the graft region.” It does not state whether a graft is in the graft region or not when the administering takes place. (Pet. 29-30; Ex. 1002, [0017]-[0019]; Ex. 1007, ¶ 100; Ex. 2001, ¶¶ 66.)

Example 1 of Wood ¶¶ [0100]-[0114] is silent as to the aspects of healing the wounded area in the absence of applying a preformed skin graft. Instead, it states “to optimize the success of the skin graft” without describing the exact kind of skin graft. (Ex. 1002, ¶ [0101].) Wood describes the types of “skin grafts” in

the Background Art (Ex. 1002, ¶¶ [0004]-[0007]) and contrasts these skin grafting techniques to the use of a “cellular suspension” (Ex. 1002, ¶ 0009). Therefore, it is unclear in Example 1 whether or not the isolated cell suspension is being used as an adjunct to standard skin grafting techniques. Example 1 of Wood also references “the healing of the wound was followed up using standard protocols for skin-graft treatment” without explaining what the standard protocols include, nor providing any evidence that the treatment provided the patient with a positive outcome. (Pet. 29-30; Ex. 1002, ¶¶ [0100]-[0114]; Ex. 2001, ¶¶ 67-71.)

In paragraph 82 of the Shupp Declaration, Dr. Shupp states:

“The wound can be treated and healed without applying a preformed skin graft; that is, prior to spraying the droplets, no other skin graft was applied to the wound. *See* Wood, ¶¶ [0017]-[0019]. *See also* Example 1, ¶¶ [0100]-[0114] of Wood where no skin graft, other than spraying of the cell suspension, was applied to the wound.”

(Ex. 1007, ¶ 82.) Dr. Shupp seems to interpret that “no other skin graft was applied to the wound” means “prior to spraying the droplets no other skin graft was applied to the wound.” However, as set forth in the Claim Constructions section, a POSA would find his interpretation to be incorrect. The ’430 patent provides a method to treat a wounded area of skin to heal the wounded area so that a preformed skin graft is not necessary for the healing process. This is consistent with how a POSA would interpret “to heal the wounded area in the absence of

applying a preformed skin graft.” (Pet. 29-30; Ex. 1002, ¶¶ [0017]-[0019]; Ex. 2001, ¶¶66, 71, 72.)

Thus, the Petition and Dr. Shupp fail to show that Wood teaches “*spraying the droplets [] so that the cells are distributed directly and evenly and the cells regenerate normal skin by in situ multiplication to heal the wounded area in the absence of applying a preformed skin graft*”. (Ex. 2001, ¶72)

6. Petitioner’s Reproduction of Wood’s Example 1 Does Not Prove A Single Cell Suspension

a. Cell Viability and Cell Composition Is Not Established By Petitioner’s Reproduction of Wood Example 1

As set forth in the Claim Constructions section, Petitioner’s definition of “single-cell suspension” is unreasonably broad and omits evidence of things such as cell viability and the relative percentage of single cells and small conglomerates of cells as opposed to the percentage of large conglomerates of cells.

Dr. Shupp presents no evidence that said uncultured cells are present in the suspension in a ratio comparable to that found in situ and no evidence of healing of a wound by the method of Wood. He merely parrots excerpts from Wood (e.g., Ex. 1002, ¶¶[0045], [0062]) for support in his declaration. (Ex. 1007, ¶¶ 82-83; Ex. 2001, ¶ 51.)

Figure 1 of Dr. Shupp's experiment will not provide evidence of viability of the cells. Figure 1 will also not provide evidence of the relative percentage of single cells and small conglomerates of cells as opposed to the percentage of large conglomerates of cells. Therefore, it is impossible for a POSA to say from Figure 1 that the method of Wood creates a single cell suspension, and other tests were not done that might have established cell viability and composition. (Ex. 1007, ¶ 75; Ex. 2001, ¶¶ 20, 48, 50.)

**b. "Similar" Morphology Is Not Established By Petitioner's
Reproduction of Wood Example 1**

If we employ Petitioner's definition of "similar" for cell morphology, it requires that "any differences [between cells in solution and cells in droplets] do not impair the viability of cells in the suspension." (Pet. at 13-14.) However, Figure 2 of Dr. Shupp's experiment will not determine similar cell morphology, because it cannot establish unimpaired viability of the cells. A POSA would know that one cannot tell similar morphology as defined by simply comparing two 20X microscope views. There are viability tests that can be performed, such as trypan blue staining or plating efficiency. No viability test data are provided. A suspension cannot alone demonstrate viability and, therefore, meet the definition of similar morphology. A POSA cannot draw the conclusions that Dr. Shupp is making by simply comparing these samples by light microscopy. (Ex. 1007, ¶ 79; Ex. 2001, ¶¶ 50, 53.)

**c. Wood Uses Physiological Saline For A Nutrient Solution In
Some Embodiments, But Uses Sterile Water Instead In
Example 1**

Petitioner discusses Wood's teaching of physiological saline in the nutrient solution. (Pet. at 18, 24; Ex. 1007, ¶¶ 72-73; and Ex. 1002 ¶¶ [0055] and [0057].) However, Wood does not promote use of physiological saline in all method steps it outlines. One notable example is in Example 1, provided by Wood ¶¶ [0100]-[0114]. For example, at Wood ¶ [0106], sterile water for injection (10 ml) is mixed with lyophilised trypsin to give a 0.5% trypsin enzyme solution. (Ex. 1002, ¶ [0106].) A tissue sample is incubated at 37 degrees C for 10-15 minutes in the enzyme solution. (Ex. 1002, ¶ [0108].) Thus, tissue (and cells) are exposed to a solution that is not physiological saline or nutrient solution. Therefore, the Petition mixes references to methods that use physiological saline (e.g., Wood ¶¶ [0055] and [0057]) with those that use sterile water (e.g., Wood Method 1, ¶¶ [0100]-[0114] and especially ¶[106]). (Ex. 1002, [0100]-[0114]; Ex. 2001, ¶ 45.)

Sterile water is not isotonic and a POSA would understand it is likely to reduce the viability of cells, so Petitioner's failure to establish viability of the cells from its reproduction of the method of Example 1 renders the results inconclusive and flawed. Without evidence of viability, there can be no assurance that the cells obtained from the method of Wood Example 1 could result in growing new skin cells for healing of a wound. (Ex. 2001, ¶¶ 45, 50, 53, 54, 70.)

d. Conclusion

Accordingly, the Petition fails to demonstrate that Wood renders obvious claim 1 of the '430 patent.

7. Claims 2-11 Are Not Obvious

a. Claim 2

Petitioner asserts that the ratio of uncultured cells in the suspension “are necessarily present in the suspension in a ratio comparable to that found in situ in the normal skin.” (Pet. at 30-31.) A POSA would disagree. A POSA would see that Wood describes saline and sterile water solutions, but fails to identify which solution it is referencing in the specification of Wood. (Ex. 2001, ¶¶ 45, 46, 70.) For example, cell viability and therefore cell ratios may be affected depending on whether an enzyme solution is generated using saline or whether it is produced using sterile water. (Ex. 1002, compare [0051], [0055], [0094], and [0106].) Wood does not establish if different solutions have same or different aspects. Consequently, Wood should not be used as a reference when it lacks a clear description of the particular solution used and its potential impact on various statements made in Wood. For example, Dr. Shupp references Wood ¶¶ [0045], [0062]. However, ¶¶ [0045], [0062] do not provide identify the type of solution (saline or sterile water) Wood is employing. Therefore, Wood does not render the subject matter of claim 2 obvious.

b. Claim 3

Much the same analysis of claim 2 applies to claim 3. Without knowledge of the solution Wood is referring to, it is unclear whether Wood ¶ [0057] is relevant. Therefore, Wood does not render the subject matter of claim 3 obvious. (Ex. 2001, ¶¶ 20, 50, 53, 90.)

c. Claim 4

Petitioner asserts that a POSA would understand that the nozzle of Wood does not significantly damage cells and concludes therefore that they are viable cells. Petitioner relies on Dr. Shupp's replication of Wood Example 1 to assert similar morphology. (Pet. at 31-32; Ex. 1007, ¶ 134.)

However, a POSA would understand that the viability could have been scientifically measured to assess it insofar as it relates to the morphology as recited in claim 4, but no viability test results were provided by Dr. Shupp. A POSA would understand that the microscopic slide comparisons do not confirm morphology, and so a POSA would disagree with the conclusions Dr. Shupp has reached with regard to them, which were referenced again in Ex. 1007, ¶ 134. (Ex. 2001, ¶¶ 20, 50, 53, 90.) Therefore, Wood does not render claim 4 obvious.

d. Claim 5

Since claim 5 depends on claim 2, the discussion above for claim 2 applies. Therefore, Wood does not render the subject matter of claim 5 obvious. (Ex. 2001, ¶¶ 20, 50, 53, 90.)

e. Claims 6 and 7

A POSA would understand that cells can fit through smaller apertures than their diameter and congregates will form in different shapes and therefore different sizes. A POSA would disagree with the way that Dr. Shupp has determined filter cutoff. (Pet. at 33-35; Ex. 1007, ¶¶ 63, 140-146; Ex. 2001, ¶ 47.) Therefore, Wood does not render claims 6 and 7 obvious.

f. Claims 8 and 9

Wood teaches a single enzyme approach. See the discussion in §VI(A)(4) above. (Pet. at 35-36; Ex. 2001, ¶¶ 55-57.) Therefore, Wood does not render claims 8 and 9 obvious.

g. Claim 10

Petitioner asserts that pressing a plunger on a syringe with a thumb “is continuous force application to the syringe.” (Pet. at 36-37; Ex. 1007, ¶¶ 153-154.)

A POSA would find it difficult to apply a continuous, even force to a syringe by hand. A POSA would understand the amount of resistance that a plunger of a syringe applies can vary substantially over its course of travel, resulting in uneven flow and control of the material being delivered. The leverage of force applied also varies with the angle of compression that the fingers have with respect to the syringe and its plunger, also complicating any attempt to apply a continuous force to a syringe. Thus, A POSA would experience varying forces to operate a syringe as set forth in Ex. 1007, ¶ 154. A POSA would understand the same can be said of

the plastic actuator or nozzle of Navarro discussed in Ex. 1007, ¶ 155. Therefore, a POSA would find it difficult to manually apply a continuous force application to a syringe of Wood.

Furthermore, a POSA would find a continuous force application to be an automated and controlled force, as set forth in the Claim Constructions section of this Preliminary Response. A hand operated syringe would not be a continuous force application. Therefore, Wood does not render claim 10 obvious.

h. Claim 11

Patent Owner repeats the arguments set forth above that Wood does not render claim 1 obvious. See the discussion in §VI(A) above. Claim 11 is dependent on claim 1 and therefore Wood does not render claim 11 obvious.

B. Wood In View of Lyles Does Not Render Claims 1-11 Obvious

1. Claim 1 Is Not Obvious

Petitioner references its prior arguments for Wood for all but element 2 of claim 1: “. . . *contacting the single-cell suspension of cells with a gas flow at an outlet of the container to create droplets of the suspension at a flow-controlled spray head.*” Petitioner relies upon Lyles for combination with Wood regarding element 2, asserting “[] as Wood suggests the use of a ‘nozzle’ and ‘propellant fluid’ for use with the cell suspension, a POSA would have been motivated to look at prior art devices for spraying cell suspensions which use propellant gases to produce aerosolized droplets.” Petitioner further states:

[] a POSA would have been amply motivated with a reasonable expectation of success to use the pressurized sprayer of Lyles because Lyles teaches that cell suspensions can be sprayed with such a device. A POSA would therefore have naturally looked to the device of Lyles which embodies the “nozzle” and “propellant fluid” features of Wood, and would have understood that Lyles’ devices are suitable for creating droplets of the cell suspension with a gas flow at a flow controlled spray head. *See* Shupp Decl, ¶ 107.

(Pet. at p. 42.) Even if Petitioner’s assertions here are assumed for the sake of argument (but which Patent Owner expressly disagrees with) Petitioner has not stated a motivation for a POSA to replace the syringe and nozzle of Wood. An assertion that a sprayer is suitable for spraying cell suspensions onto wounds does not articulate a rationale for combination of the references under *KSR*. (*Ex Parte Borgwardt*, Appeal 2012-009099 (PTAB, October 14, 2014) attached as Ex. 2006, page 3 of opinion states: “As Appellants correctly point out, the fact that references relate to the same technical field [] does not, without more, demonstrate the obviousness of their combination.” *See also In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).) Indeed, a POSA would not seek to add additional equipment which increases cost and complexity just for the sake of adding it. Contrary to Petitioner’s assertions, a POSA would see that Lyles is used to seed allograft material, construct “full thickness grafts, and create three-dimensional tissues, all of which create closed cell sheets. (Ex. 1004.) Without the flow-controlled spray

system of the '430 patent, Lyles would over coat the tissue and could result in blistering. (Ex. 1001, 4:45-46; Ex. 2001, ¶¶ 75-79.)

The Petitioner relies on Wood from the Petition §III(E)(2)(k) for “. . . spraying the droplets onto the wounded area of skin without forming a closed cell sheet . . .” (Pet. at p.42, “k.”) However, the Petition and Dr. Shupp fail to provide any evidence or teaching of how such spraying can be done with Wood to avoid forming a closed sheet when employing the sprayer of Lyles. Moreover, the Petitioner cannot rely on Wood to avoid a closed cell sheet with a sprayer that is configured thick layers of tissue, as in Lyles.

The combination of Wood with Lyles fails for at least the reasons above relating to the defects with Wood. In addition, Lyles lacks an electronically controlled spray device under Patent Owner's claim construction for “flow-controlled spray head”.

Accordingly, the Petition fails to demonstrate that Wood and Lyles would render obvious claim 1 of the '430 patent. (Ex. 1007, ¶ 104-108; Ex. 2001, ¶¶ 75-79.)

2. Claims 2-11 Are Not Obvious

Petitioner's obviousness assertions for claims 2-11 are identical to the arguments it made in section §III(E)(3)-(12) of the Petition based on Wood. In

response, Patent Owner repeats the arguments it made to Wood for claims 2-11, and submits that claims 2-11 are not obvious over Wood in view of Lyles.

C. Wood In View Of Navarro Does Not Render Claims 1-11 Obvious

1. Claim 1 Is Not Obvious

Petitioner asserts that all limitations of claim 1 of the '430 patent are taught by Wood in view of Navarro. (Pet. at p. 45; Ex. 1007, ¶¶ 109-111.) Petitioner has taken the position that “Navarro discloses several spray delivery apparatuses “selected on the basis of a uniform cell distribution with high cell viability measurements after the spray.” Petitioner further states: “[a] POSA would have been motivated to Navarro because both references are concerned with spraying cell suspensions onto wounds.” An assertion that two references relate to spraying cell suspensions onto wounds does not articulate a rationale for combination of the references under *KSR*. (*Ex Parte Borgwardt*, Appeal 2012-009099 (PTAB, October 14, 2014) attached as Ex. 2006, page 3 of opinion states: “As Appellants correctly point out, the fact that references relate to the same technical field [] does not, without more, demonstrate the obviousness of their combination.” See also *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).)

Navarro does not provide details of the design of the artist's air brush, so the configuration of that device is not established. Moreover, a POSA would review

the portion of Table 1 which shows the artist's air brush had consistently low cell viability among the tested devices after the spray (70% for all distances). Indeed, a POSA would read Navarro and be inclined to conclude the artist's air brush as the least favorable approach of Table 1. The "Results" state: "the highest viabilities [were] with the use of [Navarro's Figure 1 sprayer and nozzle]." (Ex. 1003, p. 515.) The Petition fails to state a reason why a POSA would adopt the least favorable approach of Navarro.

The combination of Wood with Navarro fails for at least the reasons above relating to the defects with Wood. In addition, Navarro lacks an electronically controlled spray device under Patent Owner's claim construction for "flow-controlled spray head".

Therefore, the Petition fails to demonstrate that Wood and Navarro would render obvious the subject matter of claim 1. (Ex. 1007, ¶ 109-113; Ex. 2001, ¶¶ 80-82.)

2. Claims 2-11 Are Not Obvious

Petitioner's obviousness arguments for claims 2-9 and 11 are identical to the arguments it made in section §III(E)(3)-(12) of the Petition based on Wood. In response, Patent Owner repeats the arguments it made to Wood for claims 2-9 and 11.

With regard to claim 10, Petitioner asserts that pressing a plunger with a thumb on Navarro's spray apparatus "is continuous force application to the syringe container." (Pet. at 50-51; Ex. 1007, ¶¶ 111-112.)

A POSA would find it difficult to apply a continuous, even force to a syringe by hand. A POSA would understand the amount of resistance that a plunger of a syringe applies can vary substantially over its course of travel, resulting in uneven flow and control of the material being delivered. The leverage of force applied also varies with the angle of compression that the fingers have with respect to the syringe and its plunger, also complicating any attempt to apply a continuous force to a syringe. Thus, A POSA would experience varying forces to operate a syringe as set forth in Ex. 1007, ¶ 154. A POSA would understand the same can be said of the plastic actuator or nozzle of Navarro discussed in Ex. 1007, ¶ 155. Therefore, a POSA would find it difficult to manually apply a continuous force application to a syringe container of Navarro and with the proposed combination of Wood and Navarro.

Furthermore, a POSA would find a continuous force application to be an automated and controlled force, as set forth in the Claim Constructions section of this Preliminary Response. A hand operated syringe would not be a continuous force application. Therefore, Wood in view of Navarro does not render claim 10 obvious.

Claims 2-11 are not obvious over Wood in view of Navarro.

D. Wood In View Of Dixon Does Not Render Claims 1-11 Obvious

1. Claim 1 Is Not Obvious

Petitioner reiterates its prior arguments for Wood for all but element 2 of claim 1: “. . . *contacting the single-cell suspension of cells with a gas flow at an outlet of the container to create droplets of the suspension at a flow-controlled spray head.*”

Petitioner asserts a combination of Dixon (Ex. 1005) with Wood regarding element 2, stating:

“a [POSA] would have been motivated to use a propellant gas to aerosolize droplets of Wood’s cell suspension at the nozzle of a sprayer. A POSA would naturally have looked to the ‘cell spray apparatus’ of Dixon to deliver the suspension of Wood to the wound site.” *See* Dixon, col. 5, ln. 66 to col. 6, ln. 5.

(Pet. at 56.) Petitioner’s assertion is that a POSA would have combined Dixon with Wood because they relate to sprays of cells to a wound site. Petitioner relies on a set of unduly broad claim constructions engineered to eliminate the flow control aspects of the ’430 patent. Furthermore, even *KSR* requires a rationale for a POSA to combine teachings, but which is lacking from Petitioner’s allegations. The assertion that two references relate to propellant gas sprayers does not articulate a rationale for combination of the references under *KSR*. (*Ex Parte Borgwardt*, Appeal 2012-009099 (PTAB, October 14, 2014) attached as Ex. 2006,

page 3 of opinion states: “As Appellants correctly point out, the fact that references relate to the same technical field [] does not, without more, demonstrate the obviousness of their combination.” See also *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).)

Petitioner turns to Dr. Shupp’s Declaration ¶ 118 to allege that Dixon teaches a flow-controlled spray head under Petitioner’s broad constructions. Dr. Shupp asserts that because “[s]pray [] is propelled outwardly from distal end 235 of barrel 230” and “then directed onto a recipient surface,” then “[a]ccordingly, a POSA would have been amply motivated with a reasonable expectation of success to use the pressurized sprayer of Dixon because Dixon teaches that cell suspensions can be sprayed with such a device comprising a flow-controlled spray head.” (Ex. 1007, ¶¶ 114-118.) Dr. Shupp again employs his broad definition of a “flow-controlled spray head” which Patent Owner has disagreed with and discussed above with respect to the Claim Constructions section, above.

Petitioner does not articulate a motivation to combine Wood and Dixon. All Petitioner appears to be asserting is that Dixon teaches that cell suspensions can be sprayed with Dixon’s pressurized sprayer, so a POSA would use it instead of the apparatus of Wood. However, Petitioner does not provide a motivation to substitute the syringe and nozzle of Wood with Dixon’s sprayer. (Ex. 1007, ¶¶ 114-119.)

The combination of Wood in view of Dixon fails for at least the reasons above relating to the defects with Wood. In addition, Dixon lacks an electronically controlled spray device under Patent Owner's claim construction for "flow-controlled spray head".

Accordingly, the Petition fails to demonstrate that Wood in view of Dixon would render obvious claim 1 of the '430 patent. (Ex. 2001, ¶¶ 83-85.)

2. Claims 2-11 Are Not Obvious

Petitioner's obviousness assertions for claims 2-11 are identical to the arguments it made in section §III(E)(3)-(12) of the Petition based on Wood. In response, Patent Owner repeats the arguments it made to Wood for claims 2-11, and submits that claims 2-11 are not obvious over Wood in view of Dixon.

E. Wood In View Of Marshall Does Not Render Claims 1-11 Obvious

1. Claim 1 Is Not Obvious

Petitioner reiterates its prior arguments for Wood for all but element 2 of claim 1: "*. . . contacting the single-cell suspension of cells with a gas flow at an outlet of the container to create droplets of the suspension at a flow-controlled spray head.*"

Petitioner asserts a combination of Marshall (Ex. 1006) with Wood regarding element 2. Petitioner states:

“A POSA would therefore have been motivated to employ the “Spraying Devices” of Marshall to deliver the suspension of Wood to the wound site since those devices use a gas propellant to aerosolize a cell suspension at a spray nozzle. See Marshall, col. 8, lns. 38-39.”

The assertion that two references relate to gas propellant to aerosolize cell suspensions does not articulate a rationale for combination of the references under *KSR*. (*Ex Parte Borgwardt*, Appeal 2012-009099 (PTAB, October 14, 2014) attached as Ex. 2006, page 3 of opinion states: “As Appellants correctly point out, the fact that references relate to the same technical field [] does not, without more, demonstrate the obviousness of their combination.” See also *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).) However, Marshall states: “When cell suspensions alone are sprayed, the above-described low liquid flow rates are preferably used.” (Ex. 1006, 8:38-39; underlining added.) Petitioner’s support relates to a liquid suspension alone being sprayed. Such suspensions are liquid delivery that is performed by drops or a stream. (Ex. 1006, 8:32-33.) Such delivery is not an aerosolized spray.

Petitioner does not assert that the syringe and nozzle of Wood suffers any problem that Marshall solves, nor has it alleged that a POSA would find some motivation to combine Marshall with Wood. Petitioner appears to assert Marshall teaches cell suspensions can be sprayed with Marshall’s pressurized sprayer, so a POSA would use it instead of the apparatus of Wood. (Ex. 1007, ¶¶ 120-125.)

However, this does not provide a motivation to substitute the syringe and nozzle of Wood with Marshall's sprayer.

The combination of Wood in view of Marshall fails for at least the reasons above relating to the defects with Wood. In addition, under Patent Owner's claim construction for "flow-controlled spray head" Marshall lacks an electronically controlled spray device.

Accordingly, the Petition fails to demonstrate that Wood in view of Marshall would render obvious claim 1 of the '430 patent. (Ex. 2001, ¶¶ 86-88.)

2. Claims 2-11 Are Not Obvious

Petitioner's obviousness assertions for claims 2-11 are identical to the arguments it made in section §III(E)(3)-(12) of the Petition based on Wood. In response, Patent Owner repeats the arguments it made to Wood for claims 2-11, and submits that claims 2-11 are not obvious over Wood in view of Marshall.

VII. THE PETITION IS NOT TIMELY

At the time of filing its Petition, Petitioner Avita "expressly denie[d]" that the '430 patent claims were entitled to priority. (Pet. at 15.) Thus, Avita effectively took the position that the '430 patent is a post-AIA patent, because it was filed after March 16, 2013. If Avita was of that belief, then it should not have certified the '430 patent was eligible for *inter partes* review until after nine months

from issue, and Avita should not have filed its IPR petition before January 4, 2018. (35 U.S.C. § 311(c)(1); 37 C.F.R. § 42.102(a)(1).)

This issue was brought before the Board and a teleconference was conducted on June 19, 2017. (See Order Summarizing Conference Call and Resetting Notice of Filing Date Accorded to Petition and Time for Filing Patent Owner Preliminary Response, Paper No. 7.) The Board asked Petitioner to stipulate to the priority claim to maintain the proceeding. In response, Petitioner stipulated that the effective filing date of the '430 patent is the priority date of September 11, 2006. (See Paper No. 8.) The Board reset the timing of the deadline for this Preliminary Response. (See Paper No. 7.)

The Board has had other cases before it where the issue of an early filing arose. In *GrowlerWerks, Inc. v. Drink Tanks Corporation*, the parties were initially unaware that a priority challenge rendered the petition untimely and the Board discovered the issue. *GrowlerWerks, Inc. v. Drink Tanks Corporation*, IPR2016-01125, Paper No. 8 (PTAB Nov. 22, 2016) (Ex. 2005). *GrowlerWerks* is distinguishable from this proceeding because in *GrowlerWerks* when the Board raised the issue with the parties the patent owner did not object to the untimely petition (at pp. 6-7.). The petitioner filed its petition again after the nine-month period to moot the issue. Furthermore, the instant proceeding is distinguishable

from *GrowlerWerks* because the Petitioner expressly denied priority in its original Petition and was apprised of the situation soon thereafter.

The Board has the power and discretion to discourage petitioners from challenging a patent on hypothetical facts that do not comport with their belief. To do otherwise encourages petitioners to take multiple, inconsistent positions on the record, weakens the filing certification, and forces patent owners to defend their patent rights from hypothetical challenges at considerable expense.

VIII. INSTITUTION SHOULD BE DENIED

None of the Petition's asserted grounds of unpatentability establish that there is a reasonable likelihood that at least one claim is unpatentable under 35 U.S.C. § 103. Accordingly, the Board should deny institution of *inter partes* review based on this petition and the evidence of record.

The Patent Trial and Appeal Board is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

Date: September 19, 2017

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**CERTIFICATION OF TYPE-VOLUME LIMITS
UNDER 37 C.F.R. § 42.24**

I hereby certify under 37 C.F.R. § 42.24(d) that this Patent Owner Preliminary Response contains 13,279 words according to the word count of Microsoft Word for Mac Version 15.38, which was used to prepare this brief.

Date: September 19, 2017 SCHWEGMAN LUNDBERG & WOESSNER PA

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Certificate of Service

The undersigned certifies service pursuant to 37 C.F.R. § 42.6(e) on the
Petitioner by email on the date below and as authorized by the Petitioner in the
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Respectfully submitted,

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