

Paper No. ____
Date October 3, 2025

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOLVENTUM CORPORATION,

Petitioner,

v.

WOUND HEALING TECHNOLOGIES, CORP.

Patent Owner.

IPR2025-01042

U.S. Patent No. 10,639,404

PATENT OWNER'S PRELIMINARY RESPONSE

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No.	Exhibit
2015	Expert Declaration of Salvatore Morgera Ph. D

I. INTRODUCTION

Patent Owner Wound Healing Technologies, Corp. submits this Preliminary Response to the Petition. Institution should be denied for two independent reasons.

First, Petitioner falls far short of showing it is reasonably likely to prevail with respect to the claims challenged in the Petition. As shown below, the Petitioner ignores claim terms, relies upon redundant references, mischaracterizes the relevant technology, and fails to meet its burden under 37 C.F.R. § 42.108. Because the Petition does not show that at least one claim is reasonably likely to be invalid, institution should be denied under 35 U.S.C. § 314.

Second, Petitioner relies on art and arguments that were already considered during examination but fails to show any material error in the PTAB's prior conclusion. Institution should therefore be denied under 35 U.S.C. § 325(d).

II. U.S. PATENT NO. 10, 639,404 (“THE ‘404 PATENT”)

A. Technical Overview

This overview of the ‘404 Patent shows why the arguments in the Petition were cumulative to arguments presented during the prosecution and considered during the Appeal to the PTAB (“the Appeal”).

Specifically, both Argenta 2008 and Argenta 2010, the primary references cited in the Petition and Prosecution/Appeal, respectively, discuss a technique for distributing the vacuum from the mouth of a tube to the rest of a wound. EX 2015, para. 44. In order to distribute the vacuum to the rest of the wound, Argenta's technique requires a serial, *in situ*, deployment of NPWT components. Further details of Argenta 2008 and Argenta 2010 are set forth, *infra*, in §§ 3, 4. Argenta 2008 and Argenta 2010 both address *in situ* deployment of components. See EX2015, para. 38.

In contrast, the independent claims of the '404 Patent, all recite "a vapor sealant sheet... comprising an adhesive... that mechanically maintains the *placement* and orientation of the fluid-absorbing/transferring layer *relative to the vapor sealant sheet*["] (emphasis added).

Neither the references cited in the prosecution nor the references cited in the Petition show or suggest the claimed ***vapor sealant sheet having an adhesive that maintains the placement and orientation of the fluid-absorbing/transferring layer relative to the vapor sealant sheet***. In fact, the Petition does not even recite the foregoing term when applying the references. See Petition at 42.

The '404 Patent discloses a wound dressing (See FIG. 12 of the '404 patent, element 1280 below). As described therein, wound dressing 1280 is ready for

application to a representative wound-bed 1202. A wound dressing according to the embodiments may be applied directly to the wound-site. *See* '404 Patent, column 4, lines 45-52.

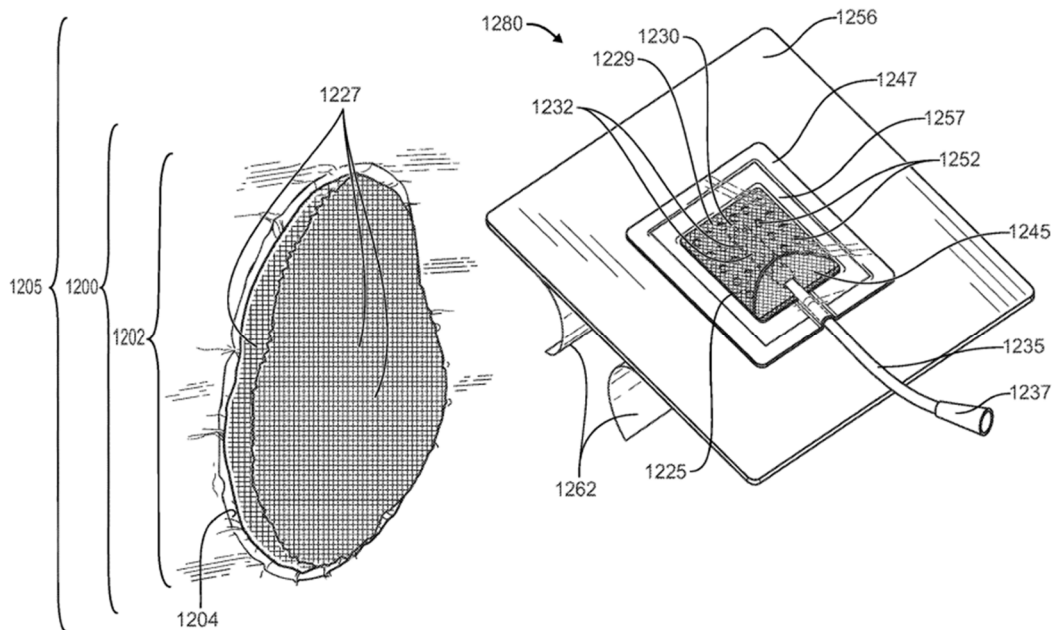


FIG. 12

When backing layer 1262 is removed, dressing 1280 is ready for application to wound bed 1202.

Prior to application to the wound, fluid-absorbing/transferring layer 1229 is already placed and oriented relative to vapor sealant sheet 1257.

FIG. 11 of the '404 patent shows a side view of an exemplary embodiment of wound dressing 1180.

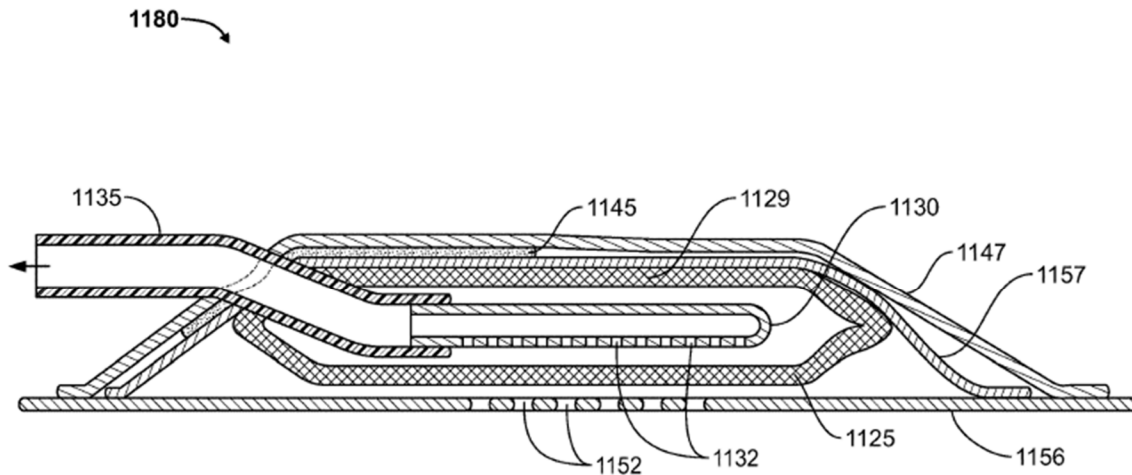


FIG. 11

FIG. 11 shows portions of a wound dressing 1180 in accordance with exemplary independent claim 3. At 1135 a vacuum drainage tube with a terminus is shown. Vapor sealant sheet 1157 is also shown. A fluid-absorbing/transferring layer is shown at 1129 is already placed and oriented relative to vapor sealant sheet 1157. A tube-exit-sealant component is shown at 1147.

Because the Petition provides no new facts, the Petition should be denied under § 325(d). Because the references cited by the Petition fail to show or suggest the claimed embodiments, the Petition should also be denied under § 314(a).

B. Claims

1. Exemplary Claim 3

Exemplary claim 3 recites:

3[a]¹ A wound dressing comprising:

3[b] a vacuum/drainage tube comprising a terminus;

3[c] fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring layer being in contact with the vacuum/drainage tube;

3[d] a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant that overlies the fluid-absorbing/transferring layer,

3[e] said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of fluid-absorbing/transferring layer relative to the vapor sealant sheet; and

3[f] a tube-exit-sealant for mechanically maintaining placement of the NPWT drain relative to the fluid-absorbing/transferring layer.

¹ Patent Owner has adopted the Petition's numbering convention. *See* Pet. at 49-51.

As explained below, the Petition fails to demonstrate a reasonable likelihood that independent claims 1-3 are unpatentable.

Patent Owner focuses on Elements 3[a] and 3[e]. Elements 3[a] and 3[e] appear in all independent claims. As such, these elements apply equally to all three grounds in the Petition.

III. RELEVANT PROSECUTION HISTORY

A. Primary References Argenta 2010 (Prosecution) and Argenta 2008 (IPR)

Argenta U.S. Publication No. 2010/0042021 (EX2007) (“Argenta 2010”) was used as the primary reference to reject each of independent claims 1-3 in the January 26, 2017 Office Action. (EX1006 at 106-116, 2017 Office Action, at *8).

The 2017 Office Action made the following statement regarding Argenta 2010, to reject element 3[e] listed above – “(See Fig. 9 [of Argenta 2010] - vapor sealant sheet with adhesive is helping to hold absorbing/transferring layer *in place*).” (EX1006 at 114 (emphasis added)). Notably, the Office Action statement failed to show the claimed *placement* of the fluid-absorbing/transferring layer relative to the vapor sealant.

Following the 2017 Office Action, Patent Owner appealed the 2017 Office Action to the PTAB. (EX1006 at 102, Notice of Appeal, 80-97, Appeal Brief).

The Examiner maintained Argenta 2010 *in rejecting only claims 3 and 14-17. (Id. at 72 et seq.)*.

On Appeal, the PTAB reversed all of the Examiner's obviousness rejections based on Argenta 2010. (EX1006 at 54 *et seq.*)

Petition now submits the identical failed reasoning as set forth in the Examiner's rejections in the 2017 Office Action with respect to all the independent claims.

B. Secondary References Biggie (Mentioned by the Examiner During Prosecution) and Hu (IPR)

Another reference cited in the Petition, Biggie, U.S. Patent No. 7,520,872 ("Biggie") (EX1008), was considered during the prosecution of the '404 Patent. Specifically, Biggie was cited as pertinent to the disclosure in an Office Action mailed by the Office on August 13, 2012 (the 2012 Office Action). (EX1006 at 343-348). In fact, Biggie was called out by the Examiner as relevant to the claims of the '404 Patent:

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patents 7,520,872, 4,969,880 and US Patent Publication 2009/0234306 teach of a similar all-in-one wound dressing for use in negative pressure therapy, including multiple layers and drainage tube adhesive means.

(EX1006 at 347) (highlights added).

Notably the Examiner characterizes Biggie as “similar to the *all-in-one wound dressing* for use in negative pressure therapy” taught by the ‘404 patent. (emphasis added)

IV. LEGAL STANDARDS

A. 35 U.S.C. § 314

“The Director *may not* authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition... shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (emphasis added).

In an inter partes review, the petitioner bears the burden to prove unpatentability of the claims of the patent-at-issue by a preponderance of the evidence. 35 U.S.C. § 316(e); *Aqua Products v. Matal*, 872 F.3d 1290, 1303 (Fed. Cir. 2017) (*en banc*).

Under 35 U.S.C. § 103, Petitioner must prove that the claimed subject matter would have been obvious to a POSITA at the time of the invention. *KSR Inter. Co. v. Teleflex*, 550 U.S. 398, 406 (2007). A complete analysis requires that the Board determine (1) the scope and content of the prior art; (2) differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) relevant

objective indicia of nonobviousness (also known as secondary considerations).

Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17 (1966). Importantly, the obviousness inquiry must be undertaken without any “hint of hindsight.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011).

An invention “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. Moreover, Petitioner is required to show, but does not, that its disparate references would have suggested to a POSITA that they should make the claimed invention and that they would have a reasonable expectation of success in doing so. *In re NuVasive, Inc.*, 842 F.3d 1376, 1381-82 (Fed. Cir. 2016); *Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.*, IPR2014-00309, Paper 83 at 19 (PTAB Mar. 23, 2014).

It is not enough to show that multiple references could be combined. Petitioner must show, but does not, that a POSITA would have been motivated to pick out the asserted multiple references and combine them in the way the claimed invention does. *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017); *Ariosa Diagnostics v. Verinata Health, Inc.*, IPR2013-00276, Paper 64 at 17-18 (PTAB Aug. 15, 2016).

Petitioner must support its obviousness contentions with articulated reasoning and based on rational, factual underpinnings; conclusory statements of obviousness will not suffice. *KSR*, 550 U.S. at 418; *In re NuVasive*, 842 F.3d at 1382–83.

Similarly, any expert testimony must explain in detail how specific references could be combined, which combinations of elements in specific references would yield a predictable result, and how any specific combination would operate or read on the asserted claims. *Activevideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012); *Ariosa*, IPR2013-00276, Paper 64 at 20.

B. 35 U.S.C. § 325(d)

Institution of inter partes review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). 35 U.S.C. § 325(d) provides that the Director may elect not to institute a proceeding when a petitioner raises “the same or substantially the same” art or arguments the USPTO has previously considered. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17-18 (P.T.A.B. Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph).

The Director will discretionarily deny institution when two conditions are

satisfied: (1) “the same or substantially the same art previously was presented to the Office” or “the same or substantially the same arguments previously were presented to the Office”; and (2) the petitioner does not “demonstrate[] that the Office erred in a manner material to the patentability of the challenged claims.”

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6, 8 (P.T.A.B. Feb. 13, 2020) (precedential).

In applying the *Advanced Bionics* two-part framework, the Board considers a number of non-exclusive factors, as set forth in *Beckton, Dickinson*, IPR2017-01586, Paper 8 at 17-18 (the “Becton, Dickinson factors”):

(a) the similarities and material differences between the asserted art and the prior art involved during examination;

(b) the cumulative nature of the asserted art and the prior art evaluated during examination;

(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in

its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

For part one of the *Advanced Bionics* two-part framework, the Board evaluates *Becton, Dickinson* factors (a), (b), and (d). *Advanced Bionics*, Paper 6 at 10. If it is determined that the same or substantially the same art or arguments were previously presented to the USPTO, the Board then considers *Beckton, Dickinson* factors (c), (e) and (f) in part two of the *Advanced Bionics* framework. *Id.*

Factors (a), (b), and (d) relate to whether the art or arguments presented in the petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, Paper 6 at 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its prior consideration of that art or arguments. *Id.*

Only if the same or substantially the same art or arguments were previously presented to the Office will the Board consider whether petitioner has demonstrated a material error by the Office. *Id.* “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

V. THE PETITION SHOULD BE DENIED UNDER § 325(D)

A. The References

The references by the Petition, unlike the '404 Patent, discuss an *in situ* serial co-location of parts that is not, prior to deployment, a wound dressing.

1. Argenta 2008, is Cumulative of Previously Considered Argenta 2010

Each of the Petition's grounds for rejection principally relies on Argenta 2008.² Though this reference was not (explicitly) considered during prosecution, as shown below, several other related Argenta references *were* considered. Moreover, there is no relevant subject matter cited from Argenta 2008 that was not included in the Argenta references cited and considered during prosecution.

The Argenta references, and their respective treatment by the Petition, are set forth in Table 1 below.

² Though this brief refers to the referenced publication (US 2008/0208147) as "Argenta 2008" for clarity, the Petition refers to it as "Argenta."

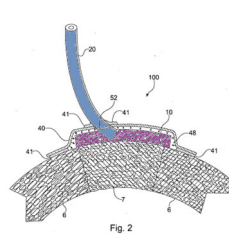
Table 1. Argenta Patents and Applications

Reference Number	Reference Name	Cited in . . .	Treatment by Petition
U.S. Publication No. 2008/0208147 (EX1004)	“Argenta 2008”	Petition	Primary Reference for All Grounds
U.S. Publication No. 2010/0042021 (EX2007)	“Argenta 2010”	During Prosecution by Examiner, and by PTAB on appeal	Described in Petition as “an apparatus for cardiac tissue modulation”
U.S. Patent No. 5,636,643 (EX2011)	“Argenta ‘643”	During Prosecution, cited by Patent Owner; incorporated by reference in Argenta 2008	Omitted

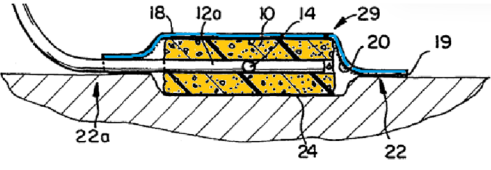
Reference Number	Reference Name	Cited in . . .	Treatment by Petition
U.S. Patent No. 5,645,081 (EX2012)	“Argenta ‘081”	During Prosecution, cited by Patent Owner; incorporated by reference in Argenta 2008	Omitted
U.S. Patent No. 7,216,651 (EX2013)	“Argenta ‘651”	During Prosecution, cited by Patent Owner	Omitted

Table 2 below shows that all portions of Argenta 2008 cited in the Petition with respect to the ‘404 Patent’s independent claims were already present in previously considered Argenta references. Argenta 2010 and Argenta 2008 are substantively identical regarding their teachings relevant to the claims of the ‘404 Patent. Argenta 2008 is therefore cumulative of Argenta 2010. Likewise, the PTAB considered and rejected the same arguments presented in the Petition (based on Argenta 2008) when it reversed the Examiner’s rejection (based on Argenta 2010).

Table 2. Argenta 2008 is cumulative in view of other Argenta references

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
3[a]A wound dressing comprising:	Petition, page 31, citing Argenta 2008, ¶¶ 3 and 4.	To the extent Argenta 2008 discloses a wound cover, Argenta '643, and the other cited Argenta references, also disclose a wound cover, Argenta '643, col. 3:1-2.
3[b] a vacuum/drainage tube comprising a terminus;	“[I]n addition to having an opening at the distal end 32, the tube 30 may be fenestrated along the portion of the tube 30 in communication with the enclosure	Argenta 2010 discloses tube 20 (FIG. 2). “The tube 20 may have one or more fenestrations 23 in that portion of the tube 20 in contact with the porous material 10.” Argenta '2010 at ¶38. 

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
	under cover 10.” Petition, at 32, citing Argenta 2008 ¶ 20.	
3[c] fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring layer being in contact with the vacuum/drainage tube;	Argenta 2008 “discloses screen 20, which is the fluid absorbing/transfer-ring layer that is described by the ‘404 Patent.” Petition at 37, citing Argenta 2008 at ¶¶17-18.	Argenta ‘643 discloses: “FIG. 10 is a schematic cross-sectional view of a reduced or negative pressure appliance comprising an open-cell polymer foam screen, a flexible hose for connecting the foam screen with the vacuum system...” “an end segment 12a of the tubing 12 is embedded within the foam screen 10 for providing suction or reduced pressure.” Col.7:2-3.

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
3[d] a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant that overlies the fluid-absorbing/transferring layer,	“One of skill in the art would understand that Argenta [2008]’s disclosure of a ‘self-adhesive’ cover that binds to the screen and holds it in place to include adhesive in a central zone.” Petition at 42.	Argenta ‘643 discloses: “The wound cover for the reduced pressure appliance may be in the form of a gas impermeable covering sheet of flexible polymer material, such polyethylene, having an adhesive backing that provides the seal for securing the sheet over the wound site...” Argenta ‘643 at col.3:52-56.  FIG. 1
3[e] Said vapor sealant sheet comprising an	See 3[d], above. (Bold portion is not taught or	See 3[d], above. (Bold portion is not taught or suggested by Argenta 2008).

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, <i>said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing transferring layer</i>	<i>suggested by Argenta 2008).</i>	

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
<i>relative to the vapor sealant sheet; and</i>		
3[f] a tube-exit-sealant component for mechanically maintaining the vacuum-drainage tube's placement relative to the fluid-absorbing/transfer-ring layer.	See 3[e], above.	See 3[e], above.

Table 2 above shows that all of the cited portions of Argenta 2008 are cumulative of the Argenta References cited and considered during prosecution of the '404 Patent.

2. Secondary Reference Hu Is Cumulative of Biggie.

The relevant teachings of the Petition's Hu reference, U.S. Patent Publication No. 2010/0042021 (EX1005), are cumulative in view of previously considered Biggie (EX1008), as set forth in Table 3 below. Because Biggie was considered during the prosecution and highlighted by the Examiner as relevant to the claims of the '404 Patent (EX1006 at 347), the Petition's citation of Hu is cumulative. And because the petition relies on substantially the same art and arguments as were considered during prosecution, institution should be denied under 35 U.S.C. § 325(d) and the *Advanced Bionics* framework as set forth *infra* in more detail.³

Notably, despite the Examiner's consideration of the challenged claims in view of Biggie, the Board ultimately found the claims patentable. (EX1006 at 55-60).

Table 3 below shows that Hu is cumulative of Biggie.

³ Secondary reference Lockwood (cited in Ground 3) does not mitigate the shortcomings of Hu, nor does the Petition even offer an explanation as to why Lockwood should fill the gaps left by Hu. (*See* Petition at 28-30).

Table 3 – Secondary Reference Hu is Cumulative of Biggie (See EX 2015 Table 2)

Claimed Element:	Petition's citation of Hu :	The citation of Hu is cumulative of Biggie:
A vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid absorbing layer;	“Hu states that the sealant layer can be ‘made of a hydrocolloid material[.]’”. Petition at 41.	The Petition fails to appreciate that Biggie included an embodiment without a protective cover. Biggie, ¶ 54, states: “In Fig. 4, a side cutaway view of the preferred embodiment of FIG. 3 is shown. In this figure, the pouch 1 is secured inside the wound cavity 11 by flexible gel 12. . . . A variety of commercially available gels can be used, such as hydro-colloids, silicones, or a gel, such as a hydrogel.”

The Petition states categorically that Biggie involves a “[hydrocolloid] gel layer is then covered with a protective cover.” (Petition at 28). The Petition implies that the protective cover differentiates Biggie from Hu.

Biggie’s FIGs. 4 and FIG. 5 are reproduced below. FIG. 4 does not include a protective cover while FIG. 5 does (item 13). Contrary to Petitioner’s assertion (that the Examiner considered only FIG. 5), the record reflects that all of Biggie was considered. Because the Examiner considered Biggie’s entire disclosure, and Hu’s teachings are redundant of Biggie’s teachings, Hu is cumulative.

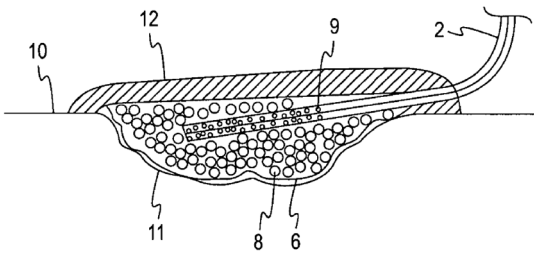


Fig. 4

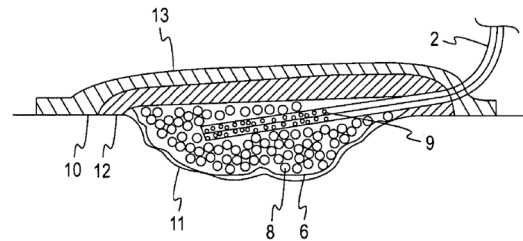


Fig. 5

In summary, Hu is cumulative of the disclosure in Biggie, particularly with respect to Biggie FIG. 4, and the portion of the Biggie specification associated therewith.

Tables 1 and 2 (above) demonstrate that substantially the same art and arguments as presented in the Petition were cited and considered during prosecution of the ‘404 Patent. Importantly, the Petitioner fails to meaningfully

distinguish the substance of the Argenta prior art and Biggie considered in the prosecution of the '404 Patent, and before the PTAB, from Argenta 2008 and Hu, respectively. The Petition also fails to demonstrate why or how the Office's prior consideration of the references was in error and does not satisfy the *Advanced Bionics* test.

Because, as explained above, Argenta 2008 and Hu are "the same or substantially the same prior art or arguments [as those] previously...presented to the Office," the decision by the Board in the Appeal and by the Examiner should be treated as undisputed facts. Petitioner does not present any new, non-cumulative, references, or why/how the Examiner erred when considering the references.

Because the same art and arguments were likewise considered (and rejected) by the PTAB on Appeal, step 1 of the *Advanced Bionics* framework is satisfied.

The following factors represent step 2 of the *Advanced Bionics* framework.

(c) *the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;*

(d) *the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;*

(e) whether the Petition has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

With respect to step (c), Argenta 2010 was the primary reference reviewed by both the Examiner during prosecution and PTAB on Appeal. Notably, the PTAB came to a different conclusion, after a thorough review, than the Petition. Biggie was also considered by the Examiner and commented on during prosecution.

With respect to step (d) – the arguments made by the Examiner during Prosecution and on Appeal are identical to the arguments made by the Petition. See argument made by Examiner during prosecution, EX1006 at 114, and identical argument made Petition, at page 42.

With respect to step (e) – the Petition has failed to point out any meaningful differences between Argenta 2010 and Argenta 2008.

Finally, with respect to step (f), the only additional evidence, Hu, has been shown (see Table 3 above) to be cumulative of Biggie.

Because the '404 Patent previously overcame the same rejection as advanced by the Petition, institution should be denied under 35 U.S.C. § 325(d) under the *Advanced Bionics* framework.

VI. PETITIONER IS UNLIKELY TO PREVAIL IN CHALLENGING THE INDEPENDENT CLAIMS

A. None of the References Teach an Adhesive that Mechanically Maintains the Placement and Orientation of the Fluid-absorbing/transferring Layer Relative to the Vapor Sealant Sheet.

Claim element 3[e] recites:

. . . [a] vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, *said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing layer relative to the vapor sealant sheet. . .*

(emphasis added).

Element 3[e], reproduced above, appears in each of independent claims 1-3. Grounds 1 and 3 rely on the same art to allegedly teach element 3[e]. (Ground 2 is directed to dependent claims 8-10 and does not apply to any of the independent claims.)

Petitioner fails to cite any references that disclose or suggest the above-emphasized element. See EX 2015 Table 1, row 3[e]. In fact, the Petition omits direct treatment of this feature. See Petition at 24 (stating Argenta 2008 teaches a dressing “in place”, as opposed to teaching the claimed vapor sealant sheet having an adhesive that mechanically maintains *placement* of the *fluid-absorbing/transferring layer relative to the vapor sealant sheet*).

The PTAB, during the appeal (EX1006 at 55-60) considered substantially the same references and rejected substantially the same arguments. Specifically, the PTAB determined that all of the challenged claims are non-obvious in view of Argenta 2008 and other secondary references. *Id.* See EX 2015 at para. 67.

**B. The Claims of the ‘404 Patent Would Require
a Change in the Principles of Operation of Argenta**

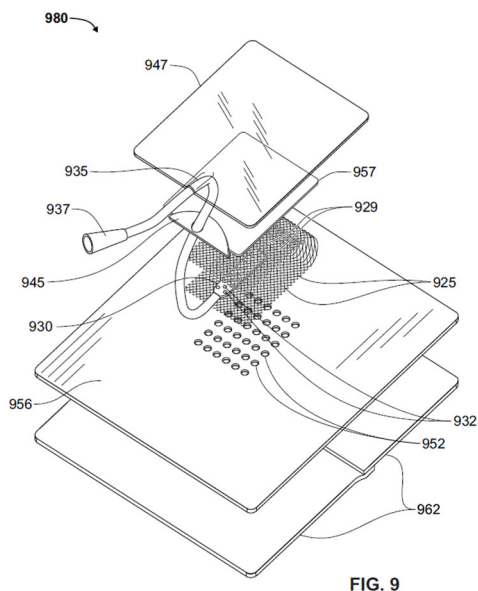
Another reason Argenta 2008 is not appropriate for use in any obviousness rejection of the claims of the ‘404 Patent is found in para. 19 of Argenta 2008. Specifically, Argenta 2008’s singular embodiment states that “[t]he screen 20 *is desirably cut and shaped to fit into and fill the wound 40.*” (See EX1004, Argenta 2008, at para. 0019, reproduced below.)

[0019] The screen 20 is desirably cut and shaped to fit into and fill the wound 40. As the wound 40 heals and becomes smaller in size, the size of the screen 20 may be decreased accordingly. The screen 20 may be held in place by contacting an adhesive coated under surface 12 of the cover 10 to assist in securing the screen 20 in a fixed position and to assist in the removal of the screen 20 when the cover 10 is removed. One particularly convenient configuration of cover 10 and screen 20 is the combination of a flexible self-adhesive polymer sheet or drape used in conjunction with an open-cell polymer foam.

Argenta 2008 has a “screen 20 [that] may be held in place by contacting an adhesive coated under surface 12 on the cover.” The fluid-absorbing layer of the ‘404 Patent, on the other hand, has been adhesively placed and oriented *relative to the vapor sealant sheet* – not in the wound and then covered by an adhesive surface 12.

Once placed relative to the vapor sealant sheet, the recited fluid material absorbing/transferring layer of the ‘404 ***cannot reasonably be*** cut, further shaped, or used to then fill a wound. *See* FIG. 9 from the ‘404 Patent below.

In fact, to cut and shape the claimed fluid-absorbing/transferring layer following placement relative to the vapor sealant sheet would disturb both the size, shape and operation of a wound dressing according to the principles of the ‘404 Patent. Certainly, such cutting and shaping would decrease ease of deployment of the claimed fluid-absorbing/transferring layer.



In view of the foregoing, the Petition has failed to show a *prima facie* rejection of the independent claims at least because the cited prior art does not show or suggest the claimed element of a vapor sealant sheet ***said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing layer relative to the vapor sealant sheet.*** Nowhere does the Petition attempt to show where the prior teaches this claim term in its entirety – i.e., with the phrase “relative to the vapor sealant sheet” specified. Furthermore – to use Argenta 2008 as a primary reference would require a change in the principles of operation of Argenta 2008.

Notably, Petitioner, in the prosecution of Petitioner’s ‘363 patent, characterized the ‘556 Publication (the ‘404 Patent) as teaching “multiple layers of

[wound] dressing components” (emphasis added) including absorbent material 1129 and sealing material 1157. (See EX2014; Petitioner’s remarks in reply to Office Action mailed 2/2/2016 in ‘363 patent prosecution.) Thus, Petitioner’s own counsel recognizes that the claimed placement of the fluid-absorbing/transferring layer relates to *a pre-deployment placement in a wound dressing* and not being *placed in a wound*. (cf. Petition at 42, applying Argenta to show only use of the adhesive *within the wound* and not a placement of the screen vis-a-vis the draping layer, stating “[o]ne of skill in the art would understand Argenta’s disclosure of a ‘self-adhesive’ cover that binds to the screen and holds it in place to include adhesive in a central zone.” Citing to the EX1002 para. 125)).

A European examiner, in the PCT International Search Report (EX2008) for Petitioner’s PCT App. No. PCT/US2013/074763, also characterizes the ‘556 publication as having “an absorbent material *associated with* the sealing material.” (emphasis added).

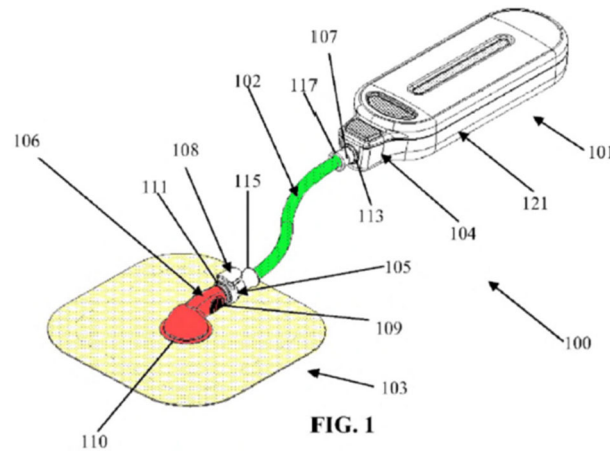
To arrive at the claimed embodiments – i.e., generally understood as an all-in-one dressing (See Petition at 27-28) -- would require a change in principles of operation of Argenta 2008 – i.e., which require *in situ* deployment of components.

This is true at least because Argenta 2008’s only embodiment requires *a screen that is cut, shaped to fit and used to fill the wound*. This Argenta principle

of operation *per se* does not show or suggest the claimed placement of the vapor sealant sheet affixed to an adhesive that maintains a placement and orientation of the claimed fluid-absorbing/transferring layer relative to the vapor sealant sheet. (See elements 929 and 957 of FIG. 9 of the '404 Patent above). The placement and orientation of the claimed fluid-absorbing/transferring layer relative to the vapor sealant sheet, as shown in FIG. 9, cannot be *cut, shaped and/or to fill the wound*. As such, Argenta 2008 cannot and, in its only relevant embodiment, does not, show or suggest a ***vapor sealant sheet that includes an adhesive that maintains a placement and orientation of the claimed fluid-absorbing/transferring layer relative to the vapor sealant sheet.***

With respect to the foregoing principles of operation of Argenta 2008, Hu is limited to the same principles of operation as Argenta 2008 – i.e., that the wound is filled prior to application of a wound cover and that the wound filling is placed in the wound prior to mating it with the wound cover. See below, Petition at page 27 stating, in pertinent part, the sealant layer in Hu, “can be used over top of a ‘contact layer matrix’ that is placed in the wound bed”. As such, Argenta 2008 and Hu are precluded from teaching an embodiment as claimed in the independent claims – i.e., a pre-deployment assembly of a wound dressing as recited 3[d].

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EX1005 at Fig. 1 (color added). The sealant layer may be “made of a hydrocolloid material” (EX1005 ¶59) and can be used over top of a “contact layer matrix” that is placed in the wound bed to “distribute the reduced pressure more evenly through the wound bed” (EX1005 at ¶57) similar to the screen in Argenta’s device,

(highlight added).

From the foregoing reasons, neither Argenta 2008 nor Hu can be used to form an obviousness rejection with respect to the independent claims of the ‘404 Patent, as neither teaches claim element 3[e].

Argenta 2008 and Hu would require a change in their principles of operation to teach, *inter alia*, the above-quoted element 3[e]. Accordingly, neither Argenta 2008 nor Hu, alone or in combination, shows nor suggests the claimed vapor sealant sheet having an adhesive that mechanically maintains *placement* of the *fluid-absorbing/transferring layer relative to the vapor sealant sheet*.

Therefore, the primary reference and the main secondary reference in each

of Grounds 1 and 3 cannot be used, let alone combined, to show obviousness. As such, neither of Grounds 1 and 3 can stand. EX 2015 para. 67. None of the other secondary references such as Hu, Biggie, or Lockwood mitigate shortcomings of the failed primary reference Argenta 2008. Nor does the Petition even apply any of the secondary references as filling the shortcomings left by Argenta 2008. As such, Ground 2 which is applied to dependent claims 8-10 can stand as well.

The Petition thus fails with respect to each of the independent claims of the '404 Patent. Because Petitioner is unlikely to prevail with respect to any of the challenged independent claims, or any of dependent claims 4-13 that depend, either directly or indirectly, therefrom, institution should be denied under 35 U.S.C. § 314(a).

**C. Petitioner Incorrectly Concludes
that the Preamble of the Independent Claims is not Limiting**

1. The Preamble is Limiting

Because all claimed components are pre-packaged and applied in unison to the patient, it follows that the claimed embodiments are fairly characterized as “a wound dressing” as stated in the preamble to each independent claim. Therefore, Petitioner’s statement that the preamble is not limiting fails.

2. The Claimed “Placement” refers to Pre-deployment Placement

The “placement” referred to in the independent claims refers to placement

and orientation of the fluid-absorbing/transferring layer *relative to the vapor sealant sheet*. This only makes sense when the placement is performed pre-deployment in a wound dressing.

The prior art has been characterized by the Petitioner in way that discusses *in situ* post-deployment. (Petition at 25 and 42, quoting Argenta 2008 at para. 19 (“The screen 20 may be held *in place* by contacting an adhesive coated under surface 12 of the cover 10 to assist in securing the screen 20 in a fixed position and to assist in the removal of the screen 20 when the cover 10 is removed”) (emphasis added)) EX 2015 para. 67. ***The Petitioner has therefore failed, in all Grounds, to show or suggest where cited references teach a wound dressing including an adhesive that maintains the placement and orientation of the fluid-absorbing/transferring layer relative to the vapor sealant sheet.*** EX 2015 para. 67.

D. Other Claim Terms In The Petition Are Not Material At This Time

Patent Owner does not find it necessary at this time to comment on Petitioner's proposed constructions and reserves the right to do so if necessitated at a later date.

VII. CONCLUSION

For the foregoing reasons, Patent Owners respectfully request that the Board deny the Petition for *Inter Partes* Review of the '404 Patent.

Respectfully submitted,

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Reg. No. 44,398

Attorney for Patent Owner

Date: October 3, 2025

CERTIFICATE OF WORD COUNT

I, Joel Weiss, Esq., Attorney for Patent Owner, hereby certify, pursuant to Title 37 C.F.R. §42.24 of the Code of Federal Regulations, that the word count for this Petition is 5,390 words, which does not include the cover, the table or the certifications. This Petition therefore complies with the rule, which limits the Patent Owner Preliminary Response to 14,000 words. I certify that this is the word count generated for this document in Microsoft® Word for Microsoft 365 MSO.

Respectfully submitted,

/Joel Weiss/

Joel Weiss

Reg. No. 44,398

Attorney for Patent Owner

Date: October 3, 2025

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the **PATENT OWNER'S
PRELIMINARY RESPONSE** was served on the 3rd day of October 2025, by
email to counsel for Petitioner:

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