

Paper No. ____
Date March 5, 2026

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 RESPONSE

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No.	Exhibit
2017*	Deposition Transcript of Dr. Morton Jensen
2018	Robinson, U.S. Pat. App. Pub. No. 2010/0305526

*already submitted

I. INTRODUCTION

Patent Owner Wound Healing Technologies, Corp. respectfully submits this Response to the Petition for Inter Partes Review of U.S. Patent No. 10,639,404 (“the ‘404 Patent”; EX1001).

The Board should deny the Petition in its entirety as the Petition fails to demonstrate fault in the Examiner’s findings regarding the all-in-one nature of the invention, fails to show why the PTAB erred and therefore has failed to show the claims are obvious.

In addition, the Petition evinces a fundamental misunderstanding of the invention disclosed in the ‘404 Patent. The ‘404 Patent discloses an all-in-one pre-assembled wound dressing for use with negative pressure wound therapy. The Petition, however, relies on references that teach bedside, *in-situ* assembly of wound dressings, not pre-assembled wound dressings. The background of the ‘404 Patent itself extensively discusses bedside, *in-situ* assembly of wound dressings, as that was the state of the art prior to the invention disclosed in the ‘404 Patent. The Office, including the Board, both agreed and found that bedside, *in-situ* assembly of wound dressings did not anticipate or render obvious the invention disclosed in the ‘404 Patent.

Independently, Patent Owner renews its assertion that the Board should exercise discretion under 35 U.S.C. § 325(d) and withdraw institution because Petitioner presents the same or substantially the same prior art and arguments previously considered by the Office.

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

A. Conventional Negative Pressure Wound Treatment Requires *In Situ* Assembly of the Wound Dressing.

Treating wounds with negative pressure (e.g., a vacuum) has been clinically demonstrated, for years, to be advantageous for certain wounds. (EX2016, Declaration of Dr. Salvatore Morgera, at 16 ¶44¹). This treatment is commonly referred to as negative pressure wound treatment (“NPT” or “NPWT”). *Id.*

In conventional NPWT, a wound is cleaned, debrided, and partially packed with a sterile material prior to treatment. (*Id.* at ¶45.)

During conventional NPWT, a drain is placed *in-situ* in a wound while a clinician packs the wound with sterile material. (*Id.* at ¶46). Additional sterile material may be placed over or around the drain. (*Id.*) The clinician then anchors the drain, usually with tape. (*Id.*) The clinician then places a drape or other

¹ Dr. Morgera’s Declaration, EX2016, restarted the numbering of its paragraphs at page 20; therefore, references to EX2016 include both page and paragraph number.

bandage over the drain and the wound, to provide an airtight seal. (*Id.*)

It is difficult to replace the sterile material within the wound in conventional NPWT practice because doing so risks displacing the drain, increases the likelihood of traumatizing the wound bed due to adherence of the packing material, complicates the maintenance of sterility, and causes significant patient discomfort. (*Id.*) These are some of the limitations and drawbacks of conventional NPWT methods. (*Id.*)

The '404 patent (and in many respects, the Petition and Petitioner's Expert Declaration, EX1002) describes how conventional preparation of a wound for NPWT is complicated, from the points of view of both the practitioner and the patient. (EX1001, the '404 Patent, at col. 1:36-38; EX2016 at 16, ¶47).

Conventionally, a wound-fluid drain is introduced into a first stage of wound packing in the wound-bed. (EX1001 at 1:43-44). The drain and dressing is thus assembled *in-situ* with the first stage of sterile packing material. (*Id.* at 1:53-54). The drain is placed on or inserted within the initial packing, *in-situ*. (*Id.*, at 1:55-56). Orientation of the drain within the wound bed or packing is a critical determinant of drainage efficiency and wound closure quality because drain orientation in the wound bed or packing will affect the efficiency of the drainage and the quality of the wound-closing. (*Id.*, at 1:57-58). Improper placement or

angulation of the drain reduces suction uniformity, limits exudate removal, and interferes with tissue approximation, leading to less effective healing outcomes. The exiting tube is taped to the patient's skin. (*Id.*, at 1:64; EX2016 at 17 ¶48).

When assembling an NPWT dressing directly on a patient, as in conventional NPWT, the practitioner must be careful to avoid disturbing the placement of the tube, which is usually held in place by the adhesion of tape to the skin. (EX1001, at 2:3-6; EX2016 at 17 ¶49). Even when the vacuum/drainage is skin-anchored close to the wound, manipulations involved in completing the wound-packing procedure may deleteriously shift the NPT drain-and-tube. (EX2016 at 17 ¶49).

Next, the drain and the tube are draped with an adherent flexible covering that is intended to provide an airtight seal against the perilesional skin. (EX1001 at 2:8-12). However, it may be challenging to consistently produce an effective airtight perimeter seal. (*Id.*, 2:13-20; EX2016 at 17 ¶50).

Creating an airtight seal with an adherent flexible covering over the drain and tube is often difficult and time-consuming due to several clinical realities such as irregular wound shapes and the natural contours of skin which make it challenging for adhesive drapes to fully conform, and the presence of moisture, wound exudate, or perspiration frequently undermines adhesion. (EX2016 at 18

¶50). Additionally, patient movement or tension from the tubing can disrupt the seal, which may require repeated adjustments. (*Id.*). These issues not only prolong the procedure but also increase patient discomfort and risk of contamination. (*Id.*).

In yet another stage of conventional NPT preparation, a sealed egress of the draping material must be formed along the outer surface of the tube. (EX1001 at 2:21-26; EX2016 at 18 ¶51). Each additional stage, including the taping of the egress tube, may be painful to the patient, as well as inconvenient and time-consuming. (EX2016 at 18 ¶51).

In conventional NPWT, “the number and intricacy of conventional NPT-required manipulations may make it difficult for a practitioner to efficiently carry out the procedure (practical and institutional constraints may limit the number of practitioners and aides available); may lead to the need to repeat part or all of the procedure so as to correct earlier errors and/or later shifting of components; may contribute to incomplete success of the procedure, depriving the patient of the full benefit of NPT.” (EX1001 at 2:44-53).

The multiple steps of conventional NPWT wound dressing are, in a typical wound, “repeatedly applied over several courses of NPT.” (*Id.* at 2:54-55). “Each course of NPT may include, at the outset, cleansing and assessment of the progressively smaller wound-bed, followed by” *in-situ* deployment of dressing

components. (*Id.* at 2:60-63). “Inherent painfulness may attend repeated manipulations of the wound-bed and surrounding wound-site, compounding the difficulties and complications involved in preparation of a wound for NPT by conventional apparatus and methods.” (*Id.* at 2:63-66; *see also* EX2016 at 18-19 ¶52).

As described by Dr. Morgera and in the ‘404 Patent, conventional NPWT wound dressing “regimens are inherently piecemeal, relying on loosely associated components that must be manually assembled and applied in ways that are often cumbersome, inconsistent, and prone to failure at critical points of therapy. Such approaches place unnecessary burdens on clinicians, increase the risk of patient discomfort and error, and undermine the reliability of outcomes.” (EX2016 at 19, ¶53).

One advantage of the conventional piecemeal, *in-situ* NPWT wound dressing regimens is that the *in-situ* dressings are fully customizable for all shapes and sizes of wound beds. (*See* EX2016 at 34 ¶62).

B. The Wound Dressing Described in the ‘404 Patent is a Fully Assembled All-In-One Dressing.

One solution to the multiple issues raised by the *in-situ* assembly of NPWT dressings is provided by the ‘404 Patent. “[T]he ‘404 patent embodies a system-level solution, designed holistically rather than as a collection of parts. It is a

coordinated structure that enhances efficiency, ensures more consistent application, and directly addresses the central clinical challenges of wound closure and healing. This systemic approach not only mitigates the shortcomings of prior methods but also elevates the standard of care by making negative pressure therapy more accessible, reliable, and clinically effective.” (EX2016 at 19-20, ¶53).

The ‘404 Patent discloses a complete, all-in-one, pre-assembled/pre-packaged wound dressing. (EX2016 at 20 ¶39; *see* FIGs. 7-12 of the ‘404 patent, including exemplary wound dressings 780 and 1280 reproduced below). As described in the ‘404 Patent, wound dressing 780, 1280 etc., is ready for application to a representative wound-bed 1202. The wound dressing, as claimed, is provided “fully assembled” (EX1001 at 17:67) and “may be provided in an appropriately labeled sterile over-wrapping. ...Additionally, the wrapped or unwrapped dressing may be supplied in (association with) a kit with suitable materials and apparatus for wound-cleansing and debridement and for initial wound-packing.” (EX1001 at 11:14-30). A wound dressing according to the embodiments may be applied directly to the wound-site and need not be assembled bedside. (*See* EX1001 at 4:45-52).

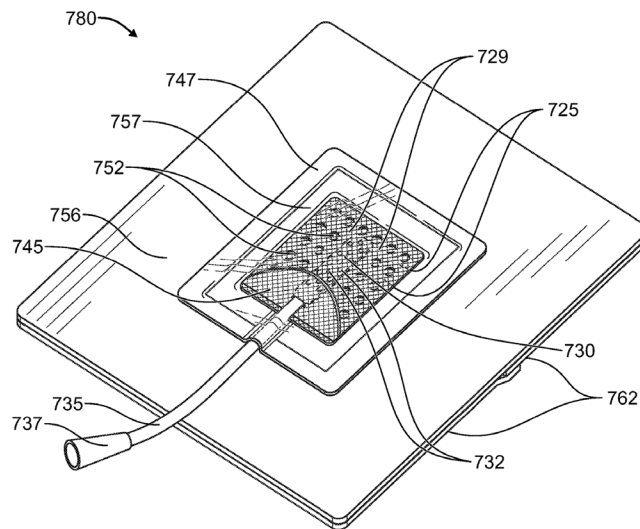


FIG. 7C

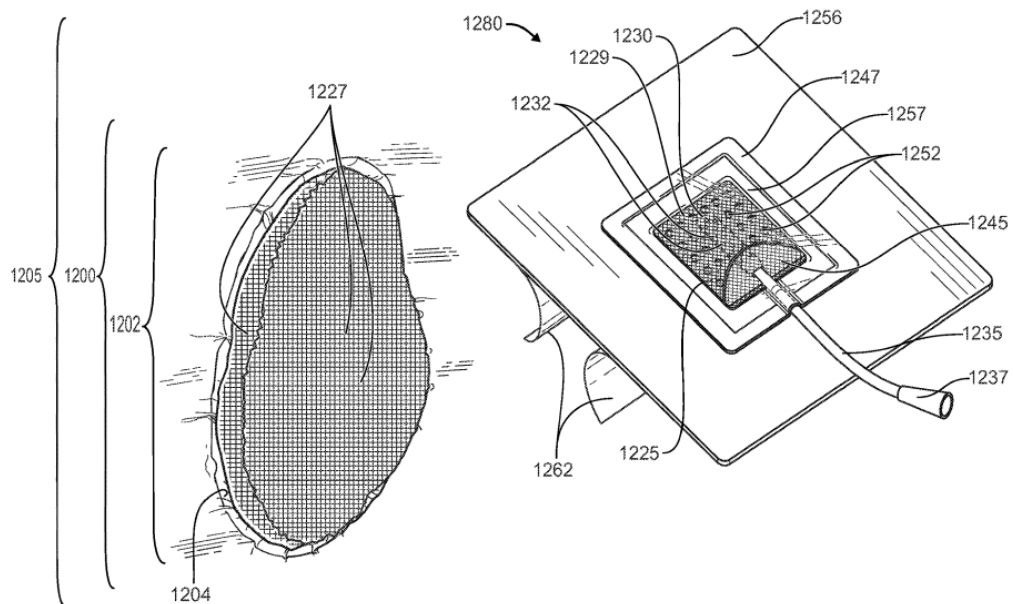


FIG. 12

As seen in the figures above, when the backing layer (elements 762 and 1262) is removed, dressing 780, 1280 is ready for application to wound bed 1202 and connection to a negative pressure wound vacuum pump.

Because the wound dressing is pre-assembled prior to application to the wound, all of the components of the wound dressing, including fluid-absorbing/transferring layer 1229, are, prior to deployment, already placed, oriented, and immovable relative to the other components. “[T]he wound-fluid drain, fluid-absorbing/transferring layer, and tube anchorage component are fixed together, and remain so, after backing layer is [removed and the wound dressing is] applied to a wound bed.” (EX2016 at 21 ¶42; EX1001 at 4:45-49). This fixed placement and orientation of the fluid-absorbing/transferring layer and other components in the ‘404 patent eliminates the risks inherent in the manual assembly of conventional piecemeal NPWT applications.

As shown in Table 1 below, the ‘404 patent also describes how the inventive wound dressing enables NPWT with fewer, simpler, and less painful steps than conventional prior art NPWT regimens. In contrast, the references relied upon by the Petition address and require a serial, *in-situ*, deployment of NPWT components including any fluid absorbing/transferring layer. (See EX2016, at 15 ¶40).

Table 1. Comparison of steps to apply conventional NPWT dressings to the inventive dressing:

Conventional NPWT dressings (<i>see supra</i>):	The '404 Patent (<i>see</i> EX1001 at 4:56-5:16; EX2016 at 22 ¶45):
1) Removing all separate components from a kit and any associated packaging	1) Removing the dressing from its sterile over-wrapping and removing the backing layer
2) Packing the wound bed with sterile packing material	2) Orienting the dressing for suitable directionality of the vacuum/drainage tube
3) Placing a wound-fluid drain on or into the packing material and ensuring the positioning of the wound-fluid drain is correct in the packing material	3) Centering the fluid absorbing/transferring material on the wound-bed
4) Connecting an exiting tube to the drain	4) Applying the dressing to the wound-site and adhering the draping layer of the dressing to

	the tissue of the surrounding wound-site
5) Taping the exiting tube to the patient's skin	5) Connecting a terminus of the vacuum/drainage tube to NPWT equipment
6) Draping the drain and tube with an adherent flexible covering that is intended to provide an airtight seal against the perilesional skin	
7) Forming a sealed egress of the draping material along the outer surface of the tube	
8) Connecting a terminus of the vacuum/drainage tube to NPWT equipment	

C. The Claims of the '404 Patent

The '404 Patent includes claims 1-13; claims 1-3 are independent. Because

Petitioner relies on references describing *in-situ* deployment and assembly of NPWT dressings, Patent Owner identifies claim elements that show the claims describe a pre-assembled all-in-one NPWT wound dressing that does not require *in-situ* assembly and customization.

Petitioner's proposed limited claim constructions (Pet. at 13-15) are irrelevant to the current proceeding because, regardless of the construction of those few terms, Petitioner has not presented a case of §103 obviousness. As such, it is unnecessary to construe those limited claim terms at this time. Applicant expressly reserves the right to construe the claims, if necessary, at a later date.

Patent Owner agrees that the plain and ordinary meaning of the claims should prevail at this stage. However, the plain and ordinary meaning must be understood by one of ordinary skill in the art.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-14 (Fed. Cir. 2005) (citation omitted). “Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, **including the specification**.” *Id.* at 1313; *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) (holding, “[w]e cannot look at the ordinary meaning of the term . . . in a vacuum. Rather we must look at the ordinary meaning in the context of the written description and the prosecution

history’’) (citation omitted) (emphasis added).

Even though a claim term may have a plain and ordinary meaning to a person skilled in the art, “the specification or the prosecution history of a patent may alter the meaning of a claim term from its conventional usage.” *Alloc Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003); *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1374 (Fed. Cir. 2009). Therefore, the specification must always be considered in construing claims, even when the terms initially appear to have a plain and ordinary meaning. Further, the prosecution history “is often of critical significance in determining the meaning of the claims.” *Advanced Cardiovascular Sys. Inc. v. SciMed Life Sys. Inc.*, 261 F.3d 1329, 1339 (Fed. Cir. 2001) (citation omitted). Where the prosecution history compares an invention to the prior art, the comparison may qualify the scope of a claim. *Sentry Prot. Products, Inc. v. Eagle Mfg. Co.*, 400 F.3d 910, 915 (Fed. Cir. 2005).

When the claims in the ‘404 Patent are read in view of the specification, the claims describe an all-in-one, pre-assembled NPWT wound dressing, not a piecemeal wound dressing that requires *in-situ* assembly as is found in Petitioner’s references and conventional NPWT wound dressings. (See *e.g.*, EX1001 at FIGs. 7-14; 2:42-3:9 (...”It would be desirable, therefore, to provide apparatus and methods for streamlining and simplifying preparation of a wound-site for NPT.

Apparatus and methods for streamlining and simplifying preparation of a wound-site for NPT are provided. Such apparatus may include a wound dressing.”); 17:66-18:2 (“...areas of non-wound-facing surface of such drape 756 may feature fully assembled, sealed and functional sets of the other non-draping-material components of dressing 780.”); 25:53-59 (“Establishment and maintenance of mutual positions and orientations of constituent components within applied, positioned and oriented dressing 1380, may be obtained as consequences of the set of structural functionalities of those components preassembled with fixity of position and of orientation within dressing 1380.”); *and see e.g.*, EX2016 at 20 ¶¶39-40; at 21 ¶43).

Additional support for the fact that the claims recite an all-in-one pre-assembled wound dressing can be found in the prosecution history at:

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). These three references, Patent 7,520,872 (“Biggie”), Patent 4,969,880 (“Zamierowski”), and Pub. 2009/0234306 (“Vitaris”), were all considered by the Examiner and all discuss all-in-one dressings “similar”

to the claimed invention. Despite the consideration of these three all-in-one references, neither the Examiner nor the Board found they render the all-in-one dressing in the '404 Patent obvious.

Exemplary claim 3 recites:

3[a]² **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**

² Patent Owner has adopted the Petition's numbering convention. *See* Pet. at 49-51. Most of the elements of claim 3 appear in the other two independent claims.

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.
(emphasis added).

The underlined language supports the view of the Examiner, Board, and Patent Owner that the claims are directed to an all-in-one wound dressing. The prior art relied on by the Petitioner includes disparate components that must be applied one by one *in-situ* and do not provide these claimed features.

As an apparatus claim, each claim of the '404 Patent cannot be claiming something that must be assembled on a patient *in-situ*; the claims must be describing a complete "wound dressing comprising:" as the preamble states. The preamble thus defines the invention as an all-in-one pre-assembled/fully assembled wound dressing that includes certain components.

D. Relevant Prosecution History

The prosecution history of the '404 Patent demonstrates that the Petition's three Grounds are cumulative and incorrect.

a. Primary Reference Argenta 2010 (Prosecution) vs. Argenta 2008³ (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).

In the 2017 Office Action, the Examiner rejected element 3[e] listed above, stating, "(See Fig. 9 [of Argenta 2010] - vapor sealant sheet with adhesive is helping to hold absorbing/transferring layer *in place*)."³ (EX1006 at 114 (emphasis added)). Notably, the Examiner failed to show the claimed *placement* of the fluid-absorbing/transferring layer relative to the vapor sealant sheet.

Following the 2017 Office Action, Patent Owner appealed the rejections in the 2017 Office Action to the PTAB. (EX1006 at 102, Notice of Appeal, 80-97, Appeal Brief). During the appeal, the Examiner continued to assert that Argenta 2010 rendered obvious *only* claims 3 and 14-17. (*Id.* at 72 *et seq.*). In particular,

³ Though this brief refers to the referenced publication (US 2008/0208147) as "Argenta 2008" for clarity, the Petition refers to it as "Argenta."

the Examiner argued that it would have been obvious to use a hydrocolloid adhesive *in-situ* (“it would have been obvious to place an adhesive on the periphery of the vapor sealant sheet of Argenta [2010]...”). (EX1006 at 58). The Examiner stated further that after placing the adhesive, the adhesive “is part of the vapor sealant sheet.” (*Id.* at 59).

On appeal, the PTAB disagreed and reversed all of the Examiner’s obviousness rejections based on Argenta 2010. (EX1006 at 59 *et seq.*). Specifically, the PTAB held that, contrary to the Examiner’s arguments, placing an adhesive around the periphery was *not* the same as having the vapor sealant sheet *formed from* a hydrocolloid material. (*Id.* at 59). Patent Owner maintains that, although the PTAB was focused on the formation of the vapor sealant sheet, the PTAB implicitly drew the distinction between an *in-situ* assembly of a wound dressing (as shown in Argenta 2010 and argued by Petitioner) and a pre-assembled wound dressing as claimed by the ‘404 Patent.

This was true at least because the Examiner had considered and characterized Biggie, Argenta 2010, and Robinson (EX2018), and the existence of a hydrocolloid with NPWT dressing components was known to the Office at the time of the appeal. Accordingly, the only reasonable reading of the allowance of the claims was that *in-situ* assembly of NPWT dressing components does not show

or suggest the claimed all-in-one NPWT dressing. In addition, the PTAB ruled that such a combination failed to teach the claimed invention even absent “rigorous claim construction analysis”. (EX1006 at 59).

It follows that the PTAB’s reasoning endorses Patent Owner’s position that it is non-obvious that Argenta 2008 in combination with Hu shows or suggests the invention as set forth in the claims and Petitioner’s grounds must be rejected. This is true at least because the combination of Argenta 2008 with Hu shows, *at best, an in-situ deployment* of the vapor sealant sheet of Hu or Argenta 2008 and the already deployed screen of Argenta 2008. This is essentially the same argument as the failed combination advanced by the Examiner during the appeal with respect to the combination of Argenta 2010 and Robinson. Just as the PTAB implicitly found that the vapor sealant sheet be formed from a hydrocolloid material pre-deployment and found that adding adhesive to the vapor sealant sheet did not teach the claimed invention, so too it follows that adding multiple components *in-situ* as done by the Petition with Argenta 2008 and Hu does not teach the claimed invention.

In view of the statements of the Examiner, in view of the PTAB Decision on Appeal, and in view of the failure of the Petitioner to find fault in the Examiner’s logic or the PTAB’s Decision on Appeal, Petitioner cannot reasonably demonstrate

that Argenta 2008 by itself, or the combination of Argenta 2008 with Hu, shows that the claims are obvious given the Board's prior rejection of the combination of Argenta 2010 and Robinson.

By basing the Petition on conventional, *in-situ* assembly of wound dressings, Petitioner submits similar failed reasoning as was set forth by the Examiner in the 2017 Office Action which were overturned on appeal.

b. Secondary Reference Biggie Was Also Considered by the Examiner During Prosecution.

Biggie is another reference from the prosecution that was cited by Petitioner in support of Ground 2. (EX1008, Biggie U.S. Patent No. 7,520,872). Specifically, Biggie was cited by the Examiner as being a “*similar all-in-one wound dressing* for use in negative pressure therapy,” just like the claims in the ‘404 Patent. (EX1006 at 348).

III. LEGAL STANDARD

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*). Because Petitioner relies on *in-situ* references, Petitioner has failed to prove unpatentability of Patent Owner's claimed wound dressing which the Examiner explicitly, and the Board implicitly, viewed as an all-in-one wound

dressings. Petitioner fails to provide evidence to overturn the prosecution history in this regard, and as such, Petitioner's invalidity arguments fail.

IV. PETITIONER FAILS TO DEMONSTRATE FAULT IN THE EXAMINER'S FINDINGS REGARDING THE ALL-IN-ONE NATURE OF THE INVENTION, AND THEREFORE HAS FAILED TO SHOW THE CLAIMS ARE OBVIOUS.

Petitioner's three grounds that all claims are obvious under 35 U.S.C. § 103 based on various combinations of Argenta 2008, Hu, Biggie, and Lockwood must fail because these combinations do not teach or suggest an all-in-one NPWT wound dressing.

Specifically, under Ground 1, Petitioner alleges that claims 1-7, 11, and 13 are obvious over Argenta 2008 by itself or Argenta 2008 in combination with Hu. Under Ground 2, Petitioner alleges that claims 8-10 are obvious over Argenta 2008 in view of Biggie, or in view of Biggie and Hu. Under Ground 3, Petitioner alleges that claims 1, 4-7, and 12 are obvious over Argenta 2008 in view of Lockwood, or in view of Lockwood and Hu.

Each of these three grounds fails because Argenta 2008 describes an *in-situ* assembly of an NPWT dressing, not the claimed all-in-one wound dressing.

Petitioner offers no credible motivation to convert Argenta 2008's kit into a single integrated device featuring the claimed functions, while also ignoring the Board's decision rejecting this reasoning. Petitioner also fails to provide references that

teach a wound-facing central-zone adhesive that mechanically maintains ***placement and orientation*** relative to the sheet, pre-deployment.

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 non-obviousness (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. 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, Inc.*, 842 F.3d 1376, 1382-83 (Fed. Cir. 2016).

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.

A. Argenta 2008 is inapt as it describes an *in-situ* deployment of a wound dressing.

All three grounds in the Petition rely on Argenta 2008 as the main (or only) reference. However, Argenta 2008 is an inapt reference as it only teaches an *in-situ* deployment and assembly of an NPWT wound dressing. *In-situ* deployment of NPWT dressings was the state of the art prior to Patent Owner's invention and this approach is incompatible with the invention's all-in-one pre-assembled wound dressing.

Argenta 2008 at ¶0019 states: "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..." According to the Petition, screen 20 may be equivalent to the fluid absorbing/transferring layer of claims 1-13. However, screen 20 is *not* pre-assembled with the cover 10.

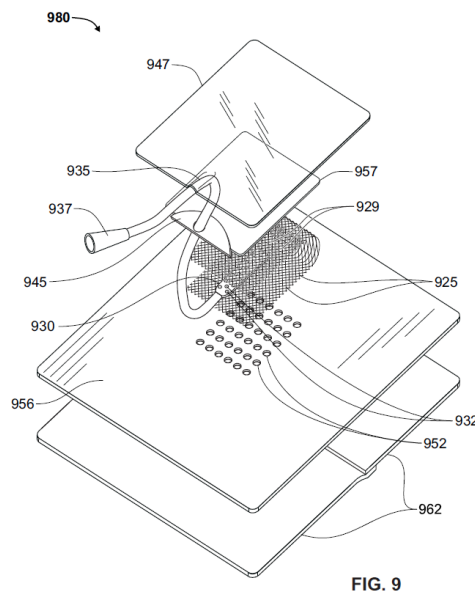
It is evident from paragraph 19 that "Argenta 2008 describes a piecemeal, manual process of cutting, shaping, and positioning individual dressing components in situ during each application of NPT therapy. This approach inherently introduces variability, complexity, and risk, as it requires repeated manipulation of wound-site materials and is highly dependent on the practitioner's skill and consistency at each step." (EX2016 at 36 ¶70). This piecemeal, *in-situ*, and manual process of assembling an NPWT dressing is in direct contrast to the claimed invention of the '404 Patent.

The '404 Patent "discloses a wound dressing system designed and manufactured as a unitary device that can be applied directly to the wound bed with minimal handling or assembly. A product embodying the '404 Patent technology addresses the standard of care in a way that Argenta [2008] never

contemplated: it ensures reliability, repeatability, and adherence to clinical best practices by reducing opportunities for error, decreasing application time, and mitigating patient pain during dressing changes.” (EX2016 at 36 ¶70).

Additionally, 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* prior to deployment on the patient—not in the wound and then covered by an adhesive surface. (EX2016 at 37 ¶71). Thus, the claimed invention achieves a pre-deployment state that is inapposite the teachings of Argenta 2008.

Further, once placed relative to the vapor sealant sheet, the recited fluid material absorbing/transferring layer of the ‘404 Patent ***cannot reasonably be*** cut, further shaped, or used to then fill a wound, unlike the unassembled components of Argenta 2008. (EX2016 at 37 ¶71; *see also* FIG. 9 from the ‘404 Patent reproduced 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 the wound dressing as claimed in the ‘404 Patent. (EX2016 at 37 ¶72). Certainly, such cutting and shaping would decrease ease of deployment of the claimed fluid-absorbing/transferring layer. (*Id.*).



Similarly, Hu does not show a pre-assembled wound dressing with a vapor sealant sheet *and* a fluid-absorbing/transferring layer. Hu at ¶0096 describes a dressing with a sealant layer and an attachment port; no fluid-absorbing/transferring layer is present.

Hu is limited to the same principles of operation as Argenta 2008 – i.e., that the wound bed is filled prior to application of a wound cover and that the wound filling is placed in the wound bed prior to mating it with the wound cover. The Petition itself recognizes this flaw in Hu (and Argenta 2008) as the Petition states that the sealant layer in Hu, “can be used over top of a ‘contact layer matrix’ that is placed in the wound bed... similar to the screen in Argenta’s device”. (Pet. at 27).

Similarly, Petitioner's Expert, Dr. Jensen, was adamant during his deposition that Biggie does not show a unitary, all-in-one wound dressing, contrary to the Examiner's statement. (*See* EX2017 at 52:24-53:1 and 53:8-11, stating, "But Biggie is not an all-in-one wound dressing delivered as a unitary device... I disagree with the fact that Biggie is showing an all-in-one wound dressing to be delivered as a unitary device because that's clearly what patent owner is trying to get to.") Nevertheless, the Examiner considered Biggie as teaching an all-in-one wound dressing and still determined that Biggie did not render the '404 claims obvious.

Besides a general disagreement with the Examiner, Office, and Board, the Petition and Dr. Jensen provide no reason as to why the Examiner, Office, and Board erred in allowing the '404 Patent to issue. (*See* EX2017 at 48:23-25, "I believe that the patent should not have been issued. So, yes, something did not go right in the examination and prosecution of the patent."; 57:15-17, "...it was not considered in the way that I think that it should have been considered."; and 60:14-16, "The result of the examination was that the patent was allowed. And so that mistake is challenged in both the petition and the declaration.").

Because they teach *in-situ* assembly of NPWT dressings, Argenta 2008 and Hu do not and cannot teach the invention described in the '404 Patent: an all-in-

one pre-assembled NPWT wound dressing. Biggie, likewise, is missing multiple elements of the invention, which is why the Examiner considered it and deemed it insufficient to reject the claims.

For this reason, 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 an all-in-one wound dressing including a pre-assembled fluid-absorbent/transferring layer. The Petition also presents no reason to combine these references to somehow achieve an all-in-one/pre-assembled wound dressing.

Furthermore, Argenta 2008 and Hu would require a change in their principles of operation to teach the invention in the '404 Patent. Accordingly, neither Argenta 2008 nor Hu, alone or in combination, shows or suggests the claimed elements.

Simply put, Argenta 2008 and Argenta 2008 plus Hu do not teach an all-in-one pre-assembled wound dressing. Petitioner offers no credible motivation to convert Argenta 2008's kit into a single integrated device featuring the claimed adhesive function with or without Hu, Biggie, or Lockwood. Argenta 2008 prioritizes patient-specific customization to its benefits and drawbacks. (*See* EX2016 at 34 ¶62, stating "Conventional NPT systems offer customized wound packing.").

Therefore, the primary reference and the main secondary references in each of Grounds 1 and 3 cannot be used, let alone combined, to show obviousness. As such, neither Ground 1 nor 3 can stand. (See EX2016 at ¶67). Ground 2, which is applied to dependent claims 8-10, also cannot stand as no independent claim is obvious. None of the other secondary references such as Hu, Biggie, or Lockwood mitigate the 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.

B. 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 the independent claims 1-3. Grounds 1 and 3 rely on the same art to allegedly teach element 3[e]. *See* Pet. at 42. The Petition claims that Argenta 2008 discloses that its unassembled cover may be “self-adhesive” which “may conveniently permit the cover 10 to be attached to and/or immobilize other components of the apparatus 100 which the cover adhesive contacts...” *Id.* And, “[t]he 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...” *Id.* However, Argenta 2008 is describing a cover that is deployed *in-situ* after the “screen 20 is desirably cut and shaped to fit into and fill the wound 40.” (EX1004 at ¶0019). This is in contrast to the invention in the ‘404 Patent, which teaches that “the wound-fluid drain, fluid-absorbing/transferring layer, and tube anchorage component are fixed together, and remain so, after backing layer is [removed and the wound dressing is] applied to a wound bed.” (EX2016 at 21 ¶42; EX1001 at 4:45-49).

These references to Argenta 2008 fail to disclose or suggest the above-emphasized element in the ‘404 Patent’s independent claims because the “placement” referred to in the ‘404 Patent refers to placement and orientation of the fluid-absorbing/transferring layer *relative to the vapor sealant sheet* before and after deployment. (EX2016 at 21 ¶43, “The wound dressing is therefore a pre-

packaged unit that is dimensioned prior to application, with the components fixed to and arranged relative to each other.”). This only makes sense when the placement is performed pre-deployment in a pre-assembled wound dressing.

Argenta 2008 simply teaches a “self-adhesive” cover that holds an *in-situ* deployed screen on the patient. (EX2016 at 35 ¶¶67). This self-adhesive cover “is fundamentally different from the claimed vapor sealant sheet that includes an adhesive specifically configured to mechanically maintain both the *placement* and the *orientation* of the fluid-absorbing layer relative to the vapor sealant sheet itself, prior to deployment on the patient.” (*Id.*). “The adhesive function in the ’404 patent is directed inward—ensuring structural stability and controlled orientation of the internal wound dressing components—during the application of the wound dressing whereas Argenta’s disclosure is related to a post-deployment phase.” (*Id.*). These two distinct functions should not and cannot be equated.

The prior art has been characterized by the Petitioner in way that discusses *in-situ* deployment, not pre-assembly. (*See e.g.*, Pet. at 25 and 42, quoting Argenta 2008 at ¶19; EX2016 at 35 ¶¶67). The Petition has therefore failed, in all Grounds, to show or suggest a prior art reference that teaches a pre-assembled wound dressing as claimed. The Petition has also failed to show or suggest a prior art reference that includes an adhesive that maintains the placement and orientation of

the fluid-absorbing/transferring layer relative to the vapor sealant sheet prior to deployment *in-situ*. (See EX2016 at ¶ 67).

To arrive at the claimed embodiments — *i.e.*, an all-in-one dressing — would require a change in principles of operation of Argenta 2008 and Hu, both of which require *in-situ* deployment of one or more components of an NPWT wound dressing.

Argenta 2008's only embodiment requires *a screen that is cut, shaped to fit and used to fill the wound*. (EX1004 at ¶19). This singular embodiment *per se* cannot and 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). 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 and/or shaped 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*** prior to and after deployment.

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 ***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 art 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.

The PTAB, during the appeal (EX1006 at 55-60) considered cumulative references and rejected similar arguments. Specifically, the PTAB determined that all of the challenged claims are non-obvious in view of Argenta 2010 and other secondary references. (*Id.*).

As cited in the PTAB’s decision on Appeal, the Examiner argued that it would have been obvious to use a hydrocolloid adhesive *in-situ* (“it would have been obvious to place an adhesive on the periphery of the vapor sealant sheet of Argenta [2010]...”). (EX1006 at 58). The Examiner stated that after placing the adhesive, the adhesive “is part of the vapor sealant sheet.” (*Id.* at 59).

On Appeal, the PTAB reversed all of the Examiner’s obviousness rejections based on Argenta 2010. (EX1006 at 59 *et seq.*). The PTAB held that placing, prior

to or at deployment, a hydrocolloid adhesive about the periphery of a vapor sealant sheet was *not* the same as having the vapor sealant sheet *formed from* a hydrocolloid material. (*Id.* at 59). Patent Owner maintains that the PTAB implicitly drew the distinction between an *in-situ* assembly of a wound dressing (as in Argenta 2010 and argued by the Petitioner) and a pre-assembled wound dressing as claimed by the '404 Patent.

It follows that the PTAB has already implicitly endorsed Patent Owner's position that it is non-obvious that Argenta 2008 by itself or in combination with Hu shows or suggests the invention as set forth in the claims. This is true at least because Argenta 2008 by itself or in combination with Hu shows, *at best, an in-situ deployment* of the vapor sealant sheet of Hu (or Argenta 2008) and the already deployed screen 20 of Argenta 2008. This is a similar argument to the already rejected *in-situ* deployment of adhesive on the periphery of the vapor sealant sheet. As such, Petitioner's references fail to teach the claimed invention.

By basing the Petition on conventional, *in-situ* assembly of wound dressings, the Petition submits similar failed reasoning as set forth in the Examiner's rejections in the 2017 Office Action and on appeal with respect to all the independent claims.

In addition, Petitioner, in the prosecution of Petitioner's U.S. Patent No. 9,733,363 (the "'363 patent'"), characterized 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, at one time, recognized 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.* Pet. at 42, applying Argenta 2008 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.>").

C. Secondary Considerations also demonstrate non-obviousness.

Secondary considerations, such as market development and success also demonstrate that the invention claimed in the '404 Patent is not obvious. (EX2016 at 38 ¶76 *et seq.*).

As Petitioner admits and the '404 Patent explains, prior to the invention, the conventional manner of deploying NPWT wound dressings was *in-situ*, leading to numerous issues with patient care. Since the invention of the all-in-one wound

dressings, hundreds of millions, if not billions of dollars of NPWT devices and dressings have been sold. After 2010, Petitioner, and numerous other parties in the NPWT market have copied Patent Owner's invention and have sold all-in-one NPWT wound dressings.

Petitioner and others have made and marketed wound-healing products that include the invention in the '404 Patent, generating hundreds of millions, or more in cumulative sales revenue, as evidenced by the substantial global and U.S. negative pressure wound therapy (NPWT) market. (EX2016 at 38 ¶76). The global NPWT market is estimated to have been around \$2.5 billion in 2023 and is projected to grow to almost \$4 billion by 2030. (*Id.*). In the United States, the NPWT market was approximately \$768 million in 2023, expected to grow to over \$1 billion by 2030. (*Id.*).

According to Dr. Morgera, the invention in the '404 Patent "is not merely incidental to the commercial success of the accused and related products, but rather *fundamental* to that success. The unique system-level design disclosed in the '404 patent addresses longstanding deficiencies in conventional negative pressure wound therapy, replacing piecemeal, error-prone techniques with a unitary wound dressing that is easier for clinicians to apply, more reliable in maintaining an effective seal, and markedly less painful and distressing for patients. These

advantages, efficiency, safety, and patient comfort, are precisely the features that drive clinical adoption, physician preference, and ultimately marketplace success. Thus, there is a direct and undeniable nexus between the asserted claims and the significant revenues realized in the negative pressure wound therapy market. Without the practical improvements embodied in the '404 patent, the widespread acceptance and sustained commercial growth of these products would not have been possible.” (EX2016 at 39 ¶78).

V. PATENT OWNER RENEWS ITS REQUEST THAT INSTITUTION OF THE PETITION SHOULD BE WITHDRAWN UNDER § 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). Here, because Petitioner raises the same (Biggie) or substantially the same (Argenta 2008 and Hu) art and argument as previously considered by the Office and the Board, Patent Owner respectfully requests that the Board exercise its discretion and withdraw the institution of this IPR.

Institution should be denied 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.* “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.

A. The References Are the Same or Substantially the Same As Those Previously Presented to the Office.

The references cited 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. Further, three of the four references relied upon by the Petition are cumulative of

(*i.e.*, the same or substantially the same as) previously considered references,⁴ and the Petition fails to demonstrate any error, much less a material error, in the Office's evaluation of the '404 Patent.

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

Argenta 2008 is the main reference in each of the Petition's three grounds. However, Argenta 2008 is cumulative of previously considered Argenta references, as several other related Argenta references *were* considered and teach, cumulatively, everything in Argenta 2008.

Specifically, every single element of Argenta 2008 cited in the Petition appears in Argenta 2010, Argenta '643, U.S. Patent No. 5,636,643 (EX2011), Argenta '651, U.S. Patent No. 7,216,651 (EX2013), and/or Argenta '081, U.S. Patent No. 5,645,081 (EX2012). All Argenta references but Argenta 2008 were previously explicitly considered by the Office and/or the Board. Although the Petition claims that Argenta 2008 is not cumulative of Argenta 2010 (Pet. at 24), the Petition does not address any of Argenta '643, Argenta '651, or Argenta '081.

⁴ All except Lockwood are cumulative. However, Lockwood is only used by the Petition to show a switch valve.

In addition, Argenta '643 and Argenta '081 are incorporated by reference in Argenta 2008.

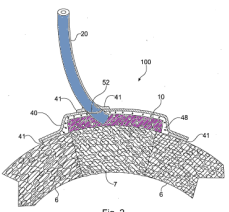
Table 2 below shows that all portions of Argenta 2008 cited in the Petition with respect to the '404 Patent's independent claims were already present in one or more previously considered Argenta references.

Patent Owner does not admit that Petitioner's references to Argenta 2008 in the Petition, and reproduced below in Table 2, nor the previously considered Argenta references, show or suggest any of the '404 Patent claim elements.

Argenta 2008 and the other Argenta references are substantively identical regarding their teachings relevant to the claims of the '404 Patent. Argenta 2008 is therefore cumulative of the previously considered Argenta references.

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 dressing, Argenta '643, and the other cited Argenta references, also disclose a

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		wound dressing. Argenta '643 at abstract and col. 3:1-2; Argenta 2010 at figure 9; Argenta '651 at abstract; and Argenta '081 at 4:36-44.
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 under cover 10.” Petition, at 32,	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.  Fig. 2

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
	citing Argenta 2008 ¶ 20.	Argenta '643 and '651 disclose a tube in figures 1-11. Argenta '081 discloses a tube in figures 1-2.
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/transferring layer that is described by the '404 Patent." Petition at 37, citing Argenta 2008 at ¶¶17-18.	Argenta '643 and '651 disclose: "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."

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		Argenta '081 also discloses: "FIG. 1 shows a cross-sectional view of a negative pressure device comprising a open-cell polymer screen, a flexible hose connecting the foam section to a suction pump, and a flexible polymer sheet overlying the foam-hose assembly to provide the necessary seal." (Col. 2:30-35). Argenta 2010 also discloses: "The method comprises placing a porous material in direct or indirect contact with the damaged cardiac tissue to provide gaseous communication between one or more pores of the

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		porous material and the damaged cardiac tissue. The porous material may comprise at least one of an electrospun material, a cast material, an open-cell foam, or a printed material. ... The porous material may be sealed in situ over the damaged cardiac tissue to provide a region about the damaged cardiac tissue for maintaining sub-atmospheric pressure at the damaged cardiac tissue. The porous material may be operably connected with a vacuum source for producing subatmospheric pressure at the damaged cardiac

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		tissue.” (Argenta 2010 at ¶¶0011-12).
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.	The component claimed to show this claim element by the Petition in Argenta 2008 <i>is also present in Argenta 2010</i> at ¶ 0008: [0008] An exemplary negative pressure therapy device of the present invention may include a vacuum dressing, e.g., porous material, for placement over the tissue to be treated. The vacuum dressing may be bio-incorporable in nature so that a second stage for removal would not be required. (As

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		used herein the term "bio-incorporable" is defined to describe a material that may be left in the patient indefinitely and is capable of being remodeled, resorbed, dissolved, and/or otherwise assimilated or modified.) The device of the present invention may also include a bio-incorporable overlay cover for placement over the vacuum dressing to form a sealed enclosure in which sub-atmospheric pressure may be provided and maintained to the vacuum dressing and the tissue to be treated. The overlay cover may

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		be adherent to the dressing and extend beyond the vacuum dressing to permit attachment of the overlay cover to surrounding non-damaged heart tissue. The overlay cover may be gelatinous in nature to contour to the heart and may be sufficiently pliable so as not to interfere with cardiac function. The overlay cover may be secured to the myocardium with fibrin glue, mini-staples, or sutures.” and Argenta 2010 ¶0040: “Specifically, with reference to FIGS. 7, 8, and 9, an overlay cover 40, 50 may be provided over the

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		damaged cardiac tissue 7 and porous material 10 by adhering the cover 40, 50 to cardiac tissues proximate the damaged cardiac tissue 7 to define an enclosed region 48, 58 about the damaged cardiac tissue 7 and porous material 10.” Argenta ‘643 and ‘651 disclose: “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

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
		the wound site..." (Argenta '643 at 3:52-56; Argenta '651 at 4:64-5:2). Argenta '081 discloses: "... said sealing means includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin." (Argenta '081 at 10:4-8).
3[e] Said vapor sealant sheet comprising an adhesive located over	See 3[d], above. <i>(Bold portion is not taught or</i>	See 3[d], above. <i>(Bold portion is not taught or suggested by Argenta 2008).</i>

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
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> The Petition claims that Argenta 2008 shows this element in ¶¶15, 19-20.	The component claimed to show this claim element by the Petition in Argenta 2008 is also present in Argenta 2010 at ¶ 0008 “[t]he overlay cover may be adherent to the dressing (i.e., the porous material for placement over the tissue to be treated.)” and ¶0040. Argenta ‘643 at 5:43-65, element 612, among other portions also shows the same element as Argenta 2008. Argenta ‘651 at 5:55-6:10, element 612, among other portions also shows the same element as Argenta 2008.

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	Previously Considered Argenta References:
<i>relative to the vapor sealant sheet; and</i>		Argenta '081 at 5:23-45, element 12 of figure 1, among other portions also shows the same element as Argenta 2008.
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.

While both Argenta 2008 and the considered Argenta references fail to teach key elements of the claims as set forth above in Table 2, every element of Argenta 2008 used by the Petition is present in one or more of previously considered Argenta 2010, Argenta '643, Argenta '651 and/or Argenta '081, proving that Argenta 2008 is cumulative and satisfying *Becton Dickinson* factor (b).

With respect to the *Becton Dickinson* factors (a) and (d), the considered Argenta references and Argenta 2008 are very similar and there are no material differences with respect to *relevant* elements. Further, Argenta 2010 was extensively relied upon by the Examiner and the Board during prosecution of the '404 Patent.

With respect to the second prong of the *Advanced Bionics* framework, the Petition, while ignoring the fact that previously considered references include all of the cited elements of Argenta 2008, fails to explain or present any error, much less a material error, in the Office's consideration of the Argenta references. Therefore, under both prongs of the *Advanced Bionics* test, the Board should withdraw its institution of the Petition.

2. Biggie was Also Previously Considered.

Biggie, used by the Petition in Ground 2 was also previously explicitly considered and characterized by the Examiner as an all-in-one dressing, and is

present on the face of the '404 Patent. The Petition handwaves this away by stating "Biggie was not relied on by the Examiner, but was made of record and considered pertinent to applicant's disclosure..." (Pet. at 27). The Petition points to no error in the Examiner's consideration of Biggie; therefore, Biggie should be unavailable for use by Petitioner under the *Advanced Bionics* test.

3. 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 2 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 also 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 *supra* in more detail.

Table 3 below shows that Hu is cumulative of Biggie. ***Patent Owner does not admit that Petitioner's references to Hu in the Petition, and reproduced below in Table 3, nor the previously considered Biggie reference, show or suggest any of the '404 Patent claim elements.***

Table 3 – Secondary Reference Hu is Cumulative of Biggie

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.	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 teaches “[a]fter that pouch is inserted into a wound, it is covered with a flexible get sealing material, for example, a hydrocolloid gel.” (Pet. at 28). The Petition also states categorically that Hu’s “sealant layer may be ‘made of a hydrocolloid material.’” (Pet. at 27).

There is no difference between Biggie's hydrocolloid sealing material and Hu's hydrocolloid sealant layer, and Hu is cumulative of the disclosure in Biggie.

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, Biggie, and Hu are "the same or substantially the same prior art ... [as those] previously...presented to the Office," and Petitioner does not show any error in the Office's prior consideration of the references, the Board should reverse its institution decision.

Because the '404 Patent previously overcame a similar rejection as advanced by the Petition and the same or substantially the same references were previously considered by the Office, institution should be withdrawn under 35 U.S.C. § 325(d) under the *Advanced Bionics* framework.

VI. CONCLUSION

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

IPR2025-01042
Patent No. 10,639,404

PATENT OWNER'S
RESPONSE

Respectfully submitted,

/Joel Weiss/

Joel Weiss

Reg. No. 44,398

Attorney for Patent Owner

Date: March 5, 2026

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 Patent Owner's Response is approximately 10,250 words, which does not include the cover, the table or the certifications. This Petition therefore complies with the rule, which limits the Patent Owner 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,

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Attorney for Patent Owner

Date: March 5, 2026

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the **PATENT OWNER'S RESPONSE** was served on the 5th day of March 2026, by email to counsel for
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