

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Solventum Corporation,
Petitioner

v.

Wound Healing Technologies, LLC,
Patent Owner

Patent No. 10,639,404
Filing Date: June 3, 2011
Issue Date: May 5, 2020

Title: Wound Dressing

IPR2025-01042

PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 10,639,404 (the “’404 Patent”)
1002	Declaration of Dr. Morten O. Jensen, Ph.D., DrMed
1003	Morten Jensen <i>curriculum vitae</i>
1004	U.S. Publication No. 2008/0208147 (“Argenta”)
1005	U.S. Publication No. 2010/0042021 (“Hu”)
1006	U.S. Patent No. 10,639,404 File History
1007	U.S. Patent No. 6,071,267 (“Zamierowski”)
1008	U.S. Patent No. 7,520,872 (“Biggie”)
1009	U.S. Publication No. 2005/0131327 (“Lockwood”)
1010	U.S. Publication No. 2010/0137775 (“Hu775”)
1011	U.S. Publication 2007/0027414 (“Hoffman”)
1012	RESERVED
1013	Okan D., et al., <i>The Role of Moisture Balance in Wound Healing</i> , Advances in Skin and Wound Care, Vol. 20, No. 1 at 39 (Jan. 2007)
1014	U.S. Publication No. 2009/0234306 (“Vitaris”)
1015	U.S. Publication No. 2004/0073151 (“Weston”)
1016	Chariker, M.E., et al., <i>Effective management of incisional and cutaneous fistulae with closed suction wound drainage</i> , Contemporary Surgery, Vol. 34 at 59 (June 1989)
1017	Jerome, D., <i>Advances in Negative Pressure Wound Therapy The VAC Instill</i> , J. of Wound, Ostomy and Continence Nursing, 34(2) at 191 (March 2007)

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Exhibit No.	Description
1018	Thomas, S., <i>Hydrocolloid Dressings in the Management of Acute Wounds: a review of the literature</i> , Int'l. Wound J., 5(5) at 602 (2008)
1019	Bui, T.D., et al., <i>Negative Pressure Wound Therapy with Off-The-Shelf components</i> , Am. J. of Surgery, 192 at 235 (2006)
1020	Reserved
1021	Orgill D.P., et al., <i>The Mechanism of Action of Vacuum Assisted Closure: More to Learn</i> , Surgery 146(1) at 40 (2009)
1022	Miller-Mikolajczyk C., et al. <i>The Evolution of Commercial Negative Pressure Wound Therapy Systems over the Past Three Decades</i> , Adv. In Wound Care, 13(8) at 375 (2024)
1023	Argenta L.C. & Morykwas, M.J., <i>Vacuum-assisted Closure: A New Method for Wound Control and Treatment: Clinical Experience</i> , Annals Plastic Surgery, 38(6) at 563-576 (1997)
1024	Morykwas, M.J., et. al., <i>Vacuum-assisted Closure: A New Method for Wound Control and Treatment: Animal Studies and Basic Foundation</i> , Annals Plastic Surgery, 38(6) at 553 (1997)
1025	The Theory and Practice of Vacuum Therapy (Christian Willy, ed.) (2006)
1026	Williams, C. <i>Granuflex</i> , Br. J. Nurs., 3(14) at 730 (1994)
1027	Williams, C. <i>Hydrocoll: A 'New Breed' of Hydrocolloid Wound Dressing</i> , Br. J. Nurs., 7(21) at 1337 (1998)
1028	RESERVED
1029	Gabriel, A., et al., <i>A Clinical Review of Infected Wound Treatment with Vacuum Assisted Closure® (V.A.C.®) Therapy: Experience and Case Series</i> , Int'l Wound J., 6 (suppl. 2) at 1 (2009)
1030	Eaglestein, W.H., <i>Moist Wound Healing with Occlusive Dressings: A Clinical Focus</i> , Dermatologic Surgery 27 at 175-181 (2001)

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Exhibit No.	Description
1031	Field, C.K. & Kerstein, M.D., <i>Overview of Wound Healing in a Moist Environment</i> , Am. J. of Surgery, 167(1A(Suppl)) at 1S (Jan. 1994)
1032	<i>Wound Healing Technologies Corp. v. Solventum Corp.</i> , No. 6:24-cv-589 (W.D. Tex filed Nov. 15, 2024)
1033	Assignment of U.S. Application No. 13/152,446 from Isaac Lichtenstein to Wound Healing Technologies, LLC (June 3, 2011)

I. INTRODUCTION

Petitioner Solventum Corp. (“Solventum” or “Petitioner”) requests *inter partes* review (“IPR”) of claims 1-13 (the “Challenged Claims”) of Wound Healing Technologies, LLC’s (“Patent Owner”) U.S. Patent No. 10,639,404 (the “’404 Patent”) (EX1001).

The ’404 Patent relates to wound dressings for administering negative pressure wound therapy (“NPT”). For over a decade before the ’404 Patent was filed, those skilled in the art understood that NPT could promote wound healing. EX1001 at 1:30-35, 2:35-41; EX1019 at 235. The ’404 Patent describes the conventional components of prior art wound dressings used to administer NPT (EX1001 at 6:26-11:6, Figs. 1-6) but then suggests that the invention uses those components to allegedly “reduce the number and complexity of steps involved in wound-preparation for NPT” (EX1001 at 6:19-23, 28-30; Figs. 7-14).

The Challenged Claims, however, are not directed to any improved dressing that reduces complexity or the number of steps in NPT. Instead, they simply recite using prior art components to apply negative pressure to a wound. During prosecution, the Examiner determined that the pending claims were unpatentable in view of the prior art until the applicant amended the claims to require that the conventional wound dressing component called a “drape,” “cover,” or “vapor sealant sheet” be formed from a hydrocolloid material. Hydrocolloids were well-known

components of prior art wound dressing that could absorb fluid and aid in wound healing. EX1010 ¶¶45, 74-75; EX1013 at 49; EX1025; EX1026; EX1030 at 178; EX1031 at 2S-5S. Despite Patent Owner's reliance on the hydrocolloid limitation to gain allowance, hydrocolloid dressings were not a focus during prosecution. This Petition explains why the Challenged Claims would have been obvious in light of the large body of prior art related to use of hydrocolloid dressings. In Ground 1 (claims 1-7, 11, and 13), a typical NPT dressing described in Argenta is combined with a hydrocolloid material, like the cover disclosed in Hu. In Ground 2 (claims 8-10), Argenta and Hu are combined with Biggie, which is one of many references disclosing multi-lumen tubes for use in NPT. And in Ground 3 (claims 1, 4-7, 12), Argenta and Hu are combined with Lockwood, which discloses a specific configuration that can both withdraw and deliver fluid using multiple drains.

The Challenged Claims would have been obvious at the time of invention. The Board should institute review and cancel the Challenged Claims.

II. MANDATORY NOTICES, STANDING, AND FEES

A. Real Party-In-Interest

Petitioner Solventum Corp. is the real party-in-interest.

B. Related Matters

Wound Healing Technologies Corp. asserted the '404 Patent against Petitioners in currently-pending patent infringement litigation captioned *Wound*

Healing Technologies Corp. v. Solventum Corporation, No. 6:24-cv-589 (W.D. Tex. 2024) (the “Litigation”). In its complaint, Wound Healing Technologies Corp. alleged that it “is the sole owner by assignment of all right, title, and interest in and to the ’404 Patent, including all right to recover for any and all infringement of the ’404 Patent.” EX1032 ¶12. The face of the ’404 Patent identifies Wound Healing Technologies, LLC as the Patent Owner and the only recorded assignment in the USPTO Assignment Database shows an assignment of the ’404 Patent’s application from inventor Isaac Lichtenstein to Wound Healing Technologies, LLC, a New Jersey Corporation. EX1033 at 2.

C. Lead and Backup Counsel

Petitioners provide the following designations of counsel:

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D. Service Information

A Power of Attorney accompanies this Petition pursuant to 37 C.F.R. § 42.10(b). Please address all correspondence to:

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E. Certification of Grounds for Standing

Petitioners certify that the '404 Patent is eligible for IPR and that Petitioners are not barred or estopped from challenging the claims of the '404 Patent.

F. Fees

Under 37 C.F.R. § 42.103(a), Petitioners authorize the Office to charge the fee set forth in 37 C.F.R. § 42.15(a) to Deposit Account No. 50-2310, as well as any additional fees that might be due in connection with this petition.

III. THE LITIGATION

On November 15, 2024, Wound Healing Technologies Corp. filed a first complaint alleging that several of Solventum’s products infringe one or more claims of the ’404 Patent. Wound Healing Technologies Corp. served that complaint on Solventum on December 13, 2024. On March 3, 2025, Wound Healing Technologies Corp. filed an amended complaint, and Solventum responded on April 17, 2025. The court has not yet held a Rule 16(b) scheduling conference, and the parties have not yet exchanged formal claim construction positions.

IV. OVERVIEW OF THE ’404 PATENT

The ’404 Patent issued on May 5, 2020, based on U.S. Patent Application No. 13/152,446 (“the ’446 App”), filed on June 3, 2011. The ’446 App claims priority to U.S. provisional application No. 61/350,988 filed on June 3, 2010. The ’404 Patent is subject to the pre-AIA provisions of Section 35 of the U.S. Code.

A. Claims

The ’404 Patent contains 3 independent and 10 dependent claims. Independent claim 1 recites:

1. [1.a] A wound dressing comprising:
 - [1.b] a wound-fluid drain for use in negative pressure wound treatment (“NPT drain”);
 - [1.c] a vacuum/drainage tube comprising a terminus associated with the NPT drain, said NPT drain being configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound;

[1.d] fluid-absorbing/transferring layer for distributing negative pressure from the NPT drain, said fluid-absorbing/transferring material being in contact with the NPT drain;

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

[1.f] 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

[1.g] a tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet and a portion of the fluid-absorbing/transferring layer, the tube-anchorage component for mechanically maintaining placement of the NPT drain relative to the fluid-absorbing/transferring layer.

Independent claim 2 eliminates the non-simultaneous fluid withdrawal and delivery limitation, but requires a second tube-anchorage component. Claim 3 does not require an NPT drain, non-simultaneous withdrawal and delivery of fluids, or tube-anchorage components, but requires a “tube-exit-sealant component.” The dependent claims relate to features of the fluid-absorbing/transferring layer, the tube, and the drain.

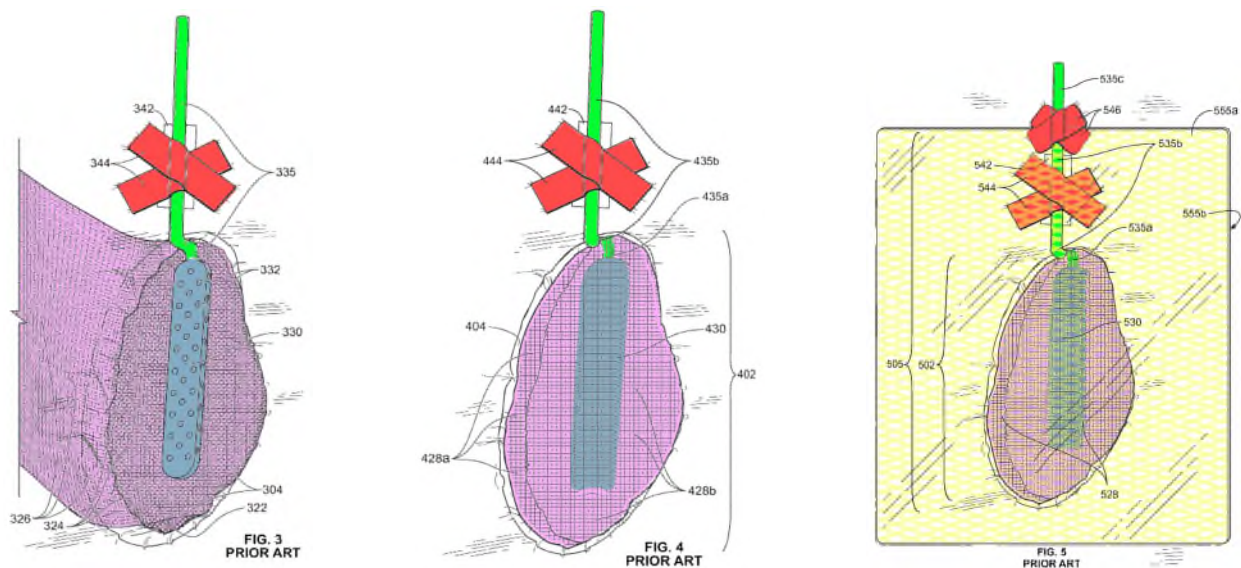
B. Specification

The '404 Patent relates to wound dressings for administering NPT. EX1001 at 1:12-15. NPT promotes wound healing by, among other things, removing wound exudate, *i.e.*, fluid generated by the healing process. EX1001 at 2:27-41. The '404

patent explains that this had conventionally been accomplished by packing a wound with material, inserting the terminus of a vacuum tube or drain, covering the wound, sealing the tube's exit from under the cover, and then applying suction from a vacuum source. EX1001 at 1:39-2:34, 7:8-11:6, Figs. 1-6.

1. Admitted Prior Art Disclosures

Figures 1 through 6 of the '404 Patent, each depicting "Prior Art," show a conventional prior art NPT dressing prepared from the initial step of wound preparation (Fig. 1) up through administration of negative pressure (Fig. 6). EX1001 at 6:26-11:6. Color coded Figures 3-5, below, depict how these admitted prior art components were assembled in a conventional NPT dressing.



EX1001 Figs. 3-5 (excerpts, color added). The '404 Patent explains that these prior art components include:

a. Drain

A drain (330/430/530 (blue)) can be of any suitable shape and is generally perforated allowing fluid communication from the packed wound to the inside of the drain. EX1001 at 8:8-13.

b. A vacuum/drainage tube

A vacuum/drainage tube (335/435a-b/535a-c (green)) has its near terminus 435a/535a associated with the blue NPT drain. EX1001 at 8:14-23. Under negative pressure, wound exudate is drawn from the wound through wound packing material and the drain and then out through the vacuum/drainage tube. EX1001 at 10:27-31.

c. Packing material

Packing material (324/326/428/528 (purple)) such as gauze or foam (e.g., “V.A.C.® GRANUFOAM™”) fills the wound bed and surrounds the drain. EX1001 at 7:58-8:3. This prior art packing material can be layered in the wound and include upper and lower layers. EX1001 at 9:8-11, 52-56.

d. Draping material

Draping material (555 (yellow hatch pattern)) covers the packing material/tube and adheres to the skin around the wound allowing a vacuum source connected to the tube to provide negative pressure under the draping material and over the wound. EX1001 at 9:33-65.

e. Adhesive strips and Adhesive material

Adhesive strips (344/444/544 (red under draping material 555)) and adhesive material (546 (red overtop of draping material 555)) are used to anchor the vacuum/drainage tube in place and seal the tube's exit from the draping layer. EX1001 at 9:59-65.

2. The Alleged Invention

After detailing conventional prior art wound dressings, the '404 Patent goes on to describe the alleged invention, which consists of these same components.

a. An NPT drain

An NPT drain (EX1001 at 11:47-12:10) is broadly described to include a hollow tube-like structure with holes (EX1001 at 11:47-53) but may be “as structurally straightforward as a section of tube featuring a single hole” (EX1001 at 11:47-64). The drain may be “integrally continuous with [the] vacuum/drainage tube.” EX1001 at 18:61-62.

b. A vacuum/drainage tube

A vacuum drainage tube (EX1001 at 12:11-13:7) has one terminus associated with the drain (EX1001 at 12:11-17). The hollow core of the tube may be continuous with the hollow tube of the drain. EX1001 at 12:19-20.

c. Fluid-absorbing/transferring material

Fluid-absorbing/transferring material (EX1001 at 13:8-57) surrounds the drain and can be made of gauze or foam. EX1001 at 13:8-10, 28-36.

d. Vapor sealant sheet

A vapor sealant sheet (EX1001 at 15:5-57) overlies the fluid-absorbing/transferring layer and can extend beyond that layer to provide a perimeter that adheres in an airtight fashion. EX1001 at 15:5-14. The vapor-sealant sheet may be made of a “suitable hydrocolloid material or other suitable material that is non-hydrocolloid.” EX1001 at 15:14-20. The vapor sealant sheet may mechanically maintain the placement and orientation of the fluid-absorbing/transferring layers. EX1001 at 15:29-32.

e. Tube-anchorage and tube-exit-sealant components

Tube-anchorage components and tube-exit-sealant components (EX1001 at 15:58-17:55), are used to maintain the vacuum tube and drain in place and to seal the location of the tube’s exit from the vapor sealant sheet. EX1001 at 15:58-63, 16:3-11. The specification explains that a single component can operate as either or both the tube-anchorage or the tube-exit-sealant components. EX1001 at 15:58-17:55. The specification describes these components as sealing the area around the tube-exit from the vapor sealant sheet to “mechanically contribute to tube-fixity.” EX1001 at 16:16-24, 17:1-6. They may overlie part or all of the vapor sealant sheet

(or may extend beyond the vapor sealant sheet), and can provide suitable flexibility, thickness, anchorage-strength, or air-tightness-sealing. EX1001 at 16:40-54, 17:6-10. Like a piece of tape, these components can be “sealed onto vapor sealant sheet 757 by adhesion of the materials of component 745 and sheet 757.” EX1001 at 16:58-60.

f. Draping layer

An unclaimed “draping layer” can lie at the bottom of the dressing, immediately below the fluid-absorbing/transferring layer, and can optionally sit on top of additional wound packing material. EX1001 at 13:58-66, 14:20-54, 19:1-4.¹ The draping layer may be the most “wound-proximal” component of the dressing. EX1001 at 19:8-9.

C. Priority Date and Prosecution History

The '404 Patent's application was filed on June 3, 2011, and the Patent issued on May 5, 2020. The '404 Patent claims priority to provisional application No. 61/350,988, filed June 3, 2010.

¹ The '404 Patent uses the term “draping” differently when discussing the prior art. The “draping material” in the description of the prior art (EX1001 at 9:37-65) covers the device and creates a seal analogous to the “vapor sealant sheet” (EX1001 at 15:5) of the alleged invention.

The originally filed claims included limitations corresponding to the drain, tube, fluid-absorbing material, draping layer, vapor sealant sheet, and tube-anchorage components. EX1006 at 430-433 (June 3, 2011 Claims). In response to various rejections, the applicant amended the claims to require, among other things, (1) the drain be configured to non-simultaneously withdraw and deliver fluid (EX1006 at 326 (Feb. 13, 2013 Amendment at 4)), (2) the vapor sealant sheet be “formed from a hydrocolloid material” (EX1006 at 261 (Mar. 5, 2014 Amendment at 4)), and (3) the vapor sealant sheet include an adhesive “located over at least a central zone of a wound-facing surface of the vapor sealant sheet” (EX1006 at 216 (Dec. 19, 2014 Amendment at 2)).

In response to a final rejection, the Applicant filed an appeal brief arguing, among other things, that one cited reference (Vitaris (EX1014)) did not disclose a drain configured to withdraw and deliver fluid because the tube in that reference included a one-way valve and could therefore not be used to deliver fluid ***at all***. Applicant also argued that another cited reference (Weston (EX1015)) did not include adhesive in the central zone. EX1006 at 157-160 (Jan. 25, 2016 Appeal Br. at 7-10).

The Examiner disagreed with the applicant’s interpretation of Weston but reopened prosecution and withdrew the relevant rejections because of a “changed interpretation” of the tube-anchorage components. Specifically, the Examiner

concluded that those terms were means-plus-function terms under 35 U.S.C. § 112(f), and the disclosed structure did not read on the art of record. But then the Examiner issued a new rejection for certain claims based on a reference that disclosed a hydrocolloid adhesive around the perimeter of a vapor sealant sheet. EX1006 at 108-111 (Jan. 26, 2017 Non-final Rejection at 2-5). The Examiner and Applicant continued to dispute construction of the alleged means-plus-function terms through an appeal. EX1006 at 86-89 (July 20, 2017 Appeal Br. at 7-10), 75-78 (Nov. 27, 2017 Examiner’s Answer at 3-6), 64-65 (Jan. 9, 2018 Reply Br. at 2-3).

The PTAB ultimately held that a hydrocolloid adhesive disposed along the periphery of a sheet made of a different material does not teach a vapor sealant sheet “formed from a hydrocolloid material.” EX1006 at 59 (Dec. 9, 2019 PTAB decision at 5). The examiner allowed the claims, reiterating her means-plus-function interpretation. EX1006 at 20-22 (Notice of Allowability at 2-4). Prior to issuance, the applicant submitted a letter stressing that the terms should **not** be construed under § 112(f) and inviting the Examiner to reopen prosecution if she continued to disagree. EX1006 at 3-7 (Mar. 27, 2020 Letter). The PTO issued the Issue Notification a few weeks later. EX1006 at 1.

V. CLAIM CONSTRUCTION

In an IPR claim terms are construed “using the same claim construction standard that would be used to construe the claim in a civil action . . . including

construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). A petition must set forth how the challenged claims are to be construed. 37 C.F.R. § 42.104(b)(3). However, the Board need only construe terms if necessary to resolve the disputes between the parties. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Petitioner does not believe any terms require specific construction except as otherwise discussed herein.

A. “tube-anchorage” and “tube-exit-sealant” components

During prosecution the Examiner and the applicant disputed the meaning of the “tube-anchorage” terms. The examiner construed these terms as means-plus-function terms and the applicant insisted they should be construed according to their plain and ordinary meaning. See § IV.C, above. For purposes of this petition, these terms should be construed based on their plain and ordinary meaning.

Where a party’s proposed construction in an IPR differs from a construction it has proposed in a different forum, the party should explain that difference. *Cambridge Mobile Telematics, Inc. v. Sfara, Inc.*, IPR2024-00952, Paper 12 (Dec. 13, 2024) (designated informative Mar. 20, 2025). This is particularly true where a party has suggested the importance of construing a term as a means-plus-function term in another forum. *Id.* at 7-8 (“Petitioner clearly and emphatically stated that

whether the ‘component’ terms are means-plus-function limitations is a dispositive issue for the litigation”). In IPR proceedings, petitioners may rely on claim constructions that a patent owner advanced in other proceedings. *See, e.g., 10X Genomics, Inc. v. Bio-Rad Labs., Inc.*, IPR2020-00086, Paper 8, 17-22 (April 27, 2020).

Here, the parties have not yet proposed any claim constructions in the district court, nor has Petitioner provided any contentions suggesting a specific construction for the terms. However, during prosecution Patent Owner repeatedly and adamantly argued for a plain meaning interpretation instead of interpretation under § 112(f) (*see* § IV.C, above). Based on Patent Owner’s forceful argument for a plain and ordinary construction during prosecution (EX1006 at 3-7 (Mar. 27, 2020 Letter)), that is presumably the interpretation Patent Owner will continue to advance during the litigation. Accordingly, for purposes of the petition, Petitioner adopts Patent Owner’s plain and ordinary construction.

B. “NPT drain being configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound”

This term should be construed as “an NPT drain capable of non-simultaneously withdrawing fluid from a wound and delivering fluid to the wound.” First, the plain claim language does not require that the drain actually withdraw and deliver fluid—only that it is configured to do so.

Second, the intrinsic record compels such a construction. The specification does not provide any description of how a drain must be configured to withdraw and deliver fluid. To the contrary, the specification refers to standard vacuum tubes for withdrawing or delivering fluid through a standard drain. EX1001 at 20:59-21:10; Figs. 7A-C (component 1135). Finally, during prosecution the applicant successfully overcame a rejection by arguing the reference did not meet this term because the drain was associated with a vacuum tube containing a one-way valve that prevented fluid from being delivered. In other words, the drain in that device could not withdraw and deliver fluid because it was configured to **only** withdraw fluid. EX1006 at 160 (Jan. 25, 2016, Appeal Br. at 10).

VI. LEVEL OF ORDINARY SKILL IN THE ART

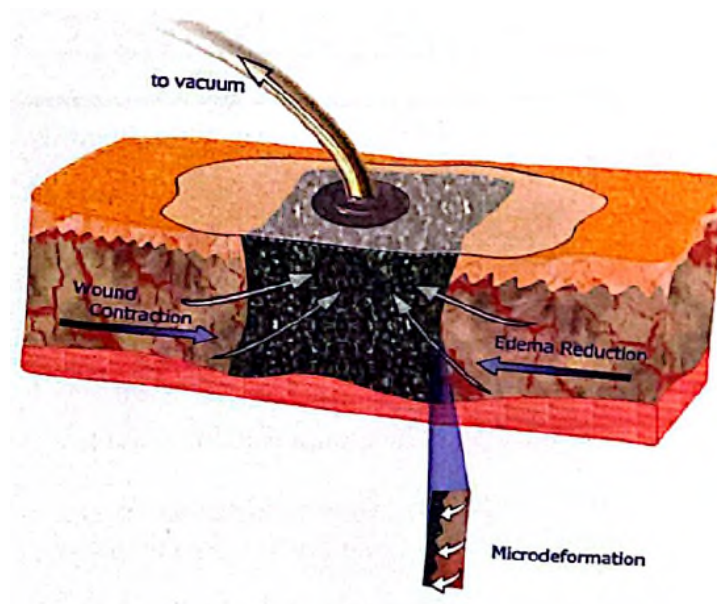
A person of ordinary skill in the art (“POSA”) at the time of the earliest priority application of the ’404 Patent would have a bachelor’s degree in biomedical engineering and either (1) a master’s degree in biomedical engineering, or (2) three years of relevant industry experience working with wound dressings as of June 3, 2010. See EX1002 ¶¶30-31.

VII. SUMMARY OF PRIOR ART

A. Negative Pressure Therapy Devices

Throughout the early-1990’s, Drs. Louis Argenta and Michael Morykwas conducted the pioneering work that led to modern NPT therapy and the first

commercial NPT device (the V.A.C.® therapy device), approved by the FDA in 1995. EX1022 at 376, 379. That device consisted of a vacuum pump, a canister and connecting tube, an open-pore foam, and a semi-occlusive dressing. EX1021 at 41. By 1997 Argenta and Morykwas published results suggesting that their device aided in healing by increasing blood flow, withdrawing fluid, and providing mechanical forces to the surrounding tissue. EX1022 at 376; EX1023 at 572-575; EX1024 at 558-561. By 2009, these, and more, benefits of NPT were well-known. EX1021 at 41-42; *see also* EX1005 ¶2 (identifying beneficial effects of NPT); EX 1002 ¶¶64-72.



EX1021 at 42, Fig. 1 (depicting mechanisms of wound healing when using a V.A.C.® device).

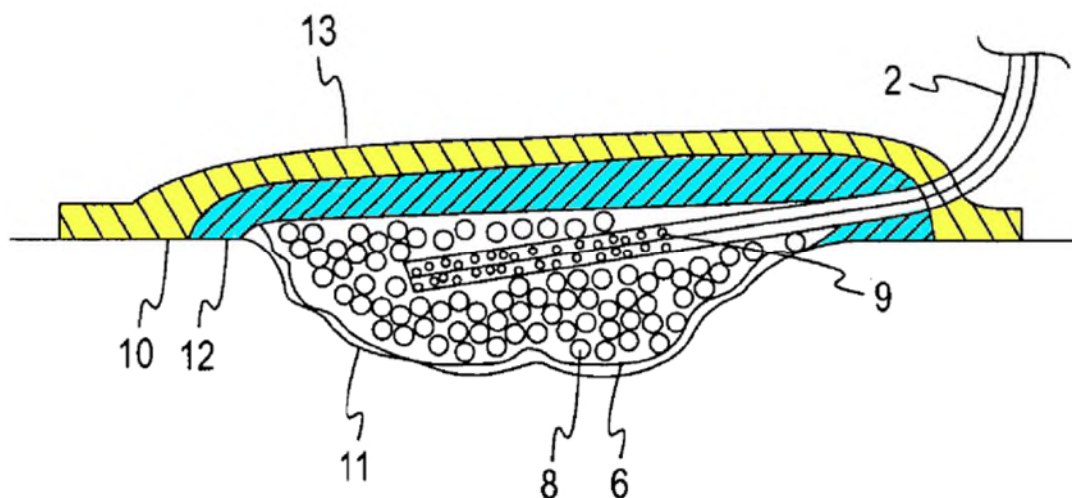
In addition to V.A.C.® therapy devices, various configurations of NPT devices were proposed that would provide these same wound healing benefits. Some

devices included a drain, or vacuum tube inserted into the foam or gauze wound packing material like the depiction of the conventional prior art device in the '404 Patent. EX1001 at 8:8-23. For example, it was common for physicians to use a standard Jackson-Pratt drain as the drain in an NPT dressing. EX1019 at 235-236 (describing creation of an NPT system using off the shelf components including a Jackson-Pratt drain); EX1016 at 60-61 (depicting and describing Jackson-Pratt drain as a flat fenestrated drain that can be inserted into a wound). EX1002 ¶¶53, 108, 141. Indeed, the admitted prior art drain depicted in Figure 3 of the '404 Patent appears nearly identical to the “Jackson-Pratt” drain used in EX1016. *Compare* EX1001 at Fig. 3 *with* EX1016 at 61; EX1002 ¶ 53.

It was also common to embed the end of the vacuum tube or the drain into the material packed into the wound, as admitted in the '404 Patent. EX1001 at 9:12-17; *see also* EX1004 ¶17 (describing tube embedded into screen); EX1015 at ¶47 (“tubing 45 is embedded within the absorbable matrix 32 for providing suction or reduced pressure within the enclosure provided under the wound cover”); EX1008 at 3:64-5:7, 5:27-28.

The prior art described a number of materials that could be used as a cover to seal the wound and allow application of negative pressure therapy. For example, many devices used either an adhesive or non-adhesive film, much like the admitted prior art in the '404 Patent. EX1001 at 9:37-65 (describing flexible, contour-

conforming drape); EX1004 ¶15 (self-adhesive Ioban® and OpSite® drapes); EX1009 ¶86 (semi-permeable films Tegaderm™ and OpSite™ used as drapes). Some references, like Hu, described using hydrocolloid material as the cover in an NPT dressing. EX1005 at ¶59 (sealant layer made of a hydrocolloid material); EX1010 at ¶¶6, 70, 74-75 (explaining advantages to using a hydrocolloid sealant sheet); §VII.B, below. Others used combinations of hydrocolloids and standard drapes. For example, Biggie, a U.S. patent that claims priority to 2002 describes a dressing that uses a pre-formed pouch as the wound filler. EX1008 at 4:40-64. Tubing is inserted into that pouch and the wound is sealed with a flexible gel—such as a hydrocolloid gel—that covers the pouch area, healthy skin, and tubing. EX1008 at 5:27-44, 7:57-8:4. A standard wound draping layer is then applied to cover the gel layer, to protect it from dirt and damage, and to “add[] extra support” to the dressing. EX1008 at 8:5-18. Figure 5 depicts the hydrocolloid layer (12, blue), and the standard drape (13, yellow).



EX1008 Fig. 5 (color added).

By at least 1996, doctors began using these devices to irrigate the wound and to instill medication into the wound area. EX1017 at 192; EX1025 at 33. Such instillation therapy includes turning off the vacuum, instilling the desired solution into the foam of an NPT dressing, and then after a set time without suction the vacuum is turned back on and the drug is removed. EX1025 at 34. This allows time for the drug to take effect. EX1025 at 34. In 2003 the V.A.C.® Instill was introduced. EX1017 at 192. The V.A.C.® Instill is a modified V.A.C.® device that allows clinicians to add solutions to a wound in between cycles of NPT. EX1017 at 192. Instillation therapy (the non-simultaneous delivery and withdrawal of fluid) is different from the continuous irrigation-suction technique (simultaneous delivery and withdrawal) that was also known at the time. EX1025 at 35 (“Instillation therapy should not be confused with the irrigation-suction drainage described by Willenegger”). Other prior art references disclose a simple switch-valve that would allow one to use the same tube/drain for both instillation/irrigation and for suction. EX1009 ¶88, Fig. 1; § VII.C.4, below.

B. Advancements in Moist Wound Healing and Types of Wound Dressings

Over the second-half of the 20th century, the medical community experienced a paradigm shift in its understanding of wound healing. EX1013 at 40. Until the 1960’s, “it was widely accepted that successful wound healing depended on

maintaining a dry wound bed.” EX1013 at 40. But by the early-1960’s, studies began to show that a moist wound environment promoted healing. EX1013 at 40; EX1030 at 175-177; EX1002 ¶¶77-79. By 2010 it had become widely accepted that moisture-retentive dressings that maintained a warm, moist wound environment hastened the healing of both acute and chronic wounds. EX1013 at 40; EX1030 at 175-177; EX1031 at 2S. Skilled artisans at this time understood that wound exudate includes natural growth factors and that a moist environment containing such exudate facilitates cellular growth, collagen proliferation, and ultimately aids in wound healing. EX1013 at 40; EX1031 at 3S; EX1002 ¶79. But POSAs also understood that it was important to properly balance the moisture of the wound environment—inadequate moisture could lead to wound desiccation, necrosis and a poor wound healing rate. EX1013 at 40; EX1010 ¶74; EX1002 ¶80. Excessive moisture could cause the surrounding skin to become irritated and macerated, and also increase the time needed to heal. EX1013 at 40. That understanding led to development of wound dressings designed to optimize moisture levels in the wound. EX1013 at 41; EX1002 ¶¶81-84.

By 2010, those skilled in the art were familiar with many types of standard wound dressings for creating a moist wound environment. EX1013 at 41, 44, Table 2; EX1030 at 177-180; EX1002 ¶¶81-84. For example, standard absorbent dressings could be made of gauze, calcium alginate, or certain types of foam. EX1013 at 47-

48; EX1030 at 178; EX1002 ¶¶83-85. Standard hydrating dressings, which trap moisture and create a moist wound environment, could be made of hydrogels, hydrocolloids, and polyurethane films. EX1013 at 48-50; EX1030 at 178; EX1002 ¶¶83-85.

Marketed since the 1970's and 1980's, hydrocolloid dressings were the first type of modern moist wound healing dressing to become widely available. EX1013 at 49. Hydrocolloids are polymers generally comprising carboxymethyl cellulose, pectin, or other materials that absorb liquid. EX1013 at 49; EX1027 at 1337; EX1030 at 177, 178; EX1002 ¶86. The hydrocolloid material is often formed between adhesive and polyurethane layers (EX1013 at 49) and can be created of varying thickness or rigidity (EX1010 ¶110).² As the hydrocolloid material becomes saturated with wound exudate it forms a gel that includes the beneficial components of the wound exudate and maintains the moist environment that aids in wound healing. EX1013 at 49; EX1018 at 610; EX1030 at 178. Importantly, the

² Hu775 (EX1010) discloses a similar device as Hu (EX1005), but claims priority to different applications. Hu775 was filed on Nov. 25, 2009, and published on June 3, 2010, the same day that the '404 Patent's provisional application was filed. Hu775 is prior art under 35 U.S.C. 102(e), but, in any event, describes what POSAs understood as of June 3, 2010.

hydrocolloid material can interact with both the wound surface and the sensitive periwound skin (the skin around the wound) to aid in healing. EX1010 ¶¶74; EX1013 at 49; EX1025 at 352-353, 373; EX1026 at 730-732; EX1027 at 1337; EX1002 ¶¶86-90.

Several studies found hydrocolloid dressings to be superior in healing time as compared to standard wet to dry dressings, more cost effective, and generating the lowest frequency of ulcer recurrence. EX1013 at 49; EX1002 ¶¶91. Hydrocolloid dressings were also understood to create a slightly acidic wound environment and were therefore associated with lower rates of infection than standard wet-to-dry saline dressings. EX1013 at 49.

A “film dressing” is another standard hydrating dressing that is generally made of polyurethane or another synthetic polymer. EX1013 at 49; EX1030 at 178. Examples of film dressings are Tegaderm™ and OpSite™ drapes, which were often used as the cover in prior art NPT dressings. EX1004 ¶15; EX1007 at 4:14-23; EX1030 at 178; EX1002 ¶ 92. Standard film dressings are semi-permeable but have no capacity to absorb wound exudate, and leakage channels can form from the periphery when excess exudate is produced. EX1013 at 49. Film dressings can include adhesive on the wound side but can be difficult to apply and “may adhere to themselves even in the hands of an experienced clinician.” EX1013 at 49; EX1002

¶ 93. Some reports have identified increased rates of infection associated with film dressings. EX1013 at 49-50.

C. Specific References Supporting Grounds of Unpatentability

1. U.S. Publication No. 2008/0208147 (EX1004) (“Argenta”)

Argenta published on August 28, 2008, is prior art under 35 U.S.C. § 102(b), and was not considered during prosecution of the '404 Patent. A different Argenta publication related to an apparatus for cardiac tissue modulation was considered. EX1006 at 114-115 (Jan. 26, 2017 non-final rejection at 8-9).

Argenta discloses an apparatus and method for treating wounds with varying negative pressure. EX1004 ¶1. Figure 1 (top view) and Figure 2 (side view) of Argenta's device are shown below.

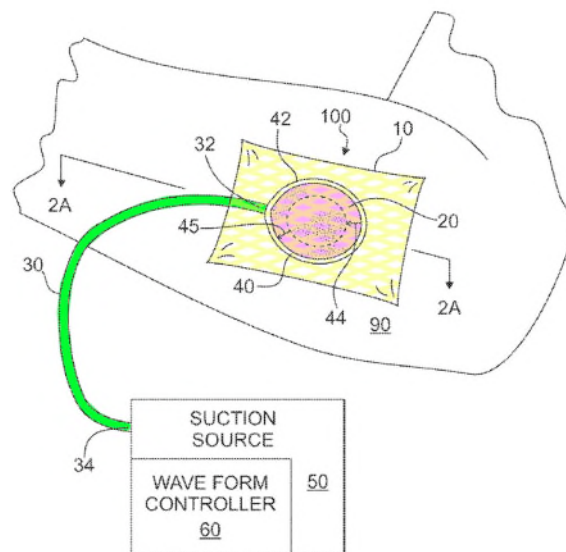


Fig. 1

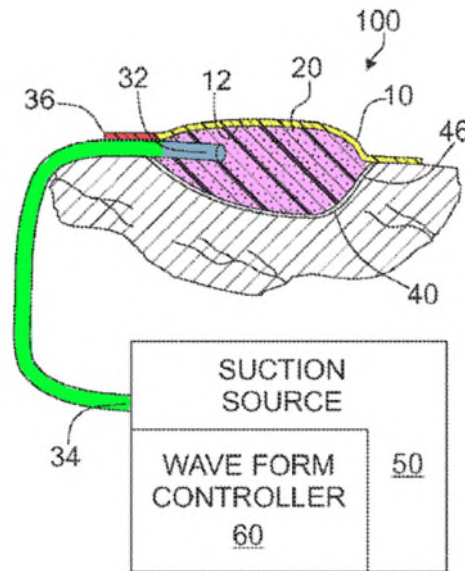


Fig. 2A

EX1004 Figs. 1 & 2A (color added). The device disclosed in Argenta includes a tube 30 (green) with a distal end 32 (blue). The distal end of the tube may be fenestrated (i.e., have holes) or may be associated with a Jackson-Pratt drain. EX1004 ¶20. Distal end 32 of the tube can be embedded in a screen 20 (purple), which can “promot[e] even distribution of sub-atmospheric pressure under the cover.” EX1004 ¶17, *see also id.* ¶20. Argenta explains that screen 20 can be cut to fit and fill a patient’s wound and can be made of a variety of materials including foam and gauze. EX1004 ¶¶18, 19.

Argenta’s wound dressing also includes a cover 10 (yellow), which is placed over top of screen 20 and adheres to the skin around the wound and to screen 20. EX1004 ¶19 (“The screen 20 may be held in place by contacting an adhesive coated

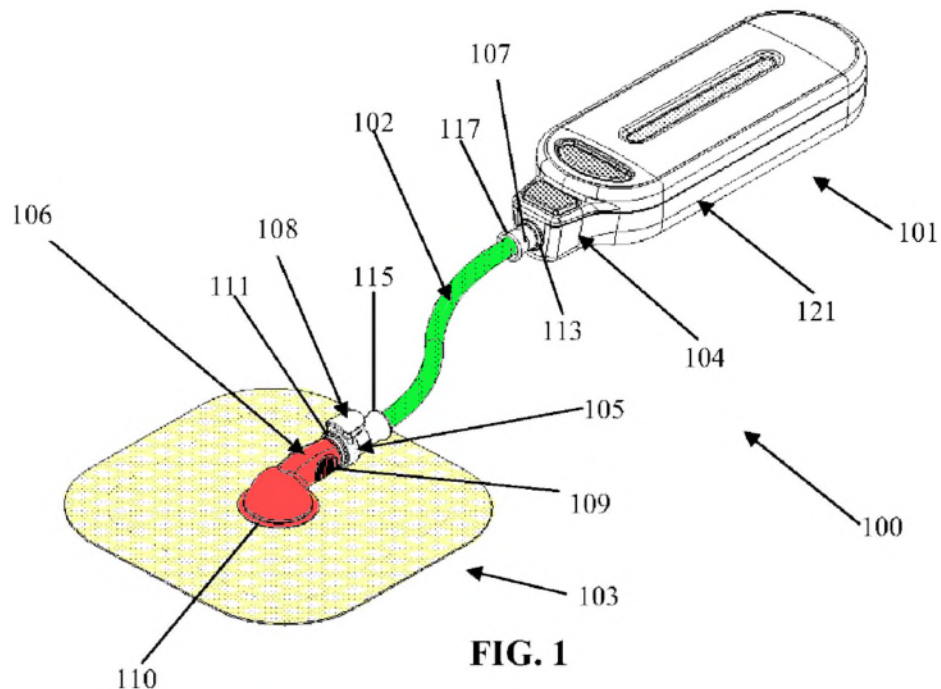
under surface 12 of the cover 10 to assist in securing the screen 20 in a fixed position and to assist in the removal of the screen 20 when the cover 10 is removed.”).

To deliver negative pressure, the tube in Argenta’s device communicates with the screen 20 through port 36 (red), which can comprise an edge of cover 10 (such as a mesentery) or can be formed as an opening, nipple, or other suitable structure on the surface of cover 10. EX1004 ¶20. Cover 10 can include an adhesive permitting it to “attach[] and/or immobilize other components of the apparatus . . . such as suction tube 30.” EX1004 ¶15. Delivery of sub-atmospheric pressure can then be provided by suction source 50.

2. U.S. Publication No. 2010/0042021 (EX1005) (“Hu”)

Hu published on February 18, 2010 based on an application filed on February 17, 2009. Hu is prior art under both 35 U.S.C. §§ 102(a) and 102(e) and was not considered during prosecution of the ’404 Patent.

Hu discloses devices configured to apply a vacuum to a wound. The devices disclosed in Hu use a sealant layer (103 (yellow)) that covers the wound, a tube (102 (green)), and a suction apparatus (101). EX1005 ¶¶55, 74, Fig. 1. The suction apparatus generates negative pressure that is transmitted through the tube and under the sealant layer 103.



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.

Fluid communication to the interior of the enclosure is provided by the attachment port (106) (red) on the sealant layer. EX1005 ¶¶57, 74, Fig. 1. Despite Hu's disclosure of an NPT device with a cover formed from a hydrocolloid material, it was not identified during prosecution.

3. U.S. Patent No. 7,520,872 (EX1008) (“Biggie”)

Biggie is a U.S. Patent issued on April 21, 2009 and is prior art under 35 U.S.C. § 102(b). Biggie was not relied on by the Examiner, but was made of record and considered pertinent to applicant's disclosure for teaching an "all-in-one wound

dressings for use in negative pressure therapy, including multiple layers and drainage tube adhesive means.” EX1006 at 347 (August 13, 2012 Non-Final Rejection at 4).

Biggie teaches a wound dressing that comprises a pouch filled with beads or other material that function as the fluid-absorbing/transferring layer. EX1008 at 4:10-24. After that pouch is inserted into a wound, it is covered with a flexible gel sealing material, for example, a hydrocolloid gel. EX1008 at 6:31-46, 7:1-6, 7:57-8:4. That gel layer is then covered with a protective cover 13. EX1008 at 6:47-53. A multi-lumen tube is inserted into the pouch, with one or more lumens connected to a vacuum source to generate negative pressure, and one or more lumens attached to other sources to, for example, deliver medicament to the wound. EX1008 at 5:8-14, 5:61-6:16.

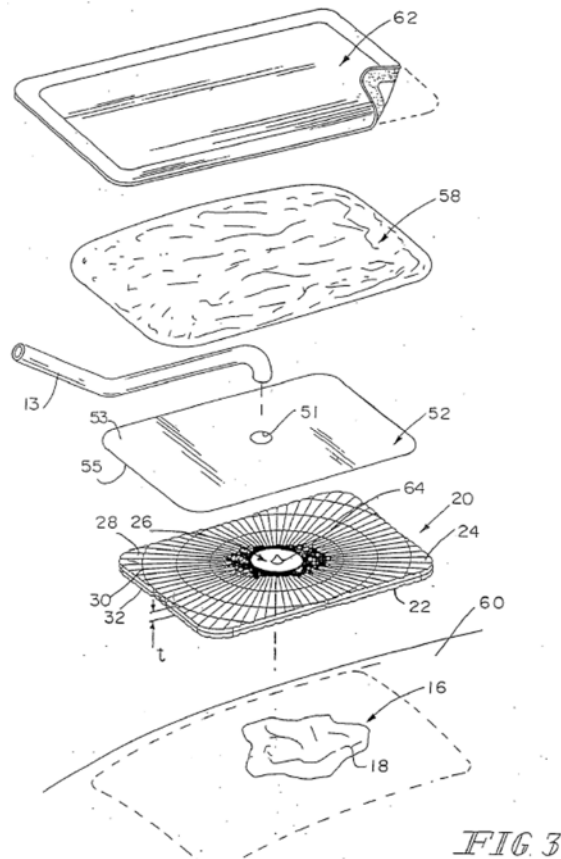
4. U.S. Publication No. 2005/0131327 (EX1009) (“Lockwood”)

Lockwood published on June 16, 2005 and is prior art under 35 U.S.C. § 102(b). Patents and publications that do not claim priority to the same applications as Lockwood, but also name Lockwood as an inventor, are identified on the face of the ’404 Patent and the Examiner relied on one of them (U.S. 2004/024073) for the disclosure that tape satisfies the ’404 Patent’s tube-anchorage component limitation.³

³ The Applicant did not dispute that U.S. 2004/024073 disclosed a tube-anchorage component and overcame that rejection based on unrelated amendment

Lockwood (U.S. 2005/0131327) was not considered during prosecution of the '404 Patent.

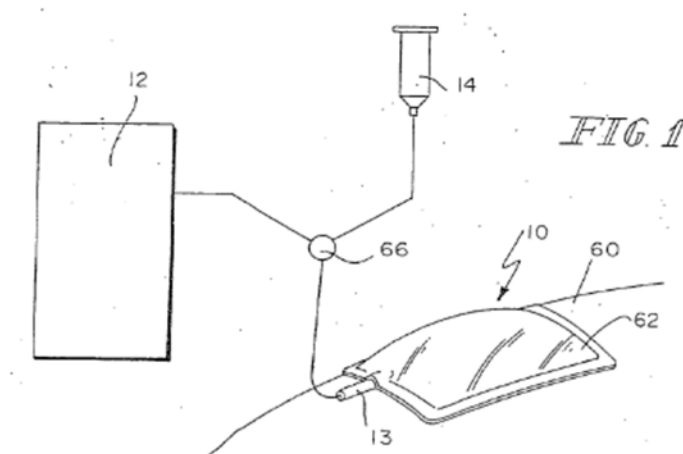
Lockwood discloses a negative pressure wound dressing that includes a flexible member 20 with channels and holes that communicate with a port 51. EX1009 ¶¶30, 78, 84, Fig. 3. A vacuum/irrigation tube 13 is connected to the port through a cover 52. Packing material 58 overlies member 20 and cover 52, and then a film 62 is placed over the packing material as shown in Figure 3:



overcoming a different reference in the combination. EX1006 at 161-163 (Jan. 25, 2016 Appeal Br. at 11-13).

EX1009, Fig. 3. Lockwood further discloses that the tube can be associated with a switch valve that can be used to toggle between vacuum and irrigation options.

EX1009 ¶88, Fig. 1:



EX1009, Fig. 1 (excerpt). Lockwood further discloses that one can use a plurality of ports and tubes to distribute the pressure and irrigation more evenly throughout the dressing. EX1009 ¶89, Fig. 15.

VIII. STATEMENT OF PRECISE RELIEF REQUESTED AND REASONS THEREFOR UNDER 37 C.F.R. §§ 42.104(B)(1) AND (2)

Petitioner requests review of the Challenged Claims under 37 C.F.R. § 42.108 and cancellation of these claims as unpatentable on the following grounds:

Ground	Claims	Obvious under 35 U.S.C. § 103
1	1-7, 11, 13	Obvious over Argenta on its own and/or in view of Hu
2	8-10	Obvious over Argenta in view of Biggie or in view of Biggie and Hu

3	1, 4-7, 12	Obvious over Argenta in view of Lockwood or in view of Lockwood and Hu
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IX. Each Challenged Claim of the '404 Patent is Unpatentable

Pursuant to 37 C.F.R. § 42.104(b)(4)-(5), the Challenged Claims are unpatentable for the reasons set forth in detail below.

A. GROUND 1: Claims 1-7, 11, and 13 Would Have Been Obvious over Argenta on its own and/or in view of Hu

1. Claim 1

1[a]. “A wound dressing comprising:”

The preamble provides only an intended use and does not provide antecedent basis for any term in the body of the claim. Accordingly, the preamble here should not be construed as limiting. *Arctic Cat Inc. v. GEP Power Prods.*, 919 F.3d 1320, 1328-29 (Fed. Cir. 2019).

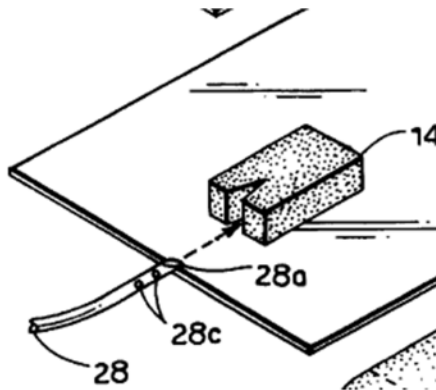
To the extent the preamble is a limitation, both Argenta and Hu disclose wound dressings. The '404 Patent admits that wound dressings for NPT were known and conventional in the prior art. EX1001 at 6:26-11:6. Argenta discloses the same type of NPT apparatus that is described as a wound dressing in the '404 Patent. EX1004 ¶¶3-4, 15; EX1001 at 6:15-30. Hu also discloses a similar NPT apparatus with a sealant layer adapted to cover a wound, that may optionally cover a contact layer matrix placed in a wound bed and promote wound healing. EX1005 ¶57. Both of these devices would be considered “wound dressings.” EX1002 ¶107.

**1[b]. “a wound-fluid drain for use in negative pressure
wound treatment (“NPT drain”);”**

The '404 Patent admits that wound-fluid drains were conventional and well-known in the prior art for use in NPT. For example, in the section discussing admitted prior art, the '404 Patent depicts a “representative conventional NPT drain” shown placed upon early layering of packing material. EX1001 at 8:5-8; Fig. 3.

Argenta discloses such an NPT drain because it discloses an NPT dressing and expressly states that tube 30 may be fenestrated along the part under the cover, or that it may comprise a Jackson-Pratt drain. EX1004 ¶20; EX1002 ¶¶108-109. Specifically, Argenta discloses that, “in 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.” EX1004 ¶20. That is the same type of “drain” described in the '404 Patent—a tube-like structure with holes that provide access to the drain and that the drain can be integrally continuous with the tube. See § IV.B.2.a, above; EX1001 at 11:47-57, 18:61-64.

Furthermore, during prosecution the examiner relied on the disclosure of the orifices (28c) at the end of suction tube 28 of Figure 1 in U.S. Patent No. 6,071,267 (“Zamierowski” (EX1007)) as disclosing the claimed drain. See EX1006 at 301-302 (May 17, 2013 Final Rejection at 6-7); EX1007 at Fig. 1.



EX1007, Fig. 1 (excerpt focusing on tube 28). The applicant did not dispute the examiner's interpretation, instead overcoming the rejection by adding limitations unrelated to the drain. See EX1006 at 280, 288-290 (Oct. 17, 2013 Amendment and Remarks at 4, 12-14).

Moreover, Argenta expressly discloses use of a Jackson-Pratt drain. EX1004 ¶20. A Jackson-Pratt drain was a common prior art drain used to remove wound exudate in an NPT dressing. EX1016 at 60-61 (explaining technique of using a Jackson-Pratt drain for NPT); EX1002 ¶¶53, 108, 141. Jackson-Pratt drains look nearly identical to the drain that the '404 Patent depicts in prior art Figure 3, and in Figure 9, depicting the claimed invention. Compare EX1016 at 61 (depicting a Jackson-Pratt drain) with EX1001 at Figs. 3 & 9; EX1002 ¶53. Argenta's express disclosure of a fenestrated end and of a Jackson-Pratt drain satisfy the limitation requiring an NPT drain. EX1002 ¶¶108-109.

1[c]. “a vacuum/drainage tube comprising a terminus associated with the NPT drain, said NPT drain being configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound;”

The '404 Patent also admits that a vacuum/drainage tube with a terminus associated with an NPT drain was conventional in the prior art. EX1001 at 8:14-23. The '404 Patent depicts such a tube in Figures 3-6 (e.g., component 335 in Figure 3).

Argenta also discloses such a tube (tube 30), which provides sub-atmospheric pressure to the wound. EX1004 ¶20. Tube 30 has distal end 32 (the “terminus”) that may be disposed under the cover and embedded within screen 20. EX1004 ¶20. The terminus of Argenta’s tube is attached or otherwise associated with both the fenestrated portion or the Jackson-Pratt drain so that Argenta can distribute negative pressure throughout the screen. EX1004 ¶20, Figs. 1, 2; EX1002 ¶110.

Argenta discloses a “drain being configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound.” The drain in Argenta is directly connected to tube 30. Tube 30 has a single lumen that could not possibly allow simultaneous delivery and withdrawal of fluid, and neither tube 30 nor the drain include a one-way valve or any other impediment from allowing fluid to be delivered to the wound. A POSA would understand such a drain to be configured to deliver and withdraw fluid. EX1002 ¶¶111-112. For example, a POSA would have been familiar with Lockwood, which discloses a stretch of single lumen vacuum tubing

inserted under a cover and explains that the system can both deliver and withdraw fluid. EX1009 ¶88. Accordingly, Argenta's tube 30 and the associated drain are "configured" to non-simultaneously deliver and withdraw fluid.

The '404 Patent confirms that Argenta's tube 30 is "configured to" non-simultaneously withdraw and deliver fluid. EX1001 at 20:59-21:10 (suggesting that reverse-flow can be carried out using vacuum drainage tube 1135); *see also id.* 12:11-54, Figs. 7A-7C, 11. The '404 Patent does not indicate that the drain must be configured in any special way to allow reverse-flow and thus the "drain" disclosed in Argenta is similarly "configured to" non-simultaneously deliver and withdraw fluid as required by limitation 1[c]. Finally, the applicant's arguments during prosecution confirm that such a drain is configured to non-simultaneously deliver and withdraw fluid. *See* EX1006 at 160 (Jan. 25, 2016 Appeal Br. at 10) (distinguishing art with a "one-way valve" because it cannot be used to deliver fluid at all). Accordingly, Argenta discloses a drain configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound. EX1002 ¶115.

To the extent Patent Owner argues that Argenta does not expressly disclose such a drain, that configuration would have been obvious based on a POSA's knowledge at the time of the invention. EX1002 ¶¶113-115. A POSA would have been familiar with multiple prior art references that taught delivering fluid to a wound using an NPT system. EX1008; EX1009; EX1017; EX1025 at 33 ("There

are currently eight *peer-reviewed* articles that have been published on the subject of ‘instillation therapy’”). A POSA would have included this functionality in Argenta to have the freedom to deliver antibiotics or other fluids to aid in wound healing. EX1025 at 33-40 (vacuum instillation therapy has been used clinically since 1996); EX1002 ¶¶73-76, 114.

Moreover, a POSA would have been motivated specifically to “non-simultaneously” deliver and withdraw fluid where the fluid was a medication, allowing sufficient time for it to reach the wound before withdrawing it. EX1025 at 33 (describing delivery of drug to wound for approximately 5-30 minutes before removal), 34-35 (describing phases of instillation therapy), 35 (distinguishing non-simultaneous and simultaneous techniques); EX1017 at 192 (describing cycles of instillation between cycles of NPT); EX1002 ¶¶73-76, 114. Finally, Lockwood specifically discloses a simple switch valve associated with the end of the tube away from the drain to toggle between either delivering or withdrawing fluid, which a POSA in this field could have easily implemented.⁴ EX1009 ¶88. To the extent the drain of Argenta is not already configured to deliver and withdraw fluid, a POSA at

⁴ POSAs in this field routinely modified known devices to provide the specific therapy they desired. *See e.g.*, EX1019 (providing instructions for creating an NPT dressing using “off-the-shelf” components).

the time could have modified the opposite end of the vacuum tube to ensure non-simultaneous delivery and withdrawal of fluid just as Lockwood teaches. EX1002 ¶115. Indeed, because this limitation was so well-known to POSAs at the time, the '404 Patent provides no teaching regarding how one would configure a drain to meet this limitation. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (“[A] patent need not teach, and preferably omits, what is well known in the art.”).

1[d]. “fluid-absorbing/transferring layer for distributing negative pressure from the NPT drain, said fluid-absorbing/transferring material being in contact with the NPT drain;”

The '404 Patent explains that this component was conventional in prior art NPT devices, which included packing a wound with gauze or foam and that a drain was “typically placed upon the gauze or inserted within the foam.” EX1001 at 1:19-24, 53-58. The '404 Patent then describes the claimed fluid-absorbing/transferring layer as also made up of gauze or foam. EX1001 at 13:21-38.

Argenta discloses screen 20, which is the fluid-absorbing/transferring layer that is described by the '404 Patent. Screen 20 can be made of a variety of foams such as “V.A.C.® GranuFoam® and V.A.C.® WhiteFoam™” and/or a suitable gauze-based materials such as Aquaphor® Gauze. EX1004 ¶¶17, 18. EX1029 at 2 (identifying differences between types of foam); EX1002 ¶¶116-118. These materials absorb and transfer fluid from the wound to the vacuum source. These are

the same materials that the '404 Patent identifies as appropriate for use as the fluid-absorbing/transferring layer. EX1001 at 1:23-24, 7:44-8:3.

Argenta also explains that screen 20 is placed in the wound bed (under cover 10) and can “promot[e] even distribution of sub-atmospheric pressure under the cover 10.” EX1004 ¶17; *see also* EX1023 at 564 (“foam ensures equal distribution of the applied subatmospheric pressure force to every surface of the wound in contact with the foam”). Argenta depicts and describes distal end 32 of tube 30 (associated with the drain) as embedded within screen 20 and thus, the drain and the tube are in contact with the fluid-absorbing/transferring layer. EX1004 ¶20, Figs. 1, 2A, 2B.

1[e]. “a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer,”

The '404 Patent explains that conventional NPT devices included a “draping layer” to cover the drain and wound packing materials and adhere to the patient’s skin around the wound, effecting an airtight seal to allow application of negative pressure. EX1001 at 9:33-65. The prior art draping layer has the same function as the claimed vapor sealant sheet. The only portion of this limitation not admitted to be in a conventional NPT dressing is the requirement that the vapor sealant sheet be formed from a hydrocolloid material.

Argenta discloses a cover 10 that overlies the screen and forms a seal with surrounding tissue to create an environment in which negative pressure may be

maintained. EX1004 ¶14. Argenta discloses that the cover can be made from one of several common hydrating film dressings, including the Ioban® or OpSite® drapes. EX1004 ¶15; EX1013 at 49; EX1030 at 178-179; EX1002 ¶¶119-120. The only portion of this limitation not expressly disclosed by Argenta is the requirement that the vapor sealant sheet be formed from a hydrocolloid material.

By 2010 it would have been obvious for a POSA to use a hydrocolloid material as the claimed vapor sealant sheet with Argenta's dressing. EX1002 ¶¶121-123, 166-177. Argenta's cover contacts the patient's periwound skin. Throughout the 2000's, POSA's understood the need to protect such periwound skin during NPT and they used hydrocolloid dressings for exactly that purpose. EX1017 at 191, 193; EX1025 at 352-353, 373; EX1010 ¶ 74; EX1002 ¶¶121, 169-174. By 2010 POSA's also understood the importance of providing a moist wound environment. *See* §VII.B, above. Hydrocolloids and film dressings were two of only a few options for creating a moist wound environment. EX1013 at 48-49; EX1030 at 178-179; §VII.B, above; EX1002 ¶¶82-93, 182. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Accordingly, it would have been obvious to a POSA to use a hydrocolloid as the vapor sealant sheet in an NPT dressing like Argenta.

A POSA would have had a reasonable expectation of success in doing so. EX1002 ¶181. Hydrocolloids were extensively used in wound dressings prior to 2010. EX1002 ¶¶82-93. POSAs knew how to incorporate known materials into NPT dressings. EX 1019 (describing construction of an NPT dressing using “off-the-shelf” components). EX1002 ¶123. And, the ’404 Patent confirms that hydrocolloids were well-known and that a POSA could incorporate one as the cover in an NPT dressing. The ’404 Patent provides ***no disclosure*** about using a hydrocolloid for that purpose other than the bare statement that hydrocolloid material may (or may not) be included in the vapor-sealant sheet. EX1001 at 15:17-20; *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (“[A] patent need not teach, and preferably omits, what is well known in the art.”). And when the specification suggests using a hydrocolloid for other purposes it specifically proposes well-known prior art hydrocolloids like Duoderm®. See EX1001 at 14:6-10, 16:51-58, 17:43-48; EX1026 (1994 article describing various Duoderm dressings). A POSA would have had a reasonable expectation of success in incorporating a hydrocolloid material as the vapor sealant sheet of Argenta. EX1002 ¶181.

Alternatively, it would have been obvious to use a hydrocolloid cover with Argenta’s NPT dressing based on the teachings of Hu. Hu discloses a similar dressing for applying negative pressure to a wound. Specifically, Hu discloses a

negative pressure dressing with a sealant layer 103, which, like the cover used by Argenta, overlies the manifolding and/or wound packing material (referred to as the “contact layer matrix” in Hu (EX1005 ¶57; EX1002 ¶101)) to cover the wound and allow application of sub-atmospheric pressure. Just like the ’404 Patent, Hu states that the sealant layer can be “made of a hydrocolloid material,” which may be semi-porous to allow the hydrocolloid to absorb moisture from the wound while protecting the skin. EX1005 ¶59.

Like film dressings, hydrocolloid dressings are also hydrating dressings that trap moisture—but unlike films, hydrocolloids can absorb exudate to create a gel with healing properties. See §VII.B, above; EX1002 ¶¶79, 86. And like the drapes disclosed in Argenta, hydrocolloid sheets were standard components of wound dressings used for decades in the prior art. See §VII.B, above; EX1002 ¶¶86-89. By the time of the invention POSAs understood that hydrocolloid dressings offered many advantages for promoting wound healing and could be incorporated into an NPT dressing to optimize wound healing. For the reasons explained in §IX.A.10, below, those skilled in the art would have been motivated to use such a hydrocolloid cover with Argenta’s device and would have had a reasonable expectation of success in doing so.

1[f]. “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”

Argenta expressly discloses limitation 1[f]. Argenta discloses that the cover in its NPT dressing 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, such as suction tube 30 or optional screen 20.” EX1004 ¶15. More specifically, “[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 and to assist in the removal of the screen 20 when the cover 10 is removed.” EX1004 ¶19. Screen 20 is located on the wound-facing side and directly below the central portion of cover 10. Ex 1004 Fig. 1, ¶19. One 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. EX1002 ¶125.

1[g]. “a tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet and a portion of the fluid-absorbing/transferring layer, the tube-anchorage component for mechanically maintaining placement of the NPT drain relative to the fluid-absorbing/transferring layer.”

The '404 Patent admits that the prior art used tube-anchorage components—typically tape—to anchor the vacuum tube to the patient’s skin and fix the tube and drain in position relative to the wound bed. EX1001 at 8:40-43, 9:27-32, 59-62, 10:1-5. The '404 Patent depicts two such anchorage components in Figures 3-6 (e.g., components 344 and 346). EX1001 at 9:52-65, Figs. 3-6. The only portion of this limitation not admitted as part of a conventional prior art NPT device is that the tube-anchorage component is in contact with a portion of the fluid-absorbing/transferring layer.

Argenta also teaches limitation 1[g]. Argenta discloses that the cover 10 can include port 36, which may be “an edge of the cover 10 under which the tube 30 passes, such as a mesentery,” or it can be an opening, or a nipple formed on the cover, or **another suitable structure** through which the tube passes. EX1004 ¶20. Each of these components is located in a fixed position on the cover 10 and would function to fix Argenta’s tube and drain relative to the rest of the dressing. EX1002 ¶¶126-127. Moreover, once the tube passes through this fixed position it is embedded within the screen 20 and cannot move relative to the screen. Argenta further discloses an adhesive on the cover that can help to “immobilize” the tube. EX1004

¶15. A POSA by early 2010 would have understood the importance of immobilizing these components of an NPT dressing, particularly in applications involving skin grafts. EX1025 at 150, 153, 255; EX1002 ¶¶126-130.

Moreover, the features disclosed in Argenta each function like component 745 described in the '404 Patent. The '404 Patent broadly describes component 745 as a structure that fixes the tube in place as the tube exits the vapor sealant sheet. EX1001 at 16:16-65, 18:47-52, Fig. 9 (component 945) (displaying a rigid structure that the tube passes through). One of skill in the art would understand that a tube embedded in screen 20 of Argenta's dressing would have to remain anchored in place by an opening, a nipple, or such other structure to prevent movement of the screen and corresponding agitation of the wound bed. EX1002 ¶129.

Once the tube is fixed in place by one of Argenta's structures, the structure will maintain the position of the drain relative to the fluid-absorbing/transferring layer. EX1002 ¶¶126-130. The features that Argenta describes to fix the tube in place are all formed on the cover itself (which is the claimed vapor sealant sheet) and therefore they "contact" the vapor sealant sheet. Similarly, because the cover 10 is adhered to screen 20 (the "fluid-absorbing/transferring layer"), these components are also in contact with a portion of the fluid-absorbing/transferring

layer, particularly while negative pressure is applied and the components are further drawn together.⁵ EX1002 ¶130.

2. Claim 2

2[a] “A wound dressing comprising”

Limitation 2[a] is identical to limitation 1[a] and is disclosed for the same reasons. See §IX.A.1.1[a], above; EX1002 ¶131.

2[b] “a wound-fluid negative pressure treatment (“NPT”) drain;”

Limitation 2[b] is disclosed for the same reasons that limitation 1[b] is disclosed. See §IX.A.1.1[b], above; EX1002 ¶132.

2[c] “a vacuum/drainage tube comprising a terminus associated with the NPT drain;”

Limitation 2[c] is disclosed for the same reasons that limitation 1[c] is disclosed. See §IX.A.1.1[c], above; EX1002 ¶133.

⁵ The ’404 Patent does not appear to provide any description or depiction of how the anchorage components are otherwise in contact with the fluid-absorbing/transferring layer.

2[d] “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;”

Limitation 2[d] is disclosed for the same reasons that limitation 1[d] is disclosed. See §IX.A.1.1[d], above; EX1002 ¶134. Specifically, Argenta depicts and describes distal end 32 of tube 30 embedded within screen 20. Distal end 32 of tube 30 is associated with the NPT drain, and, thus, both the tube and drain are embedded within the fluid-absorbing/transferring layer and are used to supply the negative pressure to the fluid-absorbing/transferring layer, which distributes that negative pressure. EX1002 ¶134; EX1004 ¶20, Figs. 1, 2A, 2B.

2[e] “a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer,”

Limitation 2[e] is identical to limitation 1[e] and is disclosed for the same reasons. See § IX.A.1.1[e], above; EX1002 ¶135.

2[f] “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 the fluid-absorbing transferring layer relative to the vapor sealant sheet;”

Limitation 2[f] is identical to limitation 1[f] and is disclosed for the same reasons. See § IX.A.1.1[f], above; EX1002 ¶136.

2[g] “a first tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet;”

Argenta discloses limitation 2[g] for the same reasons it discloses limitation 1[g]. See § IX.A.1.1[g]; EX1002 ¶137.

2[h] “and a second tube-anchorage component, the first and second tube-anchorage components for mechanically maintaining the NPT drain's placement relative to the fluid-absorbing/transferring layer.”

It would have been obvious to a POSA at the time of the invention to include a second anchorage component to improve anchorage of the tube and associated drain. EX1002 ¶¶138-142. The '404 Patent admits that use of two anchorage components was conventional in prior art NPT devices. See EX1001 at Fig. 5 (components 544 and 546), 9:59-65 (describing prior art devices where tube was anchored and sealed with adhesive materials 544 and 546), 16:3-32 (explaining that “tube-anchorage and tube-exit-sealant components may mechanically maintain drain[.]”) By the time of the invention a POSA understood the importance of anchoring the vacuum tube so the drain would not move. EX1004 ¶15 (drape “immobilize[s] other components” such as the vacuum tube”); EX1025 at 150, 153, 255 (importance of immobilizing components of NPT dressing when treating skin grafts). This was particularly true where the vacuum tube was inserted into the screen as in Argenta. EX 1004 ¶¶15, 19 (describing adhesive on cover to secure

screen in a fixed position), 20 (tube can be embedded in screen); EX1002 ¶¶139-141.

A POSA would have been well aware of other NPT designs that incorporated multiple anchorage components for similar purposes. EX1011 ¶¶61 (adhesive film layer 70), 72 (adhesive or tape component 102), Fig. 2; EX1016 at Fig. 3 (dressing is “crimped around the tube to seal” the exit), Fig. 4 (tube exit site is caulked with Stomahesive paste and then reinforced with waterproof pink tape). Accordingly, a POSA would have been motivated to include a second anchorage component, such as the admitted prior art adhesive, to improve the fixity of the tube, as admitted by the ’404 Patent.

Moreover, the combination of Argenta and Hu discloses a second anchorage component. For the reasons above, in addition to being motivated to combine Argenta and Hu by replacing Argenta’s cover with a hydrocolloid material, a POSA would also have been motivated to create an alternative combination retaining Argenta’s self-adhesive flexible cover over top of a hydrocolloid cover to provide additional anchorage for the vacuum tube. EX1011 ¶¶74, 79 (including adhesive film layer 70); §IX.A.10, below. As described above for limitation 1[g], Argenta’s first anchorage-component would be formed on the hydrocolloid cover. Argenta discloses that its cover overlies the other components and can “immobilize other components of the apparatus . . . such as suction tube 30.” POSAs would have

understood that they could improve mechanical fixity of the tube with a second component by retaining Argenta's self-adhesive cover to "immobilize . . . suction tube 30" along with Hu's hydrocolloid cover. EX1004 ¶15; EX1011 ¶61; EX1002 ¶¶140-142. This is how the '404 Patent depicts tube-anchorage component 947—as an adhesive sheet that can overlie the vapor sealant sheet to seal and immobilize the tube. EX1001 at 16:66-17:18, Fig. 9. Accordingly, a POSA would have alternatively had reason to retain the film from Argenta, which would be a second tube-anchorage component as described by the '404 Patent. EX1002 ¶142.

3. Claim 3

3[a] “A wound dressing comprising:”

Limitation 3[a] is identical to limitation 1[a] and is disclosed for the same reasons. See §IX.A.1.1[a], above; EX1002 ¶143.

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

Limitation 3[b] is broader than the limitations of claim 1, requiring only a vacuum/drainage tube, not a tube associated with an NPT drain. Limitation 3[b] is disclosed for the same reasons that limitation 1[c] is disclosed. See §IX.A.1.1[c], above; EX1002 ¶144.

3[c] “a 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;”

Limitation 3[c] is nearly identical to limitation 1[d], requiring only that the tube, as opposed to the drain, be in contact with the fluid-absorbing/transferring layer. The distal end of Argenta’s tube is fenestrated, comprising claim 1’s drain. Accordingly, for the same reason that Argenta discloses a drain meeting limitation 1[d], it also discloses a tube meeting limitation 3[c]. See §IX.A.1.1[d], above; EX1002 ¶145.

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

Limitation 3[d] is identical to limitation 1[e] and is disclosed for the same reasons. See §IX.A.1.1[e], above; EX1002 ¶146.

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 the fluid-absorbing transferring layer relative to the vapor sealant sheet; and”

Limitation 3[e] is identical to limitation 1[f] and is disclosed for the same reasons. See §IX.A.1.1[f], above; EX1002 ¶147.

3[f] “a tube-exit-sealant component for mechanically maintaining the vacuum/drainage tube's placement relative to the fluid-absorbing/transferring layer.”

The '404 Patent admits that conventional prior art NPT dressings used an adhesive, typically tape, to seal the tube egress from the cover. See §IV.B.1.e, above; EX1001 9:59-10:9, Fig. 5 (component 546).

Argenta discloses limitation 3[f] for the same reasons it discloses limitation 1[g] and 2[h]. See §§ IX.A.1.1[g], IX.A.2.2[h], above; EX1002 ¶¶148-150. Specifically, Argenta discloses that cover 10 can include port 36, which may be “an edge of the cover 10 under which the tube 30 passes, such as a mesentery,” an opening, or a nipple formed on the cover, or another suitable structure through which the tube passes. EX1004 ¶20. As explained above, each of these components is located in a fixed position on the cover 10, mechanically maintaining the drain in position. Argenta further explains that the self-adhesive cover can help to “immobilize other components . . . which the cover adhesive contacts, such as suction tube 30” and acts to seal the cover to provide an enclosure for maintaining sub-atmospheric pressure. EX1004 ¶15; EX1002 ¶148.

Alternatively, in the Argenta-Hu combination where a POSA retains Argenta's self-adhesive cover, that cover would also seal the tube exit. See §§IX.A.2.2[h], above and IX.A.10, below; EX 1002 ¶149. Because the components are in a fixed position on the cover and the tube is further immobilized and sealed by the adhesive,

a POSA would understand that the components and adhesive would seal and mechanically maintain the tube's placement relative to the fluid-absorbing/transferring layer. EX1002 ¶¶149-150.

4. Claim 4: “*The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises gauze.*”

The combination of Argenta and Hu discloses all limitations of claim 1 for the reasons above. The '404 Patent expressly admits that using gauze as the fluid-absorbing/transferring layer was conventional in prior art dressings. EX1001 at 7:44-67, 13:21-38, Fig 2 (describing and depicting prior art NPT wound dressings).

Argenta expressly discloses that screen 20, which is the fluid-absorbing/transferring layer, can be made of gauze. EX1004 ¶18 (identifying Aquaphor® Gauze as a non-adherent material that may be used for screen 20). EX1002 ¶¶151-152.

5. Claim 5—“*The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises foam.*”

The combination of Argenta and Hu discloses all limitations of claim 1 for the reasons above. The '404 Patent expressly admits that using foam such as “V.A.C.® GRANUFOAM™” as the fluid-absorbing/transferring layer was conventional in prior art dressings. EX1001 at 7:44-8:3, 13:21-38.

Argenta expressly discloses that screen 20, which is the fluid-absorbing/transferring layer, can be made of foam. EX1004 ¶18 (screen 20 may be

made of “V.A.C.® GranuFoam®” or “V.A.C.® WhiteFoam®”). V.A.C.® GranuFoam® and V.A.C.® WhiteFoam® are types of foam commonly used in prior art dressings. EX1001 at 7:44-8:3; EX1029 at 2 (identifying differences between types of foam); EX1002 ¶¶153-154.

6. Claim 6—“*The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises an upper layer and a lower layer.*”

The combination of Argenta and Hu discloses all limitations of claim 1 for the reasons above. Furthermore, Argenta expressly discloses that screen 20, which is the fluid-absorbing/transferring layer comprises both an upper and lower layer. The terms upper and lower are intended to identify aspects of a wound dressing being respectively vertically distant and vertically proximal to the wound-base. EX1001 at 7:1-7. Argenta discloses that the distal end of the vacuum tube can be located above or below the screen 20 “or may be embedded within the screen 20.” EX1004 ¶20. When the tube is embedded within the screen, as depicted in Figs. 2A and 2B, the screen is comprised of both upper and lower layers.

To the extent that upper and lower layers are interpreted to require separate physical layers of material, Argenta also discloses such layers. Argenta discloses that the “screen 20 is desirably cut and shaped to fit into and fill the wound,” (EX1004 ¶19) and that “screen 20 may be provided as a unitary structure or as a composite of separate components ***assembled upon application to the tissue*** to be

treated” (EX1004 ¶18 (emphasis added)). One of skill in the art reading Argenta would understand that if the screen is made up of more than one component cut to fit the size of the wound and then assembled on the tissue, those components would be layered on top of one another and would therefore have at least one upper and one lower layer. EX1002 ¶¶155-158. Moreover, if one were to embed the distal end of Argenta’s vacuum tube in a unitary screen made of a flexible material like Aquaphor Gauze (EX1004 ¶¶18, 20), one of skill in the art would have naturally folded the gauze over the drain to create a layer below the drain and a layer above the drain to reduce the number of materials needed and to reduce risk for the patient. EX1002 ¶158.

7. Claim 7—“*The wound dressing of claim 6 wherein the NPT drain is enfolded between the lower layer and the upper layer.*”

Argenta discloses that the NPT drain is enfolded between the lower layer and upper layer of the fluid-absorbing/transferring layer. As explained for Claim 6, a POSA would understand Argenta to disclose this limitation by disclosing a unitary screen that can be made of Aquaphor Gauze. EX1004 ¶¶18, 20; EX1002 ¶¶159-161. To the extent Argenta does not expressly disclose that the drain would be enfolded between the upper and lower layer of the gauze, that configuration would have been obvious to one of skill in the art for the reasons explained in §IX.A.6, above; EX1002 ¶¶159-161.

8. Claim 11—“*The wound dressing of claim 3 wherein the vacuum/drainage tube terminus is associated with a negative pressure treatment (“NPT”) drain.*”

The combination of Argenta and Hu discloses all limitations of claim 3 for the reasons above. Argenta discloses that the terminus of the vacuum/drainage tube is associated with an NPT drain for the same reasons as limitation 1[b]. See §IX.A.1.1[b], above; EX1002 ¶¶162-163.

9. Claim 13—“*The wound dressing of claim 3 wherein the vacuum/drainage tube is further associated with an external vacuum source.*”

The combination of Argenta and Hu discloses all limitations of claim 3 for the reasons above. The ’404 Patent expressly admits that conventional NPT dressings generated negative pressure via a connection to an external “NPT vacuum controller.” EX1001 at 10:10-15. Furthermore, Argenta discloses that a “suction source 50” which can be a “vacuum pump” provides the sub-atmospheric pressure to the NPT wound dressing. EX1004 ¶21. A vacuum pump connected to the wound dressing via a vacuum tube is such an external vacuum source, and is the same type of vacuum controller that the ’404 Patent admits is prior art. EX1002 ¶¶164-165; EX1001 at 10:10-14.

10. A POSA would have been motivated to combine Argenta with Hu

As explained above in §IX.A.1.1[e], Argenta describes an NPT dressing that uses a cover that can be a flexible sheet or surgical drape like the Ioban® or OpSite®

drapes, or a rigid/semi-rigid material that overlies a foam or gauze screen and provides a sealed space for negative pressure to be applied. EX1004 ¶15. That cover adheres to the periwound skin surrounding the wound and can immobilize the other components of the dressing, fixing the dressing and the vacuum tube in place. EX1004 ¶15; EX1002 ¶167.⁶

Hu discloses a similar NPT dressing that uses a hydrocolloid cover. By 2010 a POSA would have been familiar with the advantages of using a hydrocolloid cover for NPT—(i) it protects the periwound skin from maceration, (ii) it provides the beneficial properties of a hydrocolloid dressing to satellite lesions that could form, (iii) it optimizes moisture level in the wound environment, and (iv) it allows for easier handling/placement, and prevents fluid leaks near the most sensitive periwound skin. At the time of the claimed invention, it would have been obvious to a POSA to replace Argenta’s cover with a hydrocolloid material, adhering that hydrocolloid cover to the periwound skin.

⁶ Although the ’404 Patent refers to a draping layer to which the vapor sealant sheet can adhere (EX1001 at 13:58-15:4), such a draping layer is not claimed and the Challenged Claims do not exclude a device with the cover adhered directly to the periwound skin.

By 2010, POSAs understood that during NPT, “[p]rotection of the skin at the wound edge and periwound skin is essential.” EX1017 at 191-192. And POSAs routinely used hydrocolloids to protect that skin during NPT. For example, POSA’s understood that when using the conventional VAC dressing, “[t]he periwound skin should be protected with a skin protectant, barrier film, or **hydrocolloid dressing** to maintain the air-tight seal, essential for NPWT and **to protect the periwound skin from moisture-associated skin damage.**” EX1017 at 191(emphasis added); *see also id.* at 193 (“I recommend picture framing the wound with hydrocolloid dressing to protect the periwound skin and prevent maceration”); EX1025 at 352-353, 373 (practical advice for vacuum therapy includes protecting skin with a hydrocolloid); EX1010 ¶74. In numerous case studies, medical personnel separately added hydrocolloid sheets to protect the skin near the site of NPT when using existing NPT devices like a V.A.C.® therapy device. EX1025 at 313-14, 339-41; EX1002 ¶¶169-174.

POSAs understood that hydrocolloids were useful not only to prevent maceration of the underlying skin, but also to act as an effective dressing if satellite lesions occurred near the wound. EX1010 ¶74; EX1002 ¶173. As hydrocolloid dressings absorb wound exudate they incorporate endogenous enzymes and growth factors that aid in wound healing and autolytic debridement of the wound. EX1013, 46, 49; EX1031 at 3S; EX1002 ¶¶79-81, 175. Hydrocolloid dressings were long

known to maintain “a slightly acidic environment ... which assists the body’s own enzymes, thus contributing to the removal of necrotic tissue and encouraging angiogenesis.” EX1026 at 730. Moreover, POSAs observed greater vascularization of wounds under a hydrocolloid dressing than under a film dressing (EX1026 at 730-732; EX1031 at 2S-3S) and patients reported less pain (EX1026 at 732-733). Numerous studies have reported improved wound healing using a hydrocolloid dressing as compared to other standard dressings. EX1018 at 603-611 (summarizing studies across various types of acute wound types and concluding that “there appears to be an obvious advantage associated with the use of the hydrocolloid in most reported studies” (EX1018 at 612)).

Using a hydrocolloid as the cover in an NPT dressing provides appropriate moisture levels for healing, which is crucial to promote proper healing. EX1010 ¶74 (explaining that hydrocolloids used in NPT optimize moisture level for the underlying tissue); §VII.B, above. A POSA would have been motivated to use a hydrocolloid material in an NPT dressing to provide an optimal moist environment for the wound and to protect the periwound skin. EX1002 ¶¶166-182.

A POSA would also have understood that a wide range of hydrocolloids with different thicknesses and different moisture vapor transmission rates were available and could be optimized for the particular wound and application as needed. EX1010 ¶75 (various possible moisture vapor transmission rates), ¶110 (various possible

thicknesses). Well before 2010, hydrocolloid sheets of different sizes and shapes were commercially available. EX1026, EX1027. Those skilled in the art would be able to select a hydrocolloid of appropriate thickness, rigidity, and adhesive properties for the wound to be treated and would be able to control the level of fluid withdrawn (or delivered) to work optimally with the hydrocolloid chosen. EX1002 ¶ 176.

Using a hydrocolloid cover would also prevent the self-adhesive sheets like the Ioban® and OpSite® drapes that Argenta discloses (EX1004 ¶15) from adhering to themselves while a doctor placed them on the most sensitive immediately-adjacent periwound skin (EX1013 at 49) and would prevent the creation of leakage channels (EX1013 at 49-50). EX1002 ¶¶93, 176. Hu explains that its hydrocolloid layer is “typically thicker than other materials such as acrylic adhesives to allow for easier placement with less folding and wrinkling and to seal potential fluid leak paths.” EX1005 ¶59.

Alternatively, rather than simply replacing Argenta’s film drape with a hydrocolloid, a POSA would also have been motivated to retain Argenta’s thin self-adhesive drape over top of the hydrocolloid cover to take advantage of Argenta’s stated purpose of using the drape to immobilize the suction tube. EX1004 ¶15; EX1002 ¶¶ 142, 149, 178-179. A POSA would have been familiar with exactly that configuration described in the prior art, and would have been motivated to combine

Argenta and Hu in the same way to maximize anchorage of the vacuum tube. EX1008 at 6:31-53, 7:45-8:30, Figs. 4 & 5 (components 12 (hydrocolloid gel to seal wound and prevent exudate from escaping) and 13 (flexible drape that adds extra support)); EX1011 ¶¶61, 72, Fig. 2; EX1016 at 61, Figs. 3, 4; EX1002 ¶¶178-179.

Those skilled in the art were abundantly familiar with the benefits of using hydrocolloid material as a wound dressing. *See* §VII.B, above. By 2010 they would have been motivated to include a hydrocolloid cover in Argenta's dressing to take advantage of those benefits. EX1002 ¶¶120-124, 166-182. Unsurprisingly, the prior art (Hu) disclosed using a hydrocolloid cover for exactly that purpose. EX1005; EX1010. Simply incorporating that component into Argenta's conventional NPT dressing would have been well within the ability of a POSA and the POSA would have had a reasonable expectation of success in doing so. EX1002 ¶181. As explained above, those skilled in the art understood the benefits of using a hydrocolloid dressing to create a moist wound environment to protect the periwound skin. EX1010 ¶74. Hydrocolloids were one of a finite number of hydrating dressings available for providing an optimal moist environment and would have been obvious to try as the cover in an NPT dressing. EX1005 ¶59; EX1010 ¶¶70-75; EX1013 at 46, 48-50; EX1030 at 178-179; EX1002 ¶182. Accordingly for all of the reasons above, a POSA would have been highly motivated to make the simple

substitution or addition to Argenta, based on at least the disclosure of Hu—a similar device used for the same purpose.

B. Ground 2: Claims 8-10 Would Have Been Obvious Over Argenta in View of Biggie or in View of Biggie and Hu

1. Claim 8—“*The wound dressing of claim 2 wherein the vacuum/drainage tube comprises a plurality of lumens.*”

Claim 8 depends from claim 2 and further requires that the vacuum/drainage tube have a plurality of lumens. The combination of Argenta and Hu disclose all other limitations of claim 2 for the reasons described above.

Biggie discloses a wound dressing with a tube that has multiple lumens. Biggie’s dressing uses a “pouch” filled with beads or other filler as the wound packing material. EX1008 at 3:33-63, 4:25-39, 7:20-26. A tube with a perforated terminus (i.e., a drain) like in Argenta is inserted into the pouch. EX1008 at 7:7-19. Biggie describes that “the tubing may be a multi-lumen device which uses one lumen to apply negative pressure to the wound area, and a secondary lumen as a pathway to supply medications and/or antibacterial agents to the pouch.” EX1008 at 5:8-26, 5:61-6:9. Biggie also discloses that the secondary lumen “also provides a path for insertion of other devices, such as electrical conductors which are used to provide low-level electrical stimulus or heat for treatment of a wound area, or other measurement or treatment devices.” EX1008 at 6:6-9. Accordingly, Biggie discloses using a tube having a plurality of lumens. EX1002 ¶¶183-186.

2. **Claim 9—*“The wound dressing of claim 8 wherein the plurality of lumens comprises at least one lumen configured to deliver fluid to a wound and at least one lumen configured to withdraw fluid from the wound.”***

Claim 9 depends from claim 8 and for the same reasons identified above, Biggie describes a tube with a plurality of lumens with at least one lumen configured to withdraw fluid from the wound. See §IX.B.1, above; EX1002 ¶¶187-188.

3. **Claim 10—*“The wound dressing of claim 8 wherein at least one lumen is configured to convey a medical device.”***

Claim 10 depends from claim 8 and discloses all limitations of claim 8, as well as a lumen configured to convey a medical device. See §IX.B.1, above; EX1002 ¶¶189-190.

4. **A POSA would have been motivated to combine Biggie’s multi-lumen tubes with Argenta and Hu**

A POSA would have incorporated a hydrocolloid like the one described in Hu into Argenta for the reasons explained in Section IX.A.10, above. Biggie is directed to the same type of device and adds the simple improvement of using a multi-lumen tube, which adds the freedom to have one lumen dedicated to vacuum and another lumen for administering fluid or medical devices to the wound site. The prior art identified the long-known benefit of a medical practitioner being able to optionally provide medicine or other fluids to the wound site via a multi-lumen tube. EX1025 at 33-39. Biggie explains that the “multi-tubing 2 allows the delivery of medications

without disturbing the wound dressing.” EX1008 at 8:43-45. Finally, Biggie describes not only applying medicaments, but also the ability to insert a medical device such as a “measurement or treatment device[,],” making the dressing more versatile. EX1008 at 6:6-9. For all of these reasons, a POSA would have been motivated to incorporate these features from Biggie into the combination of Argenta and Hu. EX1002 ¶¶191-192.

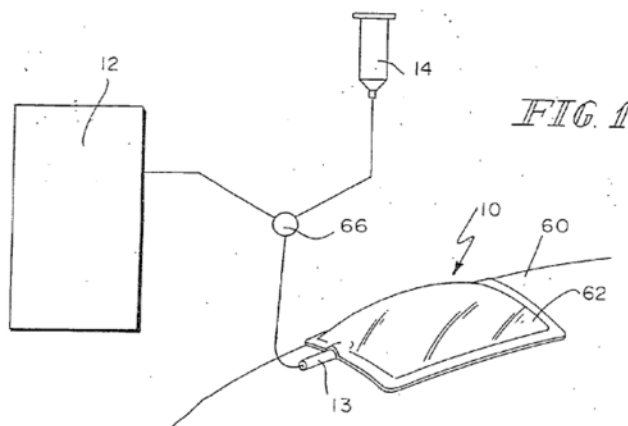
C. Ground 3: Claims 1, 4-7, And 12 Would Have Been Obvious Over Argenta in View of Lockwood or in View of Lockwood and Hu

1. Claim 1

Section IX.A.1, above explains how Argenta with or without Hu would render obvious claim 1. To the extent a POSA would not have known that combination to teach limitation 1[c]’s requirement that the drain be configured to non-simultaneously deliver and withdraw fluid, that limitation is expressly disclosed in Lockwood. A POSA would have been motivated to incorporate Lockwood’s switch valve to precisely control the non-simultaneous delivery or withdrawal of fluid in the Argenta-Hu combination. EX1002 ¶¶193-194.

Specifically, Lockwood discloses a Y- shaped vacuum tube with a switch valve. EX1009 ¶ 88, Fig. 1. Tubing on one side of the switch is connected to a vacuum source for removing fluid and tubing on the other side of the switch is connected to an irrigation source for delivering fluid. Because the switch *either* allows the vacuum source, *or* the irrigation source to communicate with the wound,

Lockwood discloses a drain configured to non-simultaneously deliver or withdraw fluid. See EX1009 ¶¶71, 72, 88 (“A switch valve 66 is illustratively provided, as shown in Fig. 1, to allow a user to switch between the use of the vacuum source 12 and the irrigation source 14.”), Fig. 1; EX1002 ¶¶193-194. So long as fluid is not prevented from being delivered, a drain connected to such a tube is “configured to” both deliver and withdraw fluid.



EX1009 Fig. 1 (excerpt from Lockwood depicting vacuum source 12, irrigation source 14, and switch valve 66 connected to a tube inserted into a wound dressing).

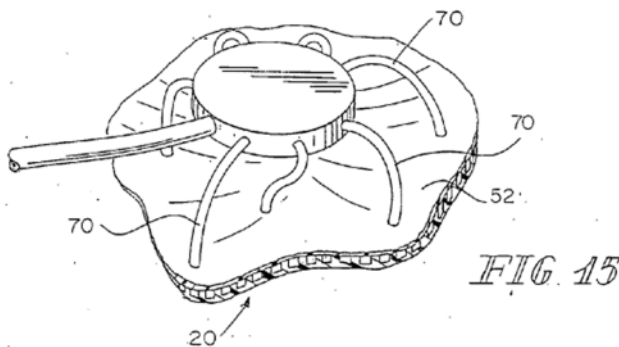
A POSA would also have a reasonable expectation of success in combining Lockwood with Argenta or with Argenta and Hu. As the '404 Patent admits, a POSA would not need to make any modifications to the drain or vacuum tube to incorporate the functionality of Lockwood. See §IX.A.1.1[c], above. Accordingly, the combination of Argenta, Hu, and Lockwood expressly discloses all limitations of claim 1.

2. Claims 4-7

The dependent limitations added to claim 1 by claims 4, 5, 6, and 7 are each disclosed by or obvious based on Argenta for the reasons discussed in Sections IX.A.4-7, respectively. The addition of Lockwood's switch valve far from the drain does not otherwise affect any of these dependent limitations.

3. Claim 12—*“The wound dressing of claim 11 wherein the NPT drain comprises a plurality of NPT drains.”*

Claim 12 depends from claim 11 and further requires that the drain comprises a plurality of drains. Lockwood discloses a wound dressing with a tube that branches out to connect with multiple ports throughout Lockwood's wound dressing member 20.



EX1009 Fig. 15. Lockwood's stated reason for providing a plurality of ports each coupled to a vacuum/irrigation tube is to provide an "evenly distributed suction force." EX1009 ¶¶41, 89, Fig. 15. A POSA would understand Lockwood to disclose this limitation. EX1002 ¶¶195-197.

**4. A POSA would have been motivated to combine
Lockwood's configuration with Argenta and Hu**

Lockwood discloses yet another standard NPT wound dressing. But Lockwood specifically recognizes the benefits of being able to both deliver and withdraw fluid from a wound—benefits that were well-known by 2010—and discloses a simple vacuum tube arrangement to do so.

A POSA would have recognized the benefit in adding this functionality to the combination of Argenta and Hu to non-simultaneously deliver and withdraw medication to allow sufficient time for the medication to reach the wound before immediately withdrawing it. EX1025 at 33-35; EX1017 at 192; EX1002 ¶¶198-199; *see also* §IX.A.1.1[c], above. A POSA would also have understood the appropriate rate and volume of fluid delivery that could have been used with a hydrocolloid dressing without generating a wound environment that would be too moist. EX1009 ¶90; EX1010 ¶75 (using materials with different MVTRs); EX1002 ¶176.

A POSA would additionally have recognized the benefits of a multi-drain configuration based on Lockwood's use of a plurality of tubes/ports. Lockwood discloses a flexible member, which is a thin silicone piece that sits near the bottom of the wound and is connected to the tube to apply negative pressure or to dispense fluid. EX1009 ¶¶73, 77-78. Lockwood explains that connecting multiple ports helps to distribute pressure throughout that flexible member. EX1009 ¶ 41, Fig. 15. One of Argenta's stated purposes of using screen 20 is to distribute the negative pressure

more evenly under cover 10. EX1004 ¶17. Based on Lockwood's disclosure, it would have been obvious to a POSA at the time of the invention to branch the distal end of Argenta's tube into multiple drains to better distribute the vacuum throughout the screen. EX1002 ¶¶198-199.

X. SECONDARY CONSIDERATIONS

Patent Owner did not raise any evidence of secondary considerations during prosecution and Petitioner is unaware of any.

XI. DISCRETIONARY DENIAL IS NOT WARRANTED

Petitioner believes that discretionary denial is unwarranted but will address any arguments to the contrary in the bifurcated process set forth in the Director's March 26, 2025 Memorandum concerning Interim Processes for PTAB Workload Management.

XII. CONCLUSION

Petitioner respectfully requests that *inter partes* review of the '404 Patent be instituted and that the Challenged Claims be cancelled as unpatentable pursuant to 35 U.S.C. § 318(b).

Respectfully submitted,

Date: June 13, 2025

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Petition for *Inter Partes* Review
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Petition for *Inter Partes* Review
of U.S. Patent 10,639,404

CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,590 words, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(1)(i).

Respectfully submitted,

Date: June 13, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), I certify that, on June 13, 2025, I caused to be served a true and correct copy of the foregoing Petition for Inter Partes Review, EX1001-EX1011, EX1013-EX1019, EX1021-EX1027, and EX1029-EX1033 by electronic means on counsel of record for Patent Owner

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at jweiss@weissarons.com, upon agreement of the parties (37 C.F.R. §42.105(b)). A copy of the foregoing was also served by electronic mail on Ariel Reinitz (Ariel@Bochner.law), counsel for Wound Healing Technologies Corp. in *Wound Healing Technologies Corp. v. Solventum Corporation*, 6:24-cv-00589-RP (W.D. Tex. filed Nov. 15, 2024).

Respectfully submitted,

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