

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Solventum Corporation,
Petitioner,

v.

M.E.A.C. Engineering Ltd.,
Patent Owner.

Case IPR2024-01002
Patent 8,858,534

Petition for *Inter Partes* Review

Mail Stop Patent Board
Patent Trial and Appeal Board
P.O. Box 1450
Alexandria, VA 22313-1450

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TABLE OF EXHIBITS¹

Exhibit No.²	Description	Publication Date (unless otherwise noted)	Type of Prior Art (Pre-AIA 35 U.S.C.)
1001	USPN 8,858,534 to Adahan (the '534 Patent) (Patent under <i>Inter Partes Review</i>)	Jul. 24, 2005 (filing date of priority PCT application)	N/A
1002	File History for USPN 8,858,534	N/A	N/A
1003	USPN 3,572,340 to Lloyd et al. (" <i>Lloyd</i> ")	Mar. 23, 1971	§ 102(b)
1004	USPN 4,569,674 to Phillips et al. (" <i>Phillips</i> ")	Feb. 11, 1986	§ 102(b)
1005	Canadian Patent No. 2,596,321 to Henley et al. (" <i>Henley</i> ")	Feb. 17, 2000	§ 102(b)

¹ For the Board's convenience, this Table of Exhibits includes all references cited in this Petition and in the corresponding Expert Declaration. Accordingly, the Table of Exhibits in the Petition and Declaration are the same with the lone exception being that Ex. 1007 is not an Exhibit to the Declaration because it is the Declaration.

² Petitioner adopts the following citation convention for this Petition and accompanying Declaration. U.S. patent references and the concurrently filed Declaration are cited by the reference's internal column:line, page:line, or ¶ number (not stamped pagination). Supporting papers (*e.g.*, file history, C.V., etc.) are cited by stamped pagination number.

Exhibit No.²	Description	Publication Date (unless otherwise noted)	Type of Prior Art (Pre-AIA 35 U.S.C.)
1006	USPN 5,636,643 to Argenta et al. (“ <i>Argenta</i> ”)	Jun. 10, 1997	§ 102(b)
1007	Declaration of Morten Olgaard Jensen in Support of Petition for <i>Inter Partes</i> Review of the ’534 Patent	N/A	N/A
1008	<i>Curriculum Vitae</i> of Morten Olgaard Jensen	N/A	N/A
1009	WO 03/030966 to Bitel et al. (“ <i>Bitel</i> ”)	Apr. 17, 2003	§ 102(b)
1010	USPN 5,599,333 to Atkinson (“ <i>Atkinson</i> ”)	Feb. 4, 1997	§ 102(b)
1011	Int’l Patent App. No. WO 98/52626 to Mantell et al. (“ <i>Mantell</i> ”)	Nov. 26, 1998	§ 102(b)
1012	USPN 8,506,554 to Adahan (the ’554 Patent) (Parent of ’534 Patent)	Jul. 24, 2005 (filing date of priority PCT application)	N/A
1013	File History for USPN 8,506,554	N/A	N/A
1014	USPN 8,157,792 to Dolliver (“ <i>Dolliver</i> ”)	Feb. 26, 2004 (filing date)	§ 102(e)
1015	USPN 6,648,862 to Watson (“ <i>Watson</i> ”)	Nov. 18, 2003	§ 102(b)

Solventum Corporation (“Petitioner”) respectfully petitions for *inter partes* review of Claims 1-22 of U.S. Patent No. 8,858,534 (the “’534 Patent”) (Ex. 1001). The ’534 Patent is directed to a wound closure and drainage system and related method. The ’534 Patent includes twenty-two total claims, of which three are independent. Petitioner respectfully requests that the Board institute trial for IPR of, and cancel, Claims 1-22 (the “Challenged Claims”) of the ’534 Patent.

The ’534 Patent is directed to a wound closure and drainage system, and method for using the same, comprised of just a few elements: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. But wound closure and drainage systems having enclosures, venting arrangements, tubes, vacuum sources, and controllers were well-known in the prior art before the ’534 Patent’s priority date. Likewise, all of the elements recited in the Challenged Claims were well-known in the prior art. Accordingly, this Petition explains why the Challenged Claims are unpatentable in view of the prior art.

I. BACKGROUND OF THE ’534 PATENT AND PRIOR ART

A. Evolution of Vacuum Therapy Wound Treatment Systems

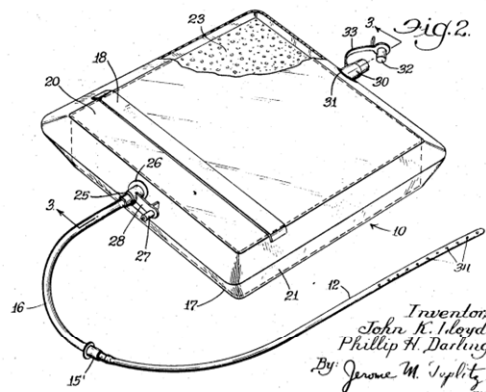
Vacuum therapy wound treatment systems were well-known for decades before the priority date of the ’534 Patent. *See* Ex. 1007, ¶¶27-29. For example, a patent from 1971, entitled “Suction Drainage Device” (“*Lloyd*”), discloses “A...disposable, sterile suction drainage device for extraction and collection of

body fluids from wounds...[that includes] a fluid-collecting pump unit.” See Ex. 1003, 1:12-15. Indeed, *Lloyd* teaches that such systems were known prior to *Lloyd*’s 1968 filing date stating, “[p]revious systems for providing closed wound suction have, in general, involved the use of cumbersome, expensive and noisy electrical or mechanical suction pumps.” *Id.*, 1:53-56. To avoid the use of electrical or mechanical suction pumps, *Lloyd* teaches manual activation of a suction pump that is “effected by applying external pressure to [a] container 17...by manually squeezing the container.” *Id.*, 5:25-27.

However, manually-operated vacuum therapy wound treatment systems such as *Lloyd* were known to suffer certain drawbacks. For example, a patent from 1986, entitled “Continuous Vacuum Wound Drainage System” (“*Phillips*”), teaches that such manually-operated devices “typically do not provide precise control of maximum negative pressure” and “are operable only for a relatively short time in that the device may pass quickly through the desired range of negative pressures prior to completely filling with drained liquid material and hence require frequent changing or emptying.” Ex. 1004, 1:30-34, 1:39-44. Thus, over time, manually-operated vacuum therapy wound treatment systems were largely replaced by systems in which the pump is electrically energized. See Ex. 1007, ¶¶30-31.

Furthermore, older vacuum therapy wound treatment systems often operated by placing a drainage tube/catheter in direct contact with the wound in a manner that exposed the wound to ambient air and the surroundings. For example, *Lloyd* teaches a drainage tube 12 having a plurality of apertures 34 at a distal end designed to be placed in direct contact with the wound, as shown in Figure 2 below:

Lloyd - Figure 2



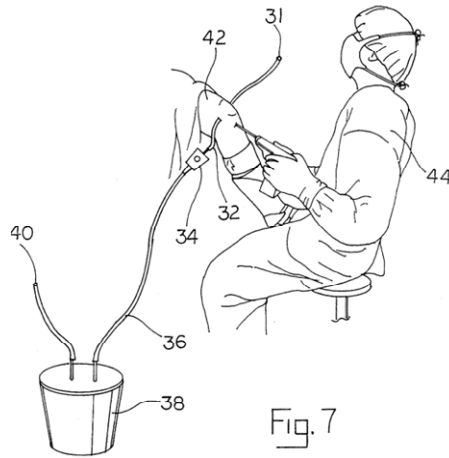
Ex. 1003, Fig. 2.

Prior art systems that utilized a drainage/tube catheter alone without any cover over the wound were also known to suffer from several drawbacks. For example, a patent from 1998, entitled “Wound Treatment Apparatus” (“*Henley*”), teaches that “[e]xposing [a] wound to the open atmosphere can increase the chance of infection” while “controlling the topical atmosphere adjacent a surface wound can enhance the healing process of the wound.” Ex. 1005, 2:13, 1:18-19. Further, a patent with a priority year of 1993, entitled “Wound Treatment Employing

Reduced Pressure” (“*Argenta*”), teaches that sealing the area around a wound is useful for “maintain[ing] reduced pressure in the vicinity of the wound during wound treatment” when using a vacuum therapy wound treatment system. Ex. 1006, 3:2-5. Thus, vacuum therapy wound treatment systems evolved over time to routinely incorporate a sealed enclosure/bandage/shield over the wound to prevent infection and facilitate improved pressure level control around the wound. See Ex. 1007, ¶¶32-33.

Conventional vacuum therapy wound treatment systems were also known to incorporate venting arrangements having flow restrictors, which allowed ambient air to enter the system’s tubes, including while under negative pressure. For example, a patent from 1997, entitled “Suction Adapter” (“*Atkinson*”), discloses a suction adapter 34 positioned along a tube (combination of “drain tube 32” and “suction tube 36”) in between a patient wound, on one side, and a waste container (referred to as a “suction canister 38”) and vacuum source (not shown) on the other side, as shown in Figure 7 below:

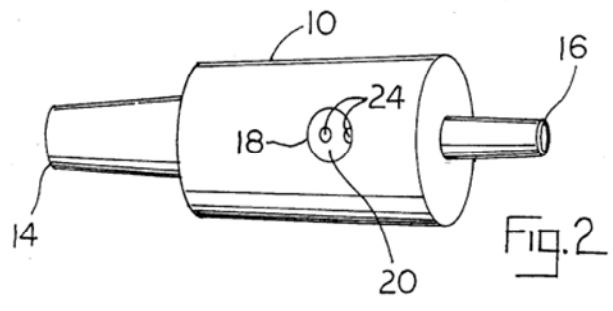
Atkinson - Figure 7



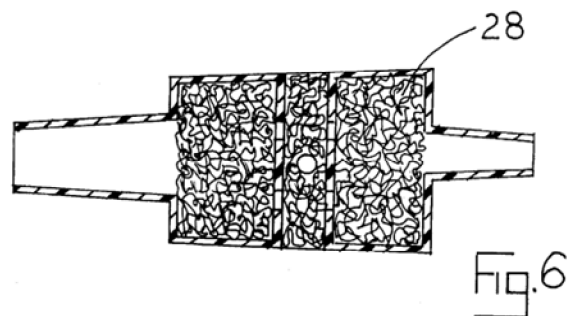
Ex. 1010, Fig. 7.

In *Atkinson*, the suction adapter 34 includes a housing 10 having a ventilation port 18 in communication with an interior space 12 of the housing 10 “to allow atmospheric air into the interior space 12,” as shown in Figure 2 below. *Id.*, 2:33-35, Fig. 2. In one embodiment of *Atkinson*, a porous foam 28 is disposed within the interior space 12 of the housing 10, including within the ventilation port 18, as shown in Figure 6 below:

Atkinson - Figure 2



Atkinson - Figure 6

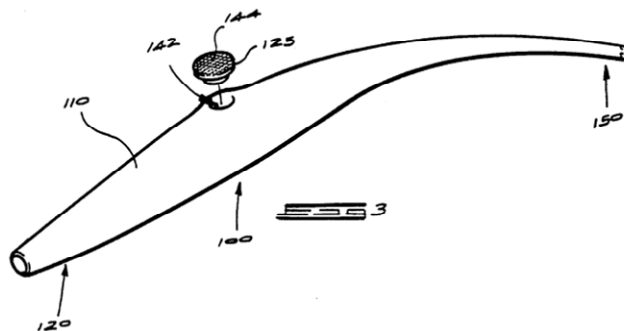


Atkinson teaches, “[t]he foam 28 is preferably a plastic foam easily permeated by the drain fluid and air...[f]or example, an open cell polyurethane foam having 10 to 30 pores per square inch has been found to work well.” *Id.*, 3:67-5:3. The porous foam 28 of *Atkinson* is described as providing sound dampening, *see id.*, 3:63-67; however, a person having ordinary skill in the art would have understood that this porous foam 28 would have also restricted the flow of ambient air into the suction adapter 34 and, consequently, into the suction tube 36 connecting the suction adapter 34 to the waste container and suction source. *See id.*, Fig. 7; Ex. 1007, ¶¶34-36.

It was also well-known in the prior art to include flow restrictor elements as part of venting arrangements in vacuum therapy wound treatment systems for other purposes, such as to permit the ingress of atmospheric air into a tube while preventing the entry of contaminants. For example, a published patent application from 1998, entitled “Nozzle For A Surgical Suction Apparatus” (“*Mantell*”), discloses a “nozzle for surgical suction apparatus...compris[ing] a suction tube (110) that is adapted for connection to the suction device at its connection end (120) and for location in the surgical area of a patient at its suction end (150).” Ex. 1011, Abstract. “The nozzle (100) includes a finger controllable suction control[] aperture (142) and a filter constituted by a gas permeable, liquid impermeable

membrane (144) that is incorporated in a plug (125) adapted to fit into the suction control aperture (142)” as shown in Figure 3 below.

Mantell - Figure 3



As shown in Figure 3, “[a] filter membrane 144 is incorporated in a plug 125 that is adapted to fit into the suction control aperture 142.” *Id.*, 6:14-16, Fig. 3. “Because of the membrane covering the suction control aperture, the possibility of contamination by wound fluids is greatly reduced...[and] the danger of a practitioner accidentally infecting a patient is likewise reduced.” *Id.*, 27-31; Ex. 1007, ¶37.

Additionally, controllers for controlling operation of vacuum sources within vacuum therapy wound treatment systems were well-known long before the priority date of the '534 Patent. For example, *Argenta* (discussed above) teaches, “[t]he vacuum pump 40 is preferably controlled by a control device 44 such as a switch or a timer which may be set to provide cyclic on/off operation of the vacuum pump 40 according to user-selected intervals,” as shown in Figure 1 below. Ex. 1006, 8:21-24. More specifically, *Argenta* teaches “[i]ntermittent or

cyclic supply of reduced pressure to an appliance may be achieved by manual or automatic control of the vacuum system.” *Id.*, 13:5-7. “A cycle ratio, the ratio of ‘on’ time to ‘off’ time, in such an intermittent reduced pressure treatment may be as low as 1:10 or as high as 10:1.” *Id.*, 13:7-10; Ex. 1007 ¶38.

Argenta - Figure 1

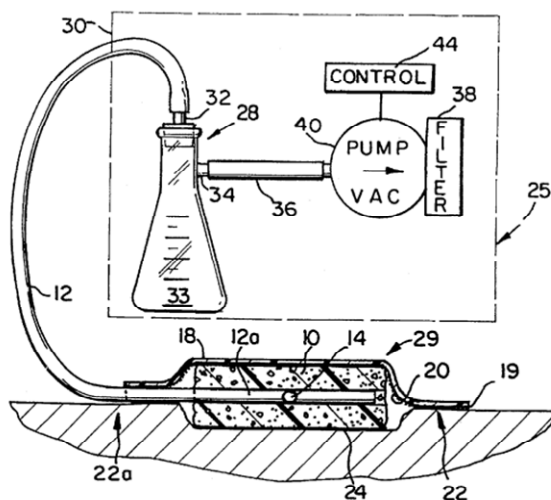


FIG. 1

Likewise, USPN 8,157,792 (“*Dolliver*”), filed in 2004, teaches a controller that controls the suction of the vacuum. *See e.g.* Ex. 1014. More specifically, *Dolliver* teaches, “[b]ased on the signal received from the one or more sensors 125, the controller 117 may verify and/or adjust the level of suction generated by the suction device 106.” *Id.*, 5:12-15, Ex. 1007, ¶39.

Despite this crowded field of prior art, the ’534 Patent issued with broad claims directed to a common vacuum therapy wound treatment system for applying negative pressure to a wound including an enclosure, a venting arrangement

comprising a flow restrictor, a tube, a vacuum source, and a controller configured for controlling operation of the vacuum source. *See infra* Part I.C (discussing the prosecution history of the '534 Patent). But these claim elements were all common components known for years prior to the time of the alleged invention. Ex. 1007, ¶40.

B. Description of the Alleged Invention of the '534 Patent

The '534 Patent, entitled “Wound Closure and Drainage System,” discloses a “vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids.” Ex. 1001, Abstract; Ex. 1007, ¶41-42.

Claim 1 recites a vacuum system for applying negative pressure to a wound having an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. The enclosure is attachable to a periphery of the wound so as to define a confined volume and has an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be created in the volume. The venting arrangement includes a flow restrictor to restrict flow through the venting arrangement and to thereby provide a controlled flow of ambient air into the vacuum system upstream of the vacuum source. The controller controls the

operation of the vacuum source to provide a desired level of negative pressure in the confined volume while vacuum system is being vented via the venting arrangement.

Claim 2 depends from Claim 1 and claims the additional feature of the flow restrictor is provided in any one of the enclosure or the tube.

Claim 3 depends from Claim 1 and claims the additional feature of a sensor for enabling determination of a level of the negative pressure in the confined volume.

Claim 4 depends from Claim 1 and claims the additional feature of a waste container in fluid communication with the vacuum source.

Claim 5 depends from Claim 1 and claims the additional feature of a vacuum pump driven by a motor.

Claim 6 depends from Claim 5 and claims the additional features of: (i) the motor is an electric motor, and (ii) the controller controls operation of the motor to thereby provide a desired level of said negative pressure in the confined volume.

Claim 7 depends from Claim 6 and claims the additional feature of the controller controls the electric current or the voltage of the motor to control the level of negative pressure in the confined volume.

Claim 8 depends from Claim 6 and claims the additional feature of the controller controls the torque of the motor to control the level of negative pressure in the confined volume.

Claim 9 depends from Claim 1 and claims the additional feature of the ambient pressure may be restored in the confined volume via the venting arrangement when the vacuum pump is not operating.

Claim 10 depends from Claim 1 and claims the additional feature of the venting arrangement comprising at least one of: (i) one or more bleeding holes, (ii) a porous body, (iii) an orifice.

Claim 11 recites a vacuum system for applying negative pressure to a wound having an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. The enclosure is attachable to a periphery of the wound so as to define a confined volume. The enclosure has an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be selectively created in the volume. The venting arrangement is located outside of the enclosure and includes a flow restrictor to restrict flow through the venting arrangement and to thereby provide a controlled flow of ambient air into the tube. The controlled flow of ambient air enters the tube via the venting arrangement without entering the enclosure. The controller controls the operation of the vacuum source to provide a

desired level of negative pressure in the confined volume while the tube is being vented via the venting arrangement.

Claim 12 depends from Claim 11 and claims the additional features of a sensor for enabling determination of a level of the negative pressure in the confined volume.

Claim 13 depends from Claim 11 and claims the additional feature of a waste container in fluid communication with the vacuum source.

Claim 14 depends from Claim 11 and claims the additional feature of the vacuum source comprises a vacuum pump driven by a motor.

Claim 15 depends from Claim 14 and claims the additional features of: (i) the motor is an electric motor, and (ii) the controller controls operation of the motor to thereby provide a desired level of said negative pressure in the confined volume.

Claim 16 depends from Claim 15 and claims the additional feature of the controller controlling at least one of: (i) the electric current of the motor, (ii) the voltage of the motor, or (iii) the torque of the motor to control the level of the negative pressure in the confined volume.

Claim 17 depends from Claim 11 and claims the additional feature of the ambient pressure may be restored in the confined volume via the venting arrangement when the vacuum pump is not operating.

Claim 18 depends from Claim 11 and claims the additional feature of the venting arrangement comprising at least one of: (i) one or more bleeding holes, (ii) a porous body, (iii) an orifice.

Claim 19 recites a method for applying negative pressure to a wound. The method includes providing a vacuum system having an enclosure, a venting arrangement, a tube, and a vacuum source. The enclosure is attachable to a periphery of the wound so as to define a confined volume. The enclosure has an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be selectively created in the volume. The venting arrangement includes a flow restrictor to restrict flow through the venting arrangement and to thereby provide a controlled flow of ambient air into the vacuum system upstream of the vacuum source. The method includes controlling operation of the vacuum source while the vacuum source is being vented via the venting arrangement to provide a desired level of negative pressure in the confined volume.

Claim 20 depends from Claim 19 and claims the additional features of: (i) the vacuum source includes a vacuum pump driven by an electric motor, and (ii) controlling operation of the motor to thereby provide a desired level of the negative pressure in said confined volume.

Claim 21 depends from Claim 20 and claims the additional features of the controller controlling at least one of: (i) the electric current of the motor, (ii) the

voltage of the motor, or (iii) the torque of the motor to control the level of the negative pressure in the confined volume.

Claim 22 depends from Claim 19 and claims the additional feature of the venting arrangement comprising at least one of: (i) one or more bleeding holes, (ii) a porous body, (iii) an orifice.

C. Summary of the Prosecution History

U.S. Application No. 13/917,865 (the “’865 Application”), which issued as the ’534 Patent, was filed on June 14, 2013. Ex. 1001, Cover Page. The ’534 Patent is a continuation of U.S. Application No. 11/989,297, which later issued as U.S. Patent No. 8,506,554 (the “’554 Patent”) *Id.*

The prosecution history of the ’554 Patent is relevant to understanding the prosecution history of the ’534 Patent. A Notice of Allowance for the ’554 Patent was mailed October 9, 2012. *See* Ex. 1013, 774-77. By way of a post-allowance amendment filed January 8, 2013, the pending independent claims were amended, *inter alia*, to replace limitations related to the “venting arrangement comprising a calibrated orifice to restrict flow through said venting arrangement” with limitations reciting that the venting arrangement comprises “a flow restrictor.” *See id.*, 807-817. Further, the “without entering said enclosure” limitation was added to claim 42. *Id.*, 811.

An applicant-initiated interview summary was mailed April 10, 2013 summarizing an interview that had been conducted as follows: “Applicant authorized the Examiner to include words ‘to restrict flow through said venting arrangement’ after words ‘flow restrictor’ in claims 11 and 42.” *Id.*, 833. Pending independent claims 11 and 42 were amended via an Examiner’s Amendment to incorporate the foregoing limitation, and a Notice of Allowance was mailed on the same date. *See id.*, 835-37. The accompanying Reasons for Allowance provided: “The closest Prior Art of record US 200110029956 and US 3,516,160 fail to teach, suggest or render obvious a flow restrictor restricting flow through the venting arrangement ***located outside of the enclosure*** that prevents the overvacuum conditions during the medical procedure.” *Id.*, 837 (emphasis added).

An Applicant’s interview summary was filed May 10, 2013 stating that “the only substantive change [to the pending independent claims] was changing ‘calibrated orifice’ to ‘flow restrictor’,” and that the Examiner considered the terms to be the same “except that ‘flow restrictor’ is a little broader.” *Id.*, 1048-49.

As-filed claims 1-22 of the ’865 Application were highly similar to the granted claims of the parent ’554 Patent, with two notable exceptions. *See Ex. 1002*, 35-38. *First*, the as-filed claims of the ’865 Application omitted the limitation of the granted claims of the ’554 Patent requiring that the “venting arrangement” be located outside the enclosure, which limitation was relied upon to

overcome the cited prior art during prosecution of the application that matured in the '554 Patent. *Compare* Ex. 1002, 35-38 with Ex. 1013, 477 and 484 (arguing around cited prior art on basis that cited prior art failed to teach a venting arrangement located outside of an enclosure). *Second*, the as-filed claims of the '865 Application recited a “controller,” which is not a claimed feature of any of the granted claims of the '554 Patent. *Compare* Ex. 1002, 35-38 with Ex. 1012, 6:17-8:29.

In a non-final office action mailed March 11, 2014 in connection with the '865 Application (the only office action issued in connection with the '865 Application), all pending claims 1-22 were rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1, 6, 8, 9, 20, and 24 of the '554 parent-Patent in view of Argenta et al. (US 2001/0029956). Ex. 1002, 171-174. Notably, the non-final office action contended that “[a]ll the limitations of [independent] claims 1 and 11 of the ['865 Application] are to be found in claim 1 of the ['554 Patent]...[t]he difference is that claim 1 of the Patent does not comprise the controller configured for controlling operation of the vacuum source.” *Id.*, 172. Relatedly, the non-final office action contended that “[a]ll the limitations of [independent] claim 19 of the ['865 Application] are to be found in claim 1 of the ['554 Patent]...[t]he difference is that claim 1 of the Patent does not comprise the step of controlling the vacuum source.” *Id.*

But the non-final office action did not appear to recognize that the pending claims of the '865 Application also differed from the granted claims of the '554 Patent because ***they did not require the venting arrangement to be located outside the enclosure***—a limitation that was required for the claims of the '554 Patent to overcome prior art-based rejections during prosecution. This failure to appreciate a material difference in scope between the granted claims of the '554 Patent and pending claims of the '865 Application constituted at least one instance of error that this Petition seeks to correct.

Furthermore, the only other meaningful difference recognized between the pending claims of the '865 Application and granted claims of the '554 Patent—the inclusion of a controller and the claimed functions attributed thereto—could not have formed the basis for patentability over the prior art where the Examiner noted that, as exemplified by prior art reference Argenta, prior art vacuum therapy wound treatment systems were well-known to incorporate controllers for controlling vacuum sources. *See* Ex. 1002, 173.

Despite the pending claims of the '865 Application omitting a key limitation that was required to overcome the prior art cited during prosecution of the parent application, and despite controllers for performing the claimed functions being well-known in the prior art, the Applicant of the '865 Application was able to overcome the double-patenting rejection by filing a terminal disclaimer on June 2,

2014. *Id.*, 257. An issue notification was mailed September 24, 2014 and the '534 Patent issued on October 14, 2014. *Id.*, 377.

II. IDENTIFICATION OF CHALLENGE: 37 C.F.R. § 42.104(b)

Petitioner challenges Claims 1-22 as follows:

Ground	Claim(s)	Pre-AIA 35 U.S.C. Basis	References
1	1-22	§ 102(b)	<i>Bitel</i>

Ground 1 shows how *Bitel* anticipates Claims 1-22.

III. SUMMARY OF THE ASSERTED PRIOR ART

A. *Bitel*: International Publication No. WO 03/030966 (Ex. 1009)

Bitel published in 2003 and is § 102(b) prior art. *Bitel* is listed on the face of the '534 Patent, but it was not applied against any of the claims during prosecution. Accordingly, neither the Applicant nor the Examiner ever commented on the applicability of *Bitel* to the Challenged Claims.

Bitel “relates to a wound treatment system and specifically to a vacuum therapy wound treatment system for...the drainage and collection of exudate from the wound surface through vacuum therapy.” Ex. 1009, 1:4-7. The “[s]ystem 10 comprises a vacuum bandage 16, a waste container or receptacle 18 coupled to the bandage 16, and a housing 20 coupled to the receptacle 18...[, which] includes a vacuum source 21...for applying negative pressure to the wound to draw exudate from the wound in order to facilitate healing.” Ex. 1009, 5:12-16, Fig. 1

(reproduced below). The system further includes “a first tube coupled to the port of the bandage and the receptacle” and “a second tube coupled to the vacuum source and the receptacle.” Ex. 1009, 3:16-18. Additionally, *Bitel* discloses “a control dominating the vacuum source to establish the amount of vacuum applied to the space and the time when the vacuum is applied to the space.” Ex. 1009, 3:19-21.

Bitel - Figure 1

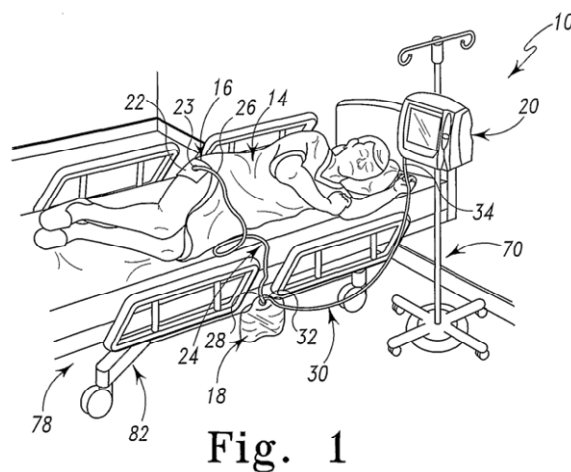


Fig. 1

The “[v]acuum bandage 16 includes a cover 22 to seal about the wound...[such that] [t]he bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum.” Ex. 1009, 5:31-33. “The bandage 16 further includes a port 23 in communication with the space above the wound.” *Id.*, 5:33-6:1. “The port 23 is coupled to receptacle 18 by a first tube 24 of the system 10.” *Id.*, 6:1-2.

The “[v]acuum source 21 may be contained within housing 20 or may be external to the housing 20.” *Id.*, 6:28-29. “Vacuum source 21 is also defined to

include any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example.” Ex. 1009, 6:31-33.

“As shown in Fig. 5 [reproduced below], receptacle 18 further includes a hydrophobic filter 60 in communication with [a] second tube 30 and thus the vacuum source 21.” *Id.*, 6:19-20, Fig. 5.

Bitel - Figure 5

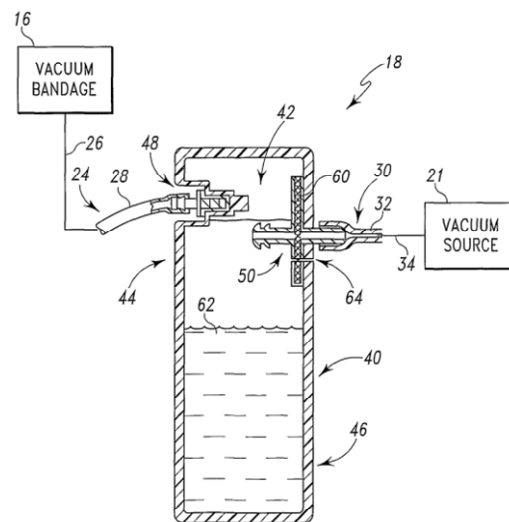


Fig. 5

A “first end 32 of [the] second tube 30 is coupled to [an] outlet port 50 of receptacle 18 and [a] second end 34 of [the] second tube 30 is coupled to [the] vacuum source 21.” *Id.*, 6:26–28. “By this series configuration, the vacuum source 21 is thus in fluid communication with the receptacle 18 through the second tube 3[0], and the space above the wound created by vacuum bandage 16 is in fluid communication with receptacle 18 through first tube 24.” *Id.*, 5:21–26. “Therefore, the vacuum source 21 operates to create negative pressure, or a vacuum, in the

space above the wound, in the first tube 24, in receptacle 18, and in second tube 30.” *Id.*, 5:26–28.

“Upper portion 44 of receptacle 18 further defines an air vent 64 to provide communication between interior cavity 42 of receptacle 18 and the outside atmosphere.” *Id.*, 6:21-23. “[A]s shown in Fig. 5, hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering receptacle 18.” *Id.*, 6:23-25.

Additionally, *Bitel* discloses “a control dominating the vacuum source to establish the amount of vacuum applied to the space and the time when the vacuum is applied to the space.” *Id.*, 3:19-21. Specifically, “[i]n addition to the vacuum source 21, it is also within the scope of the disclosure for housing 20 to include a controller [] for controlling the amount and rate of negative pressure to be applied to the wound.” *Id.*, 7:10-12.

Further, “[o]nce system 10 has become relatively static and there is little to no fluid flow from bandage 16 through first tube 24 and to receptacle 18, vacuum source 21 is still able to pull air through air vent 64 thus allowing the flow sensor to detect a fluid flow in order to keep the vacuum source 21 running. Once the level of exudate 62 collected within receptacle 18 reaches air vent 64 and/or outlet port 50, hydrophobic filter 60 will prevent liquid to pass therethrough and the flow sensor will sense that the flow has become static.” *Id.*, 8:13-16. “The flow sensor

will send a signal to the controller which will, in turn, tell the vacuum source 21 to turn off.” *Id.*, 8:16-17.

Finally, *Bitel* relates to “[a] method for treating a wound on a patient . . . including the steps of sealing a bandage having a port about the wound to define a space above the wound in which a vacuum can be formed, placing a receptacle below the wound, and placing a vacuum source spaced away from the receptacle.” *Id.*, 4:1-4.

IV. CLAIM CONSTRUCTION: 37 C.F.R. § 42.104(b)(3)

A. Applicable Law

The claim construction standard of *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) applies to this proceeding.

B. Person of Skill in the Art

A POSITA would have the following characteristics: (1) a bachelor’s degree in biomedical or mechanical engineering or a related field; and (2) either a master’s degree in biomedical or mechanical engineering or a related field, or three years of relevant industry experience. *See* Ex. 1007, ¶¶18-23.

C. Claim Term(s)

Petitioner does not propose any terms for construction at this time, but reserves the right to respond to any constructions proposed by Patent Owner and/or

offer one or more constructions in response to any constructions proposed by Patent Owner.³

V. DETAILED EXPLANATION OF GROUNDS

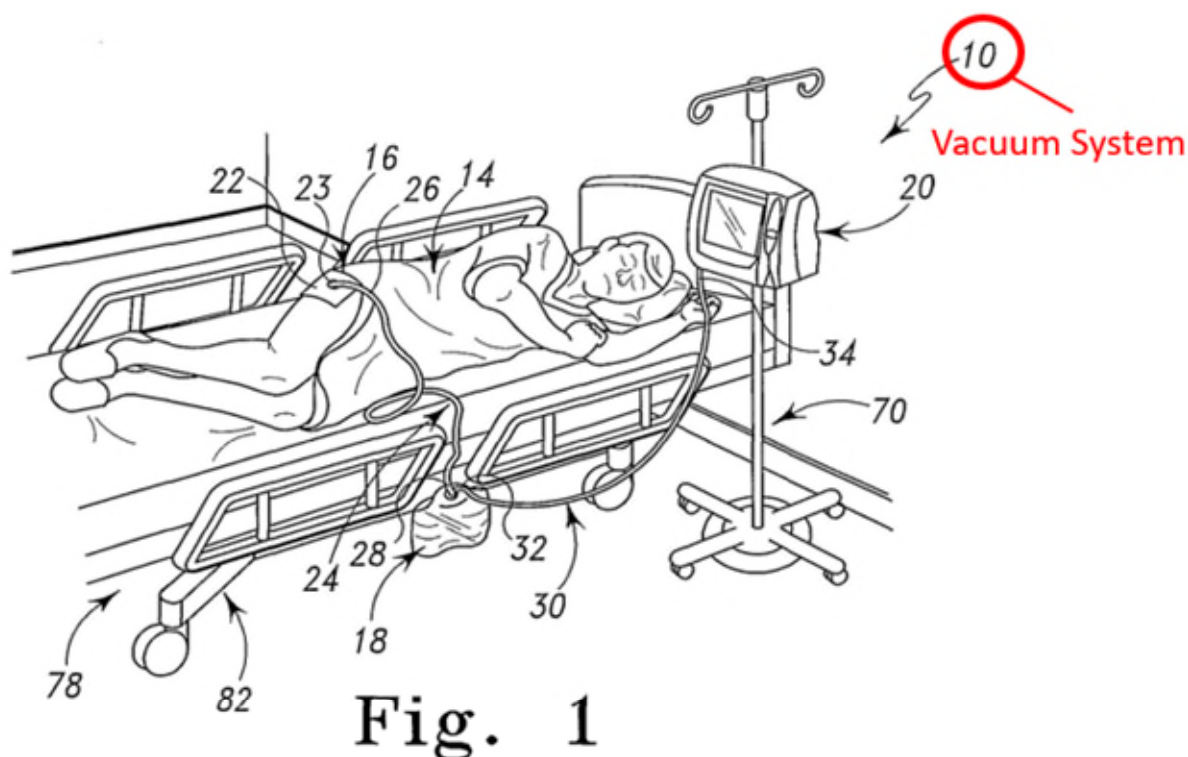
A. Ground 1: Claims 1-22 Are Anticipated Under Pre-AIA 35 U.S.C. § 102(b) by *Bitel*

1. Each Element of Claim 1 Is Found in *Bitel*

(a) [1.P] A vacuum system for applying negative pressure to a wound

Bitel discloses “a wound treatment system and specifically...a vacuum therapy wound treatment system for surface wounds.” Ex. 1009, 1:4-5. More specifically, *Bitel* teaches a vacuum therapy system 10 for treating a wound on a patient 14. *Id.*, 5:11-12; Ex. 1007, ¶94. The “[s]ystem 10 comprises a vacuum bandage 16, a waste container or receptacle 18 coupled to the bandage 16, and a housing 20 coupled to the receptacle 18.” *Id.*, 5:12-14. The “[h]ousing 20 includes a vacuum source 21...for applying negative pressure to the wound to draw exudate from the wound in order to facilitate healing.” *Id.*, 5:14-16, Fig. 1 (reproduced below).

³ Petitioner does not concede that any term in any Challenged Claim meets the statutory requirements of 35 U.S.C. § 112.



Id., Fig. 1; Ex. 1007, ¶94.

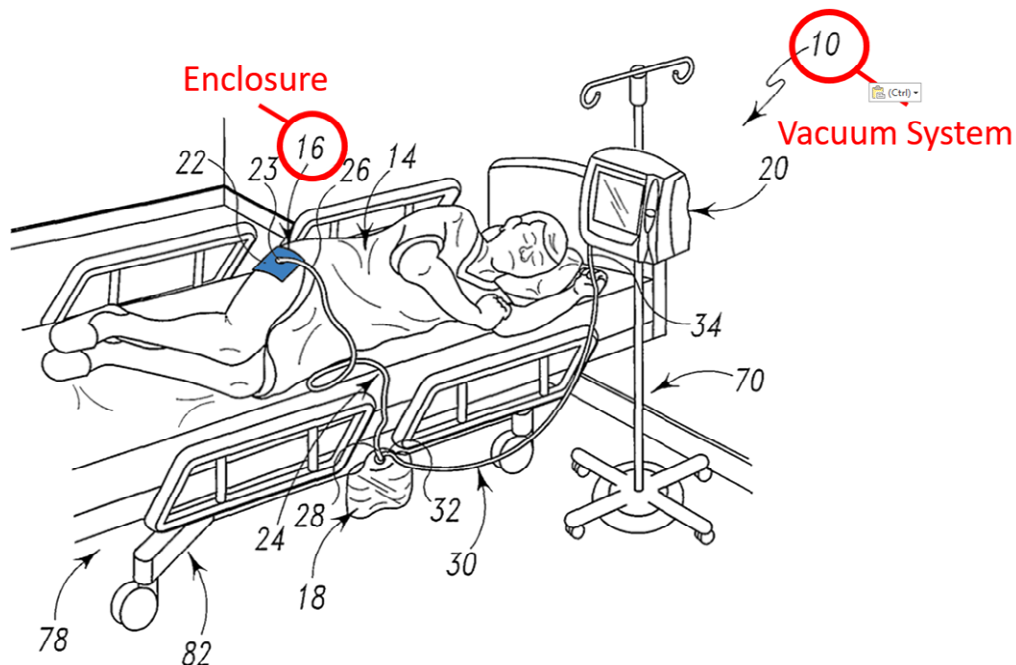
Thus, *Bitel* teaches a vacuum system (vacuum therapy system 10) for applying negative pressure to a wound. Ex. 1007, ¶95.

(b) [1.1] The vacuum system comprising: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller

Bitel teaches a vacuum system. See *supra* § V.A.1(a). In addition, *Bitel* discloses a vacuum bandage 16 that “includes a cover 22 to seal about the wound.” Ex. 1009, 5:31. “The bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum.” *Id.*, 5:31-33. The vacuum bandage 16 of *Bitel* constitutes “an enclosure” as claimed because it creates a seal about a wound and defines “a space above the wound to which

negative pressure can be applied to form a vacuum.” *Id.*, 5:31–33; Ex. 1007, ¶¶96–97.

As shown in annotated Figure 1 below, vacuum bandage 16 (blue) constitutes an enclosure.



Bitel also teaches “[u]pper portion 44 of receptacle 18 further defines an air vent 64 to provide communication between interior cavity 42 of receptacle 18 and the outside atmosphere.” Ex. 1009, 6:21-23. “Preferably, as shown in Fig. 5, [a] hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering receptacle 18.” *Id.*, 6:23-25. The “vacuum source 21 is...able to pull air through air vent 64.” *Id.*, 8:11-12. The combination of air vent 64 and hydrophobic filter 60 constitutes a “venting arrangement” as claimed in that it vents the vacuum therapy system 10 to atmosphere, including

when the vacuum source 21 is generating negative pressure within the system 10. Ex. 1007, ¶¶99-100.

Additionally, *Bitel* discloses that the “[s]ystem 10 further includes a second tube 30 coupled at a first end 32 to the receptacle 18 and coupled at a second end 34 to the vacuum source 21 which may be contained within housing 20.” Ex. 1009, 6:3-5, Fig. 5. More specifically, the second tube 30 is connected to the receptacle 18 via an outlet port 50: “first end 32 of second tube 30 is coupled to outlet port 50 of receptacle 18 and second end 34 of second tube 30 is coupled to vacuum source 21.” *Id.*, 6:26–28. The outlet port 50 constitutes a “tube” as claimed because it is an elongated, hollow cylinder for transporting gases and/or liquids. Ex. 1007, ¶¶ 101-102.

Further, *Bitel* teaches “a vacuum source 21...for applying negative pressure to the wound to draw exudate from the wound in order to facilitate healing.” *Id.*, 5:14-16, Fig. 1, Fig. 5. The vacuum source 21 of *Bitel* constitutes “a vacuum source” as claimed. Ex. 1007, ¶¶103-104.

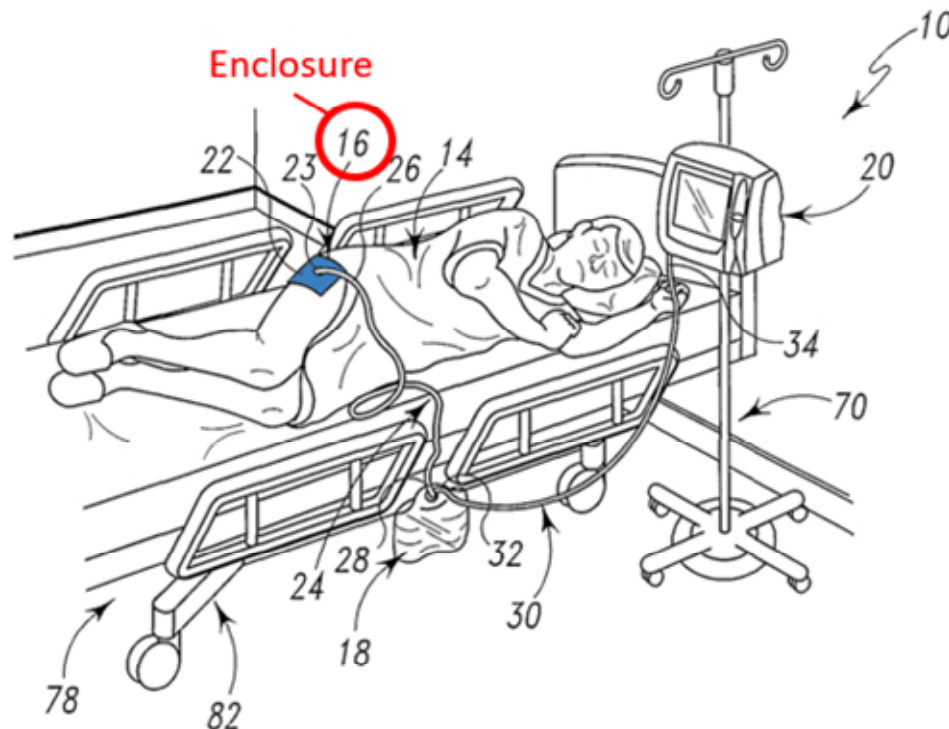
As shown in annotated Figure 5 below, air vent 64 (purple) and hydrophobic filter 60 (yellow) constitute a venting arrangement (outlined in teal), the outlet port 50 (green) constitutes a tube, and the vacuum source 21 (orange) constitutes a vacuum source.

microporous filter 60), a tube (outlet port 50), a vacuum source (vacuum source 21), and a controller (controller, no reference numeral assigned). Ex. 1007, ¶108.

(c) [1.2] The enclosure being attachable to a periphery of the wound so as to define a confined volume

Bitel discloses that its vacuum bandage 16 “includes a cover 22 to seal about the wound.” Ex. 1009, 5:31. “The bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum.” *Id.*, 5:31-33.

As shown in annotated Figure 1 below, vacuum bandage 16 (blue) constitutes the enclosure being attachable to a periphery of the wound so as to define a confined volume.



Id., Fig. 1; Ex. 1007, ¶¶109-110.

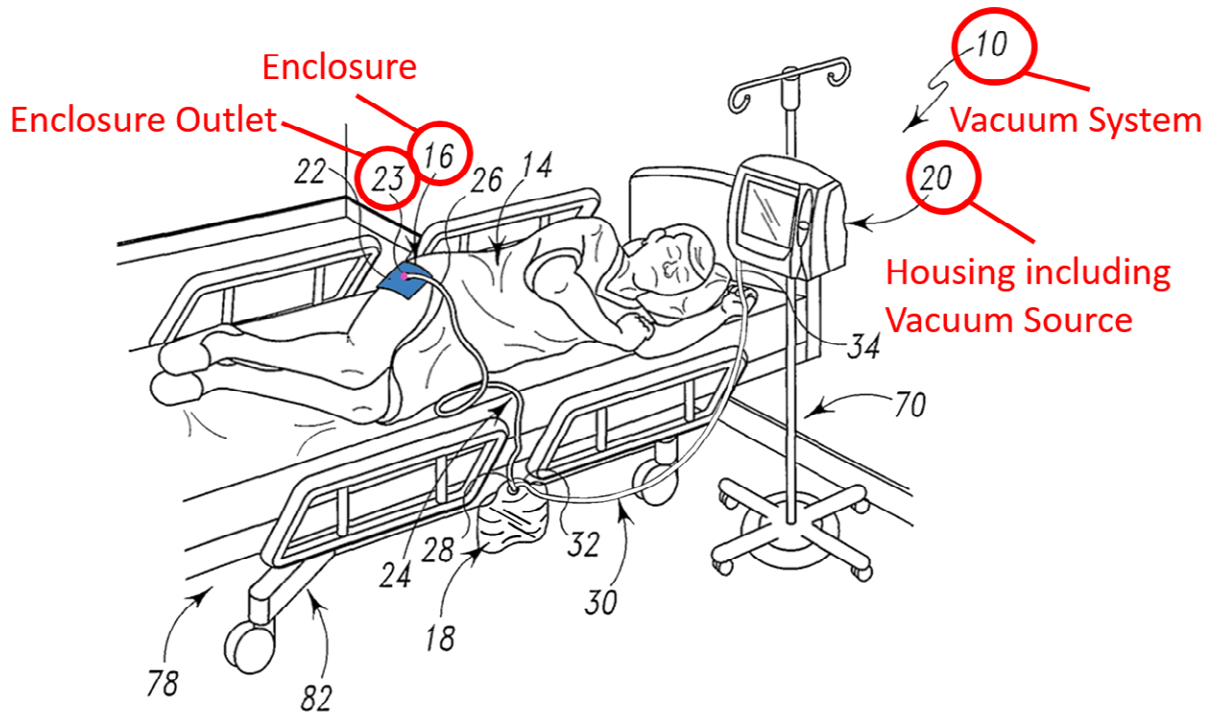
Thus, *Bitel* teaches the enclosure (bandage 16) being attachable to a periphery of the wound so as to define a confined volume (volume under bandage 16). Ex. 1007, ¶111.

(d) [1.3] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume

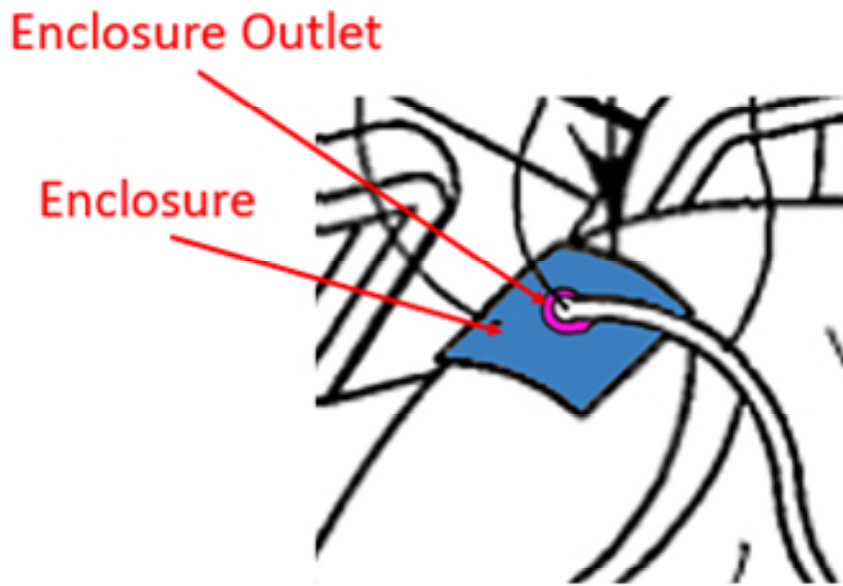
Bitel discloses “[t]he bandage 16 further includes a port 23 in communication with the space above the wound.” Ex. 1009, 5:33-6:1. “The port 23 is coupled to receptacle 18 by a first tube 24 of the system 10. First tube 24 includes a first end 26 coupled to the port 23 and a second end 28 coupled to the receptacle 18.” *Id.*, 6:1-3. “System 10 further includes a second tube 30 coupled at a first end 32 to the receptacle 18 and coupled at a second end 34 to the vacuum source 21.” *Id.*, 3-5.

The port 23 of *Bitel* constitutes an “enclosure outlet” as claimed in that it facilitates connection between the bandage 16 and the vacuum source 21 via the first tube 24, receptacle 18, outlet port 50, and second tube 30. Ex. 1007, ¶¶112-13. The port 23 is connectable to the vacuum source 21 via the outlet port 50 of the receptacle 18 so that negative pressure can be created in the volume under bandage 16. See Ex. 1009, 5:31-33 (“The bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum.”), 5:33-6:5, Figs. 1 and 5; Ex. 1007, ¶114.

As shown in annotated Figure 1 below, vacuum bandage 16 (blue) constitutes the enclosure and port 23 (pink) constitutes the enclosure outlet. A magnified view of vacuum bandage 16 and port 23 as shown in Figure 1 is also provided.



Ex. 1009, Fig. 1; Ex. 1007, ¶115.



Ex. 1009, Fig. 1 (magnified to more readily show port 23); Ex. 1007, ¶115.

Finally, *Bitel* teaches “a control dominating the vacuum source to establish the amount of vacuum applied to the space and the time when the vacuum is applied to the space.” Ex. 1009, 3:19-21; Ex. 1007, ¶116.

Thus, *Bitel* teaches the enclosure (bandage 16) having an enclosure outlet (port 23) connectable to said vacuum source (vacuum source 21) via said tube (outlet port 50) so that negative pressure can be selectively created (control dominating the vacuum source) in said volume (volume under bandage 16). Ex. 1007, ¶117.

- (e) **[1.4] The venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said vacuum system upstream of the vacuum source**

Bitel teaches “[u]pper portion 44 of receptacle 18 further defines an air vent 64 to prove communication between interior cavity 42 of receptacle 18 and the outside atmosphere.” Ex. 1009, 6:21-23. “Preferably, as shown in Fig. 5, [a] hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering receptacle 18.” *Id.*, 6:23-25, Fig. 5. The “vacuum source 21 is...able to pull air through air vent 64.” *Id.*, 8:11-12. The combination of air vent 64 and hydrophobic filter 60 constitutes a “venting arrangement” as claimed in that it vents the vacuum therapy system 10 to atmosphere, including when the vacuum source 21 is generating negative pressure within the system 10. Ex. 1007, ¶¶118-19. Furthermore, the hydrophobic filter 60 constitutes a flow restrictor as claimed in that it restricts flow through the venting arrangement. *Id.*, ¶¶120-128 (explaining how the presence of a filter adds resistance to flow, which is a form of impedance that causes a reduction in a fluid’s pressure energy as it passes through the filter).

As shown in annotated Figure 5 below, air vent 64 and hydrophobic filter 60 (outlined in teal) constitute a venting arrangement and hydrophobic filter 60 (yellow) constitutes a flow restrictor to restrict flow through the venting

arrangement. A magnified view of Figure 5 is further provided to more readily show the hydrophobic filter 60 acting as a flow restrictor.

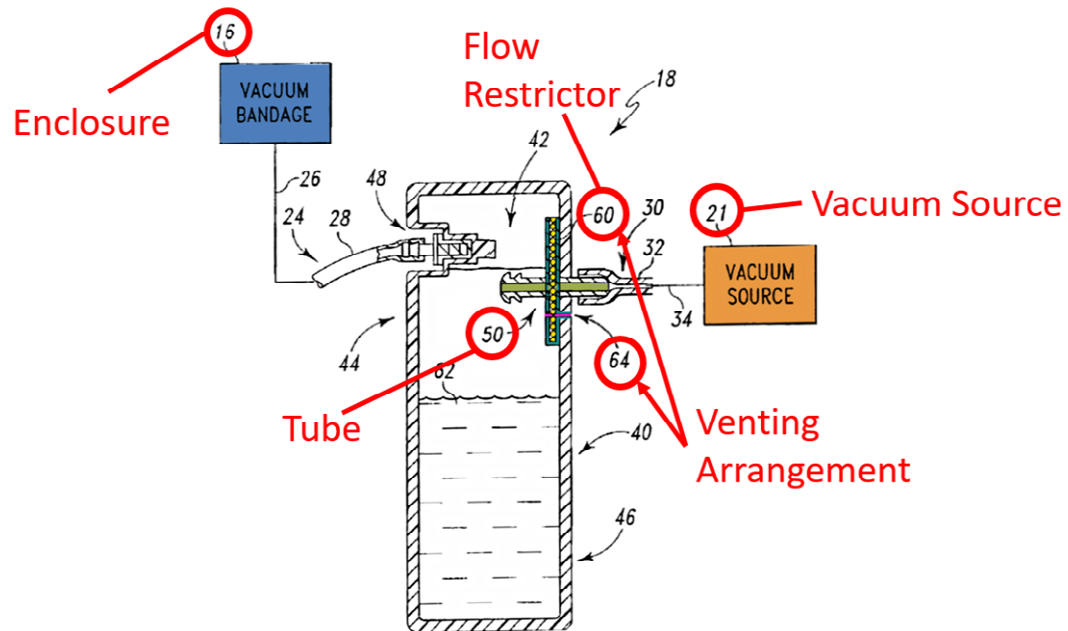
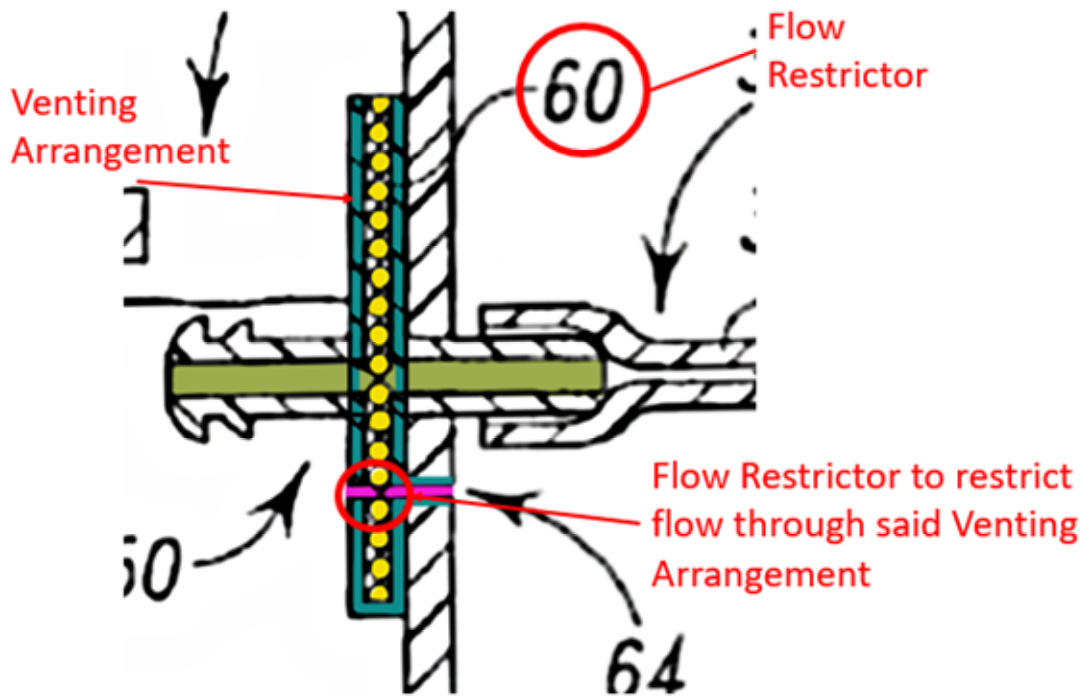


Fig. 5

Ex. 1009, Fig. 5; Ex. 1007, ¶129.



Ex. 1009, Fig. 5 (magnified to more readily show hydrophobic filter acting as a flow restrictor); Ex. 1007, ¶129.

Bitel further provides that “[o]nce system 10 has become relatively static and there is little to no fluid flow from bandage 16 through first tube 24 and to receptacle 18, ***vacuum source 21 is still able to pull air through air vent 64*** thus allowing the flow sensor to detect a fluid flow in order to keep the vacuum source 21 running.” Ex. 1009, 8:10-13 (emphasis added). Thus, the air vent 64/filter 60 configuration of *Bitel* “provide a controlled flow of ambient air into said vacuum system” as claimed. Ex. 1007, ¶¶130-31. Furthermore, the ambient air entering air vent 64/filter 60 flows towards the vacuum source 21 and is thus “upstream of the

vacuum source” as claimed. *Id.*, ¶132 (“[A] fluid flowing towards a vacuum source is ‘upstream of the vacuum source.’”); Ex. 1009, Fig. 5.

Thus, *Bitel* teaches the venting arrangement (air vent 64 and hydrophobic filter 60) comprising a flow restrictor (hydrophobic filter 60) to restrict flow through said venting arrangement (air vent 64 and hydrophobic filter 60) and to thereby provide a controlled flow of ambient air into said vacuum system (vacuum therapy system 10) upstream of the vacuum source (vacuum source 21). Ex. 1007, ¶133.

- (f) **[1.5] The controller configured for controlling operation of the vacuum source while providing venting of the vacuum system via said venting arrangement to provide a desired level of said negative pressure in said confined volume**

Bitel teaches “a control dominating the vacuum source to establish the amount of vacuum applied to the space [under bandage 16] and the time when the vacuum is applied to the space.” Ex. 1009, 3:19-21. Specifically, “[i]n addition to the vacuum source 21, it is also within the scope of the disclosure for housing 20 to include a controller [] for controlling the amount and rate of negative pressure to be applied to the wound.” *Id.*, 7:10-12.

Further, “[o]nce system 10 has become relatively static and there is little to no fluid flow from bandage 16 through first tube 24 and to receptacle 18, vacuum source 21 is still able to pull air through air vent 64 thus allowing the flow sensor

to detect a fluid flow in order to keep the vacuum source 21 running. Once the level of exudate 62 collected within receptacle 18 reaches air vent 64 and/or outlet port 50, hydrophobic filter 60 will prevent liquid to pass therethrough and the flow sensor will sense that the flow has become static.” *Id.*, 8:13-16. “The flow sensor will send a signal to the controller which will, in turn, tell the vacuum source 21 to turn off.” *Id.*, 8:16-17.

Thus, *Bitel* teaches the controller (controller) configured for controlling operation (a controller for controlling the amount and rate of negative pressure to be applied to the wound) of the vacuum source (vacuum source 21) while providing venting of the vacuum system via said venting arrangement (air vent 64 and hydrophobic filter 60) to provide a desired level of said negative pressure in said confined volume. Ex. 1007, ¶¶136-138.

Therefore, *Bitel* teaches each and every limitation of claim 1.

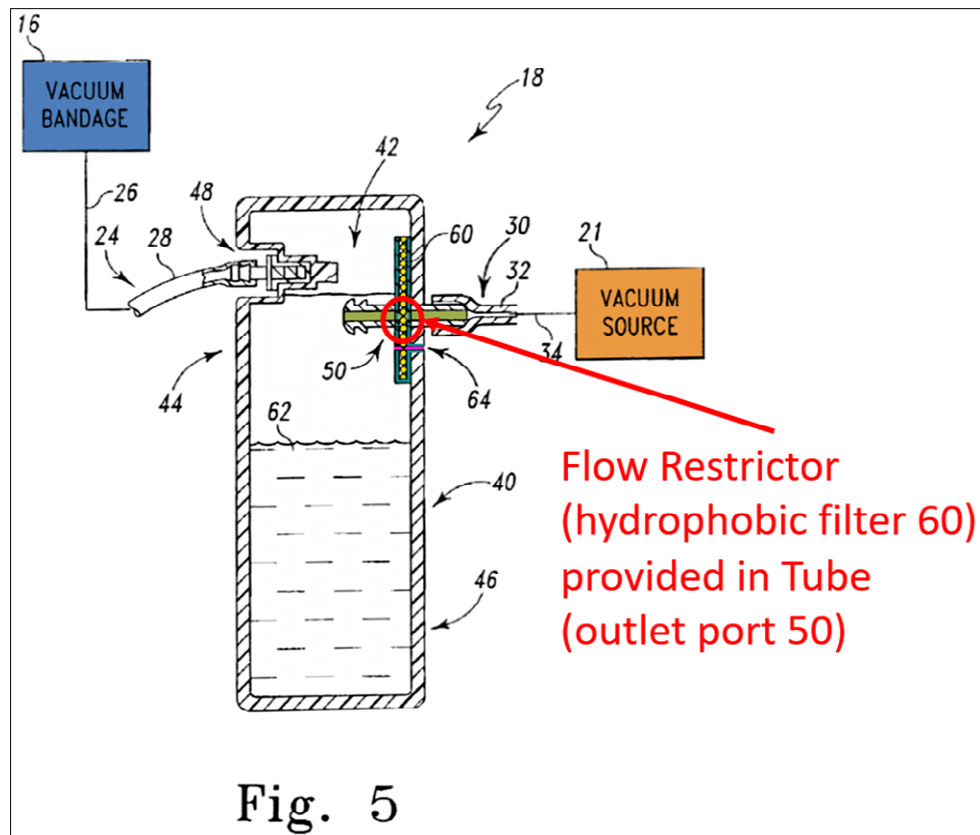
2. Each Element of Claim 2 Is Found in *Bitel*

(a) [2] The vacuum system according to claim 1, wherein said flow restrictor is provided in any one of the enclosure or the tube

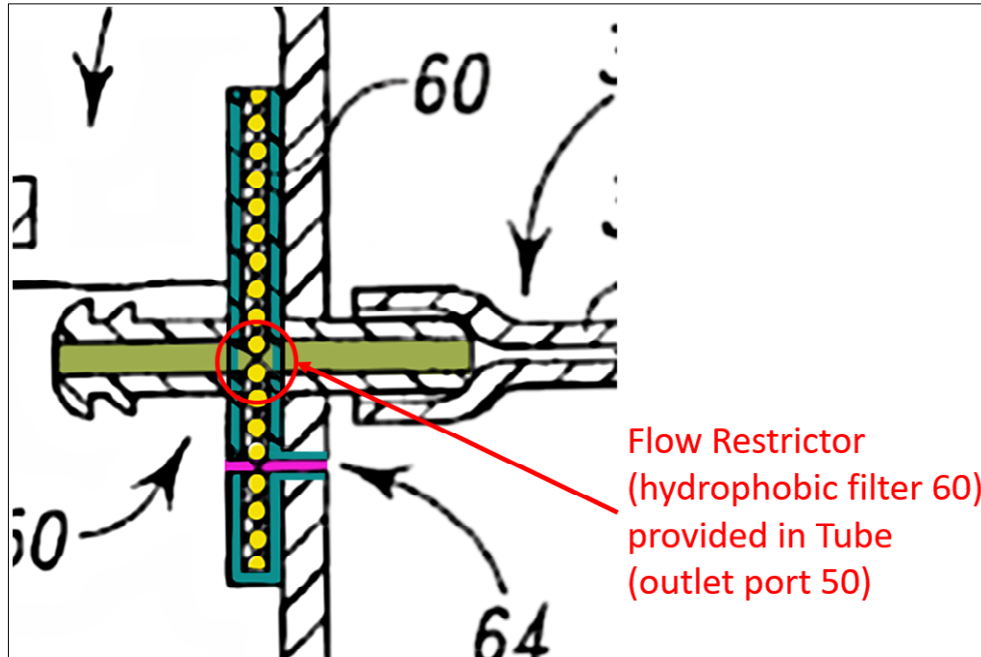
Bitel teaches the vacuum system according to claim 1. *See supra* § V.A.1. In addition, *Bitel* teaches that a “hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering the receptacle 18.” Ex. 1009, 6:23-25. “Once the level of exudate 62 collected within

receptacle 18 reaches air vent 64 and/or outlet port 50, hydrophobic filter 60 will prevent liquid to pass therethrough and the flow sensor will sense that the flow has become static.” *Id.*, 8:13-16.

Annotated Figure 5 below shows the filter 60 (yellow) within the outlet port 50 (green). Ex. 1007, ¶139.



Ex. 1009, Fig. 5; Ex. 1007, ¶139.



Ex. 1009, Fig. 5 (magnified view showing hydrophobic filter 60 within the outlet port 50); Ex. 1007, ¶139.

Thus, *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), wherein said flow restrictor (hydrophobic filter 60) is provided in the tube (outlet port 50). Ex. 1007, ¶140.

3. Each Element of Claim 3 Is Found in *Bitel*

- (a) [3] The vacuum system according to claim 1, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume

Bitel teaches the vacuum system according to claim 1. See *supra* § V.A.1. Additionally, *Bitel* teaches “a flow sensor to be connected to a vacuum line.” Ex. 1009, 3:30. “[T]he flow sensor may be configured to determine the level of

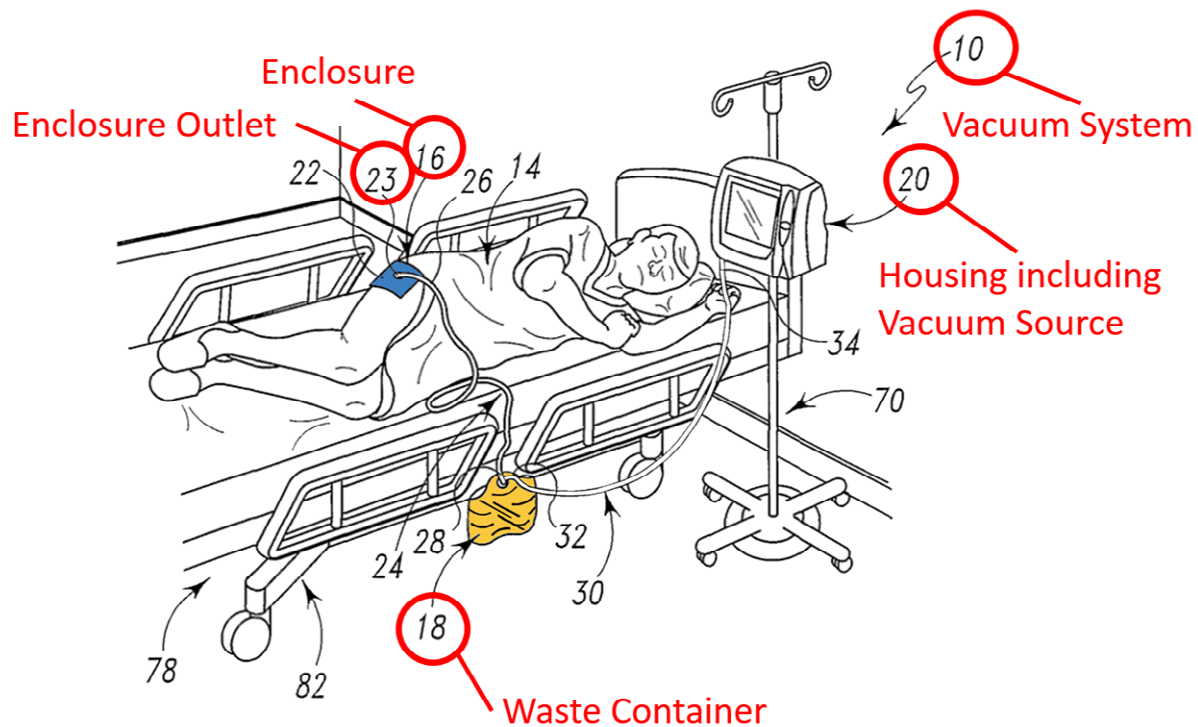
vacuum present in the receptacle.” *Id.*, 3:31-32. Specifically, the flow sensor “may be coupled to a second tube 30 between receptacle 18 and vacuum source 21 for monitoring the fluid flow from receptacle 18 to vacuum source 21.” *Id.*, 7:29-31. “The flow sensor may then provide feedback to the controller.” *Id.*, 7:31-32. “If, for example, the flow sensor detects no fluid flow, the feedback sent to the controller would signal the vacuum source 21 to turn off or cease running.” *Id.*, 7:32-8:2. In the “series configuration, the vacuum source 21 is thus in fluid communication with the receptacle 18 through the second tube 3, and the space above the wound created by vacuum bandage 16 is in fluid communication with receptacle 18 through first tube 24.” *Id.*, 7:23-26. “The bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum.” *Id.*, 5:31-33.

Thus, *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), further comprising a sensor (flow sensor, no reference numeral provided) for enabling determination of a level of said negative pressure (sensor may be configured to determine the level of vacuum present in the vacuum bandage through its series configuration) in said confined volume (volume under bandage 16). Ex. 1007, ¶¶141-42.

4. Each Element of Claim 4 Is Found in *Bitel*

(a) [4] The vacuum system according to claim 1, further comprising a waste container in fluid communication with said vacuum source

Bitel teaches the vacuum system according to claim 1. *See supra* § V.A.1. Additionally, *Bitel* discloses a receptacle 18 “to receive exudate from the wound.” Ex. 1009, Abstract. The receptacle 18 constitutes a “waste container” as claimed because it is configured to receive and store waste from the wound. *Id.*, Title (“Waste Container for Negative Pressure Therapy”), 5:16-18; Ex. 1007, ¶143. *Bitel* teaches “[s]ystem 10 further includes a second tube 30 coupled at a first end 32 to the receptacle 18 [via outlet port 50] and coupled at a second end 34 to the vacuum source 21.” Ex. 1009, 6:3-5, 6:26-28. “The vacuum source (21)...is connected to the receptacle (18), and is effective to provide a vacuum in the receptacle (18) and in the space [over the wound].” *Id.*, Abstract. As shown in annotated Figure 1 below, the receptacle 18 (gold) is in fluid communication with the vacuum source 21 (located within the housing 20) via the outlet port 50 (not shown) and second tube 30:



Ex. 1009, Fig. 1; Ex. 1007, ¶144.

Thus, *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), further comprising a waste container (receptacle 18) in fluid communication (via outlet port 50 and second tube 30) with said vacuum source (vacuum source 21). Ex. 1007, ¶145.

5. Each Element of Claim 5 Is Found in *Bitel*

- (a) [5] The vacuum system according to claim 1, wherein said vacuum source comprises a vacuum pump driven by a motor

Bitel teaches the vacuum system according to claim 1. See *supra* § V.A.1. *Bitel* also teaches “[t]he vacuum source of the system may comprise a vacuum pump.” Ex. 1009, 3:29, 6:31 (“[V]acuum pump to provide negative pressure”). The

“[v]acuum source 21 is also defined to include any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example.” *Id.*, 6:31-33. A POSITA would have understood that *Bitel*’s teaching of “any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example” would encompass “a vacuum pump driven by a motor” as claimed. Ex. 1007, ¶¶146-47.

Thus, *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), wherein said vacuum source (vacuum source 21) comprises a vacuum pump (vacuum pump, no reference numeral provided) driven by a motor (any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example). Ex. 1007, ¶148.

6. Each Element of Claim 6 Is Found in *Bitel*

- (a) [6] The vacuum system according to claim 5, wherein said motor is an electric motor, and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume**

Bitel teaches the vacuum system according to claim 5. *See supra* § V.A.5. Additionally, *Bitel* teaches “[t]he vacuum source of the system may comprise a vacuum pump and associated controls and/or a flow sensor to be connected to a vacuum line.” Ex. 1009, 3:29-30. The “[v]acuum source 21 is also defined to include any type of mechanism for providing negative pressure such as an

electrically operated or manual pump, for example.” *Id.*, 6:31-33. A POSITA would have understood *Bitel*’s teaching of “any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example” as encompassing “an electric motor” as claimed. Ex. 1007, ¶¶146-47, 150. Thus, at a minimum, *Bitel*’s teaching of “an electrically operated...pump” would have been understood by a POSITA as referring to a pump driven by an electric motor. *Id.*, ¶¶151-52; *see also* Ex. 1015 (“*Watson*”), Abstract (teaching “[a] small battery powered, electric motor drives the pump member” as part of a prior art vacuum wound therapy system).

Further, *Bitel* teaches “a controller [] for controlling the amount and rate of negative pressure to be applied to the wound, for example.” Ex. 1009, 7:11-12. “[T]he vacuum source comprises a vacuum pump and associated controls.” *Id.*, 11:24-25. A POSITA would have understood *Bitel*’s teaching of “a controller [] for controlling the amount and rate of negative pressure to be applied to the wound” as encompassing a controller that “controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume” as claimed. Ex. 1007, ¶¶153-54. This is because controlling operation of a motor of a vacuum pump was the primary mechanism for providing the desired level of negative pressure in the confined volume over a wound according to prior art vacuum wound therapy systems. Ex. 1007, ¶¶155-57; *see also* Ex. 1015, 2:64-3:2 (“An

electric motive means (an electric motor) is coupled to the vacuum pump member and drives the pump head. An electrical control circuit, including an electrical power source, is in electrical communication with the electric motive means. The control circuit is operable to control the operation of the electric motive means.”); Ex. 1014, 5:18-25 (“[T]he controller 117 controls the suction device 106...to periodically increase and decrease the application of suction at a drain catheter 102...More particularly, the controller 117 may provide, without limitation, mechanical or electrical control signals to the suction device 106 that control the amount of suction generated by the suction device 106.”).

Thus, *Bitel* teaches the vacuum system according to claim 5 (vacuum therapy system 10), wherein said motor is an electric motor (“any type of mechanism for providing negative pressure such as an electrically operated or manual pump”), and said controller (controller) controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume (a controller for controlling the amount and rate of negative pressure under the bandage 16). Ex. 1007, ¶158.

7. Each Element of Claim 7 Is Found in *Bitel*

- (a) [7] The vacuum system according to claim 6, wherein said controller controls the electric current or the voltage of said motor to control said level of said negative pressure in said confined volume**

Bitel teaches the vacuum system according to claim 6. *See supra* § V.A.6. Additionally, *Bitel* teaches “the vacuum source comprises a vacuum pump and associated controls, the pump being connected to the receptacle.” Ex. 1009, 11:24-25. The pump may be “electrically operated.” *Id.*, 6:31-33. Further, *Bitel* teaches “a controller [] for controlling the amount and rate of negative pressure to be applied to the wound, for example.” *Id.*, 7:11-12. A POSITA would have understood that the two primary mechanisms for “controlling the amount and rate of negative pressure to be applied to the wound,” as described by *Bitel*, would have included controlling the electric current or voltage of the electric motor of *Bitel*’s electrically operated pump. Ex. 1007, ¶¶159-60. This is because the amount of current or voltage supplied to an electric motor is proportional to the amount of torque applied on the motor’s shaft and therefore the amount of negative pressure generated by the vacuum pump being driven by the electric motor. Ex. 1007, ¶¶161-65.

Thus, *Bitel* teaches the vacuum system according to claim 6 (vacuum therapy system 10), wherein said controller (a controller) controls the electric current or the voltage of said motor (“any type of mechanism for providing

negative pressure such as an electrically operated or manual pump”) to control said level of said negative pressure in said confined volume (volume under the bandage 16). Ex. 1007, ¶166.

8. Each Element of Claim 8 Is Found in *Bitel*

- (a) [8] The vacuum system according to claim 6, wherein said controller controls the torque of said motor to control said level of said negative pressure in said confined volume.**

Bitel teaches the vacuum system according to claim 6. *See supra* § V.A.6. Additionally, *Bitel* teaches “the vacuum source comprises a vacuum pump and associated controls, the pump being connected to the receptacle.” Ex. 1009, 11:24-25. The pump may be “electrically operated.” *Id.*, 6:31-33. Further, *Bitel* teaches “a controller [] for controlling the amount and rate of negative pressure to be applied to the wound, for example.” *Id.*, 7:11-12. A POSITA would have understood that a mechanism for “controlling the amount and rate of negative pressure to be applied to the wound,” as described by *Bitel*, would have included controlling the torque of the electric motor of *Bitel*’s electrically operated pump. Ex. 1007, ¶¶161-63, 168-69. This is because the amount of torque applied on a motor’s shaft is proportional to the amount of negative pressure generated by the vacuum pump being driven by the electric motor. Ex. 1007, ¶¶161-63, 169-70.

Thus, *Bitel* teaches the vacuum system according to claim 6 (vacuum therapy system 10), wherein said controller (controller) controls the torque of said

motor (“any type of mechanism for providing negative pressure such as an electrically operated or manual pump”) to control said level of said negative pressure in said confined volume (volume under the bandage 16). Ex. 1007, ¶171.

9. Each Element of Claim 9 Is Found in *Bitel*

- (a) [9] The vacuum system according to claim 1, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating.**

Bitel teaches the vacuum system according to claim 1. See *supra* § V.A.1. Additionally, *Bitel* teaches “an air vent 64 to provide communication between interior cavity 42 of receptacle 18 and the outside atmosphere.” Ex. 1009, 6:22-23. “[T]he receptacle includes an air vent to allow an inner area of the receptacle to communicate with the surrounding atmosphere.” *Id.*, 10:21-23. A POSITA would have understood that when the vacuum source 21 of *Bitel* was turned off (and thus was not operating) after having been turned on, the air vent 64 of the receptacle 18 of *Bitel* would permit the ingress of ambient air into the vacuum therapy system 10 first via the receptacle 18, and then through the first tube 24 to the confined volume between the bandage 16 and the patient’s wound, therefore restoring ambient pressure in that volume. Ex. 1007, ¶172-73.

As shown in annotated Figure 5 below, ambient air can enter the enclosure when the vacuum pump is not operating.

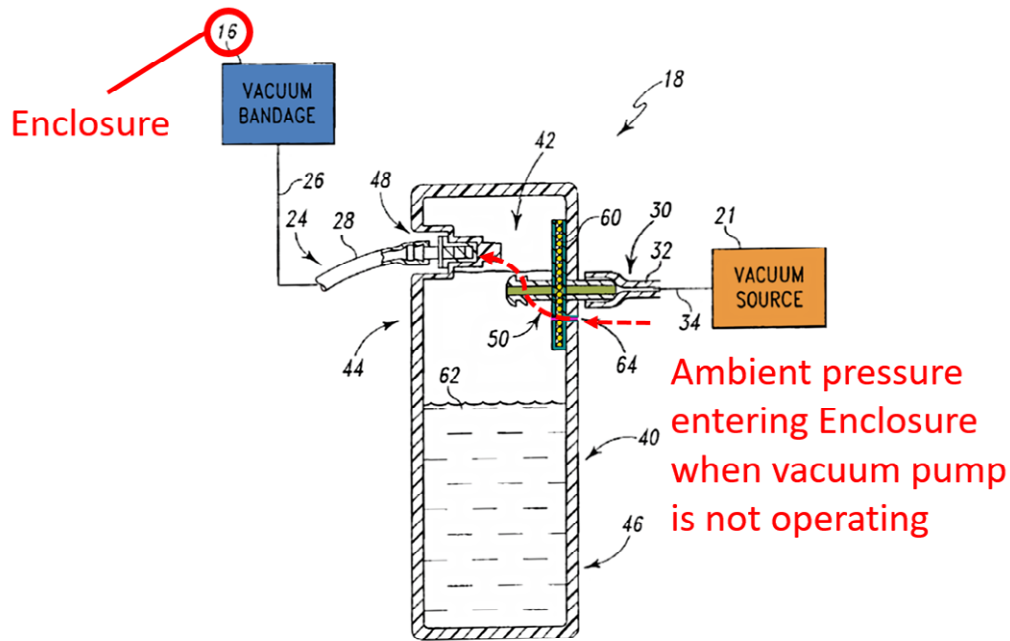


Fig. 5

Ex. 1009, Fig. 5; Ex. 1007, ¶174.

Thus, *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), wherein ambient pressure (“outside atmosphere”) may be restored in said confined volume (volume under bandage 16) via said venting arrangement (air vent 64 and hydrophobic filter 60) when said vacuum pump (vacuum pump) is not operating. Ex. 1007, ¶175.

10. Each Element of Claim 10 Is Found in *Bitel*

- (a) [10] The vacuum system according to claim 1, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice**

Bitel teaches the vacuum system according to Claim 1. *See supra* § V.A.1.

In addition, the venting arrangement of *Bitel*—i.e., the air vent 64 and hydrophobic filter 60—includes a bleeding hole, a porous body, and an orifice. Ex. 1007, ¶176-77.

Specifically, the air vent 64 of *Bitel* constitutes “one or more bleeding holes” as claimed because the air vent 64 is a hole in the side of the receptacle 18 that allows for the introduction of ambient air into the system 10. *See supra* § V.A.1(e); Ex. 1009, 6:23-25, Fig. 5; Ex. 1007, ¶178.

Furthermore, the hydrophobic filter 60 of *Bitel* constitutes a “porous body” as claimed because hydrophobic filters are porous by definition. Ex. 1009, 6:23-25, 8:13-16, Fig. 5; Ex. 1007, ¶179.

Finally, the air vent 64 of *Bitel* constitutes an orifice as claimed because it is an opening or hole of the receptacle 18. Ex. 1009, 8:10-13, Fig. 5; Ex. 1007, ¶180.

Thus, *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), wherein said venting arrangement (air vent 64 and hydrophobic filter 60) comprises at least one of: one or more bleeding holes (air

vent 64); a porous body (hydrophobic filter 60); and an orifice (air vent 64). Ex. 1007, ¶181.

11. Each Element of Claim 11 Is Found in *Bitel*

(a) [11] A vacuum system for applying negative pressure to a wound

Bitel teaches a vacuum system for applying negative pressure to a wound.

See supra § V.A.1(a).

(b) [11.1] The vacuum system comprising: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller

Bitel teaches the vacuum system comprising an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. *See supra* § V.A.1(b).

(c) [11.2] The enclosure being attachable to a periphery of the wound so as to define a confined volume

Bitel teaches the enclosure being attachable to a periphery of the wound so as to define a confined volume. *See supra* § V.A.1(c).

(d) [11.3] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume

Bitel teaches the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume. *See supra* § V.A.1(d).

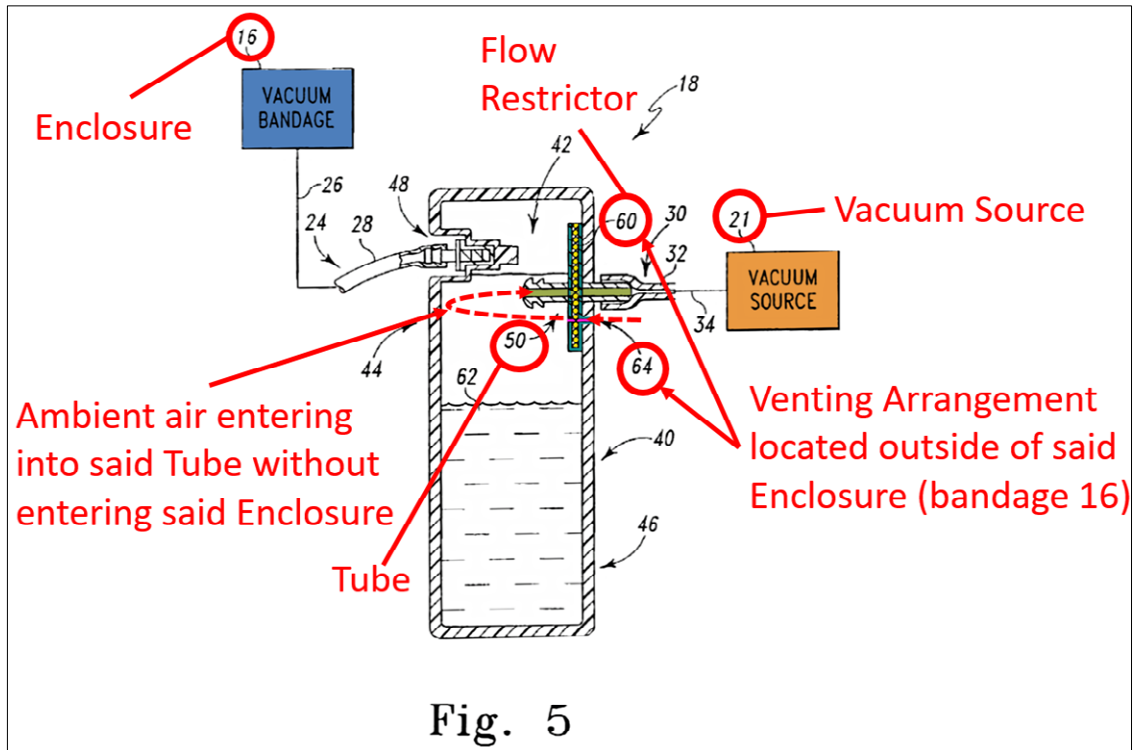
- (e) **[11.4] Said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said tube, said controlled flow of ambient air entering said tube via said venting arrangement without entering said enclosure**

Bitel teaches “a control dominating the vacuum source to establish the amount of vacuum applied to the space and the time when the vacuum is applied to the space.” Ex. 1009, 3:19-21.

Bitel further discloses that the air vent 64 and hydrophobic filter 60 are included as part of the receptacle 18 and thus are outside of the bandage 16 (corresponding to the claimed “enclosure”), as illustrated in Figures 1 and 5. Ex. 1009, 6:19-25, 8:18-19, Figs. 1 and 5; Ex. 1007, ¶¶187. In addition *Bitel* teaches that the “hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering the receptacle 18.” *Id.*, 6:23-25.

When the vacuum source 21 is activated so as to create negative pressure within the system 10, ambient air can enter the second tube 30 via the air vent 64, hydrophobic filter 60, and outlet port 50 without entering the bandage 16. Ex. 1007, ¶188.

As shown in annotated Figure 5 below, ambient air can enter through the venting arrangement (outlined in teal), which is located outside of the bandage 16 (blue) and enter the outlet port 50 (green) without entering the bandage 16.



Ex. 1009, Fig. 5; Ex. 1007, ¶189.

Thus, *Bitel* teaches said venting arrangement (air vent 64 and hydrophobic filter 60) located outside said enclosure (bandage 16) and comprising a flow restrictor (hydrophobic filter 60) to restrict flow through said venting arrangement (“hydrophobic filter 60 is positioned over air vent 64”) and to thereby provide a controlled flow of ambient air into said tube (outlet port 50), said controlled flow of ambient air entering said tube (outlet port 50) via said venting arrangement (air vent 64 and hydrophobic filter 60) and without entering said enclosure (bandage 16). Ex. 1007, ¶190.

- (f) **[11.5] The controller configured for controlling operation of the vacuum source while said tube is being vented via said venting arrangement to provide a desired level of said negative pressure in said confined volume**

Bitel teaches “a control dominating the vacuum source to establish the amount of vacuum applied to the space and the time when the vacuum is applied to the space.” Ex. 1009, 3:19-21. Specifically, “[i]n addition to the vacuum source 21, it is also within the scope of the disclosure for housing 20 to include a controller [] for controlling the amount and rate of negative pressure to the applied to the wound.” *Id.*, 7:10-12.

Further, “[o]nce system 10 has become relatively static and there is little to no fluid flow from bandage 16 through first tube 24 and to receptacle 18, vacuum source 21 is still able to pull air through air vent 64 thus allowing the flow sensor to detect a fluid flow in order to keep the vacuum source 21 running. Once the level of exudate 62 collected within receptacle 18 reaches air vent 64 and/or outlet port 50, hydrophobic filter 60 will prevent liquid to pass therethrough and the flow sensor will sense that the flow has become static.” *Id.*, 8:13-16. “The flow sensor will send a signal to the controller which will, in turn, tell the vacuum source 21 to turn off.” *Id.*, 8:16-17.

Thus, *Bitel* teaches the controller configured for controlling (controller, no reference numeral assigned) operation of the vacuum source (vacuum source 21)

while said tube (outlet port 50) is being vented via said venting arrangement (air vent 64 and hydrophobic filter 60) to provide a desired level of said negative pressure in said confined volume (bandage 16). Ex. 1007, ¶¶191-93.

Therefore, *Bitel* teaches each and every limitation of claim 11.

12. Each Element of Claim 12 Is Found in *Bitel*

- (a) [12] The vacuum system according to claim 11, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume**

Bitel teaches the vacuum system according to Claim 11. *See supra* § V.A.11.

Bitel also teaches a sensor for enabling determination of a level of said negative pressure in said confined volume. *See supra* § V.A.3.

13. Each Element of Claim 13 Is Found in *Bitel*

- (a) [13] The vacuum system according to claim 11, further comprising a waste container in fluid communication with said vacuum source**

Bitel teaches the vacuum system according to Claim 11. *See supra* § V.A.11.

Bitel also teaches a waste container in fluid communication with said vacuum source. *See supra* § V.A.4.

14. Each Element of Claim 14 Is Found in *Bitel*

- (a) [14] The vacuum system according to claim 11, wherein said vacuum source comprises a vacuum pump driven by a motor**

Bitel teaches the vacuum system according to Claim 11. *See supra* § V.A.11.

Bitel also teaches said vacuum source comprises a vacuum pump driven by a motor. *See supra* § V.A.5.

15. Each Element of Claim 15 Is Found in *Bitel*

- (a) [15] The vacuum system according to claim 14, wherein said motor is an electric motor, and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume**

Bitel teaches the vacuum system according to Claim 14. *See supra* § V.A.14.

Bitel also teaches said motor is an electric motor, and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume. *See supra* § V.A.6.

16. Each Element of Claim 16 Is Found in *Bitel*

- (a) [16] The vacuum system according to claim 15, wherein said controller controls at least one of the electric current of said motor, or the voltage of said motor, or the torque of said motor to control said level of said negative pressure in said confined volume**

Bitel teaches the vacuum system according to Claim 15. *See supra* § V.A.15.

Bitel also teaches said controller controls at least one of the electric current of said motor, or the voltage of said motor to control said level of said negative pressure in

said confined volume. *See supra* § V.A.7. *Bitel* further teaches said controller controls the torque of said motor to control said level of said negative pressure in said confined volume. *See supra* § V.A.8.

17. Each Element of Claim 17 Is Found in *Bitel*

- (a) **[17] The vacuum system according to claim 11, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating**

Bitel teaches the vacuum system according to Claim 11. *See supra* § V.A.11. *Bitel* also teaches wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating. *See supra* § V.A.9.

18. Each Element of Claim 18 Is Found in *Bitel*

- (a) **[18] The vacuum system according to claim 11, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice**

Bitel teaches the vacuum system according to Claim 11. *See supra* § V.A.11. *Bitel* also teaches wherein the venting arrangement comprises at least one of: one or more bleeding holes, a porous body, an orifice. *See supra* § V.A.10.

19. Each Element of Claim 19 Is Found in *Bitel*

(a) [19.P] A method for applying negative pressure to a wound

Bitel teaches “[a] method for treating a wound on a patient is also provided including the steps of sealing a bandage having a port about the wound to define a space above the wound in which a vacuum can be formed, placing a receptacle below the wound, and placing a vacuum source spaced away from the receptacle.” Ex. 1009, 4:1-4. “The method further includes the steps of connecting the receptacle to the port of the bandage, connecting the vacuum source to the receptacle, and operating the vacuum source to evacuate the receptacle and provide a vacuum in the space above the wound.” *Id.* 4:4-7. “The method further includes the step of controlling the level of vacuum applied to the space and the time of application of the vacuum.” *Id.*, 4:7-9.

Thus, *Bitel* teaches a method (“a method for treating a wound”) for applying negative pressure to a wound (“a vacuum can be formed”). Ex. 1007, ¶¶210-11.

(b) [19.1] (a) Providing a vacuum system

Bitel teaches providing a vacuum system. *See supra* § V.A.1(a).

(c) [19.2] [The vacuum system comprising at least] an enclosure, a venting arrangement, a tube, and a vacuum source

Bitel teaches providing a vacuum system having at least an enclosure, a venting arrangement, a tube, and a vacuum source. *See supra* § V.A.1(b).

- (d) **[19.3] The enclosure being attachable to a periphery of the wound so as to define a confined volume**

Bitel teaches the enclosure being attachable to a periphery of the wound so as to define a confined volume. *See supra* § V.A.1(c).

- (e) **[19.4] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume**

Bitel teaches the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume. *See supra* § V.A.1(d).

- (f) **[19.5] The venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said system upstream of the vacuum source**

Bitel teaches the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said system upstream of the vacuum source. *See supra* § V.A.1(e).

- (g) **[19.6] (b) Controlling operation of the vacuum source while the vacuum system is being vented via the venting arrangement to thereby provide a desired level of said negative pressure in said confined volume**

Bitel teaches “a control dominating the vacuum source to establish the amount of vacuum applied to the space and the time when the vacuum is applied to the space.” Ex. 1009, 3:19-21. Specifically, “[i]n addition to the vacuum source 21,

it is also within the scope of the disclosure for housing 20 to include a controller [] for controlling the amount and rate of negative pressure to the applied to the wound.” *Id.*, 7:10-12.

Further, “[o]nce system 10 has become relatively static and there is little to no fluid flow from bandage 16 through first tube 24 and to receptacle 18, vacuum source 21 is still able to pull air through air vent 64 thus allowing the flow sensor to detect a fluid flow in order to keep the vacuum source 21 running. Once the level of exudate 62 collected within receptacle 18 reaches air vent 64 and/or outlet port 50, hydrophobic filter 60 will prevent liquid to pass therethrough and the flow sensor will sense that the flow has become static.” *Id.*, 8:13-16. “The flow sensor will send a signal to the controller which will, in turn, tell the vacuum source 21 to turn off.” *Id.*, 8:16-17.

Thus, *Bitel* teaches controlling operation (via controller, no reference numeral assigned) of the vacuum source (vacuum source 21) while the vacuum system (wound treatment system 10) is being vented via the venting arrangement (air vent 64 and hydrophobic filter 60) to thereby provide a desired level of said negative pressure in said confined volume (bandage 16). Ex. 1007, ¶¶217-19.

Therefore, *Bitel* teaches each and every limitation of claim 19.

20. Each Element of Claim 20 Is Found in *Bitel*

- (a) [20] The method according to claim 19, wherein the vacuum source comprises a vacuum pump driven by an electric motor wherein step (b) comprises controlling operation of said motor to thereby provide a desired level of said negative pressure in said confined volume**

Bitel teaches the method according to claim 19. *See supra* § V.A.19. Further, *Bitel* teaches the vacuum source comprising a vacuum pump driven by an electric motor. *See supra* § V.A.5. *Bitel* further teaches controlling operation of said motor to thereby provide a desired level of said negative pressure in said confined volume. *See supra* § V.A.6.

21. Each Element of Claim 21 Is Found in *Bitel*

- (a) [21] The method according to claim 20, wherein step (b) comprises controlling at least one of the electric current, or the voltage, or the torque of said motor to control said level of said negative pressure in said confined volume**

Bitel teaches the method according to claim 20. *See supra* § V.A.20. *Bitel* also teaches said controller controlling at least one of the electric current or the voltage of said motor to control said level of said negative pressure in said confined volume. *See supra* § V.A.7. *Bitel* further teaches said controlling the torque of said motor to control said level of said negative pressure in said confined volume. *See supra* § V.A.8.

22. Each Element of Claim 22 Is Found in *Bitel*

- (a) [22] The method according to claim 19, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice**

Bitel teaches the method according to claim 19. *See supra* § V.A.19. Additionally, *Bitel* teaches said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice. *See supra* § V.A.10.

VI. 35 U.S.C. § 325(d) SHOULD NOT PRECLUDE INSTITUTION

The *Becton Dickinson* factors weigh in favor of institution. *Becton, Dickinson, & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017); *see Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020).

The Board has repeatedly “held that a reference that ‘was neither applied against the claims nor discussed by the Examiner’ does not weigh in favor of exercising [] discretion under § 325(d).” *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 9-10 (P.T.A.B. Nov. 5, 2019); *Bowtech, Inc. v. MCP IP, LLC*, IPR2019-00383, Paper 14 at 6 (P.T.A.B. Aug. 6, 2019). Indeed, the Board has explained that “mere citation of a reference in an IDS and consideration without comment was insufficient to indicate the examiner substantively considered the references.” *Id.* citing *Hobbico, Inc. v. Traxxas, L.P.*, IPR2018-00010, Paper 8 at 19 (P.T.A.B. Apr. 18, 2018). That is the case here; *Bitel*, the lone

reference relied on in this Petition, was merely cited on an IDS, but never applied against the claims nor discussed by the Examiner.

Regardless, as explained in Section I.C., errors material to patentability were made during prosecution of the '865 Application. For example, the lone office action issued during prosecution of the '865 Application rejected all pending claims on the basis of nonstatutory double patenting as being unpatentable over the '554 Patent in view of *Argenta*. Ex. 1002, 171–174. The applicant overcame this rejection by filing a terminal disclaimer. *Id.*, 257. However, it appears the Examiner failed to appreciate that the claims of the '865 Application did not all require the venting arrangement to be located outside the enclosure—a limitation that was required for the claims of the '554 Patent to overcome prior art-based rejections during prosecution. This failure to appreciate a material difference in scope between the granted claims of the '554 Patent and pending claims of the '865 Application constituted at least one instance of material error. Accordingly, discretionary denial under § 325(d) is not warranted.

VII. MANDATORY NOTICES, STANDING, AND FEES

A. Real Party-In-Interest: 37 C.F.R. § 42.8(b)(1)

Solvantum Corporation.

B. Related Matters: 37 C.F.R. § 42.8(b)(2)

On September 24, 2023, Patent Owner filed suit against Medela, LLC and Medela Holding AG alleging infringement of the '534 Patent and one related patent (U.S. Patent No. 8,506,554 (the "'554 Patent")): *M.E.A.C. Engineering LTD v. Medela, LLC et al.*, No. 1:23-cv-14045 (N.D. Ill. filed Sept. 24, 2023). On October 5, 2023, Patent Owner filed suit against Solventum Corporation alleging infringement of the '554 Patent and the '534 Patent: *M.E.A.C. Engineering LTD v. Solventum Corporation*, No. 5:23-cv-01256-XR (W.D. Tex. filed Oct. 5, 2023). On December 4, 2023, Patent Owner filed suit against Cardinal Health, Inc. alleging infringement of the '554 Patent and the '534 Patent: *M.E.A.C. Engineering LTD v. Cardinal Health, Inc.*, No. 1:23-cv-16471 (N.D. Ill. filed Dec. 4, 2023). On January 12, 2024, Patent Owner filed suit against Molnlycke Health Care AG and Molnlycke Health Care US LLC alleging infringement of the '554 Patent and the '534 Patent: *M.E.A.C. Engineering, Ltd. v. Molnlycke Health Care AG et al.*, No. 1:24-cv-00179-MLB (N.D. Ga. Filed Jan. 12, 2024). On April 15, 2024, Solventum was substituted for 3M in Case No. 5:23-cv-01256-XR. This is because on April 1, 2024, 3M Company spun off its healthcare business into a new independent company, Solventum. The products and claims at issue in Case No. 5:23-cv-01256-XR relate to 3M Company's former healthcare business that is now Solventum.

Petitioner files contemporaneously herewith an IPR Petition against Claims 12-17 and 26-27 of the '554 Patent.

The '534 Patent has not been the subject of any prior post-grant proceedings and has not been asserted in any other litigations.

**C. Petitioner's Lead and Back-up Counsel and Service Information:
37 C.F.R. § 42.8(b)(3) and (4)**

Lead Counsel	Back-up Counsel
Scott D. Barnett, Reg. No. 67,309 Honigman LLP 39400 Woodward Ave., Suite 101 Bloomfield Hills, MI 48304 Telephone: (248) 566-8416 Facsimile: (248) 566-8417 Email: sbarnett@honigman.com	Ron N. Sklar (to be admitted pro hac vice) Honigman LLP 155 N. Wacker Drive, Suite 3100 Chicago, IL 60606 Telephone: (312) 701-9308 Facsimile: (312) 701-9335 Email: rsklar@honigman.com David J. Roulo, (to be admitted pro hac vice) Honigman LLP 155 N. Wacker Drive, Suite 3100 Chicago, IL 60606 Telephone: (312) 429-6049 Facsimile: (312) 701-9335 Email: droulo@honigman.com Deborah (Bea) J. Swedlow, (to be admitted pro hac vice) Honigman LLP 315 East Eisenhower Parkway, Suite 100 Ann Arbor, MI 48108-3330 Telephone: (734) 418-4268 Email: bswedlow@honigman.com

D. Grounds for Standing: 37 C.F.R. § 42.104(a)

Petitioner certifies that the '534 Patent is available for IPR and that Petitioner is not barred or estopped from requesting this IPR.

E. Payment of Fees: 37 C.F.R. § 42.103

The undersigned authorizes the Director to charge any required fees, including those due under 37 C.F.R. § 42.15(a), to Deposit Account No. 503145.

VIII. CONCLUSION

Petitioner respectfully requests the Board institute an IPR for Claims 1-22 of the '534 Patent.

Respectfully submitted,

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Date: June 5, 2024

Attorney for Petitioner, Solventum Corporation.

Certificate of Service

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I hereby certify that on the 5th day of June, 2024, I caused a complete copy of the Petition for *Inter Partes* Review of USPN 8,858,534, and all supporting exhibits, to be served on the Patent Owner of the subject Patent as follows:

By Federal Express to the Patent Owner's attorney of record:

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Certificate of Compliance

Petitioner Solventum Corporation certifies the following:

1. This brief complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i). Specifically, this brief contains 11,823 words, excluding parts of the brief exempted by 37 C.F.R. § 42.24(a)(1); and
2. This brief complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and the type style requirements of 37 C.F.R. § 42.6(a)(2)(iii). Specifically, this brief has been prepared in a proportionally spaced typeface using MS Word 2016 in a 14 point Times New Roman font.

/Scott D. Barnett/

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