

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 IPR2024-01001
Patent 8,506,554

**Expert Declaration of Dr. Morten Jensen in Support of
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 8,506,554 to Adahan (the '554 Patent) (Patent under <i>Inter Partes</i> Review)	Jul. 24, 2005 (filing date of priority PCT application)	N/A
1002	File History for USPN 8,506,554	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)
1006	USPN 5,636,643 to Argenta et al. (" <i>Argenta</i> ")	Jun. 10, 1997	§ 102(b)
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 8,157,792 to Dolliver et al. (" <i>Dolliver</i> ")	Feb. 26, 2004 (filing date)	§ 102(e)
1013	USPN 6,648,862 to Watson (" <i>Watson</i> ")	Nov. 18, 2003	§ 102(b)

¹ For the Board's convenience, this Table of Exhibits is to the same as the Table of Exhibits in the corresponding Petition with the lone exception that there is no Exhibit 1007 to this Declaration because this Declaration is Ex. 1007 to the Petition.

² I adopt the following citation convention for this Declaration. U.S. patent references 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.

I, Dr. Morten Jensen, make the present Declaration in support of the request for *Inter Partes* Review (IPR) of Claims 12–17 and 26–27 (the “Challenged Claims”) of U.S. Patent No. 8,506,554 (the “’554 Patent”) (Ex. 1001). To that end, I hereby declare as follows:

I. BACKGROUND QUALIFICATIONS

1. Exhibit 1008 is a copy of my Curriculum Vitae (“CV”) and testimony history containing my qualifications, credentials, and testimony history.

2. My formal education includes a Bachelor of Science degree in Engineering, with honors, from The Engineering College of Aarhus at Aarhus, Denmark, earned in 1997. I earned a Master of Science degree in Biomedical Engineering from the Georgia Institute of Technology and Emory University School of Medicine (joint program) in 2000. After earning my masters, I pursued and earned two doctoral degrees. I graduated from the University of Aarhus School of Medicine in Denmark in November 2008 with a Ph.D. (doctorate) in medicine. In March 2015, I was granted a Dr.Med. (or dr.med.) in medical science from the University of Aarhus School of Medicine in Denmark. The Dr.Med. degree is a higher-level doctorate degree that is awarded at certain universities in Northern Europe in the field of medicine. Dr.Med. is by law a higher degree than the Ph.D. The Dr.Med. degree is awarded after a candidate’s research and publications have proven to make a significant difference in the advancement of the medical science. Historically, the

Dr.Med. degree has been given only to medical doctors, with rare exceptions. I was the third engineer in Denmark since 1479 to receive this degree.

3. I am currently an associate professor of biomedical engineering and Arkansas Research Alliance Scholar in the Department of Biomedical Engineering at the University of Arkansas, as well as an adjunct associate professor of surgery at the University of Arkansas for Medical Sciences. I have held these positions since August 2015. The Arkansas Research Alliance is a public- private partnership dedicated to elevating a fundamental belief that "research matters." This Alliance provides partial financial support for parts of my research in the field of biomedical engineering and increasing the understanding of the biomechanics and intervention while creating solutions and dedicated devices. I have secured more than \$4.5M in external research funding from the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Defense (DoD), and other funding sources for my research. My most recent curriculum vitae (CV), which includes a more detailed summary of my background, experience, and publications, is attached as **Exhibit 1008** to accompany this declaration..

4. I hold an Adjunct Associate Professorship at the University Hospital of Aarhus in Denmark where I have taught biomedical engineering to M.D./Ph.D. students and advised on biomechanical projects. I have held that position since July 2009. In 2013-2014, I was an Honorary Clinical Fellow and Senior Lecturer at

University College in London, England. Over the past two decades, I have developed and taught numerous courses at both the undergraduate and graduate level, as well as in medical schools, in the field of biomedical engineering, including biomechanics, medical device mechanics, and biomechanical modeling. As set forth in my CV, I have published numerous articles relating to aspects of biomechanics of tissues of the human body. I have also received numerous awards for my research work and teaching, and have served on various committees and boards and is still serving on many of them. This includes review panels such as the NIH RO1 Bioengineering, Technology and Surgical Sciences Study Section panel, Center for Scientific Review (CSR), and the NSF Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Medical Devices programs review panel member. Thus far, I have published 90 peer reviewed publications (hereof 68 journal papers and 22 refereed conference proceedings), 20 magazine articles, 11 books/book chapters, 7 conference keynote addresses, and given more than 170 presentations at conferences and seminars. Some of these publications are with highly relevant collaborators, such as the only Food and Drug Administration (FDA) research facility outside of the Washington DC area, located in Arkansas, near Little Rock. I am also an inventor and/or co-inventor of 9 patent application publications/trade secrets. Additionally, I currently teach the senior design course for the Biomedical Engineering Department at the University of Arkansas. I have

also actively participated, and worked alongside surgeons, radiologists, and anesthesiologists in more than 300 large animal experimental surgeries and interventions on 60-80 kg. porcine and ovine models. The pig and sheep are well-known models for the human physiological system in many aspects of medicine, as also documented in literature during the last several decades. The relevant equipment, tools and systems used on the large animal porcine and ovine model are the same as used for humans. Hence, the experience of working with these models are extremely relevant to an in-depth understanding of how devices interact with the human biomedical and biomechanical system. It should be noted that one of my research partners at my laboratory at the University of Arkansas is my wife, Dr. Hanna Jensen, who is a Medical Doctor (MD) with Ph.D and Dr.Med degrees. Dr. Hanna Jensen has practiced gastric, general and OB-GYN surgery in Europe for more than half a decade. She has also performed clinical research at the Great Ormond Street Hospital for Children in London, UK as well as the Emory University in Atlanta, GA. She is currently serving as the Associate Director of Clinical Research at the Departments of Surgery and Radiology at the University of Arkansas for Medical Sciences.

5. Prior to joining the University of Arkansas, I was employed by Vivas LLC as the Chief Technology Officer from 2017 to 2020.

6. From 2009 to 2015, I was an Associate Professor and Director of Research at The Scandinavian School of Cardiovascular Technology.

7. From 2014 to 2015, I was also a member of the Research Faculty in the Department of Biomedical Engineering at Georgia Tech/Emory in Atlanta, Georgia.

8. From 2013 to 2014, I was an Honorary Clinical Fellow and Senior Lecturer at the Department of Mechanical Engineering at the University of the College of London and in the Cardiology Department at The Heart Hospital Specialist Board in London, UK.

9. From 2007 to 2009, I was an Assistant Professor in the Department of Biomedical Engineering at the Engineering College of Aarhus in Aarhus, Denmark.

10. From 2000 to 2005, I worked in industry with a company based in Austin, Texas called National Instruments. Most of my activities with the company were with the consulting services department, where a large part of his work was to consult with manufacturers of medical devices on how to test the devices.

11. From 1992 to 1993, I was in the Communications Unit of the Danish Army Corps of Engineers in Denmark.

12. I am a member of the Biomedical Engineering Society

13. I have published articles extensively in scientific journals and presented at conferences around the world, as listed in my Curriculum Vitae attached hereto as Exhibit 1008. Thus far I have published 98 peer reviewed publications (hereof 73

journal papers and 25 refereed conference proceedings), 20 magazine articles, 11 books / book chapters, 164 conference presentations and keynote addresses. I have been invited as a guest speaker to 32 seminars and have 9 publications of Intellectual Property / Patent Applications. Since public knowledge of academic work is important for universities and funding sources, I have also been part of more than 100 public media appearances.

14. As part of my work in the field of Biomedical Engineering, I have significant additional experience directly pertaining to the technology at issue in this matter. My twenty-five years of experience in industry and academia has focused on medical devices, electrical/mechanical engineering and fluid mechanics/dynamics. Currently my lab is using vacuum assisted technology in driving fluids with soft tissue. This work has been published and continues to be used for FDA approval of medical devices. I have worked in the past with multiple medical device cases as an expert witness where dynamic vacuum technology was used on the surface of human skin. I have in the past published research in the journal "Skin Research and Technology," and I also used dynamic pressure and vacuum systems and pumps with soft tissues in my work at Georgia Tech in the late 1990s. I am also teaching fluid mechanics principles at the graduate and undergraduate college level for both engineering and medical school students. In addition, I have industry experience and competencies from my six years with National Instruments in medical device

development, motion control, and mechanical motor system identification. This work included developing sensor and controls systems using programmable logic or micro-controllers for motors that would drive many things, for example fluid pumps with controls design algorithms such Proportional-Integral-Derivative (PID) and state space controls systems.

15. During my career, I have worked on and evaluated many different medical device types, such as general surgery devices, cardiovascular devices, and orthopedic devices. Hence, because of my background, education, and experience both in industry and academia, I am highly qualified and have a keen ability to review materials and provide opinions relating to the products discussed in this case.

II. DOCUMENTS RELIED UPON

16. In reaching my opinions in this case, I carefully reviewed the currently filed Petition for *Inter Partes* Review of U.S. Patent No. 8,506,554 (IPR Petition) and the various exhibits referenced therein, such as, for example, the '554 Patent itself and the prior art references cited in the IPR Petition. I agree with the contents of the IPR Petition for at least the reasons expressed in this Declaration, and I view my opinions expressed below to be consistent with those contents.

17. I also carefully reviewed each of the documents listed in the Table of Exhibits at the beginning of this Declaration.

III. PERSON HAVING ORDINARY SKILL IN THE ART

18. I was asked to offer an opinion on the characteristics of a person having ordinary skill in the art at the time of the alleged invention (“POSITA”) for the ’554 Patent, which I understand from Petitioner’s counsel to be in the 2005 timeframe.

19. My understanding from Petitioner’s counsel is that one of ordinary skill in the art is presumed to be a person with at least a particular level of skill and knowledge in a certain field or industry and that is capable of understanding and practicing the technology described in the patent at issue (i.e., the ’554 Patent). This person is of ordinary creativity and not an automaton.

20. In assessing the level of ordinary skill, I further understand one may consider several factors including: (1) the educational level of the inventor; (2) the educational level of active workers in the field; (3) type of problems encountered in the art; (4) prior art solutions to those problems; (5) the rate of innovation in the field; and (6) the sophistication of the technology.

21. As it relates to this technology, I believe a person of ordinary skill in the art at the time of the alleged invention of the ’554 Patent would have had a bachelor’s degree in biomedical or mechanical engineering or a related field, and either a master’s degree in biomedical or mechanical engineering or a related field, or three years of relevant industry experience.

22. Based upon my education and experience as set forth above, I believe that I would qualify as at least a POSITA in the relevant time frame. At the time of the alleged invention, I had a sufficient level of knowledge, experience, and education to provide an expert opinion in the field of the '554 Patent.

23. My testimony and opinions in this Declaration are given from the perspective of a POSITA at the time of the alleged invention of the '554 Patent unless otherwise specifically indicated. This is true even if my statements are in the present tense.

IV. LEGAL ASSUMPTIONS

24. I am not a lawyer and have been informed by Petitioner's counsel about certain legal principles and standards, which I have assumed and applied for purposes of this declaration. Some of these, which form the legal framework for the opinions I am providing, are summarized below.

25. I understand that a patent claim may be found invalid or not patentable if it is anticipated or rendered obvious by prior art. I have considered references such as patents and publications to be prior art to the '554 Patent if they were patented or published more than one year before the alleged priority date (i.e., the date that the earliest patent application to which the '554 Patent claims priority was filed), or if they were patented or filed as an application for a patent, which was

subsequently published, with a date prior to the date the subject matter of the claims of the '554 Patent was allegedly invented.

26. I understand that to render a patent claim invalid or not patentable for anticipation under 35 U.S.C. § 102 (§ 102), a single prior art reference must teach, expressly or inherently, all of the elements of the claim.

27. I understand that to render a patent claim invalid or not patentable for obviousness under 35 U.S.C. § 103 (§ 103), a prior art reference or combination of prior art references must teach or suggest to a POSITA all of the elements of the claim. Rationales that support such a finding of obviousness include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; use of known techniques to improve similar devices, methods or products in the same way; applying a known technique to a known device, method or product ready for improvement to yield predictable results; it would have been “obvious to try” by choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; known work in one field of endeavor prompting variations for use in either the same field or a different field based on design incentives or other market forces if the variations are predictable to a POSITA; some teaching, suggestion, or motivation in the prior art that would have led a POSITA to modify

the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

28. I understand that the reasoning as to why combining multiple references would have been obvious, or obvious to try, can be found in the common sense of a POSITA and need not be explicitly articulated or suggested in any prior art reference. I also understand that a patent claim is more likely to be obvious when it recites only a combination of known elements, where each element performs the same function that it was known to perform, and where the combination does no more than yield predictable results.

29. I understand that the invalidity analysis is made through the eyes of a POSITA at the time of the alleged invention, and that a POSITA is not an automaton, but rather one of ordinary creativity and common sense. I also understand that, although there may be other considerations that weigh against a finding of obviousness (such as a long felt need in the art for the patented device, or unexpected results achieved by the patented device), when such a combination fails to produce an unexpected result, it is the product of common sense rather than of innovation.

V. BACKGROUND OF THE '554 PATENT AND PRIOR ART

30. In preparing this Declaration, I have reviewed patents and patent publications describing vacuum therapy wound treatment systems. These patents

and publications, which date back to 1971, show that vacuum therapy wound treatment system for applying negative pressure to a wound with an enclosure, a venting arrangement including a flow restrictor, a tube, a vacuum source, and a controller for the vacuum source have been well known for decades. In addition, the claimed features of the '554 Patent were explicitly taught by multiple references years before the '554 Patent's priority date, and the alleged inventions claimed in the '554 Patent are nothing more than the incorporation of well-known components in vacuum systems for applying negative pressure to a wound. The alleged inventions of the Challenged Claims of the '554 Patent are summarized below.

- Claim 12: a vacuum system for applying negative pressure to a wound having an enclosure, a vacuum source, a tube, a venting arrangement, and a waste container. The enclosure is attachable to the wound circumference 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 the venting arrangement is located outside the enclosure such that ambient air can enter the tube via the venting arrangement without entering the enclosure. The waste container is in fluid communication with the vacuum source;

- Claim 13: depends from Claim 12 and claims the additional features of:
(i) the vacuum system further operates to drain the wound from fluids exuded therefrom; (ii) the ambient air can enter the tube via the venting arrangement and flow together with the exuded liquids under the action of the negative pressure; and (iii) the vacuum system facilitates draining of the exuded fluids to the waste container;
- Claim 14: depends from Claim 12 and claims the additional features of:
(i) the vacuum source including a disposable pump unit detachably attachable to a non-disposable drive unit and (ii) the enclosure and waste container being disposable so that the ambient air that enters the tube via the venting arrangement contacts only the disposable elements and the drained liquids may be disposed of together with the disposable elements;
- Claim 15: depends from Claim 14 and claims the additional features of the pump unit and the drive unit being adapted for attaching and detaching by simple hand manipulations;
- Claim 16: depends from Claim 12 and claims the additional feature of the venting arrangement including one or more bleeding holes;
- Claim 17: depends from Claim 12 and claims the additional feature of the venting arrangement being provided in the form of a porous body;

- Claim 26: depends from Claim 12 and claims the additional feature of the venting arrangement being a tube orifice;
- Claim 27: depends from Claim 26 and claims the additional feature of the orifice having a smaller opening than a cross section of the tube.

As background for understanding the '554 Patent in the context of the prior art, I studied patents to review negative pressure wound therapy systems over the years.

A. Evolution of Vacuum Therapy Wound Treatment Systems

31. Vacuum therapy wound treatment systems were well-known for decades prior to the priority date of the '554 Patent. 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.

32. 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.

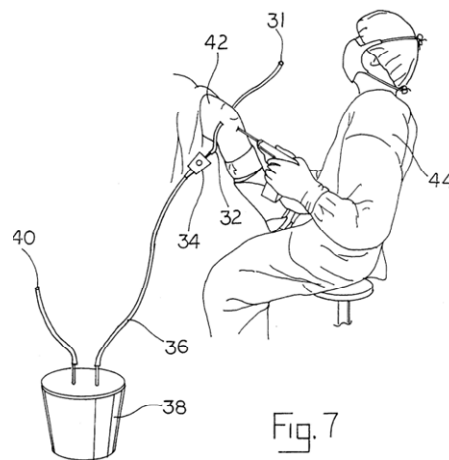
33. However, manually-operated vacuum therapy wound treatment systems such as *Lloyd* were known to suffer certain drawbacks. For example, a patent from 1986, entitled “Continuous Vacuum Wound Drainage System” (“*Phillips*”), teaches that such manually-operated devices “typically do not provide precise 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.

34. 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:

36. 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.

37. Conventional vacuum therapy based wound treatment systems were also known to incorporate venting arrangements having flow restrictors, which allowed ambient air to enter the system's tube, 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:

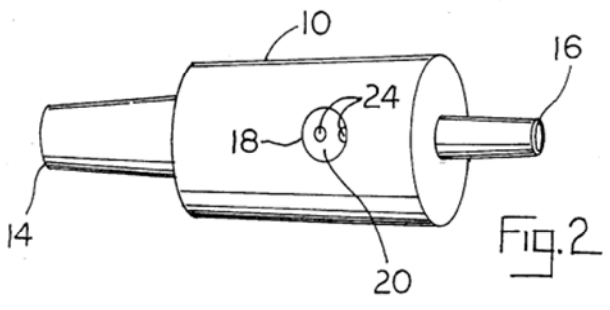
Atkinson – Figure 7



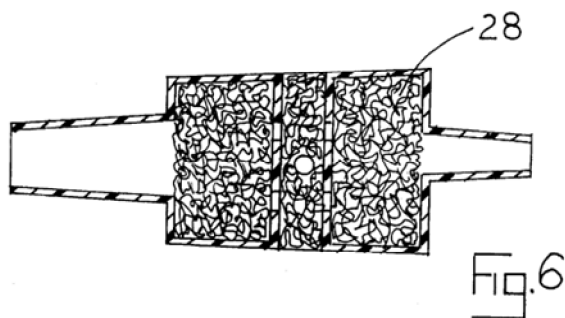
38. In *Atkinson*, the suction adapter 34 includes a housing 10 having a ventilation port 18 in communication with an interior space 12 of the housing 10 "to allow atmospheric air into the interior space 12," as shown in Figure 2 below. *Id.*, 2:33–35, Fig. 2. In one embodiment of *Atkinson*, a porous 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

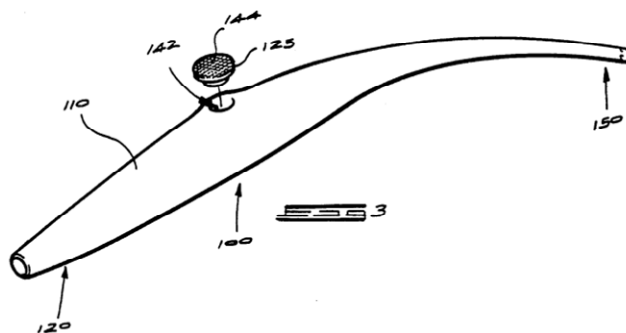


39. *Atkinson* teaches, “[t]he foam 28 is preferably a plastic foam easily permeated by the drain fluid and air...[f]or example, an open cell polyurethane foam having 10 to 30 pores per square inch has been found to work well.” *Id.*, 3:67–5:3. The porous foam 28 of *Atkinson* is described as providing 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 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.

40. 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



41. 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.

42. Despite this crowded field of prior art, the ’554 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 vacuum source, a venting arrangement comprising a flow restrictor that is located outside of the enclosure, and a waste container in fluid communication with the vacuum source. But these claim elements were all common components known for years prior to the time of the alleged invention.

B. Description of the Alleged Invention of the '554 Patent

43. Based upon my review of the '554 Patent (Ex. 1001), which is titled "Wound Closure and Drainage System," I find that it relates generally to 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. In my opinion, and as will be demonstrated below, there are and were no novel or non-obvious features claimed in the '554 Patent, as vacuum therapy wound treatment systems including all the claimed elements were known prior to the alleged invention of the '554 Patent, and there were many known design choices to accomplish such wound closure and drainage prior to the alleged invention of the '554 Patent. *See, e.g.*, Exs. 1003–1006; 1009–1013 (as discussed above).

44. The '554 Patent discloses a vacuum system including "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. The Challenged Claims of the ’554 Patent are directed to different aspects of the vacuum wound closure and drainage system.

45. Claim 12 recites a vacuum system for applying negative pressure to a wound having an enclosure, a vacuum source, a tube, a venting arrangement, and a waste container. The enclosure is attachable to the wound circumference 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 the venting arrangement is located outside the enclosure such that ambient air can enter the tube via the venting arrangement without entering the enclosure. The waste container is in fluid communication with the vacuum source.

46. Claim 14 depends from Claim 12 and claims the additional features of: (i) the vacuum source including a disposable pump unit detachably attachable to a non-disposable drive unit and (ii) the enclosure and waste container being disposable so that the ambient air that enters the tube via the venting arrangement contacts only the disposable elements and the drained liquids may be disposed of together with the disposable elements.

47. Claim 15 depends from Claim 14 and claims the additional features of the pump unit and the drive unit being adapted for attaching and detaching by simple hand manipulations.

48. Claim 16 depends from Claim 12 and claims the additional feature of the venting arrangement including one or more bleeding holes.

49. Claim 17 depends from Claim 12 and claims the additional feature of the venting arrangement being provided in the form of a porous body.

50. Claim 26 depends from Claim 12 and claims the additional feature of the venting arrangement being a tube orifice.

51. Claim 27 depends from Claim 26 and claims the additional feature of the orifice having a smaller opening than a cross section of the tube.

C. Summary of the Prosecution History

52. The following reflects a brief summary of the prosecution history of the '554 Patent. The prosecution history is relevant to understanding why the '554 Patent was deemed to meet the conditions for patentability.

53. I understand from my review of the '554 Patent and its file/prosecution history, as well as discussions with Petitioner's counsel, that the '554 Patent claims priority to International Patent Application No. PCT/IL2005/000784 (the "'784 PCT Application") filed July 24, 2005. Ex. 1001, Cover Page. The application that matured into the '554 Patent—U.S. Non-Provisional Application No. 11/989,297

(the “’297 Application”)—was filed as a U.S. national-stage entry based on the ’784 PCT Application. *Id.* As-filed, the ’297 Application included 33 total claims of which claims 1, 11, 15, 24, and 29 were independent. Ex. 1002, 14–18.

54. In response to a first non-final office action, Applicant argued that none of the cited references, alone or in combination, taught the limitation—added by way of amendment in response to that first office action—“said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement.” *Id.*, 477 (regarding pending independent claim 11), 484 (regarding the other pending independent claims, i.e., claims 42¹ and 48).

55. In response to a first final office action, Applicant argued that none of the cited references, alone or in combination, taught the limitation “such that ambient air can enter said tube via said venting arrangement ***and flow to said vacuum source without entering said enclosure.***” *Id.*, 610 (regarding pending independent claim 11), 617 (regarding the other pending independent claims, i.e., claims 42 and 48) (emphasis added). Despite being argued in conjunction with pending independent claim 48, notably, pending independent claim 42 did not include the limitation “without entering said enclosure” and, thus, it is not clear why pending claim 42 was believed to define over the cited art at this juncture. *See id.*, 617 (“It is therefore respectfully submitted that claims 38-53, in particular independent claim 48, are ***not***

¹ Claim 42 issued as claim 12—the independent claim challenged in the Petition.

taught or suggested by the combination of Lockwood and Argenta.”) (emphasis in original).

56. In response to a second non-final office action, Applicant argued that a person having ordinary skill in the art would not have been motivated to modify primary reference Lockwood based on the teachings of secondary reference Leffler because doing so would allegedly render Lockwood unsatisfactory for its intended purpose. *See, e.g., id.*, 698 (“Supplying the suction tube of Lockwood with the venting arrangement of Leffler would destroy the operation of Lockwood’s device, and intended use thereof.”). Additionally, by way of this response, Applicant amended the specification to recite, for the first time and in the only instance, the term “venting arrangement,” which appears throughout the Challenged Claims. *See id.*, 688, 696.

57. An applicant-initiated interview summary was mailed September 14, 2012, summarizing an interview as follows: “Applicant proposed the amendment: to include the limitation of ‘comprising a calibrated orifice to restrict flow through the venting arrangement located outside said enclosure’ into claims 1, 42 and 48. Examiner agreed that the proposed amendment places the Application in condition for allowance.” *Id.*, 765. The pending independent claims were amended via an Examiner’s Amendment to incorporate the foregoing limitation, and a Notice of Allowance was mailed October 9, 2012. *See id.*, 774–77. 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 calibrated orifice restricting flow through the venting arrangement located outside of the enclosure that prevents the overvacuum conditions during the medical procedure.” *Id.*, 775.

58. By way of a post-allowance amendment filed January 8, 2013, the pending independent claims were amended, *inter alia*, to replace the 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.

59. 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.

60. 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.

61. An issue notification was mailed July 24, 2013 indicating that the ’297 Application would issue on August 13, 2013 as the ’554 Patent. *Id.*, 1064.

62. Pertinent to the Challenged Claims, a Certificate of Correction was issued September 9, 2014 amending (i) Claim 12 to replace the first semi-colon with a colon and (ii) Claim 27 to replace the term “enclosure” with “vacuum system.” *Id.*, 1094.

VI. SUMMARY OF THE ASSERTED PRIOR ART

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

63. I have carefully reviewed the *Bitel* (Ex. 1009) prior art reference applied in the IPR Petition, and I deem it to be relevant to demonstrating the unpatentability of the ’554 Patent. A brief summary of *Bitel* is provided below, explaining, in part, what *Bitel* discloses to a POSITA in the context of the ’554 Patent specification and claims.

64. *Bitel*, International Publication No. WO 03/030966, is titled “Waste Container For Negative Pressure Therapy” Ex. 1009, Title. I understand that *Bitel* published in 2003 and is therefore § 102(b) prior art. *Id.* I also understand from my review that *Bitel* is listed on the face of the ’554 Patent, but it was not applied against any of the claims during prosecution. *See generally* Ex. 1001.

65. *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

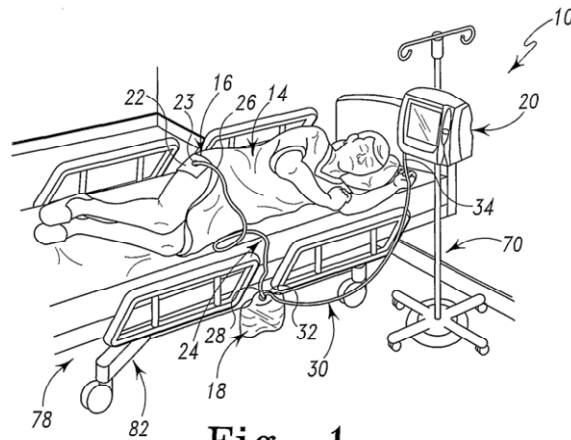


Fig. 1

66. 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.

67. “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

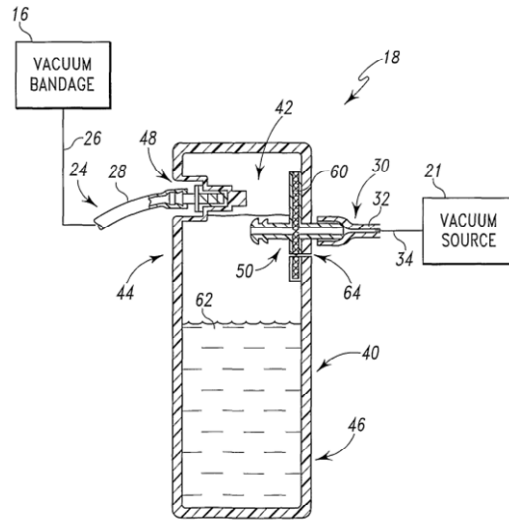


Fig. 5

68. 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 30, 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.

69. “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.

B. *Watson*: U.S. Patent No. 6,648,862 (Ex. 1013)

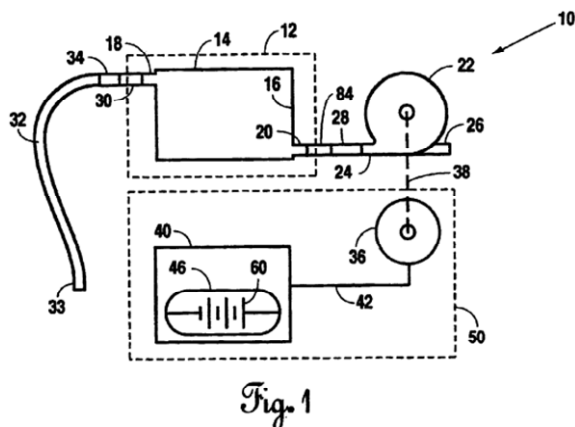
70. I have carefully reviewed the *Watson* (Ex. 1013) prior art reference applied in the IPR Petition, and I deem it to be relevant to demonstrating the unpatentability of the ’554 Patent. A brief summary of *Watson* is provided below, explaining, in part, what *Watson* discloses to a POSITA in the context of the ’554 Patent specification and claims.

71. *Watson*, U.S. Patent No. 6,648,862, is titled “Personally Portable Vacuum Desiccator” Ex. 1013, Title. I understand that *Watson* published in 2003 and is therefore § 102(b) prior art. *Id.* I also understand from my review that *Watson* is listed on the face of the ’554 Patent, but it was not applied against any of the claims during prosecution. *See generally* Ex. 1001.

72. *Watson* relates to a vacuum desiccator 10 including “a personally portable, low negative pressure, motor driven vacuum pump having an electric power storage means and a moisture trap,” Ex. 1013, 1:9–11, that “is therapeutically useful...for aspirating and collecting fluid exudate from a wound or incision.” *Id.*, 2:24–28. “The electric motive means of the vacuum desiccator includes an electric motor. The motor is coupled to the vacuum pump member to drive the pump.” *Id.*, 3:53–55.

73. The vacuum desiccator 10 of *Watson* is shown generally in Figure 1 below.

Watson – Figure 1



Id., Fig. 1.

74. *Watson* teaches that the vacuum pump member 22 may be detachably attachable to the electric motive means 36. *See id.*, 7:64–67, 8:14–28 (“[T]he motor 36 maybe [*sic*]...coupled...to the pump head 22 so as to...be readily separable from the vacuum pump member 22.”). In some embodiments, the “the vacuum pump member and the desiccator cartridge are integrated together as a unit.” *Id.*, 3:64–65.

75. In addition, *Watson* teaches “[i]n a preferred embodiment of the vacuum desiccator 10, all of the components in gas/liquid flow communication are replaceable.” *Id.*, 7:15–18. “This allows the components of the device that are exposed to contact with the wound fluids to be separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” *Id.*, 7:18–21.

C. *Dolliver*: U.S. Patent No. 8,157,792 (Ex. 1012)

76. I have carefully reviewed the *Dolliver* (Ex. 1012) prior art reference applied in the IPR Petition, and I deem it to be relevant to demonstrating the unpatentability of the '554 Patent. A brief summary of *Dolliver* is provided below, explaining, in part, what *Dolliver* discloses to a POSITA in the context of the '554 Patent specification and claims.

77. *Dolliver*, U.S. Patent No. 8,157,792, is titled “Wound Drainage Suction Relief” Ex. 1012, Title. I understand that *Dolliver* was filed in 2004 and is therefore § 102(e) prior art. *Id.* I also understand from my review that *Dolliver* is listed on the face of the '554 Patent, but it was not applied against any of the claims during prosecution. *See generally* Ex. 1001.

78. *Dolliver* is directed to “a wound drain system for implantation into and for drainage of fluid from a wound of a patient.” Ex. 2012, 2:29–31. “The system includes a drain catheter in fluid communication with a suction device via a conduit.” *Id.*, 2:31–33.

79. “A valve, such as a vent valve, may be positioned between the suction means and the drain catheter. The valve may be, for example, disposed in the conduit.” *Id.*, 2:33–35. Figure 1, reproduced below, shows a drain catheter 102 connected to an in-line container 115 (for collecting waste from the wound 102) and

a suction device 106 via a conduit 122. *Id.*, 3:29–4:3, Fig. 1. A vent valve 119 is positioned within the conduit 122. *Id.*, 4:49–5:7, Fig. 1.

Dolliver – Figure 1

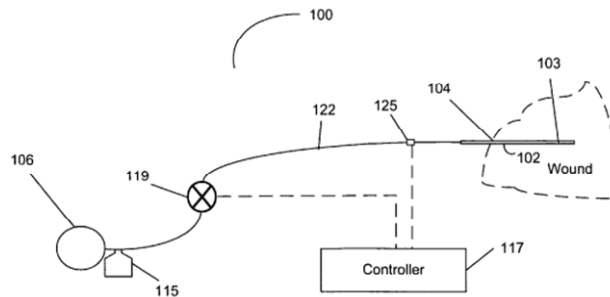


Fig. 1

Id., Figure 1.

80. The vent valve 119 “selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere, thereby decreasing the amount of suction applied at the drain catheter 102.” *Id.*, 4:59–61. “The vent valve may include a filter, such as, but not limited to a bacterial filter, for preventing introduction of outside contaminants into the conduit system 122 which may adversely affect the wound.”

81. *Dolliver*, like *Watson*, also teaches that the components of the system—such as the drain catheter 102, conduit/tubing 122, and waste container 115—may be disposable. *Id.*, 5:41–47 (“The drain catheter 102...and tubing 122 may form a disposable set in which fluids are collected and processed. The disposable set may also include various storage containers for storing, without limitation, anticoagulant

or one of the separated components, and appropriate valving to direct the fluid in the desired manner.”).

D. *Argenta*: U.S. Patent No. 5,636,643 (Ex. 1006)

82. I have carefully reviewed the *Argenta* (Ex. 1006) prior art reference applied in the IPR Petition, and I deem it to be relevant to demonstrating the unpatentability of the '554 Patent. A brief summary of *Argenta* is provided below, explaining, in part, what *Argenta* discloses to a POSITA in the context of the '554 Patent specification and claims.

83. *Argenta*, U.S. Patent No. 5,636,643, is titled “Wound Treatment Employing Reduced Pressure” Ex. 1006, Title. I understand that *Argenta* issued in 1997 and is therefore § 102(b) prior art. *Id.* I also understand from my review that a continuation of *Argenta* (U.S. Patent Application Pub. No. 2001/0029956 (“*Argenta* '956”)) was cited during prosecution of the '297 application, but was not applied in the manner set forth in Ground 3 of the accompanying Petition. *See generally* Ex. 1002.

84. *Argenta* '956 was initially cited as a secondary reference in an obviousness rejection of pending claims 38–53 for teaching the waste container claim limitation. *See* Ex. 1002, 514–15. Applicant appeared to concede that *Argenta* '956 taught a waste container as claimed and instead argued over the rejection based on a different claim limitation. *Id.*, 617 (“*Argenta* ['956] does not cure the

deficiencies of Lockwood regarding the feature that the ‘ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure’.”) (emphasis in original).

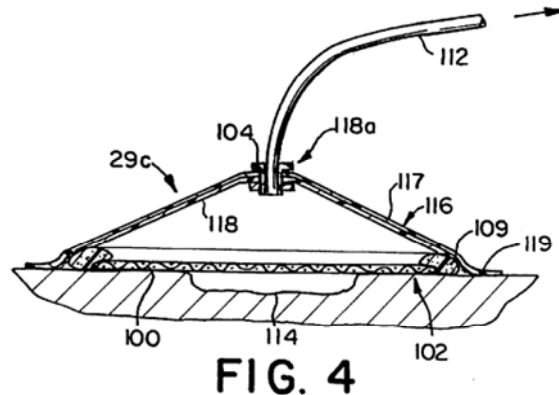
85. *Argenta* ’956 was then cited as a primary reference in an obviousness rejection of pending claims 11, 13–14, and 34–54 as teaching all pending claim limitations except “wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.” *Id.*, 736. Applicant overcame this rejection through an Examiner’s Amendment that amended the pending independent claims to recite that the venting arrangement comprises “a calibrated orifice to restrict flow through the venting arrangement located outside said enclosure.” *See id.*, 765, 774–775. However, the accompanying Petition does not rely on *Argenta* as teaching any of the foregoing limitations and instead only cites to it in Ground 3 as a secondary reference for teaching the “enclosure” and “enclosure outlet” limitations of the Challenged Claims.

86. *Argenta* is directed to “an apparatus and method for treating a wound by applying reduced pressure to the wound.” Ex. 1006, 1:10–12. “The reduced pressure application appliance includes a fluid impermeable wound cover for covering and enclosing the wound...[and] sealing means for sealing the wound cover to the surrounding tissue of the wound in order to maintain reduced pressure

in the vicinity of the wound during wound treatment.” *Id.*, 2:66–3:5. “When the wound cover is sealed in position over the wound site, a generally fluid-tight or gas-tight sealed **enclosure** is formed over the wound site.” *Id.*, 3:5–8 (emphasis added). “The reduced pressure appliance also includes a suction port for supplying reduced pressure within the sealed volume enclosed beneath the wound cover. The suction port may be in the form of a nipple on the wound cover.” *Id.*, 3:17–21.

87. One embodiment of the enclosure of *Argenta* is shown in Figure 4 below, wherein a fluid-impermeable wound covering 116 is positioned over a wound 114. *Id.*, 10:61–11:31, Fig. 4.

Argenta – Figure 4



88. “A suction port 104 is provided at the top of the [enclosure] to permit gas-tight connection to suction tube 112...[which] functions to connect the appliance 29c to a suitable vacuum system 30.” *Id.*, 11:14–20.

VII. CONCLUSIONS REGARDING PATENTABILITY

89. It is my opinion that the Challenged Claims of the '554 Patent are not patentable for at least the reasons proposed in Grounds 1–3 of the IPR Petition:

Ground	Claim(s)	Pre-AIA 35 U.S.C. Basis	References
1	12–13 and 16–17	§ 102(b)	<i>Bitel</i>
2	14–15	§ 103(a)	<i>Bitel</i> in view of <i>Watson</i>
3	12–13, 16–17 and 26–27	§ 103(a)	<i>Dolliver</i> in view of <i>Argenta</i>

90. Ground 1 shows how *Bitel* anticipates Claims 12–13 and 16–17.

91. Ground 2 shows how a POSITA, based on *Watson*'s teaching of the desirability of having detachable and disposable pump units, enclosures, and waste containers in a vacuum therapy wound treatment system, would have modified *Bitel*'s vacuum therapy wound treatment system such that (i) a pump unit of the vacuum source was detachably attachable to a drive unit of the vacuum source and (ii) the pump unit, enclosure, and waste container were disposable rendering Claims 14–15 obvious.

92. Ground 3 shows how a POSITA would have modified *Dolliver*'s vacuum therapy wound treatment system to include an enclosure, such as the enclosure taught by *Argenta*, to control the topical atmosphere adjacent a wound thereby enhancing the healing process of a wound rendering Claims 12–13, 16–17 and 26–27 obvious.

A. Ground 1: Claims 12–13 and 16–17 Are Anticipated Under Pre-AIA 35 U.S.C. § 102(b) by *Bitel*

1. Each Element of Claim 12 is Found in *Bitel*

(a) [12.P] A vacuum system for applying negative pressure to a wound

93. *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. 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).

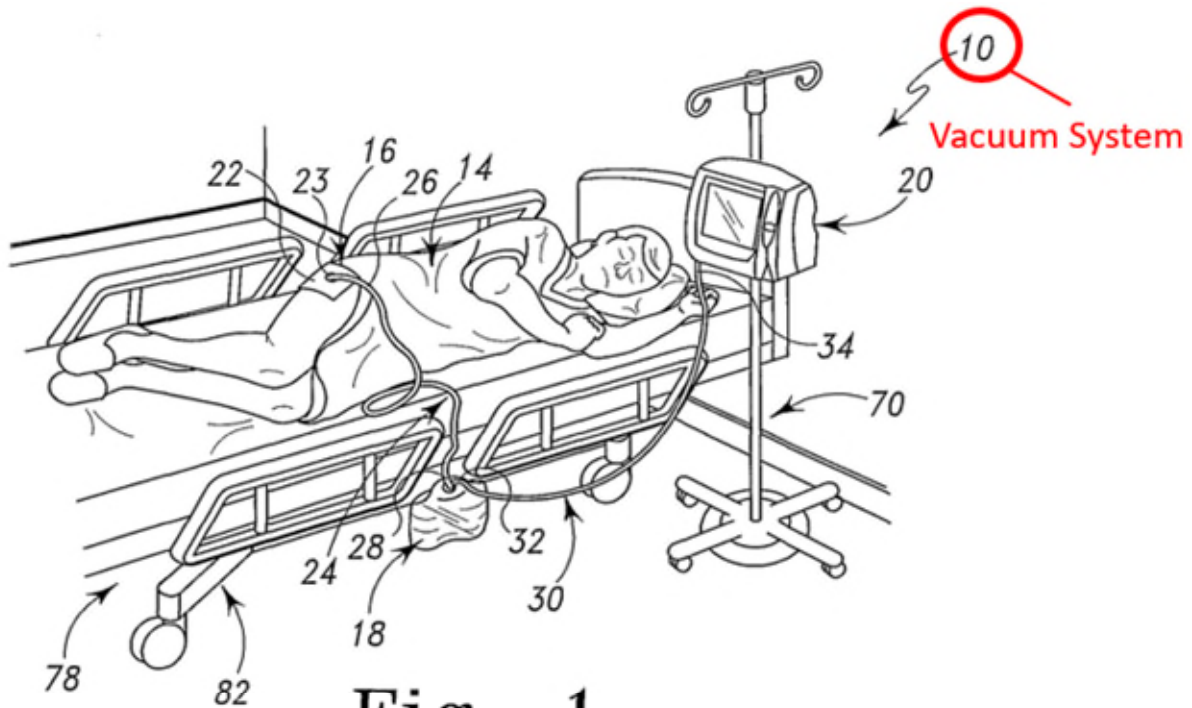


Fig. 1

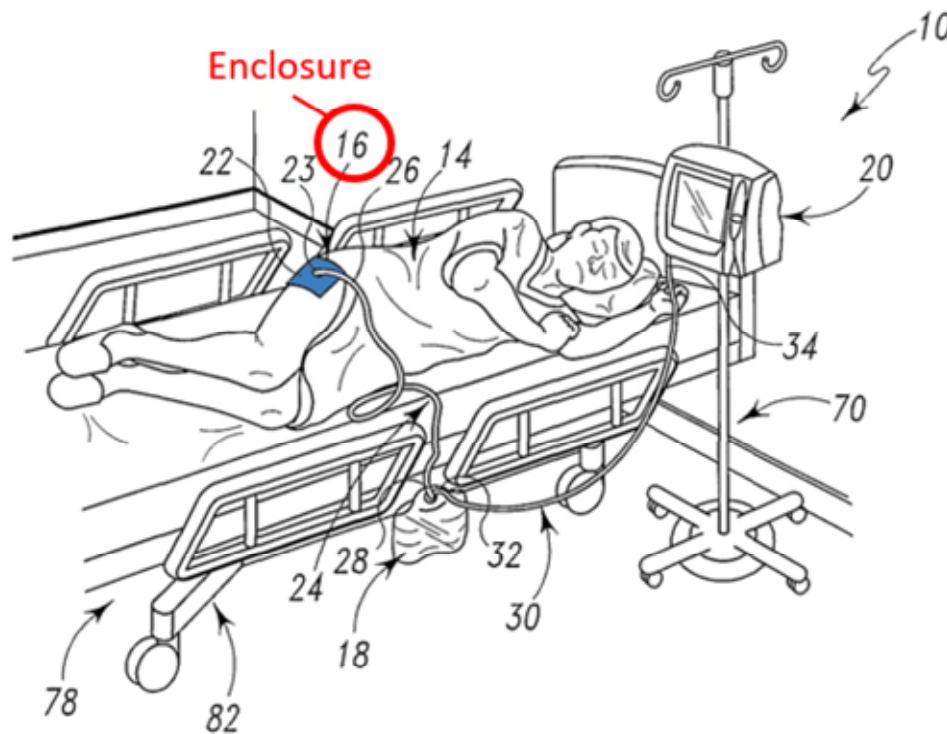
94. In this way, it is my opinion that *Bitel* teaches a vacuum system (vacuum therapy system 10) for applying negative pressure to a wound.

(b) [12.1] An enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume

95. *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. It is my opinion that 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.

96. 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. It is my opinion that the vacuum source 21 of *Bitel* constitutes “a vacuum source” as claimed.

97. As shown in annotated Figure 1 below, vacuum bandage 16 (blue) constitutes an enclosure attachable to the wound circumference so as to define a confined volume:



Id., Fig. 1.

98. As further shown in annotated Figure 5 below, vacuum source 21 (orange) constitutes a vacuum source:

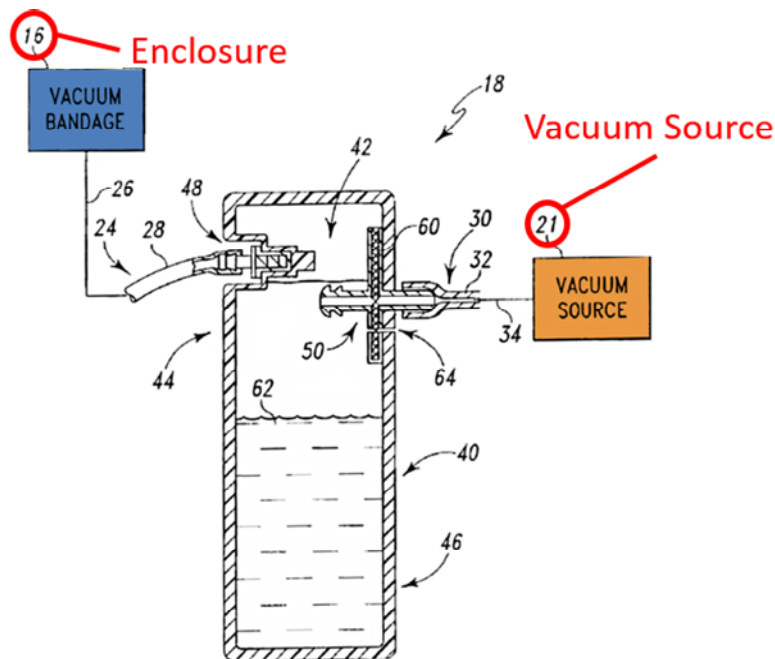


Fig. 5

Ex. 1009, Fig. 5.

99. In this way, it is my opinion that *Bitel* teaches an enclosure (bandage 16) and a vacuum source (vacuum source 21), the enclosure being attachable to the wound circumference so as to define a confined volume (volume under bandage 16).

(c) [12.2] A tube

100. *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. 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.

101. It is my opinion that the outlet port 50 constitutes a “tube” as claimed because it is an elongated, hollow cylinder for transporting gases and/or liquids.

102. As shown in annotated Figure 5 below, the outlet port 50 (green) constitutes a tube:

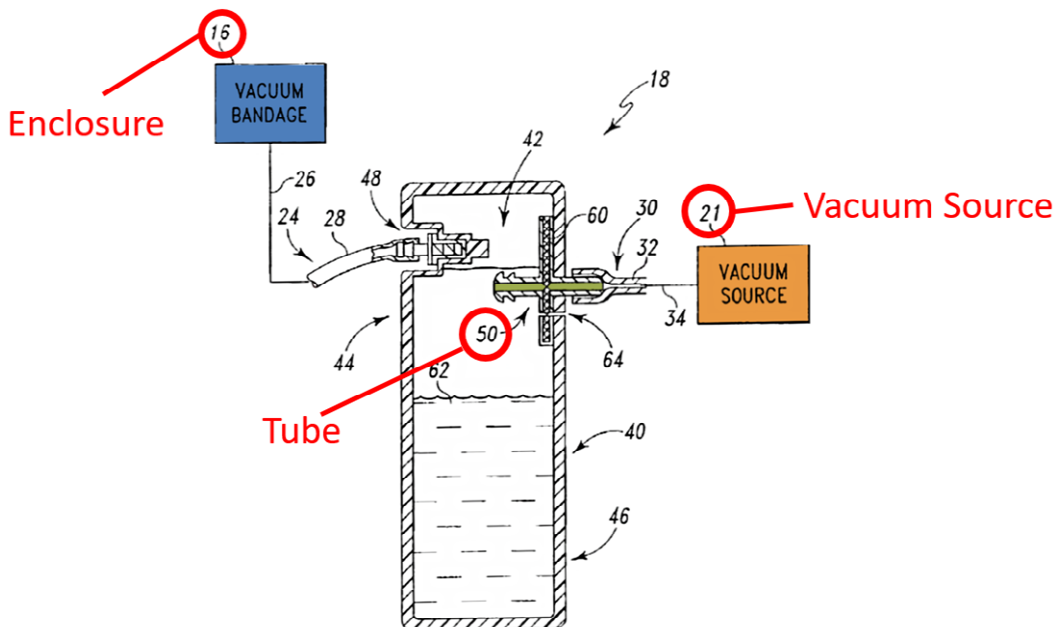


Fig. 5

Id., Fig. 5.

103. In this way, it is my opinion that *Bitel* teaches a tube (outlet port 50).

(d) [12.3] A venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement

104. *Bitel* discloses “[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, Fig. 5. The “vacuum source 21 is...able to pull air through air vent 64.” 8:11–12.

105. It is my opinion that 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.

106. Furthermore, it is my opinion that the hydrophobic filter 60 constitutes a flow restrictor as claimed in that it restricts flow through the venting arrangement. A mechanical filter to remove substance matter dissolved in a fluid flow (laminar or turbulent, liquid or gas) necessarily will decrease the pressure in the fluid, such that the pressure energy in the fluid is lower downstream of the filter, compared to upstream of the filter (see below for details on upstream vs. downstream).

107. A mechanical filter is designed to remove particulate matter or contaminants from a fluid flow, which can be in the form of a liquid or gas. The presence of a filter in the flow path adds resistance to the flow, which is a form of impedance. This impedance causes a reduction in the fluid’s pressure energy as it passes through the filter. Essentially, the work done by the fluid to overcome the filter’s resistance results in a pressure drop from the upstream (before the filter) to the downstream (after the filter) side of the filter.

108. This is explained by the way filters work, and a combination of Bernoulli's, Poiseuille's, and Ohm's Law equivalent for fluid impedance. How and if these concepts are used, depends on the type of fluid, if it is a liquid or gas:

109. Bernoulli's principle states that for an incompressible fluid flowing in a streamline motion, an increase in the fluid's velocity leads to a decrease in its pressure and potential energy. While Bernoulli's principle primarily applies to ideal fluids (without viscosity), it sets the foundation for understanding how pressure can vary within a flowing fluid. In the context of a filter, the constriction and flow resistance introduced by the filter can be seen as causing an effect similar to a change in velocity, leading to a decrease in pressure downstream of the filter.

110. Poiseuille's law relates to laminar flow of viscous liquids through pipes. It quantitatively describes how the volume flow rate of a liquid through a pipe depends on the liquid's viscosity, the pipe's length and diameter, and the pressure difference across the pipe. When a filter is introduced into the system, it effectively adds to the system's resistance, thereby influencing the pressure drop across the filter, much like how the pipe's characteristics affect the flow and pressure in Poiseuille's law.

111. Ohm's law for electrical circuits ($V = I \cdot R$, where V is voltage, I is current, and R is resistance) has an analogue in fluid dynamics, where the pressure drop across a filter (" ΔP ") (akin to voltage drop) is proportional to the flow rate (akin

to current) and the hydraulic resistance (“ R_h ”) (akin to electrical resistance) of the filter. This relationship is identical to Ohm’s law for electrical circuits: $\Delta P = Q \cdot R_h$. The greater the resistance offered by the filter, the greater the pressure drop for a given flow rate.

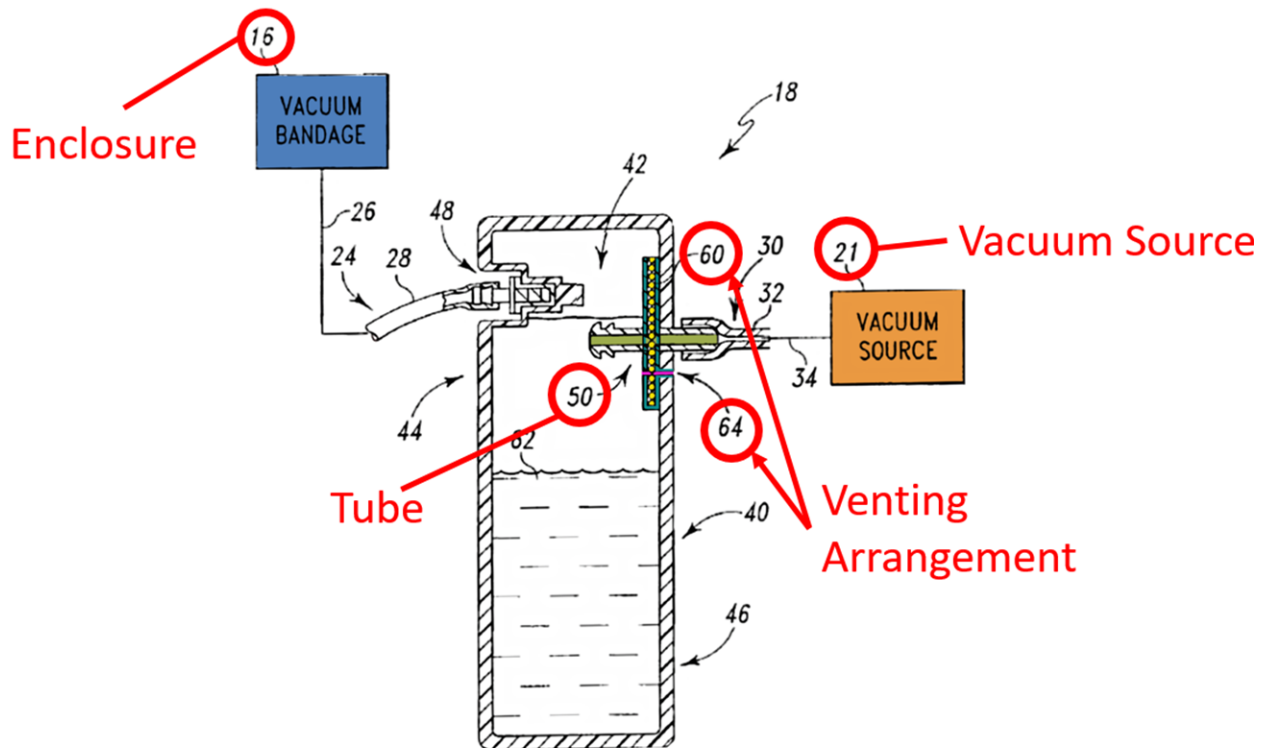
112. The amount of flow restriction determines the pressure drop. It is important to note that when the fluid is not flowing, a mechanical filter has no influence on the fluid pressure, because the principles causing the pressure drop (related to fluid motion and resistance) are not in effect. The filter only influences the pressure when the fluid is in motion. In addition, for a mechanical filter, as the flow rate increases, the pressure drop across the filter also increases, due to the higher amount of work the fluid must do to overcome the filter's resistance. This relationship is influenced by the factors mentioned earlier and can be complex, varying with the filter and fluid characteristics.

113. These relationships are determined by factors such as the filter type, geometry, fluid properties (viscosity, density, etc.), and the pressure drop across a filter is determined by a combination and variety of those factors. Different filters have different designs (e.g., pore size, surface area) that affect how they impede flow. The viscosity and density of the fluid play significant roles. Higher viscosity fluids result in greater resistance and hence a higher pressure drop, all else being

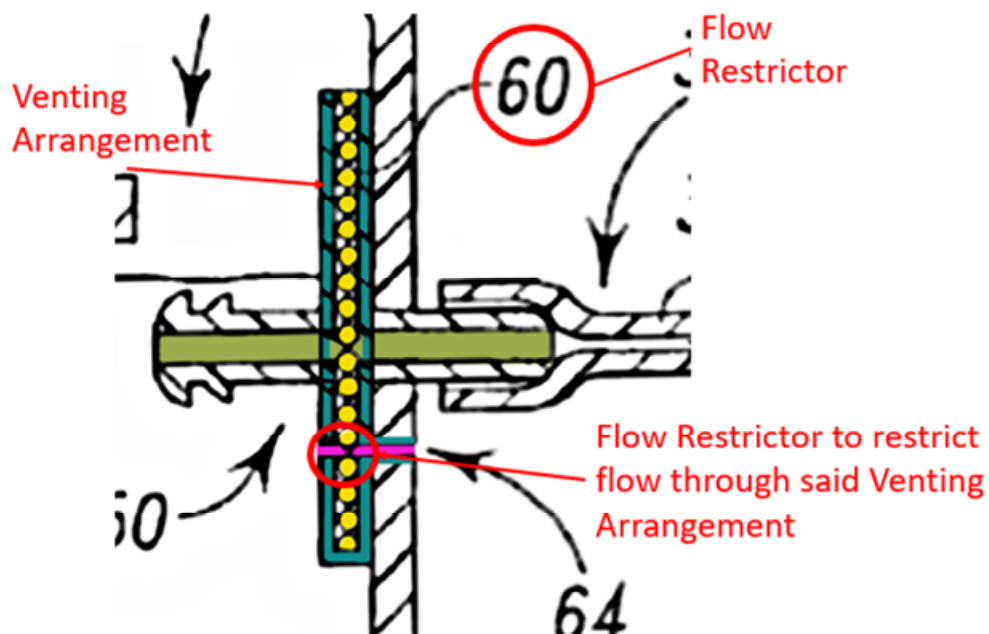
equal. Higher flow rates increase the pressure drop because they require the fluid to do more work to overcome the filter's resistance.

114. If the flow through the filter becomes turbulent (which can occur at high flow rates or with irregular filter surfaces), the energy losses due to turbulence can further decrease the fluid's flow rate. This is because Poiseuille's law is no longer valid in its traditional form, and a modified version of the law will have to be used. Turbulent flow requires more energy to maintain than laminar flow, partly because of the chaotic eddies and vortices that form, which increase the resistance against the flow.

115. As shown in annotated Figure 5 below, air vent 64 (purple) and hydrophobic filter 60 (yellow) together constitute a venting arrangement (outlined in teal) and the 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.



Id., Fig. 5.



Id., Fig. 5 (magnified to more readily show hydrophobic filter 60 acting as a flow restrictor).

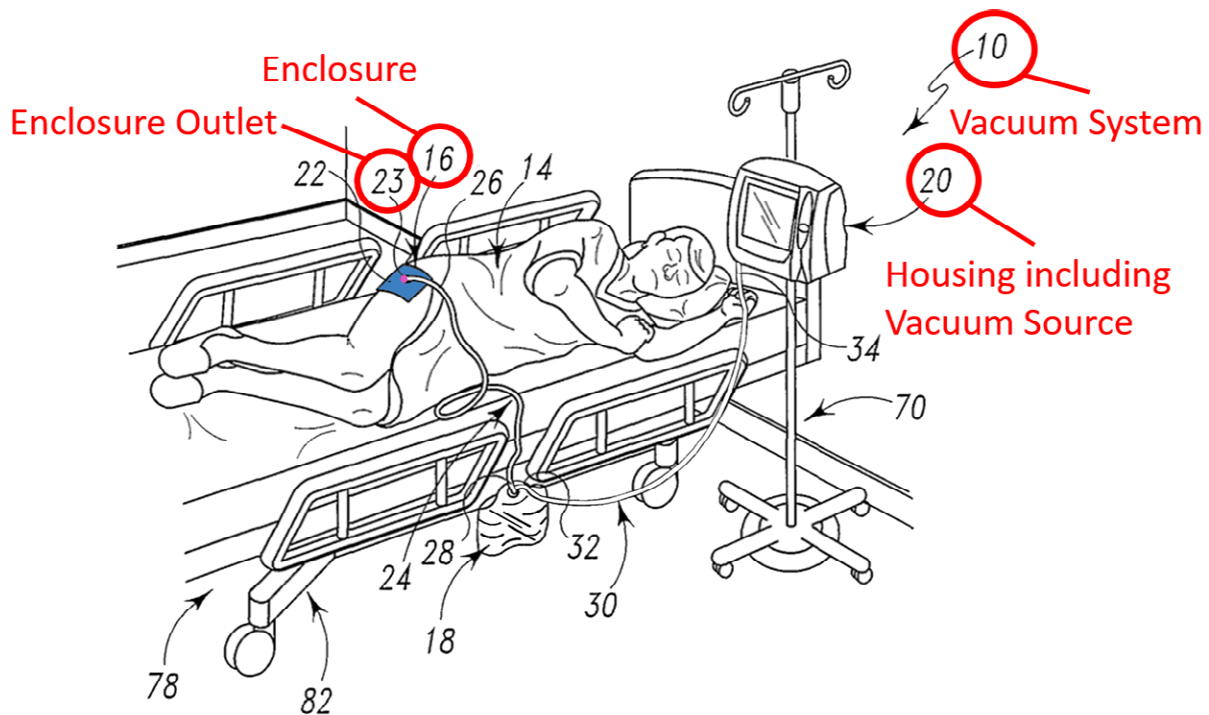
116. In this way, it is my opinion that *Bitel* teaches a venting arrangement (air vent 64 and hydrophobic filter 60) comprising a flow restrictor (hydrophobic filter 60) to restrict flow through said venting arrangement.

(e) [12.4] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be created in said volume

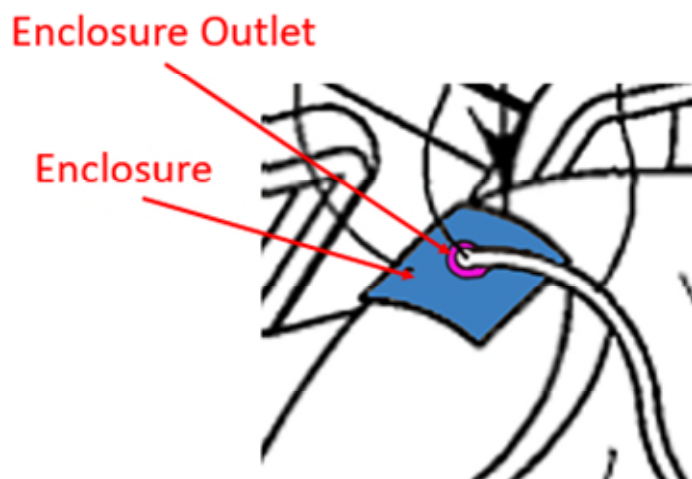
117. *Bitel* discloses “[t]he bandage 16 further includes a port 23 in communication with the space above the wound.” Ex. 1009, 5:33–6:1. “The port 23 is coupled to receptacle 18 by a first tube 24 of the system 10. First tube 24 includes a first end 26 coupled to the port 23 and a second end 28 coupled 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.

118. As shown in annotated figure 1 below, the port 23 of *Bitel* (pink) 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. Furthermore, 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. 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. A magnified view of vacuum bandage 16 and port 23 as shown in Figure 1 is also provided below.



Ex. 1009, Fig. 1.



Id., Fig. 1 (magnified to more readily show port 23).

119. In this way, it is my opinion *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 created in said volume (volume under bandage 16).

(f) [12.5] Said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure

120. *Bitel* discloses that the air vent 64 and hydrophobic filter 60 (collectively, corresponding to the claimed “venting arrangement”) are included as part of the receptacle 18 and thus are outside of the bandage 16 (corresponding to the claimed “enclosure”). Ex. 1009, 6:19–25, 8:18–19, Figs. 1 and 5.

121. It is my opinion that when the vacuum source 21 is activated so as to create negative pressure within the system 10, ambient air can enter the outlet port 50 via the air vent 64 and hydrophobic filter 60 without entering the bandage 16. A vacuum source creates a region of low pressure relative to the surrounding fluid. Fluids flow from areas of higher pressure to areas of lower pressure. This is a fundamental principle of fluid dynamics, governed by the laws of thermodynamics and fluid mechanics. Hence, fluid (liquid or gas) will necessarily flow in the direction towards a lower pressure, in an attempt to evenly distribute the energy

within the fluid. Therefore, the air will not flow through the first tube to the enclosure.

122. This is illustrated in annotated Figure 5 below where ambient air is shown first entering the receptacle 18 via the air vent 64 (purple) and hydrophobic filter 60 (yellow), and then entering the outlet port 50 (green) toward the vacuum source 21:

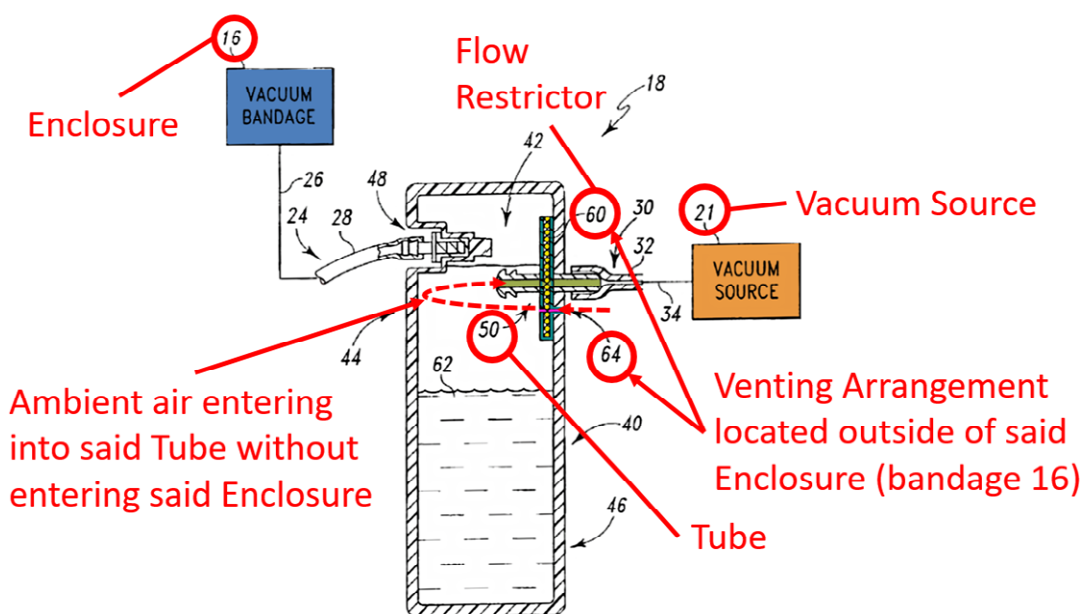


Fig. 5

Ex. 1009, Fig. 5.

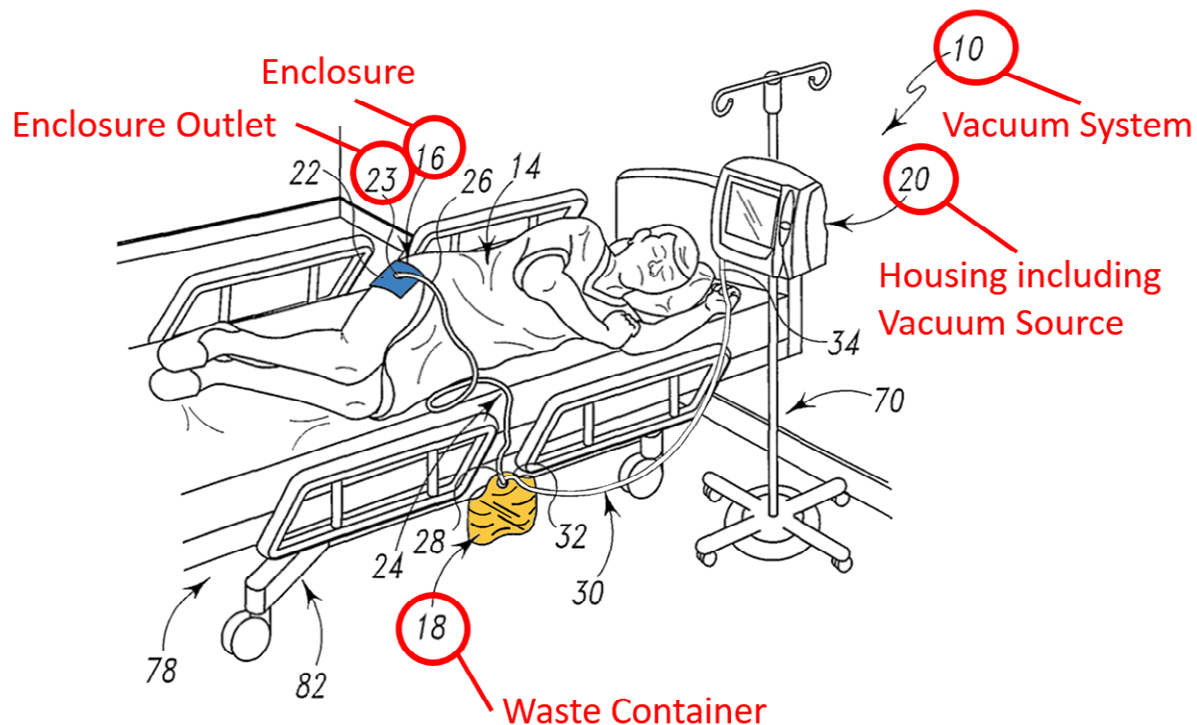
123. In this way, it is my opinion that *Bitel* teaches said venting arrangement (air vent 64 and hydrophobic filter 60) located outside said enclosure (bandage 16) such that ambient air can enter said tube (outlet port 50) via said venting arrangement without entering said enclosure.

(g) [12.6] A waste container in fluid communication with said vacuum source

124. *Bitel* discloses a receptacle 18 “to receive exudate from the wound.” Ex. 1009, Abstract. It is my opinion that 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, Figs. 1 and 5.

125. *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, 6:28-28. “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].” Ex. 1009, Abstract.

126. 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.

127. In this way, it is my opinion that *Bitel* teaches a waste container (receptacle 18) in fluid communication (via outlet port 50 and second tube 30) with said vacuum source (vacuum source 21).

2. Each Element of Claim 13 is Found in *Bitel*

(a) [13.1] The vacuum system of claim 12, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom

128. *Bitel* discloses the vacuum system of Claim 12, as previously described.

129. *Bitel* also teaches “the present invention relates to the drainage and collection of exudate from the wound surface through vacuum therapy.” Ex. 1009, 1:46–7. The vacuum source 21 of *Bitel* is used “for applying negative pressure to

the wound to draw exudate from the wound in order to facilitate healing.” *Id.*, 5:14–16.

130. In this way, it is my opinion that *Bitel* teaches wherein said vacuum system (vacuum therapy system 10) further operates to drain the wound from fluids exuded therefrom.

(a) **[13.2] Wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container**

131. *Bitel* discloses that ambient air can enter the second tube 30 via the venting arrangement (i.e., air vent 64 and hydrophobic filter 60), as discussed previously.

132. It is my opinion the system 10, from the enclosure to the vacuum source, is in fluid communication.

133. Therefore, it is my opinion that when the vacuum source 21 of *Bitel* is activated so as to create negative pressure within the system 10, the entire system 10 is operational and the ambient air will flow together with the exuded liquids under the action of negative pressure—the exuded liquids flowing from the bandage 16 through the first tube 26 to the receptacle 18 and the ambient air flowing from the air vent 64 and hydrophobic filter 60 through the outlet port 50 and second tube 30. Ex. 1009, 7:23–28.

134. Further it is my opinion that this facilitates draining of the exuded liquids under negative pressure. The incorporation of a venting arrangement in a tube system, operating under negative pressure to drain exuded liquids, harnesses the Venturi effect, a phenomenon where fluid speed increases while pressure decreases as the fluid flows through a constricted section of a pipe or an opening. By allowing ambient air to enter the tube through these vents, the system uses the negative pressure not just to pull the exuded liquids towards the vacuum source but also to accelerate the air-liquid mixture through narrower sections of the tube. This acceleration results in a reduction of pressure loss at these constricted points, further enhancing the downstream effects of the vacuum. Consequently, the differential pressure created by this arrangement propels the exuded liquids more effectively, facilitating their drainage. The Venturi principle, thus, amplifies the efficiency of the negative pressure system, ensuring that even viscous or semi-solid exudates are mobilized and drained away with greater ease. This method optimizes the removal of liquids and also minimizes the risk of blockages, ensuring a smooth, continuous flow. A POSITA would know that that is critical in wound care.

135. For example, if ambient air in such a system does not flow together with the exuded liquids, the exudate may clog and collapse the tubes of that system, which would terminate the fluid connection between the enclosure and the vacuum source. As such, it is my opinion that *Bitel's* venting arrangement reduces the risk of such a

collapse, thereby helping to maintain fluid communication between the enclosure and the vacuum source thereby facilitating draining of the exuded fluids to said waste container.

136. In this way, it is my opinion that *Bitel* teaches wherein the ambient air can enter said tube (outlet port 50) via said venting arrangement (air vent 64 and hydrophobic filter 60) and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

3. Each Element of Claim 16 is Found in *Bitel*

(a) [16] The vacuum system according to claim 12, wherein said venting arrangement comprises one or more bleeding holes

137. *Bitel* teaches the vacuum system according to Claim 12, as previously described.

138. It is my opinion that the air vent 64 of *Bitel* constitutes at least one bleeding hole 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.

139. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 12 (vacuum therapy system 10), wherein said venting arrangement (air vent 64 and hydrophobic filter 60) comprises one or more bleeding holes (air vent 64).

4. Each Element of Claim 17 is Found in *Bitel*

(a) [17] The vacuum system according to claim 12, wherein said venting arrangement is provided in the form of a porous body

140. *Bitel* teaches the vacuum system according to claim 12, as previously described.

141. *Bitel* also discloses that “[a] hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering receptacle 18.” Ex. 1009, 6:23–25, Fig. 5. The “hydrophobic filter 60 [is] in communication with second tube 30 and thus the vacuum source 21.” *Id.*, 6:19–20. “Illustratively, filter 60 is a 0.2-micron hydrophobic anti-microbial filter.” *Id.*, 6:21. The hydrophobic filter 60—which along with the air vent 64 constitutes a “venting arrangement” as claimed—is provided in the form of a porous body because it permits ambient air to flow therethrough into the receptacle 18 while “prevent[ing] bacteria, etc. in the surrounding atmosphere from entering receptacle 18.” Ex. 1009, 6:23–25, Fig. 5; *see supra*, ¶106 (discussing how hydrophobic filter 60 constitutes the flow restrictor).

142. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 12 (vacuum therapy system 10), wherein said venting arrangement (air vent 64 and hydrophobic filter 60) is provided in the form of a porous body (hydrophobic filter 60).

B. Ground 2: Claims 14–15 Are Rendered Obvious Under Pre-AIA 35 U.S.C. § 103(a) over *Bitel* in View of *Watson*

1. Obviousness Standards and Analysis

(a) Differences Between the Claimed Subject Matter and *Bitel*

143. Dependent Claim 14 recites the vacuum system of Claim 12 (i) wherein the vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit and (ii) the enclosure and waste container are also disposable so that ambient air that enters the tube via the venting arrangement contacts only disposable elements and the drained liquids may be disposed of together with the disposable elements.

144. As previously described, *Bitel* teaches almost every element of Claim 14, including a vacuum system having a vacuum source including a pump unit attachable to a drive unit, an enclosure, a waste container, and a venting arrangement.

145. However, *Bitel* does not expressly teach that the pump unit and drive unit are detachably attachable to one another, or that the pump unit, enclosure, and waste container are disposable so that ambient air that enters the tube via the venting arrangement contacts only disposable elements and the drained liquids may be disposed of together with the disposable elements.

146. But the features of a pump unit and drive unit being detachably attachable to one another, and pump units, enclosures, and waste containers being disposable were well-known in the art.

147. For example, *Watson* teaches a vacuum source having a pump unit and drive unit that are detachably attachable to one another. Ex. 1013, 8:8–28. Further, *Watson* teaches that all “components of the device that are exposed to contact with the wound fluids [are]...separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” *Id.*, 7:16–21.

148. It is my opinion that *Bitel* in view of *Watson* also teaches all of the elements of dependent Claim 15.

(b) Obviousness Rationale for Why a POSITA Would Have Enhanced *Bitel* with *Watson* to Arrive at the Claimed Subject Matter with a Reasonable Expectation of Success

149. In light of the collective teachings of *Bitel* and *Watson*, it is my opinion that it would have been obvious to a POSITA to provide a detachably attachable connection between the pump unit and drive unit of *Bitel* based on the teachings of *Watson*.

150. *Watson* describes several ways to achieve a detachable and re-attachable connection between pump units and drive units in a vacuum therapy wound treatment system, as well as a rationale as to why such a connection would be desirable.

151. For example, *Watson* discloses one embodiment in which “a motor shaft coupling 38 may be mechanically coupled to the vacuum pump head 22 so as to be readily separable from the pump head 22.” *Id.*, 8:14–16. Such a structure would

create a detachable and re-attachable connection between the pump unit and drive unit.

152. In another embodiment, *Watson* teaches “[a]s a further alternative, the motor 36 maybe [sic] magnetically coupled (not shown) to the pump head 22 so as to again be readily separable from the vacuum pump member 22.” Ex. 1013, 8:22–25.

153. *Watson* also describes why such a separable connection would be desirable in providing that “[a] readily separable motive means 36 is particularly useful where the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit.” *Id.*, 8:25–28. Moreover, *Watson* explains that providing a detachably attachable connection between components within the device 10, including but not limited to the pump member 22 and motive means 36, is advantageous in that it “allows the components of the device that are exposed to contact with the wound fluids to be separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” *Id.*, 7:18–21.

154. Thus, insofar as *Bitel* fails to expressly teach a detachably attachable connection between its pump unit and drive unit, this feature was well-known in the art and there would have been a myriad of rationales as to why a POSITA would have been motivated to modify *Bitel* in such a way based on the teachings of *Watson*.

155. In my opinion, such a modification would constitute a simple substitution of one known element (i.e., a permanent connection between a pump unit and drive unit) for another (i.e., a detachable and re-attachable connection between a pump unit and drive unit) to obtain predictable results.

156. It is also my opinion that such an enhancement would also have been “obvious to try” in light of *Watson*’s express teachings of various structural options for achieving a separable connection between a pump unit and a drive unit, and express rationales as to why such separable connections are advantageous in the field of vacuum therapy wound treatment systems.

157. Furthermore, it is my opinion that a modification of *Bitel* based on the teachings of *Watson* would be met with a reasonable expectation of success because the various structures described in *Watson* providing for a separable connection between a pump unit and drive unit were known to work long before the priority date of the ’554 Patent.

158. In addition, in light of the collective teachings of *Bitel* and *Watson*, it is my opinion that it would have been obvious to a POSITA to make the pump unit, enclosure, and waste container of *Bitel* disposable, as taught by *Watson*, so that ambient air that enters the tube via the venting arrangement contacts only disposable elements and the drained liquids may be disposed of together with the disposable elements.

159. Like *Bitel*, *Watson* also teaches an “enclosure” as claimed in the form of an “occlusive dressing” that covers the wound and connects to the trap 12 and pump member 22 via a delivery tube 32. Ex. 1013, 6:16–20 (“[A] delivery tube 32 is included with the desiccator device 10 to put the trap 1[2] in gas/liquid flow communication with a location to which a low negative vacuum pressure is to be applied, such as a wound site covered by an occlusive dressing.”); *see also id.*, 5:48–61 (describing the interrelationship between the trap 12 and desiccator cartridge 14). In some embodiments of *Watson*, “the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit.” *Id.*, 8:25–28. *Watson* further teaches all “components of the device that are exposed to contact with the wound fluids [are]...separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” *Id.*, 7:16–21.

160. Thus, according to the embodiment of *Watson* in which the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit, the occlusive dressing (equivalent to the claimed “enclosure”), pump member 22 (equivalent to the claimed “pump unit”), and desiccator cartridge 14 (equivalent to the claimed “waste container”) may all be disposable. *See id.*, 2:27–31 (“A further benefit of the present invention for such applications involving biological waste is that the trap and all other components of the desiccator device that contact the aspirated biological materials are removable from the device and are replaceable.”).

161. Accordingly, to the extent that *Bitel* fails to expressly teach that the pump unit, enclosure, and waste container are disposable so that ambient air that enters the tube via the venting arrangement contacts only disposable elements and the drained liquids may be disposed of together with the disposable elements, it is my opinion that *Watson* teaches these features.

162. Further, a POSITA would have been motivated to modify *Bitel* based on the teachings of *Watson* to make such components disposable because “[t]his allows the components of the device that are exposed to contact with the wound fluids to be separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” Ex. 1013, 7:16–21. Furthermore, whether a component is “disposable” depends on what a user does with the component. Anything can be disposed of if desired, and Claim 14 does not recite any unique structure or material composition that makes the pump unit, enclosure, and waste container uniquely disposable. Further still, there are a myriad of reasons why a POSITA would have been motivated to dispose of various components, including a pump unit, of a vacuum wound therapy system. In addition to the contamination issue discussed above, a POSITA would have known that such components could be disposed of if they malfunctioned or were subjected to excessive wear in a manner that could compromise the effectiveness of the system.

163. It is my opinion that such a modification would constitute a simple substitution of one known element (i.e., non-disposable pump unit, enclosure, and waste container) for another (i.e., disposable pump unit, enclosure, and waste container) to obtain predictable results.

164. It is also my opinion that such an enhancement would also have been “obvious to try” in light of *Watson*’s express teaching of the desirability of all components of the device that contact wound fluids to be “separable from the other components of the device to facilitate cleaning or disposal of contaminated components,” and a POSITA’s knowledge that wear and tear on a component could necessitate disposal and replacement of a component so as not to have to replace the entire system. Ex. 1013, 7:16–21.

165. Furthermore, it is my opinion that such a modification of *Bitel* based on the teachings of *Watson* would be met with a reasonable expectation of success because there is nothing about the system of *Bitel* that would foreclose making the aforementioned components of the vacuum therapy wound treatment system of *Bitel* disposable and it was known in the art that such components could be disposable and replaceable without having a negative impact on the overall functionality of the system.

2. Each Element of Claim 14 is Rendered Obvious by *Bitel* in view of *Watson*

- (a) [14.1] The vacuum system according to claim 12, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit**

166. *Bitel* in view of *Watson* teaches this limitation. *Bitel* teaches the vacuum system of Claim 12, as previously described.

167. *Bitel* also teaches that its vacuum source 21 includes a pump unit attachable to a drive unit. Specifically, *Bitel* teaches a “vacuum pump to provide negative pressure.” Ex. 1009, 6:31. It is my opinion that the vacuum pump of *Bitel* constitutes a “pump unit” as claimed.

168. *Bitel* further teaches that the “[v]acuum source 21 is also defined to include any mechanism for providing negative pressure such as an electrically operated or manual pump, for example.” *Id.*, 6:31–33. Thus, it is my opinion that *Bitel* teaches a vacuum pump that may be actuated electrically or manually.

169. It is also my opinion that the structure that provides the electrical or manual actuation of the vacuum pump—for example a motor—constitutes a “drive unit” as claimed. A structure that enables the electrical actuation of a vacuum pump, such as a motor, is termed a “drive unit” because it serves as the primary mechanism responsible for converting electrical energy into mechanical energy, thereby driving the operation of the vacuum pump. This conversion process is fundamental to the

pump's functionality, as the drive unit provides the necessary torque and rotational speed to the pump's impeller or rotor, facilitating the creation of negative pressure or vacuum. In electrically actuated systems, the motor translates electrical power into rotational motion, directly influencing the pump's efficiency, capacity, and overall performance. The drive unit is critical not only for initiating the pump's action but also for controlling its operational parameters, such as flow rate and pressure levels. Therefore, the drive unit embodies the “heart” of the vacuum pump system, providing the essential energy conversion and control the vacuum generation.

170. In this way, it is my opinion that *Bitel* teaches a vacuum source including a pump unit attachable to a drive unit.

171. However, *Bitel* does not explicitly teach (i) that its pump unit is detachably attachable to its drive unit or (ii) that its pump unit is disposable and its drive unit is not. But it is my opinion that *Watson* explicitly teaches a disposable pump unit detachably attachable to a non-disposable drive unit, and a POSITA would have found it obvious to enhance *Bitel* such that the pump unit is detachably attachable to the drive unit and the pump unit is disposable, as taught by *Watson*.

172. Specifically, *Watson* discloses an embodiment in which “a motor shaft coupling 38 may be mechanically coupled to the vacuum pump head 22 so as to be readily separable from the pump head 22.” *Id.*, 8:14–16. It is my opinion that such a

structure would to a POSITA be an obvious creation of a detachable and re-attachable connection between the pump unit and drive unit. A motor shaft coupling designed for connection to a vacuum pump head often employs a quick-release or detachable mechanism that facilitates both a secure mechanical coupling and easy separation. This coupling mechanism typically includes features such as a clamping system, bayonet mount, clutched, or threaded connection that allows for straightforward engagement and disengagement with minimal tools or effort. The design would be known to a POSITA, and ensures that the motor's rotational energy is efficiently transmitted to the pump head when connected, driving the pump's operation. When maintenance, inspection, or replacement is needed, the coupling allows the motor to be quickly and safely detached from the pump head without compromising the alignment or integrity of the system. Such couplings are engineered for durability and precise fit, ensuring a reliable connection that minimizes vibration and wear during operation, while also offering the convenience of easy separation for operational flexibility and system upkeep. A POSITA would be aware of this.

173. In another embodiment, *Watson* teaches “[a]s a further alternative, the motor 36 maybe magnetically coupled (not shown) to the pump head 22 so as to again be readily separable from the vacuum pump member 22.” Ex. 1013, 8:22–25.

174. *Watson* explains that such an arrangement is desirable because “[a] readily separable motive means 36 is particularly useful where the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit.” *Id.*, 8:25–28. Moreover, *Watson* explains that providing a detachably attachable connection between components within the device 10, including but not limited to the pump member 22 and motive means 36, is desirable in that it “allows the components of the device that are exposed to contact with the wound fluids to be separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” *Id.*, 7:18–21.

175. Thus, it is my opinion that *Bitel* in view of *Watson* teaches wherein the vacuum source includes a pump unit detachably attachable to a drive unit. A POSITA would have found the above modification to be an obvious and predictable design choice, and well-within the realm of knowledge of a POSITA at the time of the alleged invention.

176. *Watson* also teaches a disposable pump unit and non-disposable drive unit. Specifically, in some embodiments of *Watson*, “the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit.” *Id.*, 8:25–28. *Watson* further teaches all “components of the device that are exposed to contact with the wound fluids [are]...separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” *Id.*, 7:16–21.

177. Thus, according to the embodiment of *Watson* in which the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit, the pump member 22 may all be disposable. *See id.*, 2:27–31 (“A further benefit of the present invention...is that the trap and all other components of the desiccator device that contact the aspirated biological materials are removable from the device and are replaceable.”).

178. In this way, it is my opinion that *Bitel* in view of *Watson* teaches a disposable pump unit and non-disposable drive unit.

179. It is also my opinion that a POSITA would have found the above modification to be an obvious and predictable design choice, and well-within the realm of knowledge of a POSITA at the time of the alleged invention.

(b) **[14.2] Said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements**

180. *Bitel* in view of *Watson* teaches this limitation. *Bitel* teaches an “enclosure” as claimed in the form of the vacuum bandage 16 and a “waste container” as claimed in the form of the receptacle 18, as previously described.

181. *Bitel* does not explicitly teach that the enclosure and waste container are disposable so that the ambient air that enters the tube via the venting arrangement

contacts only the disposable elements and the drained liquids may be disposed of together with said disposable elements.

182. But *Watson* explicitly teaches a disposable enclosure and disposable waste container so that the ambient air that enters the tube via the venting arrangement contacts only the disposable elements and the drained liquids may be disposed of together with said disposable elements, and a POSITA would have found it obvious to enhance *Bitel* to make the enclosure, waste container, and optionally the outlet port 50 and second tube 30 disposable, based on the teachings of *Watson*.

183. Like *Bitel*, *Watson* also teaches an “enclosure” as claimed in the form of an “occlusive dressing” that covers the wound and connects to the trap 12 and pump member 22 via a delivery tube 32. Ex. 1013, 6:16–20 (“[A] delivery tube 32 is included with the desiccator device 10 to put the trap 1[2] in gas/liquid flow communication with a location to which a low negative vacuum pressure is to be applied, such as a wound site covered by an occlusive dressing.”); *see also id.*, 5:48–61 (describing the interrelationship between the trap 12 and desiccator cartridge 14). In some embodiments of *Watson*, “the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit.” *Id.*, 8:25–28. *Watson* further teaches all “components of the device that are exposed to contact with the wound fluids [are]...separable from the other components of the device to facilitate cleaning or disposal of contaminated components.” *Id.*, 7:16–21.

184. Thus, according to the embodiment of *Watson* in which the vacuum pump member 22 and the desiccator cartridge 14 are integrated together as a unit, the occlusive dressing (equivalent to the claimed “enclosure”), delivery tube 32 (equivalent to the claimed “tube”), pump member 22 (equivalent to the claimed “pump unit”), and desiccator cartridge 14 (equivalent to the claimed “waste container”) may all be disposable. *See id.*, 2:27–31 (“A further benefit of the present invention...is that the trap and all other components of the desiccator device that contact the aspirated biological materials are removable from the device and are replaceable.”).

185. Furthermore, it is my opinion that modifying *Bitel* in view of the teachings of *Watson* in the manner described herein would result in a configuration in which the ambient air entering the system would only contact disposable components, as claimed.

186. In this way, it is my opinion that *Bitel* in view of *Watson* teaches a disposable enclosure and disposable waste container so that the ambient air that enters the tube via the venting arrangement contacts only the disposable elements and the drained liquids may be disposed of together with said disposable elements. A POSITA would have found the above modification to be an obvious and predictable design choice, and well-within the realm of knowledge of a POSITA at the time of the alleged invention.

3. Each Element of Claim 15 is Rendered Obvious by *Bitel* in View of *Watson*

187. Claim 15 recites: “The vacuum system according to claim 14, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.” Ex. 1001, 7:38–40. *Bitel* in view of *Watson* teaches the vacuum system according to Claim 14, as previously described.

188. Additionally, it is my opinion that *Bitel* in view of *Watson* teaches the limitation of Claim 15.

189. Specifically, as previously described, *Watson* teaches a pump unit and drive unit that are adapted for attaching and detaching to one another. Furthermore, *Watson* repeatedly emphasizes that the pump unit and drive unit may be “readily separable” from one another via mechanical or magnetic couplings. See Ex. 1013, 3:57–65, 8:14–28.

190. It is my opinion that a POSITA would understand that the mechanical or magnetic couplings of *Watson* would permit an operator to attach and detach the pump unit from the drive unit using simple hand manipulations.

191. For example, *Watson* does not teach the need to use any special tools or the like to attach or detach the pump unit and drive unit, and *Watson*’s repeated emphasis that the pump and drive unit be “readily separable” indicates that the parts should be separable with relative ease. Ex. 1013, 3:57–65, 8:14–28; see *supra* ¶172.

192. In this way, it is my opinion that *Bitel* in view of *Watson* teaches the vacuum system according to claim 15, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

C. Ground 3: Claims 12–13, 16–17 and 26–27 Are Rendered Obvious Under Pre-AIA 35 U.S.C. § 103(a) over *Dolliver* in View of *Argenta*

1. Obviousness Analysis

(a) Differences Between the Claimed Subject Matter and *Dolliver*

193. Claim 12 recites a vacuum system including an enclosure having an enclosure outlet, a vacuum source, a tube, a venting arrangement including a flow restrictor located outside of the enclosure, and a waste container in fluid communication with the vacuum source.

194. In my opinion, *Dolliver* teaches almost every element of Claim 12 including a vacuum system having a vacuum source, a tube, a venting arrangement including a flow restrictor located outside of the enclosure, and a waste container in fluid communication with the vacuum source. However, *Dolliver* does not teach an enclosure having an enclosure outlet.

195. But enclosures having enclosure outlets for use within vacuum therapy wound treatment systems were well-known in the art. For example, *Argenta* teaches a vacuum therapy wound treatment system with an enclosure having an enclosure outlet. Ex. 1006, 1:10–12, 2:66–3:8, 3:17–21, Fig. 4.

196. In my opinion, *Dolliver* in view of *Argenta* also teaches all of the elements of dependent Claims 13, 16–17 and 26–27.

(b) Obviousness Rationale for Why a POSITA Would Have Enhanced *Dolliver* with *Argenta* to Arrive at the Claimed Subject Matter with a Reasonable Expectation of Success

197. In light of the collective teachings of *Dolliver* and *Argenta*, it is my opinion that it would have been obvious to a POSITA to enhance *Dolliver* by replacing *Dolliver*'s perforated drain catheter with an enclosure having an enclosure outlet, based on the teachings of *Argenta*. A POSITA would have been motivated to enhance *Dolliver* in this manner for a variety of reasons.

198. For example, prior art systems such as *Dolliver* utilizing a catheter to draw fluid from the wound, without any wound cover, were known to increase the chance for infection. *See* Ex. 1005 (*Henley*), 2:13, 1:18–19 (“Exposing [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.”). Further, catheter-based vacuum therapy wound treatment systems such as *Dolliver* did not lend themselves to maintaining reduced pressure in the vicinity of the wound, a known desire in the art. *See* Ex. 1006 (*Argenta*), 3:2–5 (teaching that sealing the area around a wound is useful for “maintain[ing] reduced pressure in the vicinity of the wound during wound treatment”).

199. Thus, it is my opinion that a POSITA would have been motivated to enhance the system of *Dolliver* by replacing *Dolliver*'s drain catheter with an enclosure such as the enclosure of *Argenta* to prevent infection and facilitate improved pressure level control around the wound. Furthermore, catheters and enclosures reflected a finite number of end-piece types in the prior art for treating a wound site in a vacuum wound therapy system, and a POSITA would have found it obvious to use an appropriate end-piece type for a given application as doing so would not require alteration of, or compromise, the rest of the components of the system.

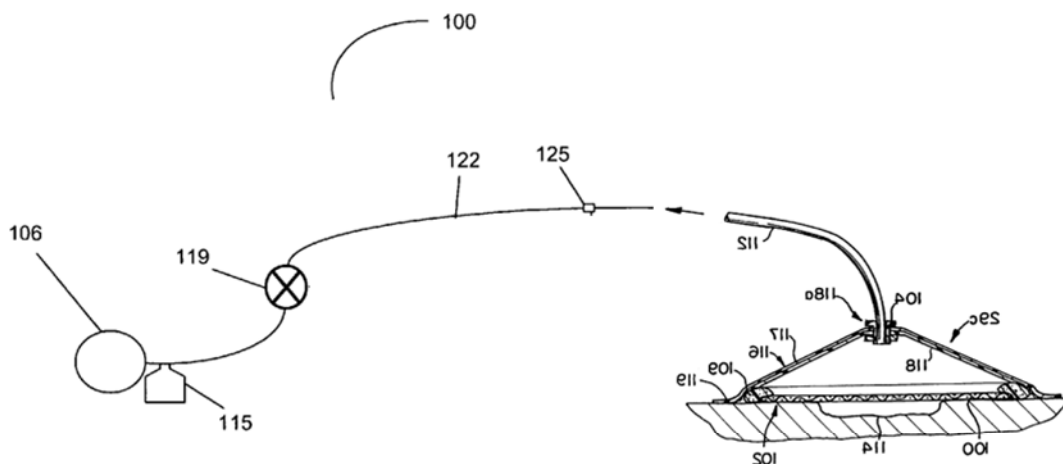
200. In my opinion, such a modification would constitute a simple substitution of one known element (i.e., drain catheter) for another (i.e., enclosure having an enclosure outlet) to obtain predictable results.

201. It is also my opinion that such an enhancement would also have been "obvious to try" in light of *Argenta*'s express teaching of the desirability of sealing the area around a wound for "maintain[ing] reduced pressure in the vicinity of the wound during wound treatment." Ex. 1006, 3:2–5.

202. Furthermore, a POSITA would have understood that replacing *Dolliver*'s drain catheter with an enclosure such as the enclosure taught by *Argenta* would be met with a reasonable expectation of success.

203. Specifically, the modification of *Dolliver* could be accomplished by simply removing *Dolliver*'s drain catheter 102 and replacing it with an enclosure having an enclosure outlet, such as the fluid impermeable wound cover 116 having a suction port 104 of *Argenta*. See Ex. 1012, 3:29–4:3 (describing *Dolliver*'s drain catheter 102); Ex. 1006, 10:65–11:31 (describing *Argenta*'s fluid impermeable wound cover 116 having a suction port 104). *Argenta*'s fluid impermeable wound cover 116 could connect to *Dolliver*'s conduit 122 through *Argenta*'s suction port 104. Ex. 1012, 3:29–4:3; Ex. 1006, 10:65–11:31.

204. An exemplary schematic illustrating enhancement of the wound drainage system 100 of *Dolliver* to replace *Dolliver*'s drain catheter 102 with an enclosure having an enclosure outlet, such as *Argenta*'s fluid impermeable wound cover 116 having a suction port 104, is illustrated below:



Ex. 1012, Fig. 1 (annotated to omit catheter 102 and controller 117); Ex. 1006, Fig. 4 (annotated by flipping figure about its vertical axis).

205. A skilled artisan would have readily appreciated how to combine the teachings of the references relied upon herein.

2. Each Element of Claim 12 is Rendered Obvious by *Dolliver* in View of *Argenta*

(a) [12.P] A vacuum system for applying negative pressure to a wound

206. *Dolliver* discloses “a wound drainage system for draining fluid from a wound of a patient.” Ex. 1012, 1:47–48. “The system includes a drain catheter in fluid communication with a suction device via a conduit.” *Id.*, 2:31–33. The suction device 106 “applies suction at the drain catheter such that fluid is drawn from the wound.” *Id.*, 1:49–50. “The suction device 106 provides a region of low pressure such that fluid is drawn into the drain catheter 102 towards the suction device.” *Id.*, 3:55–57.

207. In this way, it is my opinion that *Dolliver* teaches a vacuum system (wound drainage system 100) for applying negative pressure to a wound. *Id.*, Fig. 1 (reproduced and annotated below).

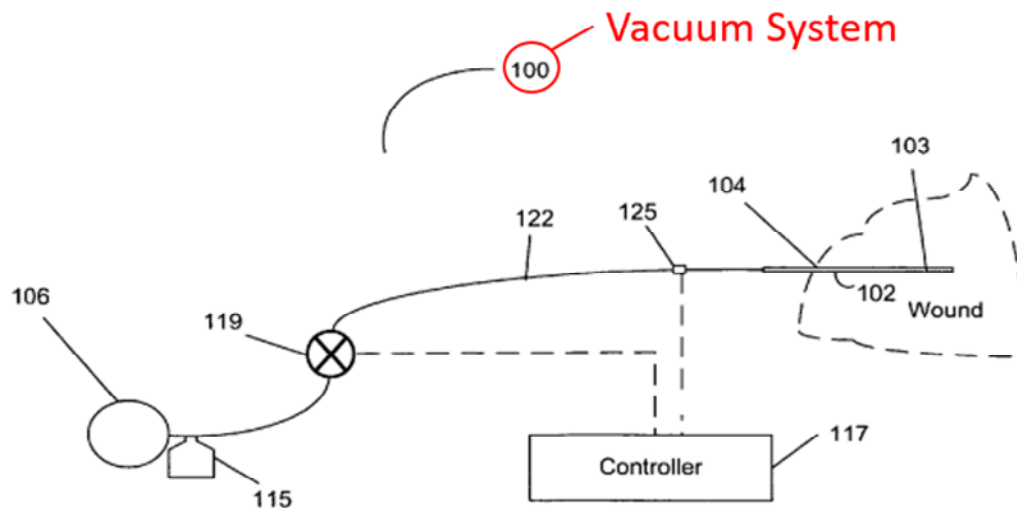


Fig. 1

(b) [12.1] An enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume

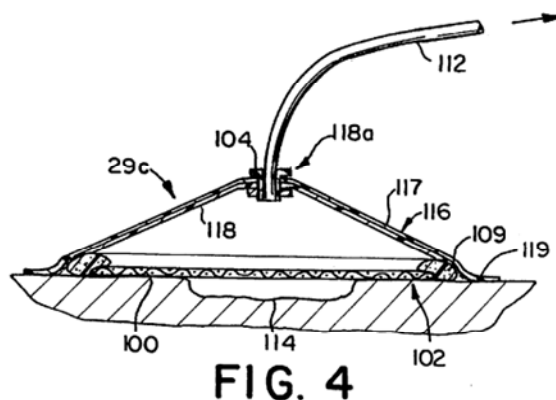
208. It is my opinion that *Dolliver* in view of *Argenta* teaches this limitation.

209. *Dolliver* teaches a vacuum source in the form of suction device 106 that “may be, without limitation, a pump or a bellows apparatus that creates a vacuum or partial vacuum.” Ex. 1012, 3:57–59.

210. *Dolliver* does not teach an enclosure. But *Argenta* teaches an enclosure being attachable to a wound circumference so as to define a confined volume, and a POSITA would have found it obvious to enhance *Dolliver* by replacing the drain catheter 102 with an enclosure, such as the enclosure taught by *Argenta*.

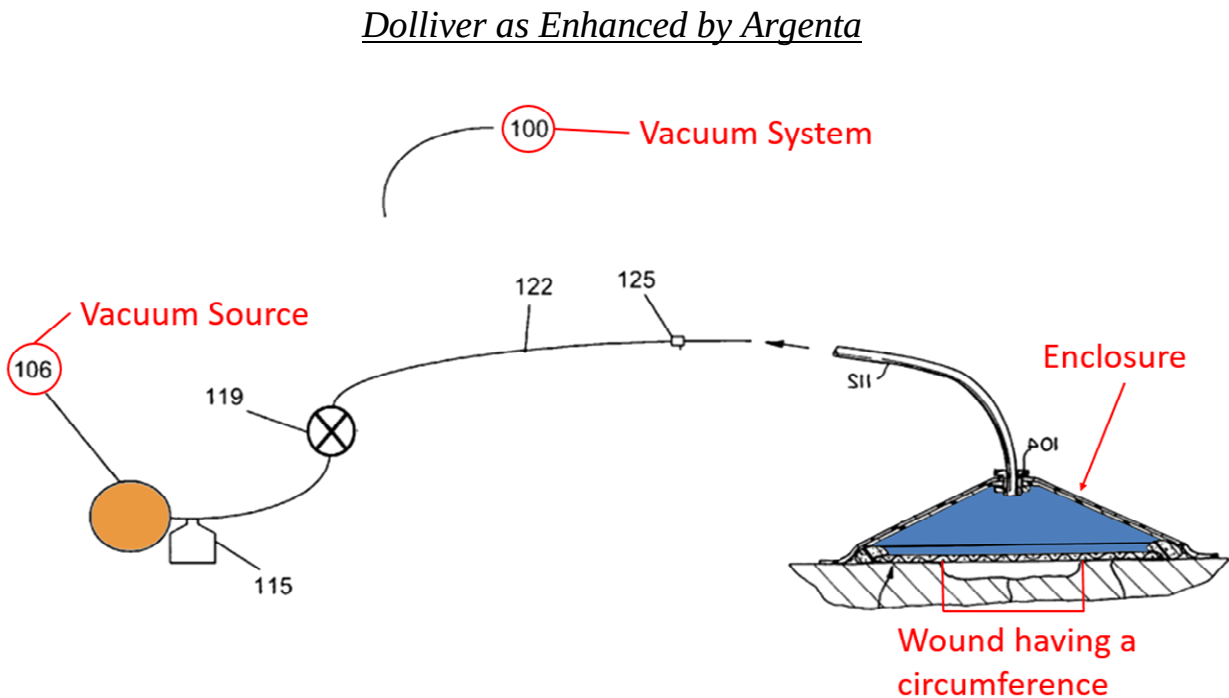
211. Specifically, *Argenta* teaches “an apparatus and method for treating a wound by applying reduced pressure to the wound.” Ex. 1006, 1:10–12. “The

reduced pressure application appliance includes a fluid impermeable wound cover [116] for covering and enclosing the wound...[and] sealing means for sealing the wound cover to the surrounding tissue of the wound in order to maintain reduced pressure in the vicinity of the wound during wound treatment.” *Id.*, 2:66–3:5. “When the wound cover [116] is sealed in position over the wound site, a generally fluid-tight or gas-tight sealed enclosure is formed over the wound site.” *Id.*, 3:5–8. One embodiment of the enclosure of *Argenta* is shown in Figure 4 below wherein a fluid-impermeable wound covering 116 is positioned over a wound 114. *Id.*, 10:61–11:31, Fig. 4.



212. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches an enclosure (fluid-impermeable wound covering 116 of *Argenta*, shown in blue below) and a vacuum source (suction device 106 of *Dolliver*, shown in orange below), the enclosure being attachable to the wound circumference so as to define a confined volume.

213. An illustration of the *Dolliver* system as enhanced by *Argenta* is shown below.



Ex. 1012, Fig. 1; Ex. 1006, Fig. 4.

214. It is my opinion that a POSITA would have found it obvious to enhance the wound drainage system 100 of *Dolliver* by replacing the drain catheter 102 of *Dolliver* with an enclosure, such as the enclosure taught by *Argenta*, to, among other things, prevent infection of the wound from contaminants outside of the wound (such as from the surroundings) and facilitate improved pressure level control around the wound.

215. It is also my opinion that a POSITA would have found the above modification to be an obvious and predictable design choice, and well within the realm of knowledge of a POSITA at the time of the alleged invention.

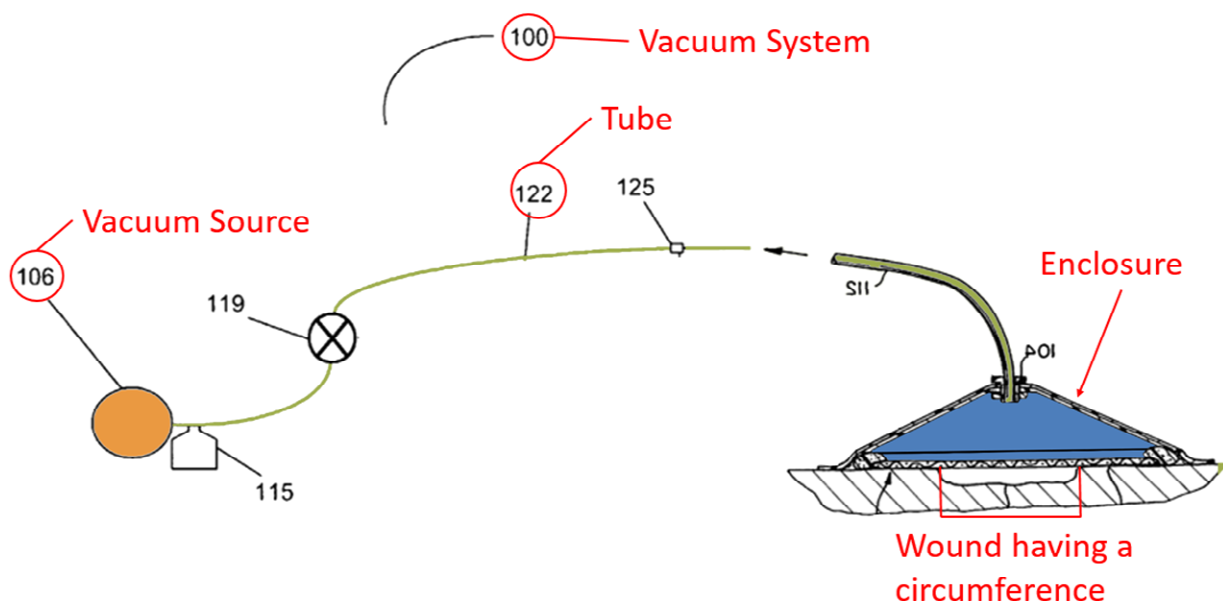
(c) [12.2] A tube

216. *Dolliver* in view of *Argenta* teaches this limitation.

217. Specifically, *Dolliver* teaches “a conduit 122, which may be, without limitation, plastic tubing.” Ex. 1006, 3:53–55. The conduit 122 of *Dolliver* facilitates the transfer of fluids aspirated from the wound site into an in-line container 115 when the suction device 106 is applying negative pressure. *Id.*, 3:53–4:3, Fig. 1.

218. An illustration of the *Dolliver* system as enhanced by *Argenta* showing the tube (green) is provided below.

Dolliver as Enhanced by *Argenta*



Ex. 1012, Fig. 1; Ex. 1006, Fig. 4.

219. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches a tube.

(d) [12.3] A venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement

220. *Dolliver* in view of *Argenta* teaches this limitation.

221. *Dolliver* teaches a vent valve 119 is positioned within the conduit 122. *Id.*, 2:33–35 (“A valve, such as a vent valve [119], may be positioned between the suction means and the drain catheter...[and] may be, for example, disposed in the conduit.”), 4:49–5:7, Fig. 1 (reproduced below).

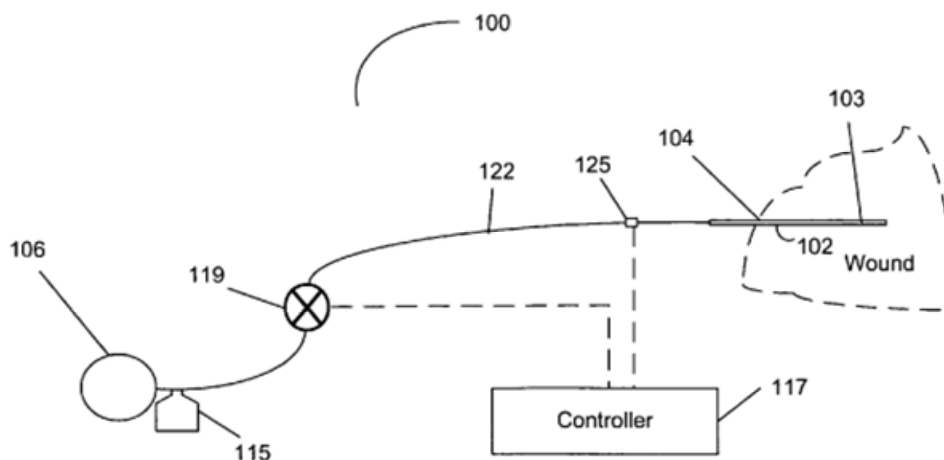


Fig. 1

222. The vent valve 119 “selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere, thereby decreasing the amount of suction applied at the drain catheter 102.” *Id.*, 4:59–61. “The vent valve may include a filter,

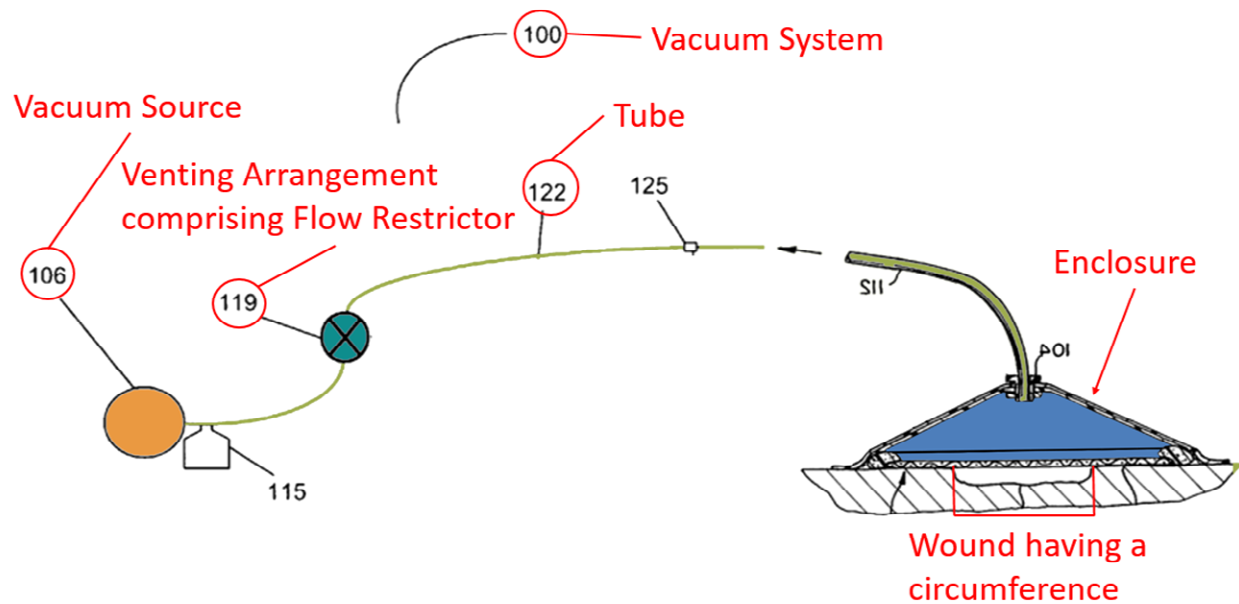
such as, but not limited to a bacterial filter, for preventing introduction of outside contaminants into the conduit system 122 which may adversely affect the wound.”
Id., 4:61–65.

223. It is my opinion that the vent valve 119 and filter of the vent valve 119 constitute a “venting arrangement” as claimed in that they vent the wound drainage system 100 to atmosphere, including when the suction device 106 is generating negative pressure within the system 100.

224. Furthermore, it is my opinion that the filter of *Dolliver*’s vent valve 119 constitutes a flow restrictor as claimed in that it restricts flow through the venting arrangement. The manner in which a filter serves to restrict flow is described above at paragraphs ¶¶106-14 herein.

225. An illustration of the *Dolliver* system as enhanced by *Argenta* showing the venting arrangement (teal) is provided below.

Dolliver as Enhanced by Argenta



Ex. 1012, Fig. 1; Ex. 1006, Fig. 4.

226. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches a venting arrangement (vent valve 119 and filter of the vent valve 119 of *Dolliver*) comprising a flow restrictor (filter of the vent valve 119 of *Dolliver*) to restrict flow through said venting arrangement.

(e) [12.4] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be created in said volume

227. *Dolliver* in view of *Argenta* teaches this limitation.

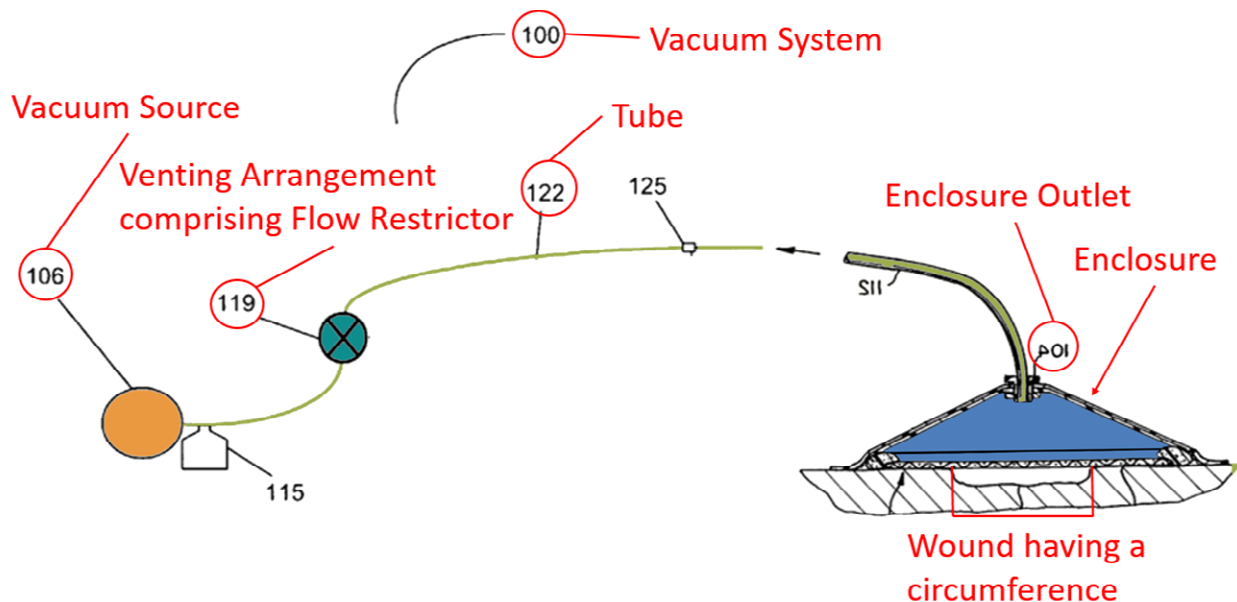
228. Specifically, in accordance with the enhancement of *Dolliver*'s wound drainage system 100 by *Argenta* as set forth above with regard to claim element [12.1], the enhanced wound drainage system of *Dolliver/Argenta* would include an

enclosure (fluid-impermeable wound covering 116 of *Argenta*) connectable to a vacuum source (suction device 106 of *Dolliver*) via a tube (conduit 122 of *Dolliver*) so that negative pressure can be created in the volume under the enclosure.

229. In addition, the fluid-impermeable wound covering 116 of *Argenta* includes a suction port 104 at its top that constitutes an enclosure outlet as claimed because it facilitates the transfer of aspirated exudate to outside of the fluid-impermeable wound covering 116. See Ex. 1006, 3:17–23.

230. An illustration of the *Dolliver* system as enhanced by *Argenta* showing the enclosure outlet is provided below.

Dolliver as Enhanced by Argenta



Ex. 1012, Fig. 1; Ex. 1006, Fig. 4.

231. In this way, it is my opinion that the enhanced wound drainage system of *Dolliver/Argenta* would include an enclosure (fluid-impermeable wound covering 116 of *Argenta*) having an enclosure outlet (suction port 104 of *Argenta*) connectable to said vacuum source (suction device 106 of *Dolliver*) via said tube (conduit 122 of *Dolliver*) so that negative pressure can be created in said volume (volume under the fluid-impermeable wound covering 116 of *Argenta*).

(f) [12.5] Said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure

232. *Dolliver* in view of *Argenta* teaches this limitation.

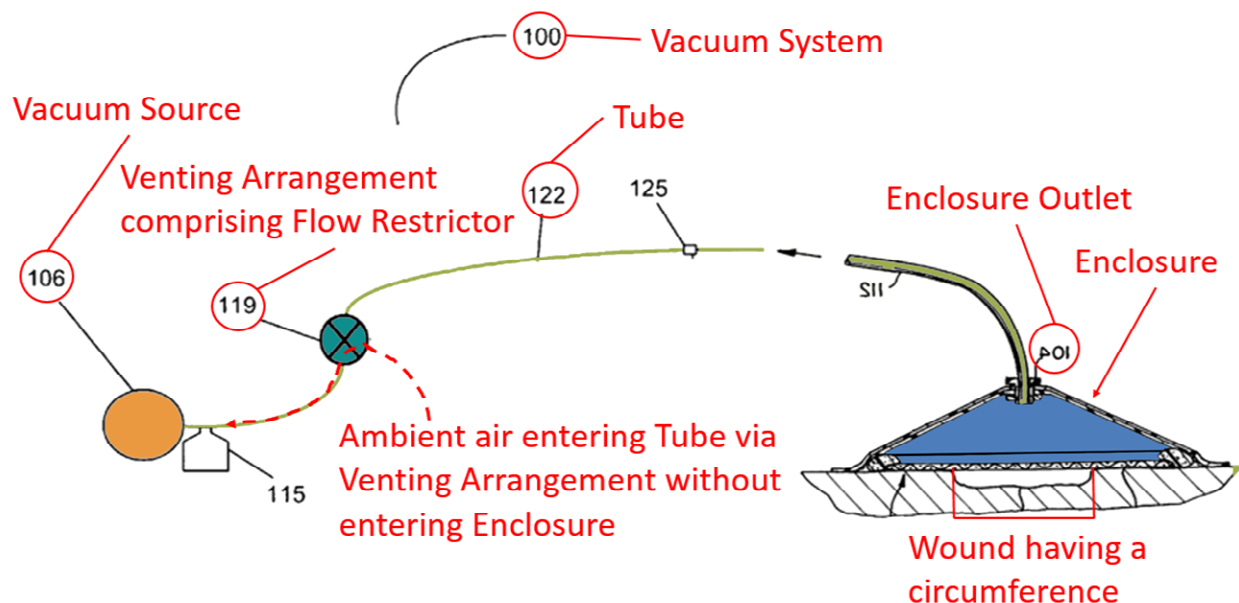
233. Specifically, in accordance with the enhancement of *Dolliver's* wound drainage system 100 by *Argenta* as set forth above with regard to claim element [12.1], the enhanced wound drainage system of *Dolliver/Argenta* would include a venting arrangement (vent valve 119 and filter of the vent valve 119 of *Dolliver*) located outside said enclosure (fluid-impermeable wound covering 116 of *Argenta*) such that ambient air can enter said tube (conduit 122 of *Dolliver*) via said venting arrangement without entering said enclosure.

234. Specifically, the enhanced wound drainage system of *Dolliver/Argenta* would include the conduit 122 of *Dolliver* disposed between the enclosure of *Argenta* at one end and the suction device 106 of *Dolliver* at the other end. See Ex. 1012, 2:3–5, 2:24–25, 2:33–35, 4:57–58, Fig. 1.

235. The vent valve 119 and filter of the vent valve 119, which constitute the venting arrangement as claimed, would be located within the conduit 122 of *Dolliver*, outside the enclosure of *Argenta*, and would allow for ambient air to enter the conduit 122 via the vent valve 119/filter of *Dolliver* when the suction device 106 is operating without entering the enclosure of *Argenta*. See Ex. 1012, 4:59–60 (“The vent valve selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere.”), Fig. 1.

236. Annotated Figure 1 below shows how ambient air can enter the conduit 122 via the vent valve 119 and valve filter and would flow towards the suction device 106 when the suction device 106 is generating negative pressure:

Dolliver as Enhanced by Argenta



Ex. 1012, Fig. 1; Ex. 1006, Fig. 4.

237. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure.

(g) [12.6] A waste container in fluid communication with said vacuum source

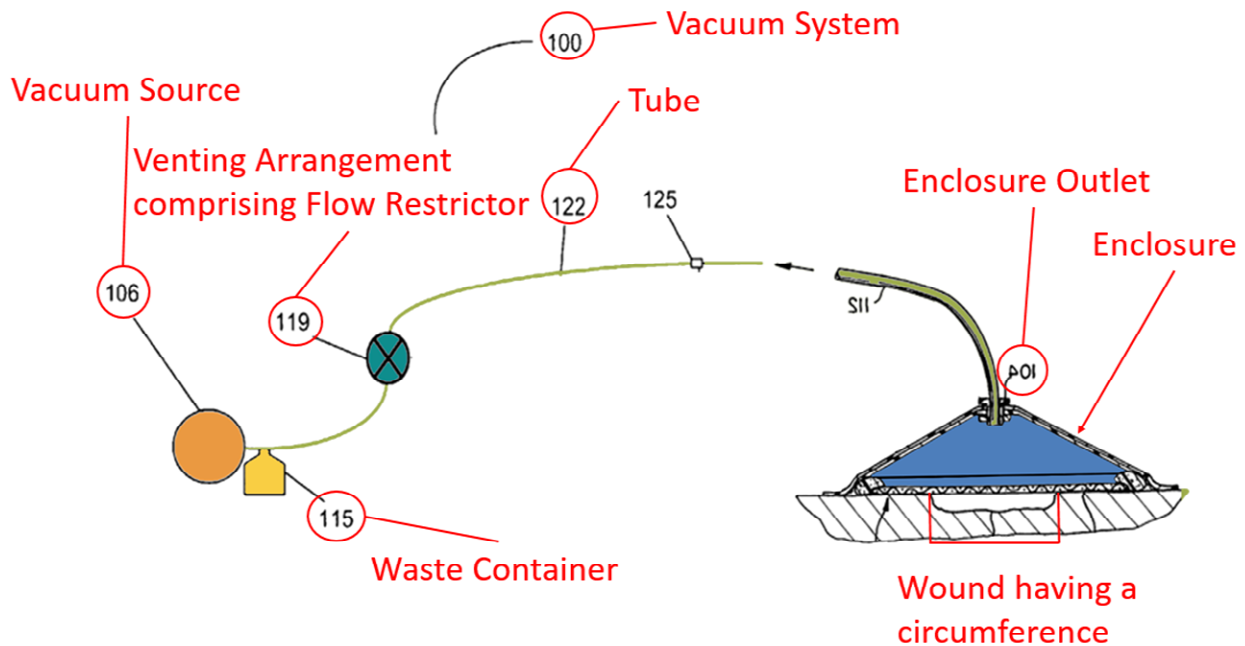
238. *Dolliver* in view of *Argenta* teaches this limitation.

239. Specifically, in accordance with the enhancement of *Dolliver*'s wound drainage system 100 by *Argenta* as set forth above with regard to claim element [12.1], the enhanced wound drainage system of *Dolliver/Argenta* would include a waste container (in-line container 115 of *Dolliver*) in fluid communication with a vacuum source (suction device 106 of *Dolliver*).

240. For example, *Dolliver* teaches "[s]uction provided by the suction device 106 causes fluids and/or other material from the wound to be aspirated...into the container 115." Ex. 1012, 3:66–4:3. The in-line container 115 of *Dolliver* constitutes a waste container as claimed because it collects and stores "[a]ny fluid aspirated from the wound." Ex. 1012, 3:63–64.

241. An illustration of the *Dolliver* system as enhanced by *Argenta* showing the waste container 115 (gold) is provided below.

Dolliver as Enhanced by Argenta



Ex. 1012, Fig. 1; Ex. 1006, Fig. 4.

242. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches a waste container (in-line container 115 of *Dolliver*) in fluid communication with said vacuum source (suction device 106 of *Dolliver*).

3. Each Element of Claim 13 is Rendered Obvious by *Dolliver* in View of *Argenta*

- (a) [13.1] The vacuum system of claim 12, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom

243. *Dolliver* in view of *Argenta* discloses the vacuum system of Claim 12, as previously described.

244. Furthermore, it is my opinion that the enhanced wound drainage system of *Dolliver/Argenta* would also operate to drain the wound from fluids exuded therefrom.

245. On this point, *Dolliver* teaches “a wound drainage system...for aspirating fluids from a wound.” Ex. 1012, 3:24–26.

246. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches the vacuum system of claim 12, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom.

(b) [13.2] Wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container

247. *Dolliver* in view of *Argenta* teaches this limitation.

248. Specifically, the enhanced wound drainage system of *Dolliver/Argenta* would permit ambient air to enter the tube (conduit 122 of *Dolliver*) via the venting arrangement (vent valve 119 and filter of the vent valve 119 of *Dolliver*) and flow together with the exuded liquids under the action of negative pressure (provided by the suction device 106 of *Dolliver*) and facilitate the draining of the exuded fluids to the waste container (in-line container 115 of *Dolliver*).

249. *Dolliver* provides, “[t]he vent valve selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere.” Ex. 1012, 4:59–60. In a condition

in which the vent valve 119 is at least partially open while the suction device 106 is generating negative pressure, ambient air would flow together with exuded liquids through the conduit 122 such that the exuded fluids would drain into the container 115. See Ex. 1012, 3:65–4:3, 4:57–61, Fig. 1.

250. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches wherein the ambient air can enter said tube (conduit 122 of *Dolliver*) via said venting arrangement (vent valve 119 and filter of the vent valve 119 of *Dolliver*) and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

4. Each Element of Claim 16 is Rendered Obvious by *Dolliver* in View of *Argenta*

(a) [16] The vacuum system according to claim 12, wherein said venting arrangement comprises one or more bleeding holes

251. *Dolliver* in view of *Argenta* discloses the vacuum system of Claim 12, as previously described.

252. Furthermore, the enhanced wound drainage system of *Dolliver/Argenta* teaches a venting arrangement including one or more bleeding holes. Specifically, *Dolliver* teaches a vent valve 119 is positioned within the conduit 122. *Id.*, 2:33–35 (“A valve, such as a vent valve [119], may be positioned between the suction means and the drain catheter...[and] may be, for example, disposed in the conduit.”), 4:49–5:7, Fig. 1.

253. The vent valve 119 “selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere, thereby decreasing the amount of suction applied at the drain catheter 102.” *Id.*, 4:59–61.

254. It is my opinion that the vent valve 119 of *Dolliver*, when open fully or partially, constitutes at least one bleeding hole as claimed because it creates a hole in the conduit 122 allowing for the introduction of ambient air into the system 100.

255. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches the vacuum system according to claim 12, wherein said venting arrangement (vent valve 119 and filter of the vent valve 119 of *Dolliver*) comprises one or more bleeding holes (vent valve 119 of *Dolliver* in a fully or partially open position).

5. Each Element of Claim 16 is Rendered Obvious by *Dolliver* in View of *Argenta*

(a) [17] The vacuum system according to claim 12, wherein said venting arrangement is provided in the form of a porous body

256. *Dolliver* in view of *Argenta* discloses the vacuum system of Claim 12, as previously described.

257. Furthermore, the enhanced wound drainage system of *Dolliver/Argenta* teaches a venting arrangement provided in the form of a porous body. Specifically, *Dolliver* teaches that the vent valve 119 “may include a filter, such as, but not limited to a bacterial filter, for preventing introduction of outside contaminants into the conduit system 122 which may adversely affect the wound.” Ex. 1012, 4:61–65. The

filter of *Dolliver*—which along with the vent valve 119 constitutes a “venting arrangement” as claimed—is provided in the form of a porous body because it permits ambient air to flow therethrough into the conduit 122 while “preventing introduction of outside contaminants into the conduit system 122 which may adversely affect the wound.”

258. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches the vacuum system according to claim 12, wherein said venting arrangement (vent valve 119 and filter of the vent valve 119 of *Dolliver*) is provided in the form of a porous body (filter of the vent valve 119 of *Dolliver*).

6. Each Element of Claim 26 is Rendered Obvious by *Dolliver* in View of *Argenta*

(a) [26] The vacuum system according to claim 12, wherein the venting arrangement is a tube orifice

259. *Dolliver* in view of *Argenta* discloses the vacuum system of Claim 12, as previously described.

260. Furthermore, the enhanced wound drainage system of *Dolliver/Argenta* teaches a venting arrangement in the form of a tube orifice. Specifically, *Dolliver* teaches “a vent valve 119 that may be positioned within the conduit 122.” Ex. 1012, 4:57–58. “The vent valve selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere, thereby decreasing the amount of suction applied at the drain catheter 102.” *Id.*, 4:59–61. “The vent valve may include a filter, such as, but

not limited to a bacterial filter, for preventing introduction of outside contaminants into the conduit system 122 which may adversely affect the wound.” *Id.*, 4:61–65.

261. In my opinion, the venting arrangement of *Dolliver* (i.e., the vent valve 119 and filter of the vent valve 119 of *Dolliver*) is a tube orifice because, when opened partially or fully, it creates a hole or aperture in the conduit 122, which constitutes a “tube” as claimed.

262. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches the vacuum system according to claim 12, wherein the venting arrangement (vent valve 119 and filter of the vent valve 119 of *Dolliver*) is a tube orifice (partially or fully opened vent valve in the conduit 122).

7. Each Element of Claim 27 is Rendered Obvious by *Dolliver* in View of *Argenta*

(a) [27] The vacuum system according to claim 26, said orifice having a smaller opening than a cross-section of the tube

263. *Dolliver* in view of *Argenta* discloses the vacuum system of Claim 26, as previously described.

264. Furthermore, the enhanced wound drainage system of *Dolliver/Argenta* teaches the orifice having a smaller opening than a cross-section of the tube. Specifically, *Dolliver* teaches “a vent valve 119 that may be positioned within the conduit 122.” Ex. 1012, 4:57–58. “The vent valve selectively opens (fully or

partially) to allow conduit 122 to vent to the atmosphere, thereby decreasing the amount of suction applied at the drain catheter 102.” *Id.*, 4:59–61.

265. At least according to an embodiment of *Dolliver* in which the vent valve 119—which is positioned within the conduit 122—is only partially open, the hole or aperture created by the partially open vent valve 119 may have a smaller opening than a cross-section of the conduit 122.

266. In this way, it is my opinion that *Dolliver* in view of *Argenta* teaches the vacuum system according to claim 26, said orifice (vent valve 119 in a partially open configuration) having a smaller opening than a cross-section of the tube (cross section of conduit 122).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 25, 2024.

By: Morten G. Jensen
Dr. Morten Jensen