

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Solventum Corporation,
Petitioner,

v.

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

Case IPR2024-01002
Patent 8,858,534

**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

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND QUALIFICATIONS.....	2
II. DOCUMENTS RELIED UPON	8
III. PERSON HAVING ORDINARY SKILL IN THE ART	9
IV. LEGAL ASSUMPTIONS	10
V. BACKGROUND OF THE '534 PATENT AND PRIOR ART.....	11
A. Evolution of Vacuum Therapy Wound Treatment Systems	16
B. Description of the Alleged Invention of the '534 Patent	24
C. Summary of the Prosecution History	29
VI. SUMMARY OF THE ASSERTED PRIOR ART	33
A. <i>Bitel</i> : International Publication No. WO 03/030966 (Ex. 1009)	33
VII. CONCLUSIONS REGARDING PATENTABILITY	38
A. Ground 1: Claims 1–22 Are Anticipated Under Pre-AIA 35 U.S.C. § 102(b) by <i>Bitel</i>	38
1. Each Element of Claim 1 Is Found in <i>Bitel</i>	38
(a) [1.P] A vacuum system for applying negative pressure to a wound	38
(b) [1.1] The vacuum system comprising: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller.....	39
(c) [1.2] The enclosure being attachable to a periphery of the wound so as to define a confined volume	43
(d) [1.3] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume.....	44

(e)	[1.4] The venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said vacuum system upstream of the vacuum source	47
(f)	[1.5] The controller configured for controlling operation of the vacuum source while providing venting of the vacuum system via said venting arrangement to provide a desired level of said negative pressure in said confined volume.....	53
2.	Each Element of Claim 2 Is Found in <i>Bitel</i>	55
(a)	[2] The vacuum system according to claim 1, wherein said flow restrictor is provided in any one of the enclosure or the tube.....	55
3.	Each Element of Claim 3 Is Found in <i>Bitel</i>	57
(a)	[3] The vacuum system according to claim 1, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.....	57
4.	Each Element of Claim 4 Is Found in <i>Bitel</i>	58
(a)	[4] The vacuum system according to claim 1, further comprising a waste container in fluid communication with said vacuum source.....	58
5.	Each Element of Claim 5 Is Found in <i>Bitel</i>	60
(a)	[5] The vacuum system according to claim 1, wherein said vacuum source comprises a vacuum pump driven by a motor.....	60
6.	Each Element of Claim 6 Is Found in <i>Bitel</i>	61
(a)	[6] The vacuum system according to claim 5, wherein said motor is an electric motor, and said controller controls operation of said motor to	

	thereby provide a desired level of said negative pressure in said confined volume	61
7.	Each Element of Claim 7 Is Found in <i>Bitel</i>	65
	(a) [7] The vacuum system according to claim 6, wherein said controller controls the electric current or the voltage of said motor to control said level of said negative pressure in said confined volume	65
8.	Each Element of Claim 8 Is Found in <i>Bitel</i>	68
	(a) [8] The vacuum system according to claim 6, wherein said controller controls the torque of said motor to control said level of said negative pressure in said confined volume.	68
9.	Each Element of Claim 9 Is Found in <i>Bitel</i>	70
	(a) [9] The vacuum system according to claim 1, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating.	70
10.	Each Element of Claim 10 Is Found in <i>Bitel</i>	72
	(a) [10] The vacuum system according to claim 1, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice	72
11.	Each Element of Claim 11 Is Found in <i>Bitel</i>	73
	(a) [11] A vacuum system for applying negative pressure to a wound	73
	(b) [11.1] The vacuum system comprising: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller	73
	(c) [11.2] The enclosure being attachable to a periphery of the wound so as to define a confined volume	73

(d)	[11.3] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume.....	73
(e)	[11.4] Said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said tube, said controlled flow of ambient air entering said tube via said venting arrangement without entering said enclosure	74
(f)	[11.5] The controller configured for controlling operation of the vacuum source while said tube is being vented via said venting arrangement to provide a desired level of said negative pressure in said confined volume	76
12.	Each Element of Claim 12 Is Found in <i>Bitel</i>	77
(a)	[12] The vacuum system according to claim 11, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.....	77
13.	Each Element of Claim 13 Is Found in <i>Bitel</i>	77
(a)	[13] The vacuum system according to claim 11, further comprising a waste container in fluid communication with said vacuum source.....	77
14.	Each Element of Claim 14 Is Found in <i>Bitel</i>	78
(a)	[14] The vacuum system according to claim 11, wherein said vacuum source comprises a vacuum pump driven by a motor.....	78
15.	Each Element of Claim 15 Is Found in <i>Bitel</i>	78
(a)	[15] The vacuum system according to claim 14, wherein said motor is an electric motor, and said	

	controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume	78
16.	Each Element of Claim 16 Is Found in <i>Bitel</i>	79
	(a) [16] The vacuum system according to claim 15, wherein said controller controls at least one of the electric current of said motor, or the voltage of said motor, or the torque of said motor to control said level of said negative pressure in said confined volume	79
17.	Each Element of Claim 17 Is Found in <i>Bitel</i>	79
	(a) [17] The vacuum system according to claim 11, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating	79
18.	Each Element of Claim 18 Is Found in <i>Bitel</i>	80
	(a) [18] The vacuum system according to claim 11, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice	80
19.	Each Element of Claim 19 Is Found in <i>Bitel</i>	80
	(a) [19.P] A method for applying negative pressure to a wound.....	80
	(b) [19.1] (a) Providing a vacuum system.....	81
	(c) [19.2] [The vacuum system comprising at least] an enclosure, a venting arrangement, a tube, and a vacuum source	81
	(d) [19.3] The enclosure being attachable to a periphery of the wound so as to define a confined volume	81

(e)	[19.4] The enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume	81
(f)	[19.5] The venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said system upstream of the vacuum source	81
(g)	[19.6] (b) Controlling operation of the vacuum source while the vacuum system is being vented via the venting arrangement to thereby provide a desired level of said negative pressure in said confined volume	82
20.	Each Element of Claim 20 Is Found in <i>Bitel</i>	83
(a)	[20] The method according to claim 19, wherein the vacuum source comprises a vacuum pump driven by an electric motor wherein step (b) comprises controlling operation of said motor to thereby provide a desired level of said negative pressure in said confined volume	83
21.	Each Element of Claim 21 Is Found in <i>Bitel</i>	84
(a)	[21] The method according to claim 20, wherein step (b) comprises controlling at least one of the electric current, or the voltage, or the torque of said motor to control said level of said negative pressure in said confined volume	84
22.	Each Element of Claim 22 Is Found in <i>Bitel</i>	84
(a)	[22] The method according to claim 19, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice	84

TABLE OF EXHIBITS¹

Exhibit No.²	Description	Publication Date (unless otherwise noted)	Type of Prior Art (Pre-AIA 35 U.S.C.)
1001	USPN 8,858,534 to Adahan (the '534 Patent) (Patent under <i>Inter Partes</i> Review)	Jul. 24, 2005 (filing date of priority PCT application)	N/A
1002	File History for USPN 8,858,534	N/A	N/A
1003	USPN 3,572,340 to Lloyd et al. (" <i>Lloyd</i> ")	Mar. 23, 1971	§ 102(b)
1004	USPN 4,569,674 to Phillips et al. (" <i>Phillips</i> ")	Feb. 11, 1986	§ 102(b)
1005	Canadian Patent No. 2,596,321 to Henley et al. (" <i>Henley</i> ")	Feb. 17, 2000	§ 102(b)
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 8,506,554 to Adahan (the '554 Patent) (Parent of '534 Patent)	Jul. 24, 2005 (filing date of priority PCT application)	N/A
1013	File History for USPN 8,506,554	N/A	N/A
1014	USPN 8,157,792 to Dolliver et al. (" <i>Dolliver</i> ")	Feb. 26, 2004 (filing date)	§ 102(e)
1015	USPN 6,648,862 to Watson (" <i>Watson</i> ")	Nov. 18, 2003	§ 102(b)

¹ For the Board's convenience, this Table of Exhibits is 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 1–22 (the “Challenged Claims”) of USPN 8,858,534 (the “’534 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 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. 8,858,534 (IPR Petition) and the various exhibits referenced therein, such as, for example, the '534 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 ’534 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 ’534 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 ’534 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 '534 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 '534 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 '534 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 '534 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 '534 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.

V. BACKGROUND OF THE '534 PATENT AND PRIOR ART

27. 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 systems 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 '534 Patent were explicitly taught by multiple references years before the '534 Patent's priority date, and alleged inventions claimed in the '534 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 '534 Patent are summarized below.

- Claim 1: a vacuum system for applying negative pressure to a wound having an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. The enclosure is attachable to a periphery of the wound

so as to define a confined volume and has an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be created in the volume. The venting arrangement includes a flow restrictor to restrict flow through the venting arrangement and to thereby provide a controlled flow of ambient air into the vacuum system upstream of the vacuum source. The controller controls the operation of the vacuum source to provide a desired level of negative pressure in the confined volume while vacuum system is being vented via the venting arrangement;

- Claim 2: depends from Claim 1 and claims the additional feature of the flow restrictor is provided in any one of the enclosure or the tube;
- Claim 3: depends from Claim 1 and claims the additional feature of a sensor for enabling determination of a level of the negative pressure in the confined volume;
- Claim 4: depends from Claim 1 and claims the additional feature of a waste container in fluid communication with the vacuum source;
- Claim 5: depends from Claim 1 and claims the additional feature of a vacuum pump driven by a motor;
- Claim 6: depends from Claim 5 and claims the additional features of:
(i) the motor is an electric motor, and (ii) the controller controls

operation of the motor to thereby provide a desired level of said negative pressure in the confined volume;

- Claim 7: depends from Claim 6 and claims the additional feature of the controller controls the electric current or the voltage of the motor to control the level of negative pressure in the confined volume;
- Claim 8: depends from Claim 6 and claims the additional feature of the controller controls the torque of the motor to control the level of negative pressure in the confined volume;
- Claim 9: depends from Claim 1 and claims the additional feature of the ambient pressure may be restored in the confined volume via the venting arrangement when the vacuum pump is not operating;
- Claim 10: depends from Claim 1 and claims the additional feature of the venting arrangement comprising at least one of: (i) one or more bleeding holes, (ii) a porous body, (iii) an orifice;
- Claim 11: a vacuum system for applying negative pressure to a wound having an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. The enclosure is attachable to a periphery of the wound so as to define a confined volume. The enclosure has an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be selectively created in the volume. The venting arrangement is

located outside of the enclosure and includes a flow restrictor to restrict flow through the venting arrangement and to thereby provide a controlled flow of ambient air into the tube. The controlled flow of ambient air enters the tube via the venting arrangement without entering the enclosure. The controller controls the operation of the vacuum source to provide a desired level of negative pressure in the confined volume while the tube is being vented via the venting arrangement;

- Claim 12: depends from Claim 11 and claims the additional features of a sensor for enabling determination of a level of the negative pressure in the confined volume;
- Claim 13: depends from Claim 11 and claims the additional feature of a waste container in fluid communication with the vacuum source;
- Claim 14: depends from Claim 11 and claims the additional feature of the vacuum source comprises a vacuum pump driven by a motor;
- Claim 15: depends from Claim 14 and claims the additional features of:
(i) the motor is an electric motor, and (ii) the controller controls operation of the motor to thereby provide a desired level of said negative pressure in the confined volume;
- Claim 16: depends from Claim 15 and claims the additional feature of the controller controlling at least one of: (i) the electric current of the

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

- Claim 17: depends from Claim 11 and claims the additional feature of the ambient pressure may be restored in the confined volume via the venting arrangement when the vacuum pump is not operating;
- Claim 18: depends from Claim 11 and claims the additional feature of the venting arrangement comprising at least one of: (i) one or more bleeding holes, (ii) a porous body, (iii) an orifice;
- Claim 19: a method for applying negative pressure to a wound. The method includes providing a vacuum system having an enclosure, a venting arrangement, a tube, and a vacuum source. The enclosure is attachable to a periphery of the wound so as to define a confined volume. The enclosure has an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be selectively created in the volume. The venting arrangement includes a flow restrictor to restrict flow through the venting arrangement and to thereby provide a controlled flow of ambient air into the vacuum system upstream of the vacuum source. The method includes controlling operation of the vacuum source while the vacuum source is being

vented via the venting arrangement to provide a desired level of negative pressure in the confined volume;

- Claim 20: depends from Claim 19 and claims the additional features of:
(i) the vacuum source includes a vacuum pump driven by an electric motor, and (ii) controlling operation of the motor to thereby provide a desired level of the negative pressure in said confined volume;
- Claim 21: depends from Claim 20 and claims the additional features of the controller controlling at least one of: (i) the electric current of the motor, (ii) the voltage of the motor, or (iii) the torque of the motor to control the level of the negative pressure in the confined volume;
- Claim 22: depends from Claim 19 and claims the additional feature of the venting arrangement comprising at least one of: (i) one or more bleeding holes, (ii) a porous body, (iii) an orifice

As background for understanding the '534 Patent in the context of the prior art, I studied patents and other publications to review negative pressure wound therapy systems over the years.

A. Evolution of Vacuum Therapy Wound Treatment Systems

28. Vacuum therapy wound treatment systems were well-known for decades prior to the priority date of the '534 Patent. For example, a patent from 1971, entitled "Suction Drainage Device" ("*Lloyd*"), discloses "A...disposable, sterile

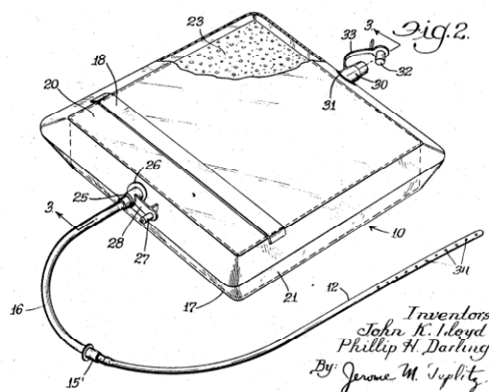
suction drainage device for extraction and collection of body fluids from wounds...[that includes] a fluid-collecting pump unit.” See Ex. 1003, 1:12–15.

29. Indeed, *Lloyd* teaches that such systems were generally known prior to *Lloyd*’s 1968 filing date in providing: “[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.

30. 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.

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

Lloyd – Figure 2



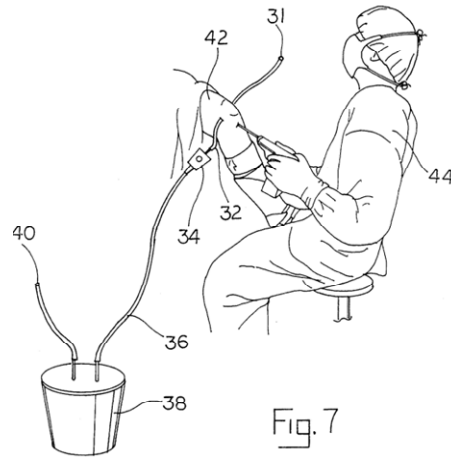
32. Prior art systems that utilized a drainage/tube catheter alone without any cover for the wound were known to suffer from several drawbacks. For example, a patent from 1998, entitled “Wound Treatment Apparatus” (“*Henley*”), teaches that “[e]xposing [a] wound to the open atmosphere can increase the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

33. 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.

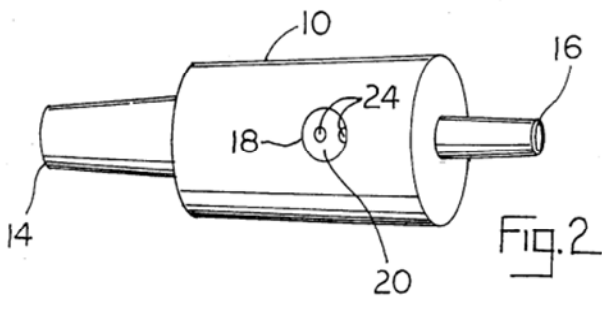
34. Conventional vacuum therapy based wound treatment systems were also known to incorporate venting arrangements—including flow restrictor elements—in tubes connecting the wound to the vacuum source and waste container to allow ambient air to enter the tube, including while under negative pressure. 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

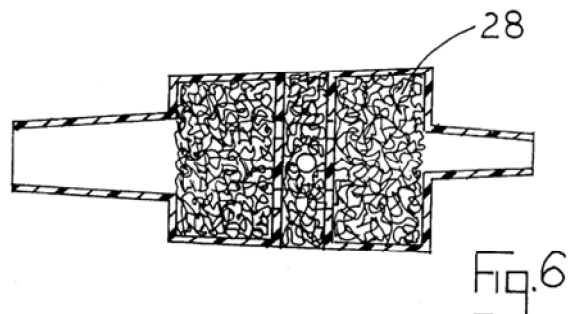


35. The suction adapter 34 includes a housing 10 having a ventilation port 18 in communication with an interior space 12 of the housing 10 “to allow atmospheric air into the interior space 12,” as shown in Figure 2 below. *Id.*, 2:33–35, Fig. 2. In one embodiment of *Atkinson*, a porous foam 28 is disposed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

Atkinson – Figure 2



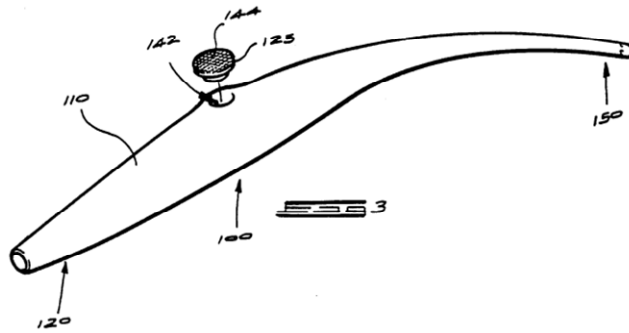
Atkinson – Figure 6



36. *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 understand that the porous foam 28 of *Atkinson* would also serve to restrict 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.

37. It was also well-known in the prior art to include flow restrictor elements as part of venting arrangements in suction tubes of vacuum therapy wound treatment systems for other purposes, such as to permit the ingress of atmospheric air into a tube while preventing the entry of contaminants. For example, a published patent application from 1998, entitled “Nozzle For A Surgical Suction Apparatus” (“*Mantell*”), discloses a “nozzle for surgical suction apparatus...compris[ing] a suction tube (110) that is adapted for connection to the suction device at its connection end (120) and for location in the surgical area of a patient at its suction end (150).” Ex. 1011, Abstract. “The nozzle (100) includes a finger controllable suction control[] aperture (142) and a filter constituted by a gas permeable, liquid impermeable membrane (144) that is incorporated in a plug (125) adapted to fit into the suction control aperture (142)” as shown in Figure 3 below.

Mantell – Figure 3



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

38. Additionally, controllers for controlling operation of vacuum sources within vacuum therapy wound treatment systems were well-known long before the priority date of the '534 Patent. For example, *Argenta* (discussed above) teaches, “[t]he vacuum pump 40 is preferably controlled by a control device 44 such as a switch or a timer which may be set to provide cyclic on/off operation of the vacuum pump 40 according to user-selected intervals,” as shown in Figure 1 below. Ex. 1006, 8:21–24. More specifically, *Argenta* teaches “[i]ntermittent or cyclic supply of reduced pressure to an appliance may be achieved by manual or automatic control of the vacuum system.” *Id.*, 13:5–7. “A cycle ratio, the ratio of ‘on’ time to ‘off’

time, in such an intermittent reduced pressure treatment may be as low as 1:10 or as high as 10:1.” *Id.*, 13:7–10.

Argenta – Figure 1

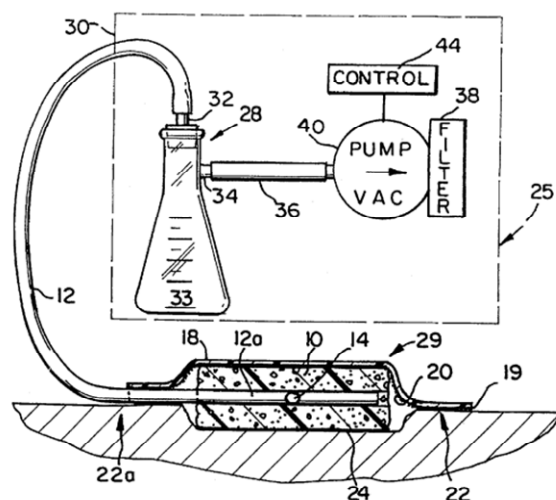


FIG. 1

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

40. Despite this crowded field of prior art, the ’534 Patent issued with broad claims directed to a common vacuum therapy wound treatment system for applying negative pressure to a wound including an enclosure, a venting arrangement comprising a flow restrictor, a tube, a vacuum source, and a controller configured for controlling operation of the vacuum source. But these claim elements were all

common components that had been known for years prior to the time of the alleged invention.

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

41. Based upon my review of the '534 Patent (Ex. 1001), which is titled “Wound Closure and Drainage System,” I find that it relates generally to a vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids. Ex. 1001, Abstract. In my opinion, and as will be demonstrated below, there are and were no novel features claimed in the '534 Patent, as vacuum therapy wound treatment systems including all the claimed elements were known prior to the alleged invention of the '534 Patent, and there were many known design choices to accomplish such wound closure and drainage prior to the alleged invention of the '534 Patent. *See, e.g.*, Exs. 1003–1006; 1009–1011; 1014–1015 (as discussed above).

42. The '534 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 '534 Patent are directed to different aspects of the vacuum system.

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

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

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

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

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

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

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

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

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

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

53. Claim 11 recites a vacuum system for applying negative pressure to a wound having an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. The enclosure is attachable to a periphery of the wound so as to define a confined volume. The enclosure has an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be selectively created in the volume.

The venting arrangement is located outside of the enclosure and includes a flow restrictor to restrict flow through the venting arrangement and to thereby provide a controlled flow of ambient air into the tube. The controlled flow of ambient air enters the tube via the venting arrangement without entering the enclosure. The controller controls the operation of the vacuum source to provide a desired level of negative pressure in the confined volume while the tube is being vented via the venting arrangement.

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

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

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

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

58. Claim 16 depends from Claim 15 and claims the additional feature of the controller controlling at least one of: (i) the electric current of the motor, (ii) the

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

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

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

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

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

63. Claim 21 depends from Claim 20 and claims the additional features of the controller controlling at least one of: (i) the electric current of the motor, (ii) the voltage of the motor, or (iii) the torque of the motor to control the level of the negative pressure in the confined volume.

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

C. Summary of the Prosecution History

65. The following reflects a brief summary of the prosecution history of the '534 Patent. The prosecution history is relevant to understanding why the '534 Patent was deemed to meet the conditions for patentability.

66. I understand from my review of the '534 Patent and its file history, as well as discussions with Petitioner's counsel, that U.S. Application No. 13/917,865 (the "'865 Application"), which issued as the '534 Patent, was filed on June 14, 2013. Ex. 1001, Cover Page. The '534 Patent is a continuation of U.S. Application No. 11/989,297, which later issued as U.S. Patent No. 8,506,554 (the "'554 Patent")

Id. The earliest patent application to which the '554 Patent claims priority is International Patent Application No. PCT/IL2005/000784 (the "'784 PCT Application") filed July 24, 2005. *Id.*

67. In my view, the prosecution history sheds little light on why the Challenged Claims of the '534 Patent were allowed. For example, none of the features set forth in the Challenged Claims were ever identified during prosecution as distinguishing over the art of record.

68. The prosecution history of the '554 Patent is relevant to understanding the prosecution history of the '534 Patent.

69. A Notice of Allowance for the '554 Patent was mailed October 9, 2012. *See* Ex. 1013, 774–77.

70. By way of a post-allowance amendment filed January 8, 2013, the pending independent claims were amended, *inter alia*, to replace limitations related to the "venting arrangement comprising a calibrated orifice to restrict flow through said venting arrangement" with limitations reciting that the venting arrangement comprises "a flow restrictor." *See id.*, 807–817. Further, the "without entering said enclosure" limitation was added to claim 42. *Id.*, 811.

71. 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.

72. 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.

73. 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.

74. 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.

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

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

76. In a non-final office action mailed March 11, 2014, in connection with the '865 Application (the only office action issued in connection with the '865 Application), all pending claims 1–22 were rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1, 6, 8, 9, 20, and 24 of the '554 parent-Patent in view of Argenta et al. (US 2001/0029956). Ex. 1002, 171–174.

77. Notably, the non-final office action contended that “[a]ll the limitations of [independent] claims 1 and 11 of the ['865 Application] are to be found in claim 1 of the ['554 Patent]...[t]he difference is that claim 1 of the Patent does not comprise the controller configured for controlling operation of the vacuum source.” *Id.*, 172. Relatedly, the non-final office action contended that “[a]ll the limitations of [independent] claim 19 of the ['865 Application] are to be found in claim 1 of the ['554 Patent]...[t]he difference is that claim 1 of the Patent does not comprise the step of controlling the vacuum source.” *Id.*

78. But the non-final office action did not appear to recognize that the pending claims of the '865 Application also differed from the granted claims of the

'554 Patent because *they did not require the venting arrangement to be located outside the enclosure*—a limitation that was required for the claims of the '554 Patent to overcome prior art-based rejections during prosecution.

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

80. The Applicant of the '865 Application was able to overcome the double-patenting rejection by filing a terminal disclaimer on June 2, 2014. *Id.*, 257. An issue notification was mailed September 24, 2014 and the '534 Patent issued on October 14, 2014. *Id.*, 377.

VI. SUMMARY OF THE ASSERTED PRIOR ART

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

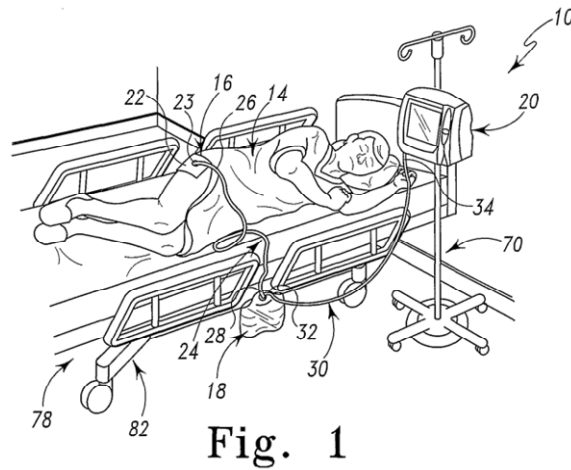
81. I have carefully reviewed the *Bitel* (Ex. 1009) prior art reference applied in the IPR Petition, and I deem it to be relevant to demonstrating the unpatentability of the '534 Patent. A brief summary of *Bitel* is provided below,

explaining, in part, what *Bitel* discloses to a POSITA in the context of the '534 Patent specification and claims.

82. *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 '534 Patent, but it was not applied against any of the claims during prosecution. *See generally* Ex. 1001.

83. *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



84. 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.

85. The “[v]acuum source 21 may be contained within housing 20 or may be external to the housing 20.” *Id.*, 6:28–29. “Vacuum source 21 is also defined to include any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example.” Ex. 1009, 6:31–33.

86. “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

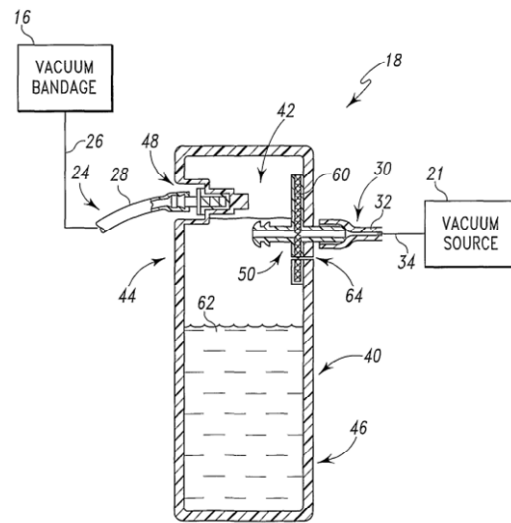


Fig. 5

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

88. “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.

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

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

91. Finally, *Bitel* relates to “[a] method for treating a wound on a patient . . . including the steps of sealing a bandage having a port about the wound to define a space above the wound in which a vacuum can be formed, placing a receptacle

below the wound, and placing a vacuum source spaced away from the receptacle.”

Id., 4:1–4.

VII. CONCLUSIONS REGARDING PATENTABILITY

92. It is my opinion that the Challenged Claims of the ’534 Patent are not patentable for at least the reasons proposed in Ground 1 of the IPR Petition:

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

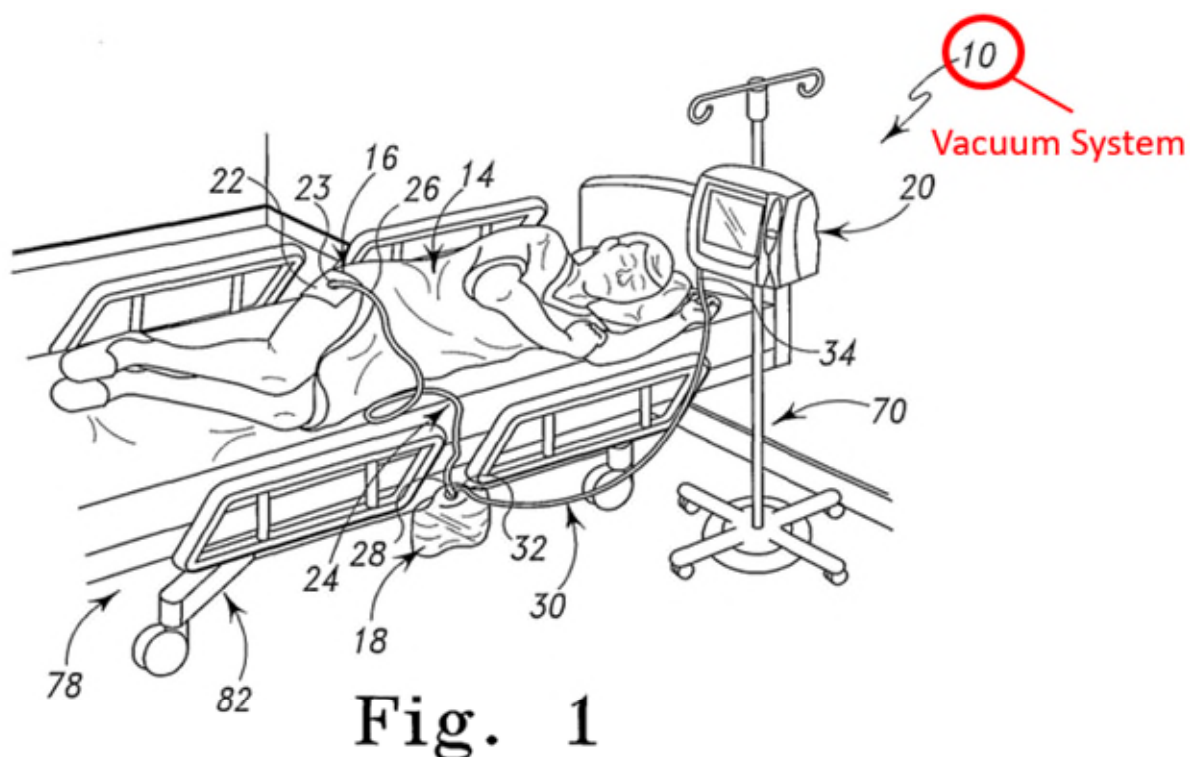
93. Ground 1 shows how *Bitel* anticipates Claims 1–22.

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

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

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

94. *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).



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

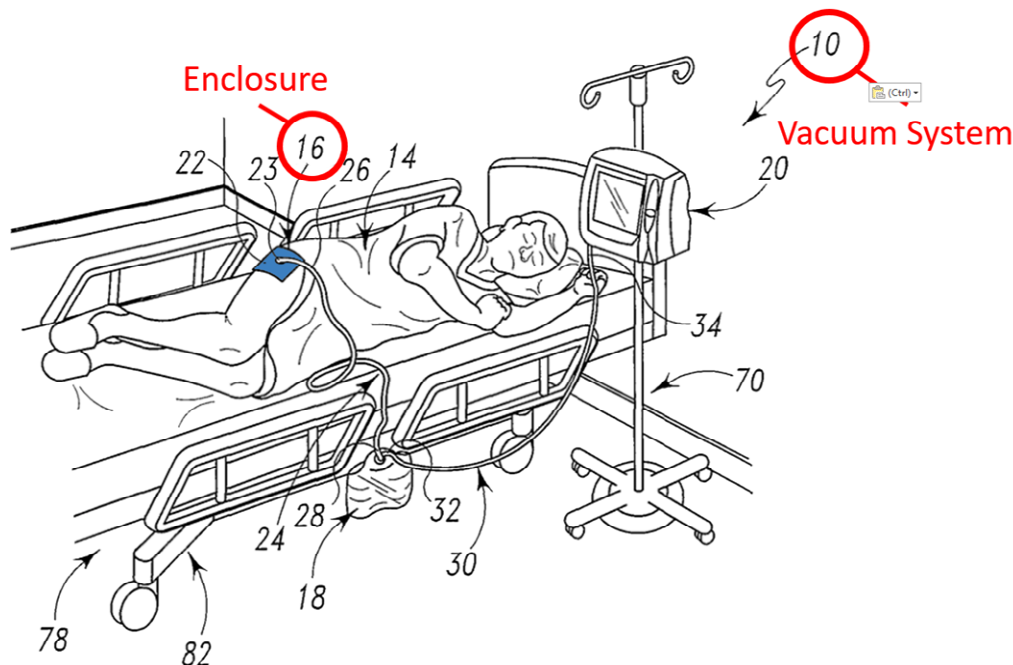
(b) **[1.1] The vacuum system comprising: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller**

96. *Bitel* teaches a vacuum system, as previously described. In addition, *Bitel* discloses a vacuum bandage 16 that “includes a cover 22 to seal about the wound.” Ex. 1009, 5:31. “The bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum.” *Id.*, 5:31–33.

97. 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.

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



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

100. 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.

101. Additionally, *Bitel* discloses that the “[s]ystem 10 further includes a second tube 30 coupled at a first end 32 to the receptacle 18 and coupled at a second end 34 to the vacuum source 21 which may be contained within housing 20.” Ex. 1009, 6:3–5, Fig. 5. More specifically, the second tube 30 is connected to the receptacle 18 via an outlet port 50: “first end 32 of second tube 30 is coupled to outlet port 50 of receptacle 18 and second end 34 of second tube 30 is coupled to vacuum source 21.” *Id.*, 6:26–28.

102. 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.

103. 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.

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

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

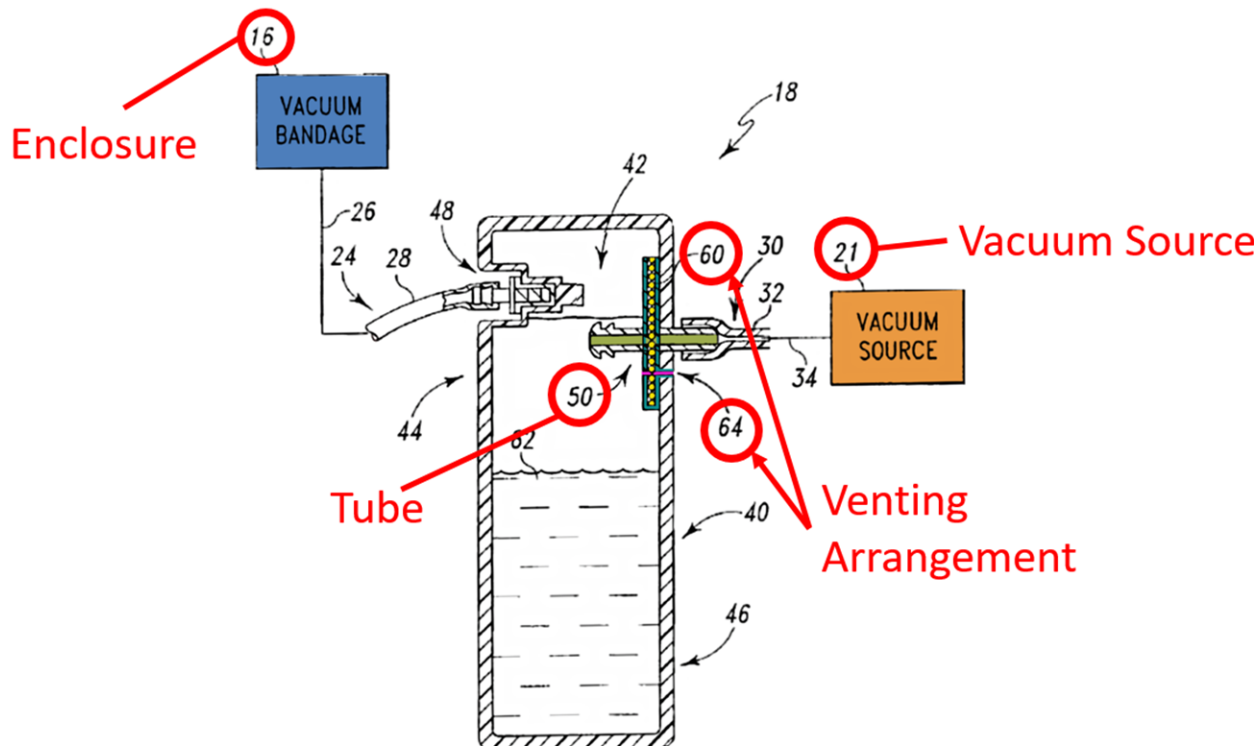


Fig. 5

106. Finally, *Bitel* discloses, “[i]n addition to the vacuum source 21, it is also within the scope of the disclosure for housing 20 to include a controller (not shown) for controlling the amount and rate of negative pressure to be applied to the wound, for example.” *Id.*, 7:10–12.

107. It is my opinion that the controller of *Bitel* (no reference numeral assigned and not shown in any figures) constitutes “a controller” as claimed.

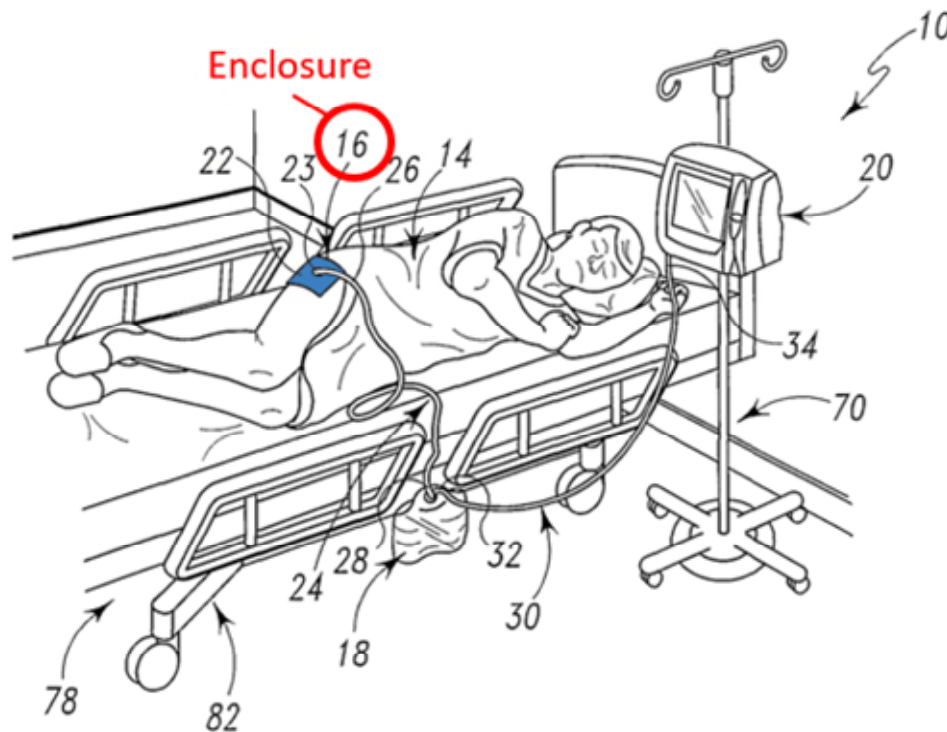
108. In this way, it is my opinion that *Bitel* teaches a vacuum system (vacuum therapy system 10) comprising an enclosure (bandage 16), a venting arrangement (air vent 64 and microporous filter 60), a tube (second tube 30), a

vacuum source (vacuum source 21), and a controller (controller, no reference numeral assigned).

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

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

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



Id., Fig. 1.

111. In this way, it is my opinion that *Bitel* teaches the enclosure (bandage 16) being attachable to a periphery of the wound so as to define a confined volume (volume under bandage 16).

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

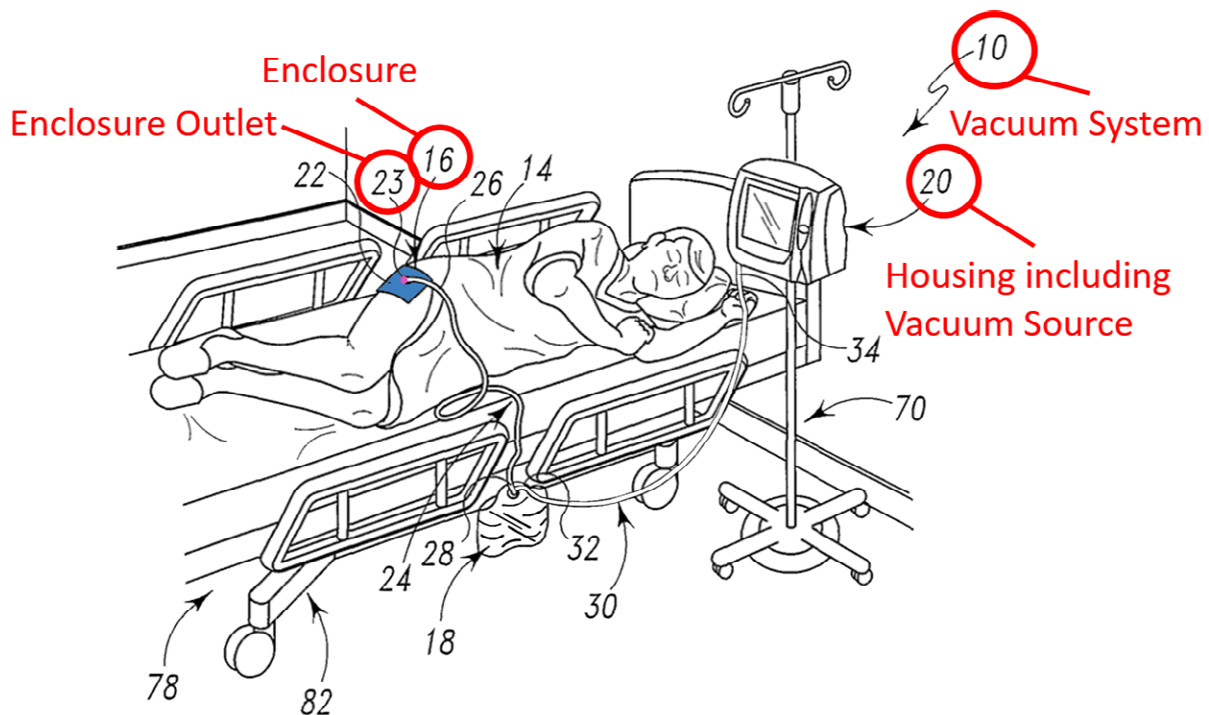
112. *Bitel* discloses “[t]he bandage 16 further includes a port 23 in communication with the space above the wound.” Ex. 1009, 5:33–6:1. “The port 23 is coupled to receptacle 18 by a first tube 24 of the system 10. First tube 24 includes a first end 26 coupled to the port 23 and a second end 28 coupled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

113. It is my opinion that the port 23 of *Bitel* constitutes an “enclosure outlet” as claimed in that 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.

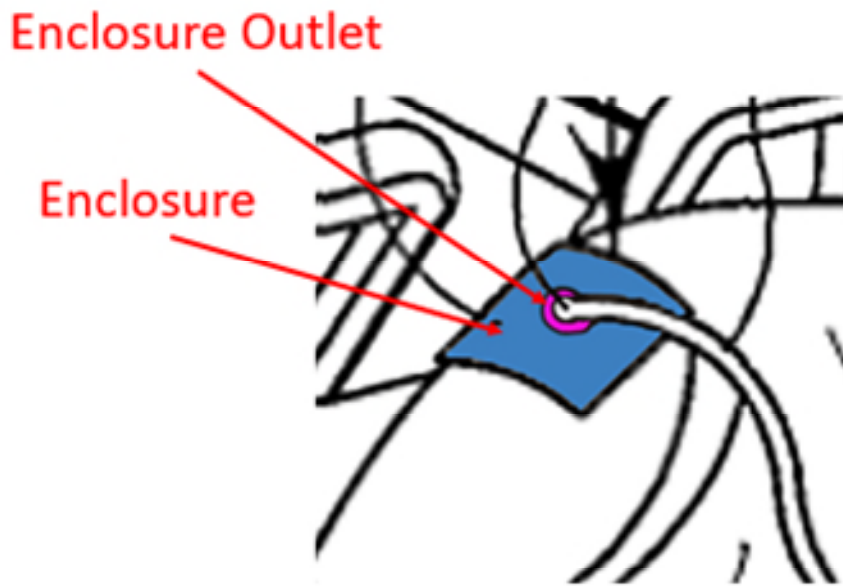
114. The port 23 is connectable to the vacuum source 21 via the outlet port 50 of the receptacle 18 so that negative pressure can be created in the volume under bandage 16. See Ex. 1009, 5:31–33 (“The bandage 16 operates to define a space

above the wound to which negative pressure can be applied to form a vacuum.”), 5:33–6:5, Figs. 1 and 5.

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



Ex. 1009, Fig. 1.



Ex. 1009, Fig. 1 (magnified to more readily show port 23).

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

117. In this way, it is my opinion that *Bitel* teaches the enclosure (bandage 16) having an enclosure outlet (port 23) connectable to said vacuum source (vacuum source 21) via said tube (outlet port 50) so that negative pressure can be selectively created (control dominating the vacuum source) in said volume (volume under bandage 16).

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

118. *Bitel* teaches “[u]pper portion 44 of receptacle 18 further defines an air vent 64 to prove communication between interior cavity 42 of receptacle 18 and the outside atmosphere.” Ex. 1009, 6:21–23. “Preferably, as shown in Fig. 5, [a] hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering receptacle 18.” *Id.*, 6:23–25, Fig. 5. The “vacuum source 21 is...able to pull air through air vent 64.” *Id.*, 8:11–12.

119. 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.

120. It is also 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).

121. 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.

122. 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:

123. 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.

124. 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.

125. 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.

126. 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.

127. 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.

128. 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.

129. As shown in annotated Figure 5 below, air vent 64 and hydrophobic filter 60 (outlined in teal) constitute a venting arrangement and hydrophobic filter 60 (yellow) constitutes a flow restrictor to restrict flow through the venting arrangement. A magnified view of Figure 5 is further provided to more readily show the hydrophobic filter 60 acting as a flow restrictor.

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

130. *Bitel* further provides that “[o]nce system 10 has become relatively static and there is little to no fluid flow from bandage 16 through first tube 24 and to receptacle 18, vacuum source 21 is still able to pull air through air vent 64 thus allowing the flow sensor to detect a fluid flow in order to keep the vacuum source 21 running.” Ex. 1009, 8:10–13.

131. In this way, the air vent 64/filter 60 configuration of *Bitel* “provide[s] a controlled flow of ambient air into said vacuum system” as claimed.

132. Furthermore, the ambient air entering the air vent 64/filter 60 flows towards the vacuum source 21 and thus “upstream of the vacuum source” as claimed. Ex. 1009, Fig. 5. Traditional nomenclature for fluid mechanics dictates that fluid flowing towards an object, is “upstream” of that object. Likewise fluid flowing away from an object, is “downstream” of that object. This object can be a source of negative or positive pressure, such as a vacuum source. Hence, a fluid flowing towards a vacuum source is “upstream of the vacuum source”.

133. In this way, it is my opinion *Bitel* teaches the venting arrangement (air vent 64 and hydrophobic filter 60) comprising a flow restrictor (hydrophobic filter 60) to restrict flow through said venting arrangement (air vent 64 and hydrophobic filter 60) and to thereby provide a controlled flow of ambient air into said vacuum

system (vacuum therapy system 10) upstream of the vacuum source (vacuum source 21).

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

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

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

136. A fluid pressure controller system is standard equipment to accomplish control of negative or positive pressure driven fluids. Integral to maintaining precise vacuum conditions, this typically comprises a vacuum pump, sensors or transducers for real-time vacuum level measurement, and a central controller unit, often a programmable logic controller (PLC) or a microcontroller. This system is tasked with regulating the vacuum by processing inputs from the sensors to manage the operation of the vacuum pump and auxiliary components like valves. I have worked with these systems as early as the late 1990s. The system operates on a feedback loop principle, where sensor data on the current pressure levels is continuously analyzed by the controller to initiate corrective actions, such as modulating pump speed or valve positions, ensuring the pressure (vacuum) level remains within desired thresholds. Modern systems may also incorporate advanced features like PID (Proportional-Integral-Derivative) control for precise pressure adjustments and data logging for performance analysis. This is aimed at enhancing efficiency, safety, and reliability of the vacuum / pressure system, and is a very common setup in all fluids pressure controls systems, negative or positive pressure.

137. In this way, it is my opinion that *Bitel* teaches the controller (controller) configured for controlling operation (a controller for controlling the amount and rate of negative pressure to the applied to the wound) of the vacuum source (vacuum source 21) while providing venting of the vacuum system via said venting

arrangement (air vent 64 and hydrophobic filter 60) to provide a desired level of said negative pressure in said confined volume.

138. Therefore, it is my opinion that *Bitel* teaches each and every limitation of claim 1.

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

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

139. *Bitel* teaches the vacuum system according to claim 1, as previously described. In addition, *Bitel* teaches that a “hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering the receptacle 18.” Ex. 1009, 6:23–25. “Once the level of exudate 62 collected within receptacle 18 reaches air vent 64 and/or outlet port 50, hydrophobic filter 60 will prevent liquid to pass therethrough and the flow sensor will sense that the flow has become static.” *Id.*, 8:13–16. Annotated Figure 5 below shows the filter 60 (yellow) within the outlet port 50 (green).

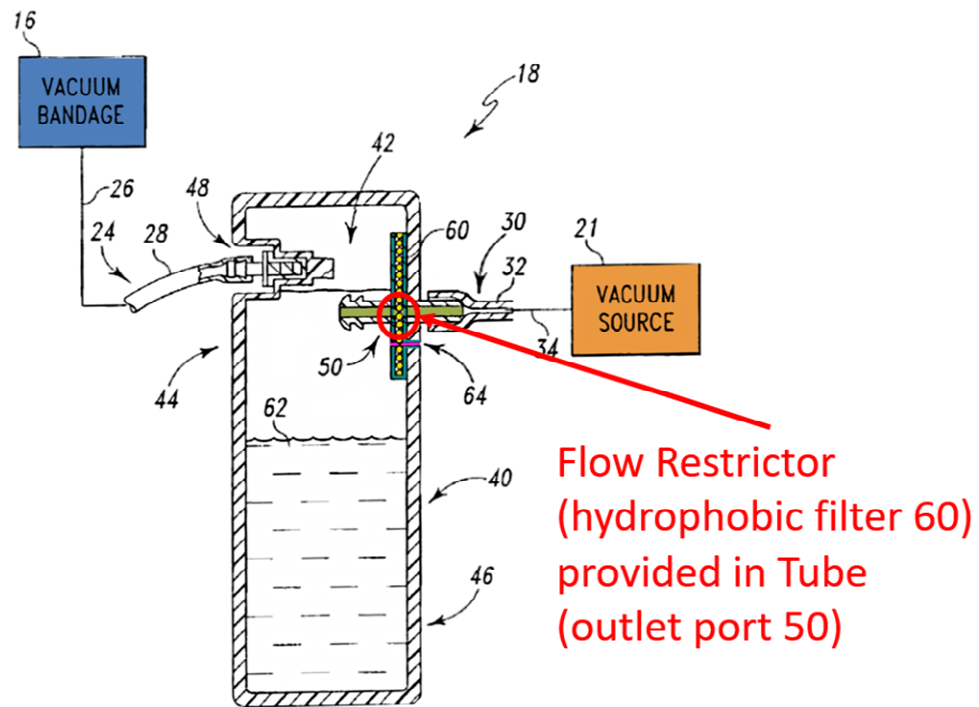
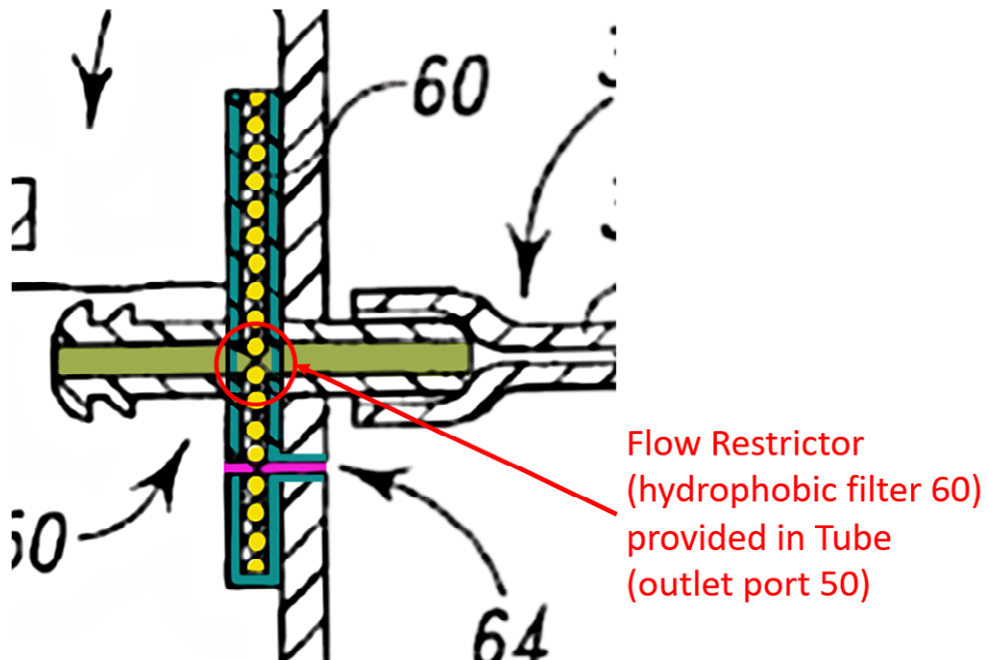


Fig. 5

Ex. 1009, Fig. 5.



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

140. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), wherein said flow restrictor (hydrophobic filter 60) is provided in the tube (outlet port 50).

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

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

141. *Bitel* teaches the vacuum system according to claim 1, as previously described. Additionally, *Bitel* teaches “a flow sensor to be connected to a vacuum line.” Ex. 1009, 3:30. “[T]he flow sensor may be configured to determine the level of vacuum present in the receptacle.” *Id.*, 3:31–32. Specifically, the flow sensor “may be coupled to a second tube 30 between receptacle 18 and vacuum source 21 for monitoring the fluid flow from receptacle 18 to vacuum source 21.” *Id.*, 7:29–31. “The flow sensor may then provide feedback to the controller.” *Id.*, 7:31–32. “If, for example, the flow sensor detects no fluid flow, the feedback sent to the controller would signal the vacuum source 21 to turn off or cease running.” *Id.*, 7:32–8:2. In the “series configuration, the vacuum source 21 is thus in fluid communication with the receptacle 18 through the second tube 3, and the space above the wound created by vacuum bandage 16 is in fluid communication with

receptacle 18 through first tube 24.” *Id.*, 7:23–26. “The bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum.” *Id.*, 5:31–33.

142. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), further comprising a sensor (flow sensor, no reference numeral provided) for enabling determination of a level of said negative pressure (sensor may be configured to determine the level of vacuum present in the vacuum bandage through its series configuration) in said confined volume (volume under bandage 16).

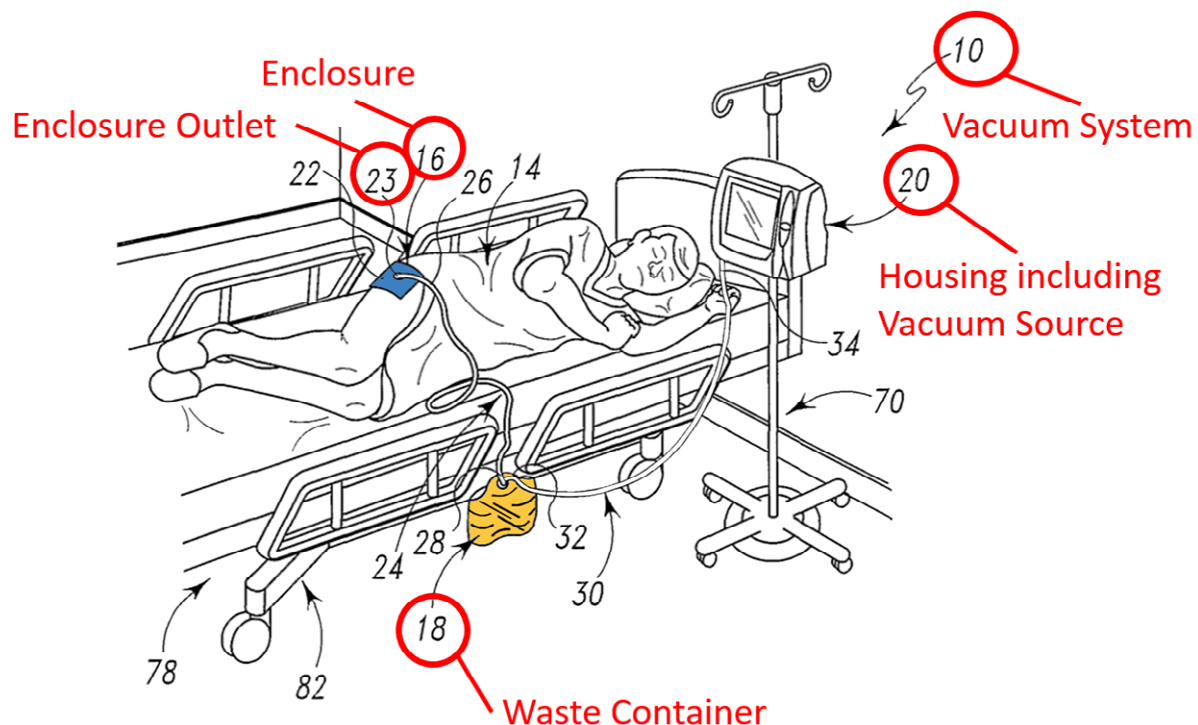
4. Each Element of Claim 4 Is Found in *Bitel*

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

143. *Bitel* teaches the vacuum system according to claim 1, as previously described. Additionally, *Bitel* discloses a receptacle 18 “to receive exudate from the wound.” Ex. 1009, Abstract. The receptacle 18 constitutes a “waste container” as claimed because it is configured to receive and store waste from the wound. *Id.*, Title (“Waste Container for Negative Pressure Therapy”), 5:16–18. *Bitel* teaches “[s]ystem 10 further includes a second tube 30 coupled at a first end 32 to the receptacle 18 [via outlet port 50] and coupled at a second end 34 to the vacuum source 21.” Ex. 1009, 6:3–5, 6:26–28. “The vacuum source (21)...is connected to

the receptacle (18), and is effective to provide a vacuum in the receptacle (18) and in the space [over the wound].” *Id.*, Abstract.

144. 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.

145. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), further comprising a waste container (receptacle 18) in fluid communication (via outlet port 50 and second tube 30) with said vacuum source (vacuum source 21).

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

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

146. *Bitel* teaches the vacuum system according to claim 1, as previously described. *Bitel* also teaches “[t]he vacuum source of the system may comprise a vacuum pump.” Ex. 1009, 3:29, 6:31 (“[V]acuum pump to provide negative pressure”). The “[v]acuum source 21 is also defined to include any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example.” *Id.*, 6:31–33.

147. A POSITA would have understood that *Bitel*’s teaching of “any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example” would encompass “a vacuum pump driven by a motor” as claimed. This is because a POSITA would understand *Bitel*’s teaching of an “electrically operated...pump” as a pump driven by an electric motor.

148. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), wherein said vacuum source (vacuum source 21) comprises a vacuum pump (vacuum pump, no reference numeral provided) driven by a motor (any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example).

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

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

149. *Bitel* teaches the vacuum system according to claim 5, as previously described. Additionally, *Bitel* teaches “[t]he vacuum source of the system may comprise a vacuum pump and associated controls and/or a flow sensor to be connected to a vacuum line.” Ex. 1009, 3:29–30. The “[v]acuum source 21 is also defined to include any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example.” *Id.*, 6:31–33.

150. A POSITA would have understood *Bitel*’s teaching of “any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example” as encompassing “an electric motor” as claimed for the reasons discussed above in relation to Claim 5.

151. In addition, electrically operated pumps, including vacuum pumps such as described by *Bitel*, commonly employ electric motors due to the versatility, efficiency, and reliability that electric power offers. I worked with motion control of electrical motors as part of my job with National Instruments starting in year 2000. The work involved stepper and servo motors, brushed and brushless, to create linear and rotational actuators. Electric motors can be precisely controlled and easily

modulated to adjust a vacuum pump's speed and performance, allowing for fine-tuning of the vacuum levels to match specific requirements of various applications. Additionally, electric motors provide a clean and convenient source of power, free from the emissions associated with for example combustion engines, making them suitable for use in a wide range of environments, including laboratories, manufacturing facilities, clean rooms, and medical devices. Their widespread availability, ease of integration into existing electrical infrastructure of medical devices, and compatibility with automation and control systems further make electric motors the preferred choice for driving vacuum pumps. This synergy between electric motors and pumps would be well-known to a POSITA to facilitate the development of compact, efficient, and versatile vacuum systems that can cater to the demanding needs of modern wound healing applications.

152. Thus, at a minimum, *Bitel*'s teaching of "an electrically operated...pump" would have been understood by a POSITA as referring to a pump driven by an electric motor. See Ex. 1015 ("*Watson*"), Abstract (teaching "[a] small battery powered, electric motor drives the pump member" as part of a prior art vacuum wound therapy system). See *supra* ¶151.

153. Further, *Bitel* teaches "a controller [] for controlling the amount and rate of negative pressure to be applied to the wound, for example." Ex. 1009, 7:11–

12. “[T]he vacuum source comprises a vacuum pump and associated controls.” *Id.*, 11:24–25.

154. A POSITA would have understood *Bitel*’s teaching of “a controller [] for controlling the amount and rate of negative pressure to be applied to the wound” as encompassing a controller that “controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume” as claimed.

155. This is because controlling operation of a motor of a vacuum pump was the primary mechanism for providing the desired level of negative pressure in the confined volume over a wound according to prior art vacuum wound therapy systems. See Ex. 1015, 2:64–3:2 (“An electric motive means (an electric motor) is coupled to the vacuum pump member and drives the pump head. An electrical control circuit, including an electrical power source, is in electrical communication with the electric motive means. The control circuit is operable to control the operation of the electric motive means.”); Ex. 1014, 5:18–25 (“[T]he controller 117 controls the suction device 106...to periodically increase and decrease the application of suction at a drain catheter 102...More particularly, the controller 117 may provide, without limitation, mechanical or electrical control signals to the suction device 106 that control the amount of suction generated by the suction device 106.”).

156. In the context of vacuum wound therapy systems, the operation and control of the vacuum pump motor are central to achieving the therapeutic goals. These systems rely on precisely managing the level of negative pressure applied. The electric motor is directly coupled to the vacuum pump, driving the pump head responsible for generating suction. This setup allows for a controlled environment where negative pressure can be carefully modulated according to the therapeutic needs. An electrical control circuit, which includes a power source, interfaces with the electric motor, providing the necessary electrical communication and controls system as described above to manage the motor's operation. *See supra*, ¶¶ 136, 151. The sophistication of this control circuit is crucial as it determines the system's ability to maintain the desired vacuum levels, adjust to changes, and respond to various requirements, ensuring that the negative pressure applied to the wound is within the optimal range for successful healing.

157. The controller's role extends beyond simple on/off functionality; it intricately modulates the suction power delivered by the vacuum pump, with methods as described above. *See supra*, ¶¶ 136, 151. This is achieved through the provision of either mechanical or electrical control signals to the suction device, allowing for a dynamic adjustment of the suction intensity. *See supra*, ¶¶ 136, 151. In more advanced applications, this might involve periodic increases and decreases in suction application at the wound site, catering to the nuanced needs of the wound

therapy. Such a capability is pivotal for removing exudates and promoting blood flow to the wound area, thus enhancing the overall healing process. The controller's ability to fine-tune the suction levels enables the vacuum wound therapy system to adapt to varying wound conditions and stages of healing. This dynamic control mechanism, facilitated by the electric motor and its control circuit, embodies prior art vacuum wound therapy systems including *Bitel*, offering targeted, adjustable, optimized setups.

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

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

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

159. *Bitel* teaches the vacuum system according to claim 6, as previously described. Additionally, *Bitel* teaches “the vacuum source comprises a vacuum pump and associated controls, the pump being connected to the receptacle.” Ex.

1009, 11:24–25. The pump may be “electrically operated.” *Id.*, 6:31–33. Further, *Bitel* teaches “a controller [] for controlling the amount and rate of negative pressure to be applied to the wound, for example.” *Id.*, 7:11–12.

160. A POSITA would have understood that the two primary mechanisms for “controlling the amount and rate of negative pressure to be applied to the wound,” as described by *Bitel*, would have included controlling the electric current or voltage of the electric motor of *Bitel*’s electrically operated pump.

161. As described above, Ohm's Law is a fundamental principle in electrical engineering. *See supra*, ¶125. It states the relationship between voltage (V), current (I), and resistance (R) in an electrical circuit, expressed as $V = IR$. This law underpins the operation and control of electric motors, including those used in vacuum pumps. By controlling either the current or the voltage supplied to an electric motor, the motor's output characteristics can effectively be managed, such as speed and torque. In the context of a vacuum pump driven by an electric motor, adjusting the current or voltage alters or modulates the pump's performance and the level of negative pressure it generates. For instance, increasing the voltage typically leads to a higher speed, and increasing the current, typically would potentially increase the torque. Both would result in greater suction power from the vacuum pump. The conversion between torque and speed depends on the impedance of the pump, which is again described by the principle of Ohm’s Law, as outlined above.

162. Generally, it is understood by a POSITA that controlling the current allows for precise regulation of the motor's torque, directly influencing the pump's capability to maintain or alter the vacuum level within a system.

163. Different methods are used for controlling the torque on an electric motor's shaft, which, in turn, affects the level of negative pressure generated by a vacuum pump: The voltage supplied to the motor enables fine control over the motor's speed and torque. This method is particularly effective for applications requiring precise speed control and dynamic adjustments to the vacuum level, as it allows for smooth acceleration and deceleration cycles. On the other hand, motor control by current achieves torque regulation through the adjustment of the current flow to the motor. By varying the amount of current, the torque produced by the motor is directly influenced, offering precise control over the motor's performance. This may be crucial in vacuum pump applications where the required negative pressure may vary based on the specific requirements of the process or task at hand. These different methods provide effective means to control the motor's torque and speed, and the relationship between the two depend on the electrical impedance of the motor. A POSITA would have this knowledge available to enabling the tailored generation of negative pressure levels necessary for the applications described in the '534 patent, and would have appreciated that the disclosure of *Bitel* encompassed

these core concepts of the interrelationship of voltage, current, and torque discussed herein.

164. This is because the amount of current or voltage supplied to an electric motor is proportional to the amount of torque applied on the motor's shaft and therefore the amount of negative pressure generated by the vacuum pump being driven by the electric motor. *See supra*, ¶¶161–63.

165. Furthermore, electric motors were known for over one-hundred years before the priority date of the '534 Patent. Since their advent, such motors have been controlled by varying the voltage and current.

166. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 6 (vacuum therapy system 10), wherein said controller (a controller) controls the electric current or the voltage of said motor (“any type of mechanism for providing negative pressure such as an electrically operated or manual pump”) to control said level of said negative pressure in said confined volume (volume under the bandage 16).

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

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

167. *Bitel* teaches the vacuum system according to claim 6, as previously described. Additionally, *Bitel* teaches “the vacuum source comprises a vacuum

pump and associated controls, the pump being connected to the receptacle.” Ex. 1009, 11:24–25. The pump may be “electrically operated.” *Id.*, 6:31–33. Further, *Bitel* teaches “a controller [] for controlling the amount and rate of negative pressure to be applied to the wound, for example.” *Id.*, 7:11–12.

168. A POSITA would have understood that a mechanism for “controlling the amount and rate of negative pressure to be applied to the wound,” as described by *Bitel*, would have included controlling the torque of the electric motor of *Bitel*’s electrically operated pump. *See supra*, ¶¶161–63.

169. This is because the amount of torque applied on a motor’s shaft is proportional to the amount of negative pressure generated by the vacuum pump being driven by the electric motor. *See supra*, ¶¶161–63.

170. As previously stated, electric motors were invented and have been known since well before the priority date of the ’534 Patent. Since the advent of electric motors, they have been controlled by setting a torque value and varying the voltage and current to match the set torque value. Therefore, a POSITA would understand *Bitel* as disclosing these concepts.

171. In this way, it is my opinion *Bitel* teaches the vacuum system according to claim 6 (vacuum therapy system 10), wherein said controller (controller) controls the torque of said motor (“any type of mechanism for providing negative pressure

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

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

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

172. *Bitel* teaches the vacuum system according to claim 1, as previously described. Additionally, *Bitel* teaches “an air vent 64 to provide communication between interior cavity 42 of receptacle 18 and the outside atmosphere.” Ex. 1009, 6:22–23. “[T]he receptacle includes an air vent to allow an inner area of the receptacle to communicate with the surrounding atmosphere.” *Id.*, 10:21-23.

173. A POSITA would have understood the system of *Bitel* to operate in the following manner, consistent with the limitations of Claim 9. When the vacuum source 21 of *Bitel* is turned on, the system 10 is under negative pressure. When the vacuum source 21 is turned off, the air vent 64 of the receptacle 18 of *Bitel* would permit the ingress of ambient air into the vacuum therapy system 10 first via the receptacle 18, and then through the first tube 24 to the confined volume between the bandage 16 and the patient’s wound, therefore restoring ambient pressure in that volume. In other words, after a sufficient amount of time has passed following deactivation of the vacuum source 21, the system 10 will equalize to the ambient air pressure by virtue of air vent 64.

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

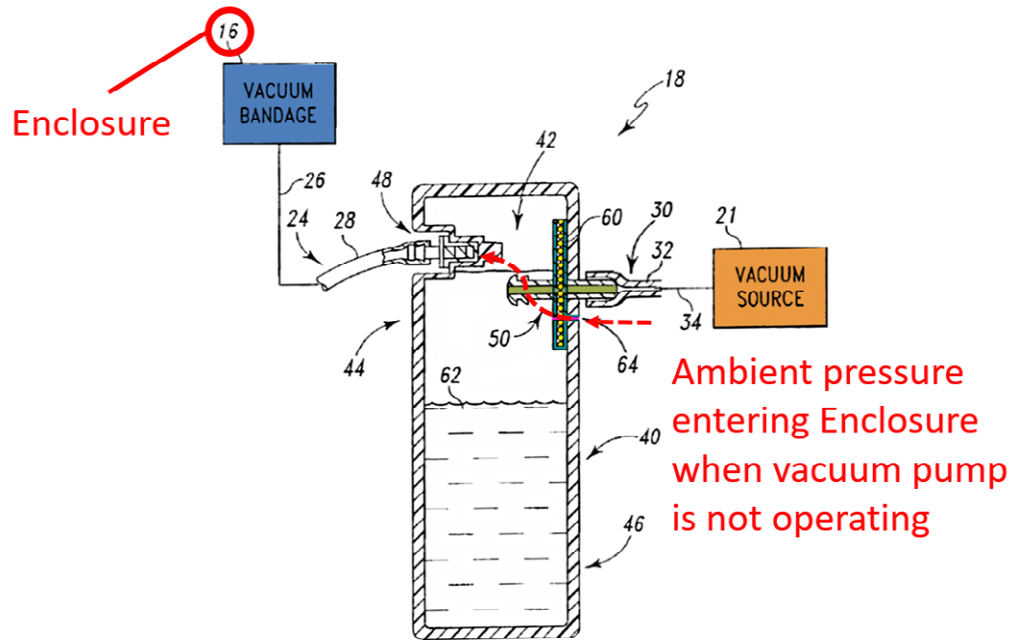


Fig. 5

Ex. 1009, Fig. 5.

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

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

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

176. *Bitel* teaches the vacuum system according to claim 1, as previously described.

177. Additionally, it is my opinion that venting arrangement of *Bitel*—i.e., the air vent 64 and hydrophobic filter 60—includes a bleeding hole, a porous body, and an orifice.

178. Specifically, the air vent 64 of *Bitel* constitutes “one or more bleeding holes” as claimed because the air vent 64 is a hole in the side of the receptacle 18 that allows for the introduction of ambient air into the system 10. Ex. 1009, 6:23–25, Fig. 5.

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

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

181. In this way, it is my opinion that *Bitel* teaches the vacuum system according to claim 1 (vacuum therapy system 10), wherein said venting arrangement (air vent 64 and hydrophobic filter 60) comprises at least one of: one or more

bleeding holes (air vent 64); a porous body (hydrophobic filter 60); and an orifice (air vent 64).

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

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

182. *Bitel* teaches a vacuum system for applying negative pressure to a wound, as previously described.

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

183. *Bitel* teaches the vacuum system comprising an enclosure, a venting arrangement, a tube, a vacuum source, and a controller, as previously described.

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

184. *Bitel* teaches the enclosure being attachable to a periphery of the wound so as to define a confined volume, as previously described.

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

185. *Bitel* teaches the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume, as previously described.

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

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

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

188. 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 second tube 30 via the air vent 64, hydrophobic filter 60, and outlet port 50 without entering the bandage 16.

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

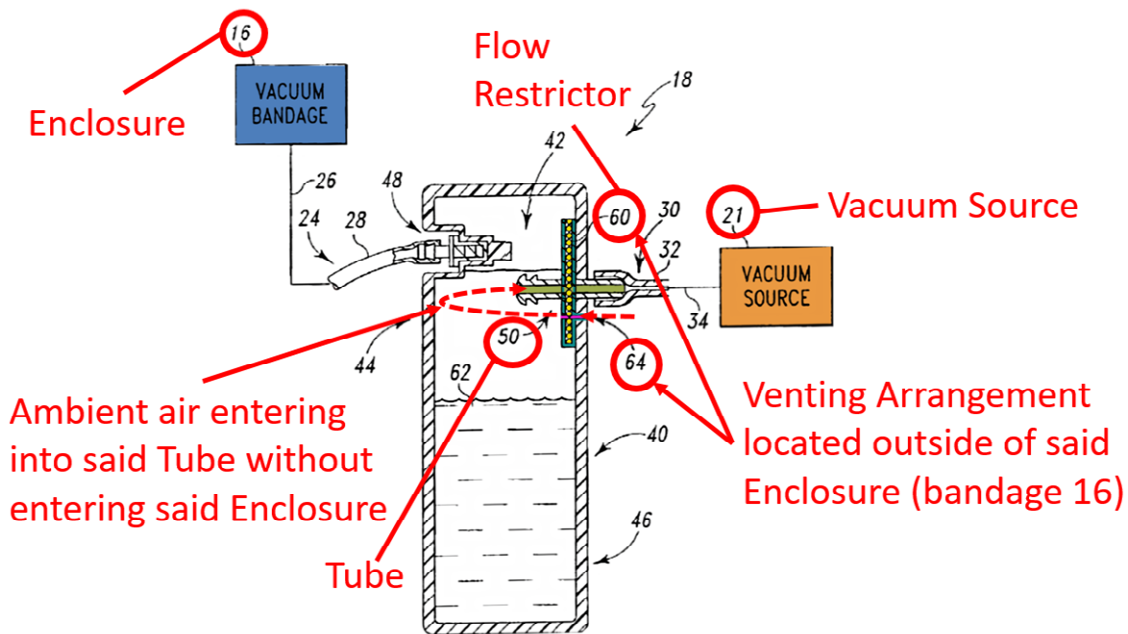


Fig. 5

Ex. 1009, Fig. 5.

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

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

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

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

193. In this way, it is my opinion that *Bitel* teaches the controller configured for controlling (controller, no reference numeral assigned) operation of the vacuum

source (vacuum source 21) while said tube (outlet port 50) is being vented via said venting arrangement (air vent 64 and hydrophobic filter 60) to provide a desired level of said negative pressure in said confined volume (bandage 16).

194. Therefore, it is my opinion that *Bitel* teaches each and every limitation of claim 11.

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

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

195. *Bitel* teaches the vacuum system according to Claim 11, as previously described.

196. *Bitel* also teaches a sensor for enabling determination of a level of said negative pressure in said confined volume, as previously described.

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

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

197. *Bitel* teaches the vacuum system according to Claim 11, as previously described.

198. *Bitel* also teaches a waste container in fluid communication with said vacuum source, as previously described.

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

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

199. *Bitel* teaches the vacuum system according to Claim 11, as previously described.

200. *Bitel* also teaches said vacuum source comprises a vacuum pump driven by a motor, as previously described.

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

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

201. *Bitel* teaches the vacuum system according to Claim 14, as previously described.

202. *Bitel* also teaches said motor is an electric motor, and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume, as previously described.

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

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

203. *Bitel* teaches the vacuum system according to Claim 15, as previously described.

204. *Bitel* also teaches said controller controls at least one of the electric current of said motor, or the voltage of said motor to control said level of said negative pressure in said confined volume, as previously described.

205. *Bitel* further teaches said controller controls the torque of said motor to control said level of said negative pressure in said confined volume, as previously described.

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

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

206. *Bitel* teaches the vacuum system according to Claim 11, as previously described.

207. *Bitel* also teaches wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating, as previously described.

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

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

208. *Bitel* teaches the vacuum system according to Claim 11, as previously described.

209. *Bitel* also teaches wherein the venting arrangement comprises at least one of: one or more bleeding holes, a porous body, an orifice, as previously described.

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

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

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

211. In this way, it is my opinion that *Bitel* teaches a method (“a method for treating a wound”) for applying negative pressure to a wound (“a vacuum can be formed”).

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

212. *Bitel* teaches providing a vacuum system, as previously described.

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

213. *Bitel* teaches providing a vacuum system having at least an enclosure, a venting arrangement, a tube, and a vacuum source, as previously described.

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

214. *Bitel* teaches the enclosure being attachable to a periphery of the wound so as to define a confined volume, as previously described.

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

215. *Bitel* teaches the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume, as previously described.

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

216. *Bitel* teaches the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said system upstream of the vacuum source, as previously described.

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

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

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

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

219. In this way, it is my opinion that *Bitel* teaches controlling operation (via controller, no reference numeral assigned) of the vacuum source (vacuum source 21) while the vacuum system (wound treatment system 10) is being vented via the venting arrangement (air vent 64 and hydrophobic filter 60) to thereby provide a desired level of said negative pressure in said confined volume (bandage 16).

220. Therefore, it is my opinion that *Bitel* teaches each and every limitation of claim 19.

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

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

221. *Bitel* teaches the method according to claim 19, as previously described.

222. Further, *Bitel* teaches the vacuum source comprising a vacuum pump driven by an electric motor, as previously described.

223. *Bitel* further teaches controlling operation of said motor to thereby provide a desired level of said negative pressure in said confined volume, as previously described.

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

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

224. *Bitel* teaches the method according to claim 20, as previously described.

225. *Bitel* also teaches said controller controlling at least one of the electric current or the voltage of said motor to control said level of said negative pressure in said confined volume, as previously described.

226. *Bitel* further teaches said controlling the torque of said motor to control said level of said negative pressure in said confined volume, as previously described.

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

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

227. *Bitel* teaches the method according to claim 19, as previously described.

228. Additionally, *Bitel* teaches said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice, as previously described.

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

Executed on May 25, 2024.

By: Morten G. J. Jensen
Dr. Morten Jensen