

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDELA LLC and MEDELA AG,
Petitioners

v.

M.E.A.C. ENGINEERING LTD.,
Patent Owner

Case No. IPR2024-01076

U.S. Patent No. 8,858,534 B2

Filing Date: June 14, 2013
Issue Date: October 14, 2014

Title: WOUND CLOSURE AND DRAINAGE SYSTEM

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,858,534 B2**

Table of Contents

I. Introduction	1
II. Mandatory Notices under 37 CFR § 42.8(a)(1)	1
A. Real Parties-In-Interest under § 42.8(b)(1)	1
B. Related Matters under § 42.8(b)(2)	1
C. Lead and Back-Up Counsel under § 42.8(b)(3)	2
D. Service Information under § 42.8(b)(4)	3
III. Fee Payment Under 37 CFR § 42.103	3
IV. Requirements Under 37 CFR §§ 42.104 and 42.108	3
A. Grounds for Standing	3
B. Identification of Challenge and Statement of Precise Relief Requested	3
C. Considerations Under 35 U.S.C. § 325(d)	4
D. The Board Should Not Exercise its Discretion Under 35 U.S.C. § 314(a) to Deny Institution	6
V. Technical Background and State of the Art	9
A. Negative Pressure Wound Therapy was Well-Known at the Time of Invention	9
B. The Role of Ambient Air in NPWT Systems	10
C. Motors Are Used to Control NPWT Pumps	11
VI. Overview of the '534 Patent	12
A. Level of Ordinary Skill in the Art	12
B. Priority Date	12
C. Specification	12
D. The Challenged Claims	13
E. Claim Listing	13
VII. Claim Construction	14
VIII. The Challenged Claims are Invalid	
14	
A. Summary and Date Qualification of the Prior Art	14
1. Risk (Ex. 1003)	14
2. Watson (Ex. 1004)	15

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534 B2

3. Lina (Ex. 1005)	16
4. Hunt (Ex. 1006).....	17
5. Dolliver (Ex. 1007)	18
B. Ground 1: Obviousness of Claims 1-5, 9, 10, 19, and 22 Based on Risk in View of Watson.....	19
1. Claim 1	19
2. Claim 2	33
3. Claim 3	33
4. Claim 4	34
5. Claim 5	35
6. Claim 9	36
7. Claim 10	36
8. Claim 19	37
9. Claim 22	38
C. Ground 2: Obviousness of Claims 6-8, 20, and 21 Based on Risk in View of Watson and Lina.....	38
1. Claim 6	38
2. Claim 7	43
3. Claim 8	44
4. Claim 20	45
5. Claim 21	46
D. Ground 3: Anticipation of Claims 1-6, 9-15, 17-20, and 22 By Hunt	46
1. Claim 1	46
2. Claim 2	54
3. Claim 3	56
4. Claim 4	57
5. Claim 5	57
6. Claim 6	57
7. Claim 9	59
8. Claim 10	59

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534 B2

9. Claim 11	60
10. Claim 12	64
11. Claim 13	64
12. Claim 14	64
13. Claim 15	64
14. Claim 17	64
15. Claim 18	65
16. Claim 19	65
17. Claim 20	66
18. Claim 22	67
E. Ground 4: Obviousness of Claims 7-8, 16, and 21 Based on Hunt in View of Lina.....	67
1. Claim 7	67
2. Claim 8	69
3. Claim 16	70
4. Claim 21	70
F. Ground 5: Obviousness of Claims 11-18 Based on Hunt in View of Lina and Dolliver	71
1. Claim 11	71
2. Claim 12	78
3. Claim 13	78
4. Claim 14	79
5. Claim 15	79
6. Claim 16	79
7. Claim 17	79
8. Claim 18	80
IX. Secondary Considerations.....	81
X. Conclusion.....	81

List of Exhibits

Exhibit No.	Description of Document
1001	U.S. Patent No. 8,858,534 B2 to Carmeli Adahan (Application filed June 14, 2013, issued October 14, 2014)
1002	Declaration of John M. Collins, Ph.D
1003	U.S. Patent No. 6,764,462 to James R. Risk, et al. (Application filed May 31, 2002, issued July 20, 2004)
1004	U.S. Patent No. 7,790,945 to Richard L. Watson, Jr. (Application filed April 5, 2004, issued September 7, 2010)
1005	U.S. Patent No. 6,695,823 to Cesar Z. Lina, et al. (Application filed April 7, 2000, issued February 24, 2004)
1006	U.S. Patent No. 6,142,982 to Kenneth William Hunt, et al. (Application filed May 13, 1998, issued November 7, 2000)
1007	U.S. Patent Application Publication No. US 2005/0192548 to Phillip B. Dolliver, et al. (Application filed February 26, 2004, published September 1, 2005)
1008	'534 Patent Claim Listing
1009	Complaint, <i>M.E.A.C. Engineering Ltd. v. Medela, LLC, et al.</i> , Case No. 1:23-cv-14045 (N.D. Ill.)
1010	U.S. Patent No. 8,506,554 B2 to Carmeli Adahan (Application filed July 24, 2005, issued August 13, 2013)
1011	File History of U.S. Patent No. 8,858,534
1012	File History of U.S. Patent No. 8,506,554
1013	Northern District of Illinois Time-to-Trial Statistics, Lex Machina, available at https://law.lexmachina.com/court/ilnd/cases?pending-from=2009-01-

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534 B2

Exhibit No.	Description of Document
	01&filters=true&view=analytics&tab=timing&cols=475 (last accessed June 14, 2024)
1014	Medela Answer and Counterclaims, <i>M.E.A.C. Engineering Ltd. v. Medela LLC, et al.</i> , Case No. 1:23-cv-14045 (N.D. Ill.)
1015	Christine Miller, “The History of Negative Pressure Wound Therapy (NPWT): From ‘Lip Service’ to the Modern Vacuum System,” <i>J. Am. Coll. Clin. Wound Spec.</i> 4: 61-62 (2014)
1016	U.S. Patent No. 1,889,425 to George L. Sorenson (Application filed March 2, 1931, issued November 29, 1932)
1017	U.S. Patent No. 3,026,874 to R.C. Stevens (Application filed November 6, 1959, issued March 27, 1962)
1018	U.S. Patent No. 4,569,674 to Earl G. Phillips, et al. (Application filed August 3, 1982, issued February 11, 1986)
1019	Michael J. Morykwas, Louis C. Argenta, Eric I. Shelton-Brown, Wyman McGuirt, “Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Animal Studies and Basic Foundation,” <i>Annals of Plastic Surgery</i> , Vol. 38, No. 6 (June 1997)
1020	U.S. Patent No. 7,678,102 to Keith Patrick Heaton (PCT Application filed November 8, 2008, issued March 16, 2010)
1021	U.S. Patent No. 6,071,267 to David S. Zamierowski (Application filed February 6, 1998, issued June 6, 2000)
1022	U.S. Patent No. 5,735,833 to Daniel H. Olson (Application filed December 11, 1996, issued April 7, 1998)
1023	U.S. Patent Publication No. 2003/0125649 to Laura Janet McIntosh, et al. (Application filed October 29, 2002, published July 3, 2003)
1024	U.S. Patent No. 7,708,724 to Richard Scott Weston (Application filed April 4, 2005, issued May 4, 2010)

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534 B2

Exhibit No.	Description of Document
1025	Richard F. Edlich, et al., “Evaluation of a New, Improved Surgical Drainage System,” Dep’t Plastic Surgery, U. of Va., New Instruments, Vol. 149 (February 1995)
1026	U.S. Patent No. 6,241,739 to Stephen H. Waldron (Application filed November 12, 1999, issued June 5, 2001)
1027	U.S. Patent No. 6,045,516 to James Phelan (Application filed December 18, 1998, issued April 4, 2000)
1028	U.S. Patent No. 7,955,318 to Joseph P. Schultz, et al. (Provisional Application filed July 16, 2004, Application filed July 11, 2005, issued June 7, 2011)
1029	M.H. Worth, et al., “The Effectiveness of Bacterial Filtration in Vented Wound Drains,” N.Y.U. School of Medicine (Jan. 29, 1979)
1030	U.S. Patent No. 5,549,584 to James R. Gross (Application filed February 14, 1994, issued August 27, 1996)
1031	U.S. Patent No. 6,135,116 to Richard C. Vogel et al. (Application filed July 30, 1997, issued October 24, 2000)
1032	U.S. Patent No. 4,795,448 to Gary R. Stacey et al. (Application filed December 30, 1987, issued January 3, 1989)

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534

I. INTRODUCTION

Petitioners Medela LLC and Medela AG respectfully submit this Petition for *Inter Partes* Review of claims 1-22 (the “Challenged Claims”) of U.S. Patent No. 8,858,534 (the “’534 patent”) (EX1001). Petitioners request institution of *Inter Partes* Review (“IPR”) and a finding that all Challenged Claims are unpatentable.

II. MANDATORY NOTICES UNDER 37 CFR § 42.8(A)(1)

A. Real Parties-In-Interest under § 42.8(b)(1)

Medela LLC and Medela AG (collectively, “Petitioners”) are the real parties-in-interest to this IPR petition.

B. Related Matters under § 42.8(b)(2)

The ’534 patent is asserted in pending litigation involving Petitioner Medela LLC and Patent Owner, *M.E.A.C. Engineering Ltd. v. Medela, LLC, et al.*, Case No. 1:23-cv-14045 (N.D. Ill.). The complaint in the related case was first served on Medela LLC on November 1, 2023. (EX1009). There are three other related cases involving Patent Owner and the ’534 patent: (1) *MEAC Engineering LTD v. Solventum Corp.*, Case No. 5:23-cv-01256 (W.D. Tex.); (2) *MEAC Engineering LTD v. Cardinal Health, Inc.*, Case No. 1:23-cv-16471 (N.D. Ill.); and (3) *MEAC Engineering LTD v. Molnlycke Health Care AG*, Case No. 1:24-cv-00179 (N.D. Ga.). The complaints in these three actions were filed on October 5, 2023, December 4, 2023, and January 12, 2024, respectively. Solventum Corp. filed an *inter partes*

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534 B2

review proceeding challenging all claims of the '534 Patent on June 5, 2024. PTAB-IPR2024-01002.

Petitioners have concurrently filed a petition for *Inter Partes* review of a related patent also asserted in the pending litigation: IPR2024-01075.

C. Lead and Back-Up Counsel under § 42.8(b)(3)

Petitioners provide the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
Erik B. Milch (Reg. No. 42,887) emilch@proskauer.com Proskauer Rose LLP 1001 Pennsylvania Ave., NW Suite 600 Washington, DC 20004 Tel: (202) 416-6800	Elizabeth Shrieves <i>Pro hac vice</i> (application to be filed) eshrieves@proskauer.com Proskauer Rose LLP 1001 Pennsylvania Ave., NW Suite 600 Washington, DC 20004 Tel: (202) 416-6800
	Joseph Drayton <i>Pro hac vice</i> (application to be filed) jdrayton@proskauer.com Proskauer Rose LLP Eleven Times Square New York, NY 10036 Tel: (212) 969-3000
	Baldassare Vinti (Reg. No. 43,970) bvinti@proskauer.com Proskauer Rose LLP Eleven Times Square New York, NY 10036 Tel: (212) 969-3000

D. Service Information under § 42.8(b)(4)

This Petition is being served by Federal Express to the attorney of record for the '534 patent, Erik Lund, Whitestone Law, PLLC, 1850 Towers Crescent Plaza, Suite 550, Tysons, VA 22182. Petitioners consent to electronic service at the addresses provided above for lead and back-up counsel.

III. FEE PAYMENT UNDER 37 CFR § 42.103

Petitioners request review of 22 claims, with a \$43,750 payment.

IV. REQUIREMENTS UNDER 37 CFR §§ 42.104 AND 42.108

A. Grounds for Standing

Petitioners certify the '534 patent is available for IPR and Petitioners are not barred or otherwise estopped.

B. Identification of Challenge and Statement of Precise Relief Requested

Petitioners request the Board institute IPR of claims 1-22 based on:

Ground	'534 Patent Claims	Basis for Challenge (35 U.S.C. §§ 102, 103)	Application of Prior Art
1	1-5, 9-10, 19, 22	§ 103	Risk in view of Watson
2	6-8, 20-21	§ 103	Risk in view of Watson and Lina
3	1-6, 9-15, 17-20, 22	§ 102	Hunt
4	7-8, 16, 21	§ 103	Hunt in view of Lina
5	11-18	§ 103	Hunt in view of Dolliver and Lina

Submitted with this Petition is the Declaration of John M. Collins, Ph.D. (“Collins”) (EX1002), a qualified technical expert.

C. Considerations Under 35 U.S.C. § 325(d)

This Petition does not present a situation in which “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). After receiving the initial application, the patent examiner issued a Non-Final Rejection for non-statutory double patenting over U.S. Patent No. 8,506,554 (the “’554 patent”) (EX1010). (EX1011, 146). In response, applicant filed a terminal disclaimer to the ’554 patent. (*Id.*, 123-35). On June 18, 2014, a notice of allowance was issued for claims 1-22 of the ’534 application. (*Id.*, 28-34).

The ’534 patent is a continuation of the ’554 patent, which issued on August 13, 2013. (EX1010). During prosecution of the ’554 application, applicant received rejections, in response to which applicant amended the claims. The examiner issued a Non-Final Rejection on October 14, 2010, finding the claims anticipated by Lerman. (EX1012, 954-961). Applicant amended the claims to require “applying negative pressure” through a tube including a “venting arrangement, outside of said enclosure, such that ambient air can enter said tube via said venting arrangement.” (*Id.*, 620-639).

The examiner next issued a Final Rejection over different prior art references, Lockwood and Argenta, on April 20, 2011. (*Id.*, 575-584). To traverse the rejection,

applicant clarified that ambient air in Lockwood's disclosed system necessarily "**has to flow over the wound**" which is in contrast to the amended claims which require that ambient air "goes **directly** to the pump under suction *without passing through the enclosure*" (*Id.*, 498 (emphasis in original)).

On October 11, 2011, the examiner issued another Non-Final Rejection over Lockwood in view of Leffler and Argenta based on Leffler's disclosure of "a venting arrangement outside of the wound area." (*Id.*, 432-438). In response, applicant argued Leffler's system "would destroy the operation of Lockwood's device" and, thus, there would be no motivation to combine the two. (*Id.*, 349-355). Applicant then agreed to add the claim limitation: "comprising a calibrated orifice to restrict flow through the venting arrangement located outside said enclosure" to overcome the examiner's rejection. (*Id.*, 319). Applicant amended the claims again, modifying the examiner's amendment above to recite a "flow restrictor". (*Id.*, 48).

The prior art references identified in this Petition were never discussed nor analyzed during prosecution of the '534 or '554 patents, however, some were disclosed to the Patent Office. Dolliver was disclosed along with certain patents and publications that are related to Hunt, Risk, and Watson. Lina was not disclosed during prosecution and is not listed on the face of the '534 patent. None of the other cited prior art references, discussed in this Petition to evidence the state of the art at the time of invention, were discussed or analyzed during prosecution.

D. The Board Should Not Exercise its Discretion Under 35 U.S.C. § 314(a) to Deny Institution

Some of the Challenged Claims are presently asserted by Patent Owner in the parallel district court litigation. In *Apple v. Fintiv* (Paper 11), the Board issued precedential guidance on six non-dispositive factors to be considered when there is a co-pending district court litigation (“*Fintiv* Factors”). Taken as a whole, these factors weigh against exercising discretion to deny institution.

***Fintiv* Factor 1: Whether the court granted a stay or evidence exists that one may be granted if the proceeding is instituted.** Petitioner Medela LLC has not yet moved for a stay in the co-pending litigation; therefore, *Fintiv* Factor 1 is neutral. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019 (Paper 12) (PTAB Dec. 1, 2020) at 14; *Sand Revolution II, LLC v. Continental Intermodal Grp. Trucking LLC*, IPR2019-01393 (Paper 24) (PTAB June 16, 2020). The court, however, indicated a willingness to grant a stay once IPR Petitions are filed, which weighs in favor of not exercising discretion to deny institution.

***Fintiv* Factor 2: Proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision.** The co-pending litigation is in its early stages and, at the time of filing this Petition, the parties have only exchanged initial disclosures, infringement, and invalidity contentions. The parties have not engaged in any other discovery. The court has yet to set a trial date

and there are no deadlines set after fact discovery. Based on the court's estimated case schedule, however, a trial is not likely to occur before December 26, 2025. Additionally, the Northern District of Illinois' median time-to-trial is 1,007 days. (EX1013). Thus, the likely trial date based on the median time-to-trial is not until June 29, 2026. The projected statutory deadline for a final written decision is December 22, 2025. Thus, this factor weighs in favor of not exercising discretion to deny institution.

***Fintiv* Factor 3: Investment in the parallel proceedings by the court and the parties.** This factor also weighs in favor of not exercising discretion to deny institution. Petitioners filed this petition expeditiously, well in advance of the 1-year statutory deadline. The district court case is in its early stages as the parties have not begun discovery and no scheduling order past fact discovery has been entered. Where, as here, a petitioner files "promptly after becoming aware of the claims being asserted, this fact has weighed against exercising discretion to deny institution." *Fintiv, Inc.*, IPR2020-00019 (Paper 11) at 10.

Moreover, the district court has expended minimal resources to this case. The court has not yet considered any substantive issues or arguments relating to the '534 patent. The date for the claim construction hearing is not yet set, but based on the court's estimated patent schedule, a *Markman* hearing will not occur until January 2025.

***Fintiv* Factor 4: Overlap between issues raised in the petition and the parallel proceeding.** This factor weighs in favor of not exercising discretion to deny institution. Medela LLC's invalidity contentions featured a system art primary reference, Kinetic Concepts, Inc.'s VAC system that is identified in its counterclaims. (EX1014 at 24, 30). For full and complete disclosure, Medela LLC also included prior art within this Petition in its invalidity contentions, but if this Petition is instituted, Medela LLC stipulates that it will not rely on any grounds in the district court that were raised or reasonably could have been raised in this Petition. The Board has held that where Petitioner so stipulates, this factor weighs in favor of not exercising discretion to deny institution. *See Sotera Wireless, Inc.*, IPR2020-01019 (Paper 12), at 18-19; *San Revolution II, LLC*, IPR2019-01393 (Paper 24), at 12.

***Fintiv* Factor 5: Whether the petitioner and the defendant in the parallel proceedings are the same party.** Medela LLC is the defendant in the parallel proceeding; however, this factor alone should not be dispositive. *See Sand Revolution II, LLC*, IPR2019-01393 (Paper 24), at 12-14, 57.

***Fintiv* Factor 6: Other circumstances that impact the Board's discretion, including the merits.** This Petition presents a strong case for invalidity of the '534 patent. Director Vidal's Interim Guidance, dated June 21, 2022, indicated that the Board would not exercise discretion to deny institution where a petition presents

compelling evidence of unpatentability. The claims at issue are broad and anticipated and/or rendered obvious by the asserted grounds. Where, as here, a strong case for anticipation and/or obviousness is presented, this factor weighs in favor of not exercising discretion to deny institution. *See Fintiv, Inc.*, IPR2020-00019 (Paper 11), at 14-16; *Sand Revolution II, LLC*, IPR2019-01393 (Paper 24), at 12-14, 57.

Thus, *Fintiv* factors 1-4 and 6 weigh in favor of not exercising discretion to deny institution and only factor 5 favors denying institution. Taken together, the factors weigh in favor of not exercising discretion to deny institution and the merits of this Petition warrant consideration.

V. TECHNICAL BACKGROUND AND STATE OF THE ART

A. Negative Pressure Wound Therapy was Well-Known at the Time of Invention

None of the features described and claimed in the '534 patent are new. Negative pressure wound therapy (“NPWT”) has been used for decades to accelerate wound healing by promoting blood flow and removing exudate from wounds. In fact, such techniques date back to humans sucking on wounds to remove contaminants. (EX1015 at 1; EX1002 ¶39).

As early as the 1930s, the manipulation of pressure levels of suction devices was known. (EX1016; EX1002 ¶40). Vacuum-assisted drainage was in use by 1960

(EX1017), and by the 1980s, the use of negative pressure devices was common. (EX1018 at 1:14-17; EX1002 ¶40).

The more recent types of devices were invented in the 1990s by a group at Wake Forest University. (EX1019; EX1002 ¶41). The Wake Forest concept was commercialized by Kinetic Concepts, Inc. in a product called the “V.A.C.” system. The system used an open-cell polyurethane foam dressing, an exudate removal tube, a canister to collect exudate, and an adjustable vacuum pump generating negative pressure. (EX1002 ¶42).

NPWT devices were well-known in the art by the late 1990s and early 2000s. (EX1003-1006; EX1020; EX1021; EX1002 ¶43). NPWT was “accepted as a highly effective way of improving the rate of healing patients suffering from pressure sores, ulcers, partial thickness burns and wounds that fail to heal quickly after an operation.” (EX1020 at 1:4-14; EX1002 ¶43). Controllers and sensors were used to modulate the level of negative pressure in the system. (EX1003; EX1005-1007; EX1002 ¶43).

B. The Role of Ambient Air in NPWT Systems

One of the dangers of NPWT devices is using too great a negative pressure that could damage tissue or otherwise create a dangerous situation for the patient. (EX1002 ¶44). To mitigate against such risk, NPWT systems often include a vent, valve, or other opening to allow ambient air into the system. (EX1002 ¶45). The

introduction of ambient air into the system can regulate the negative pressure at the wound, restore ambient pressure when the vacuum is turned off, allow air into the wound, and unclog blockages in the tube between the wound dressing and the collection canister. (*Id.*).

Ambient air openings have been used in NPWT systems in different locations. (EX1002 ¶46). For example, several patents disclose a vent on the wound dressing. (EX1003; EX1021-1024; EX1002 ¶46). Others disclose an air opening on the tubing connecting the wound cover to the vacuum source. (EX1003; EX1017; EX1025; EX1002 ¶47). In other cases, the suction tube may include an opening through the wall of the tube that allows air to enter the tube directly. (EX1026-1028; EX1002 ¶47). Other devices include the air opening within the housing of the vacuum system itself, near the pump, such as the air orifice included within the housing of a vacuum system as shown in U.S. Patent. 6,695,823 to Cesar Z. Lina, et al. (EX1005, Fig. 1 (orifice 86); EX1002 ¶48).

C. Motors Are Used to Control NPWT Pumps

NPWT devices use electric motor driven pumps and control systems to control the amount of negative pressure at a wound. (EX1002 ¶50). As Dr. Collins explains, “[m]otors convert input electrical power (proportional to voltage times current) into a pump’s mechanical shaft power (proportional to speed times torque) which generates fluid dynamic power (proportional to flow rate times pressure)”. (EX1002

¶51). Motors can be configured to output desired levels of negative pressure by modulating voltage or current to change the motor speed and applied torque. (EX1002 ¶¶52-54).

VI. OVERVIEW OF THE '534 PATENT

A. Level of Ordinary Skill in the Art

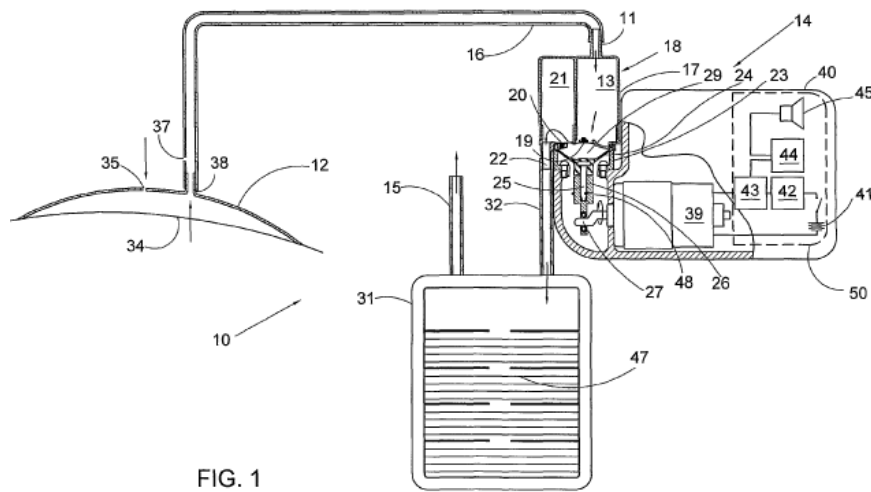
A person of ordinary skill in the art (“POSITA”) as of July 24, 2005 (the presumptive alleged priority date) would have possessed at least a bachelor’s degree in mechanical engineering, biomedical engineering, or a related field with at least two years of experience researching, developing, or practicing with medical pumping systems, including pressure-generating pumps. Additional education could compensate for less practical experience and vice versa. (EX1002 ¶74).

B. Priority Date

Patent Owner has alleged that the priority date for the Challenged Claims is July 24, 2005. Petitioners thus use July 24, 2005 as the priority date for the purposes of this Petition, but do not concede that the Challenged Claims are entitled to that date.

C. Specification

The '534 patent is directed to a vacuum system to drain an open wound that includes a wound enclosure, pump, waste container, and tubing. (EX1001, Abstract). Figure 1 illustrates the disclosed vacuum system.



The vacuum pump is connected to the wound enclosure and waste container so liquids can be drawn from the wound and deposited in the waste container. (*Id.*, 2:41-44, 3:17-22). The specification also teaches “[o]ne or more bleeding holes are provided in the enclosure or adjacent to its outlet such that ambient air can enter the tube and flow together with the exuded liquids when negative pressure is present.” (*Id.*, 2:14-17). The system utilizes “flow restrictors,” including “a hole plugged with open cell foam or an open pore sintered metal plug” to control the flow of air. (*Id.*, 4:40-45).

D. The Challenged Claims

This Petition challenges claims 1-22 of the '534 patent.

E. Claim Listing

Exhibit 1008 is a claim listing enumerating each claim element. Bracketed notations (e.g., [a], [b], etc.) are used to refer to individual limitations.

VII. CLAIM CONSTRUCTION

For purposes of the prior art cited herein, Petitioners do not, at this time, contend that any term requires express construction. All terms should be accorded their plain and ordinary meaning. Petitioners consider the plain and ordinary meanings for these terms without conceding the claims satisfy 35 U.S.C. § 112. Patent Owner has not affirmatively stated any specific constructions for these claim terms. Should Patent Owner disagree with Petitioners' applied meaning, or subsequently change its interpretations, Petitioners reserve the right to address such constructions. Should the Board apply a specific construction to any terms of the '534 patent, Petitioners reserve the right to address those constructions and revise their arguments regarding the relevant claim limitations for the cited prior art.

VIII. THE CHALLENGED CLAIMS ARE INVALID

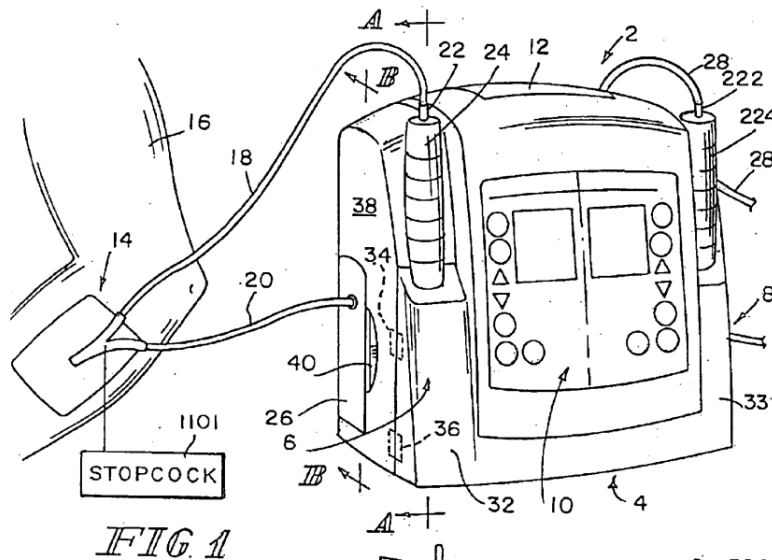
As detailed below, claims 1-22 of the '534 patent are anticipated by and/or obvious in view of the identified prior art.

A. Summary and Date Qualification of the Prior Art

1. Risk (Ex. 1003)

U.S. Patent No. 6,764,462 to James R. Risk, et al. ("Risk") is a patent entitled "Wound Treatment Apparatus," filed May 31, 2002, issued July 20, 2004, and qualifies as prior art under 35 U.S.C. §§ 102(a), (b), and (e) (pre-AIA).

Risk discloses a portable wound therapy system that provides vacuum treatment to a patient. (EX1003, Abstract, Fig. 1).



Risk teaches that the vacuum pump is coupled to a bandage on the patient's wound using evacuating tubes which remove exudate from the wound, which is deposited into a waste canister. (*Id.*, 4:21-43). The disclosed bandage over the wound has a vent to the atmosphere. (*Id.*, 14:63-15:4). The system includes a control unit, including sensors, to operate the pump and monitor the system's status. (*Id.*, 5:21-24, 7:39-8:12).

2. Watson (Ex. 1004)

U.S. Patent No. 7,790,945 to Richard L. Watson, Jr. ("Watson") is a patent entitled "Wound Dressing with Absorption and Suction Capabilities," filed April 5, 2004, issued September 7, 2010, and qualifies as prior art under 35 U.S.C. § 102(e) (pre-AIA).

Watson discloses a wound dressing connected to a vacuum source via a tube to promote healing. (EX1004, Abstract, Fig. 2).

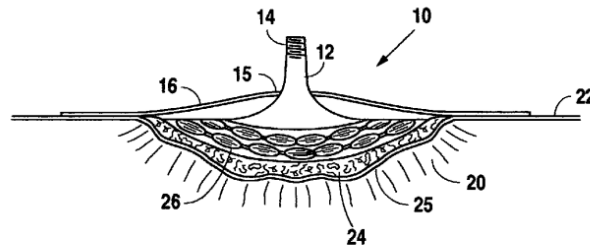


Fig. 2

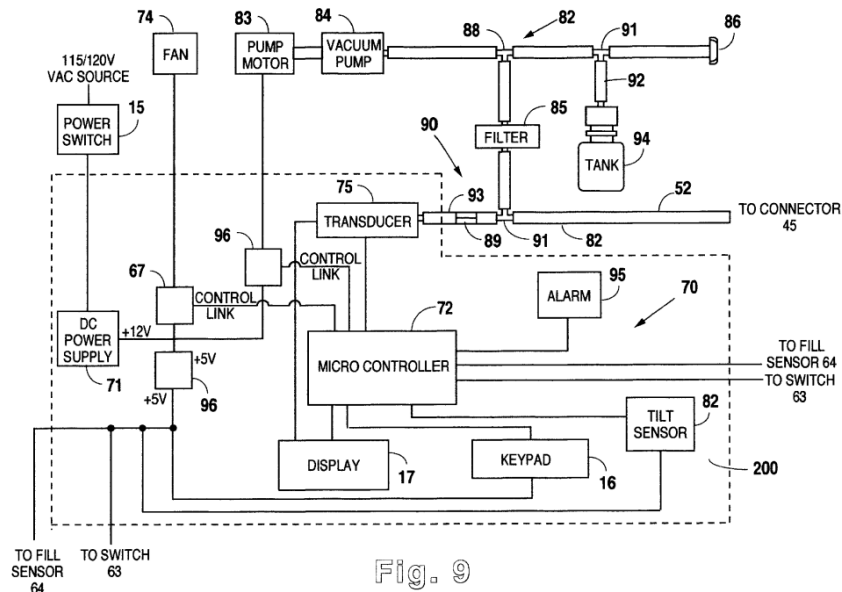
The wound cover effectively seals the wound but is “semi-permeable” and “allows air to pass through it so that the wound can breathe, which aids the healing process, but does not allow undesirable things, such as liquids, bacteria, or viruses, to pass through.” (*Id.*, 3:24-41).

3. Lina (Ex. 1005)

U.S. Patent No. 6,695,823 to Cesar Z. Lina, et al. (“Lina”) is a patent entitled “Wound Therapy Device,” filed April 7, 2000, issued February 24, 2004, and qualifies as prior art under 35 U.S.C. §§ 102(a), (b), and (e) (pre-AIA).

Lina discloses a wound closure apparatus with a vacuum pump connected to a wound pad and canister to remove exudate from a wound. (EX1005, Abstract). Lina teaches a controller that operates the vacuum pump, including a voltage regulator to adjust that pump’s speed. (*Id.*, 11:19-12:6, Fig. 9). Lina also teaches the

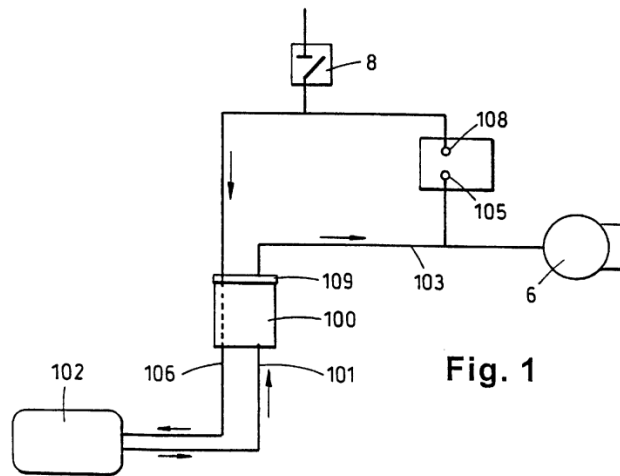
use of sensors to determine the pressure applied at the wound site. (*Id.*, 13:20-50, Fig. 9).



4. Hunt (Ex. 1006)

U.S. Patent No. 6,142,982 to Kenneth William Hunt, et al. (“Hunt”) is a patent entitled “Portable Wound Treatment Apparatus,” filed May 13, 1998, issued November 7, 2000, and qualifies as prior art under 35 U.S.C. §§ 102(a), (b), and (e) (pre-AIA).

Hunt discloses a portable wound treatment system that utilizes tubes to connect the wound dressing to a suction pump and waste canister. (EX1006, Abstract, Fig. 1).



Hunt also teaches a pressure relief valve that allows ambient air to enter the wound treatment system. (*Id.*, 3:63-4:1). The system includes a controller that monitors the system's operation and sensors that determine the amount of suction being applied to the wound. (*Id.*, 1:55-63, 4:9-16).

5. Dolliver (Ex. 1007)

U.S. Patent Application Publication No. 2005/0192548 to Phillip B. Dolliver, et al. ("Dolliver") is a patent publication entitled "Wound Drainage Suction Relief," filed February 26, 2004, published September 1, 2005, and qualifies as prior art under 35 U.S.C. § 102(e) (pre-AIA).

Dolliver discloses a wound drainage system that removes fluid from a patient's wound via a drain catheter that applies suction to the wound. (EX1007, Abstract, Fig. 1).

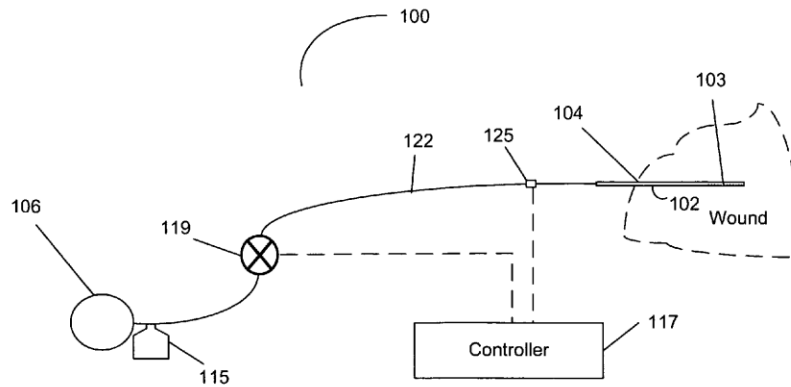


Fig. 1

The drain catheter tubing taught by Dolliver includes a “vent valve” with a filter that is vented to the atmosphere. (*Id.*, [0029]). Dolliver also discloses a controller that operates the suction device. (*Id.*, [0031]).

B. Ground 1: Obviousness of Claims 1-5, 9, 10, 19, and 22 Based on Risk in View of Watson

1. Claim 1

Claim 1 is obvious over Risk in view of Watson.

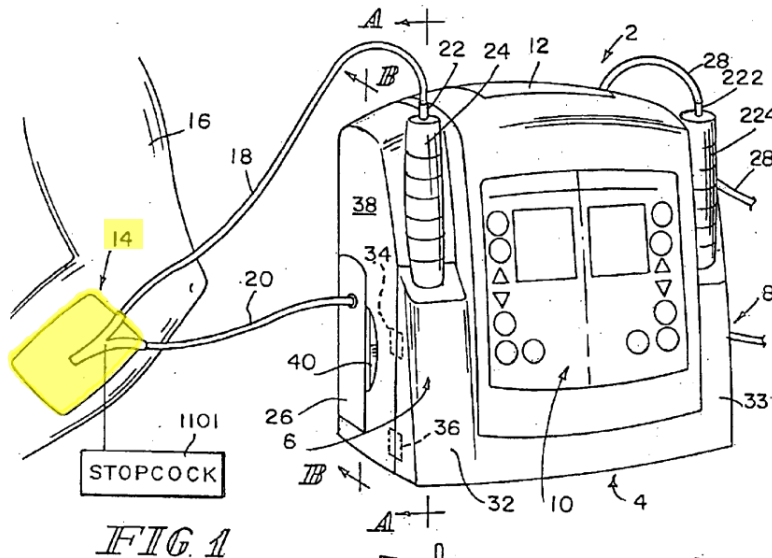
i. Claim 1, Preamble

To the extent the preamble is limiting, it is taught by Risk. The preamble recites “A vacuum system for applying negative pressure to a wound, the vacuum system comprising.” Risk teaches “a wound treatment apparatus” that “provide[s] negative pressure . . . to the wound.” (EX1003, 1:44-48). A POSITA would have understood that Risk’s disclosed apparatus is a vacuum system for applying negative

pressure to a wound. (EX1002 ¶¶129-130). Thus, Risk teaches the preamble of claim 1.

ii. Element 1[a]

Risk discloses “an enclosure, a venting arrangement, a tube, a vacuum source, and a controller.” Risk teaches bandage 14 covers the wound on a patient. (EX1003, 4:30-32, Fig. 1).



(*Id.*, Fig. 1 (annotated)). Bandage 14 includes a cover film 602 which covers and seals the wound. (*Id.*, 11:14-20; Fig. 9). Bandage 14 corresponds to the enclosure recited in element 1[a]. (EX1002 ¶132).

Risk further discloses “bandage 14 has a vent in communication with atmosphere, and air enters interior region 866 through bandage 14” (EX1003, 14:63-15:1). A POSITA would have understood this vent on bandage 14, venting the wound to the atmosphere, as a “venting arrangement” based on the plain and

[illegible]

Risk also teaches a vacuum source. (EX1003, Fig. 32 (“Vacuum Source 110”). The vacuum source in Risk “draws a desired negative pressure through system 6.” (*Id.*, 8:19-20). Thus, Risk discloses a “vacuum source.” (EX1002 ¶136).

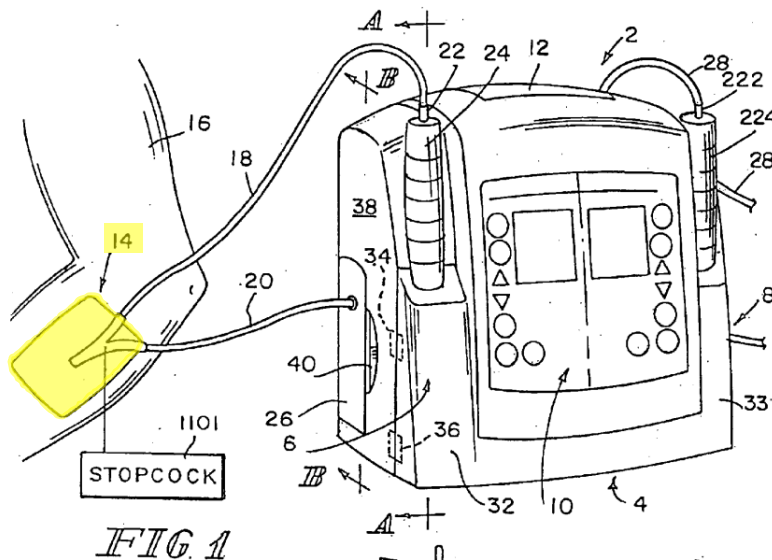
21

cooperate to provide feedback control of the vacuum pressure provided to bandage 14.” (EX1003, 14:35-37).

Thus, Risk teaches element 1[a].

iii. Element 1[b]

Risk teaches “the enclosure being attachable to a periphery of the wound so as to define a confined volume.” As explained above, Risk teaches bandage 14 which corresponds to the claimed “enclosure”. In an embodiment, Risk discloses that “bandage 14 [is] attached to a patient’s leg” (EX1003, 4:30-34), depicted in Figure 1 below.



(*Id.*, Fig. 1 (annotated)).

Additionally, Risk teaches that bandage 14, comprising cover film 602, “seals wound 300 about its outer perimeter.” (*Id.*, 11:14-20). Thus, bandage 14, including cover film 602, operatively seals the wound by attaching to the outer perimeter and

providing “a protective environment.” (*Id.*, 10:47-48; EX1002 ¶¶140-142). The enclosure is depicted in Figure 9 below:

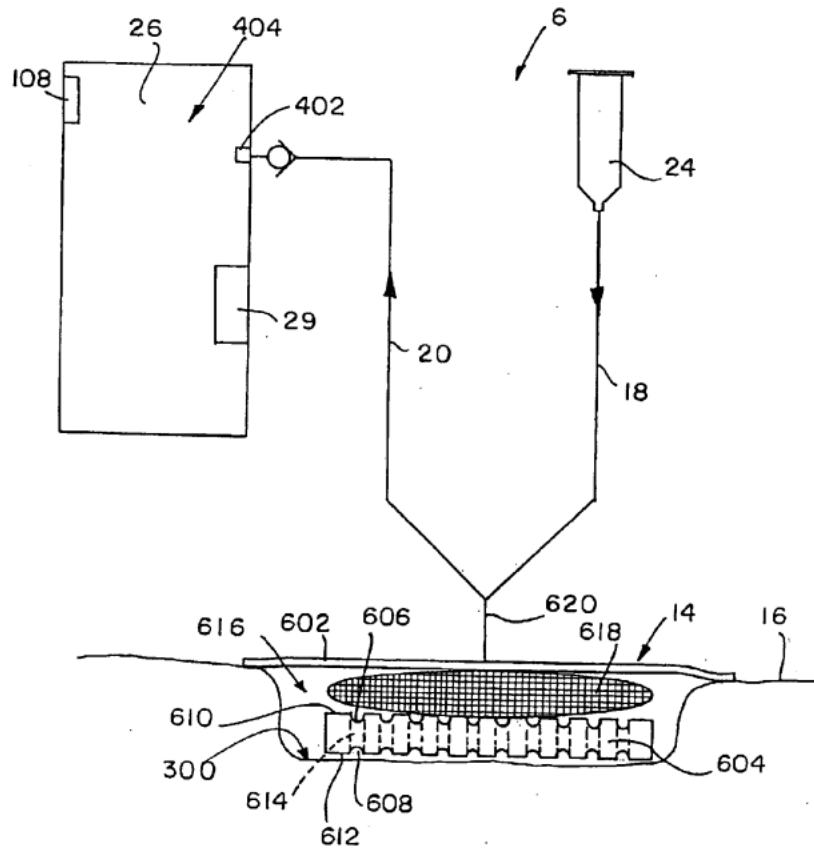


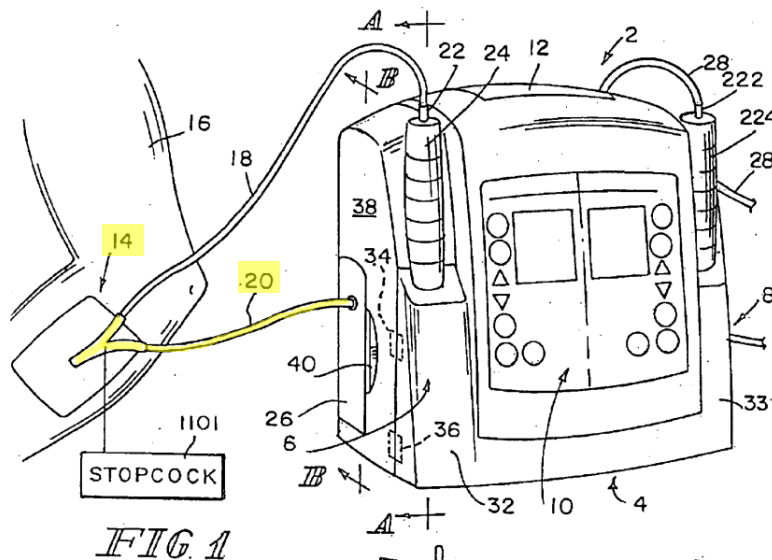
FIG. 9

A POSITA would have understood that bandage 14, which is attachable to the perimeter of a patient's wound, defines a confined volume thereunder. (EX1002 ¶142).

Accordingly, Risk teaches element 1[b].

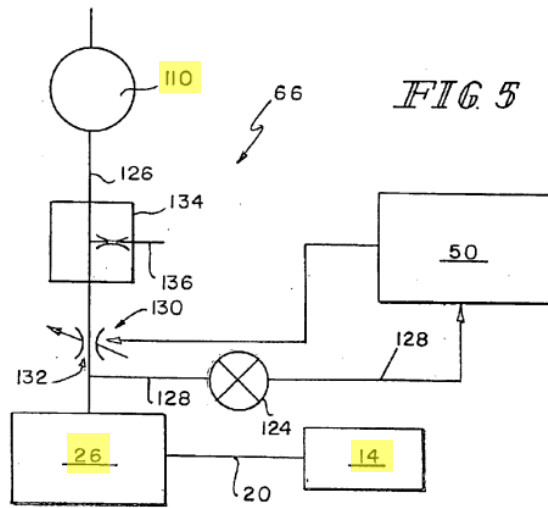
iv. Element 1[c]

Risk discloses “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.” Specifically, Risk explains “[d]ispensing and evacuating tubes 18, 20 are coupled to both bandage 14 and system 6.” (EX1003, 4:32-34). Based on this disclosure and the teachings of Risk, a POSITA would have understood that the enclosure (i.e., bandage 14) necessarily includes an outlet connectable to the vacuum source (within system 6). (EX1002 ¶144). The connection is shown in Figure 1:



(*Id.*, Fig. 1 (annotated)).

As shown above, evacuating tube connects bandage 14 to system 6, which includes a waste canister and vacuum source. (*Id.*, Fig. 1, 10:47-57). Figure 5 depicts the connection between bandage 14 and canister 26, which is connected to vacuum source 110 via tube 126:



(*Id.*, annotated). A POSITA would have understood that vacuum source 110, as shown in Figure 5 above, is operatively connected to bandage 14 (i.e., the enclosure) via tubes 126 and 20—thereby necessarily including an enclosure outlet—because vacuum source 110 applies negative pressure through canister 26 and evacuating tube 20 that travels to bandage 14¹. (EX1002 ¶145; EX1003, 7:31-32 (“Vacuum pump 110 creates the negative pressure that is present through canister 26”); *id.*, 8:58-59 (“Vacuum 110 applies a negative pressure through waste canister 26 and bandage 314”)). This negative pressure is selectively created in Risk, which describes “set[ting] the level of negative pressure” and “choos[ing] between continuous, intermittent (profile), and no negative pressure modes.” (EX1003, 12:8-17).

¹ In certain embodiments of Risk, bandage 14 is referred to as bandage 314.

A POSITA would have understood that element 1[c] does not require a direct connection between the enclosure and vacuum source; therefore, Risk teaches an operative connection between the two. (EX1002 ¶146).

Thus, Risk teaches element 1[c].

v. Element 1[d]

Risk in view of Watson discloses “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.” As explained regarding element 1[a], Risk discloses a “venting arrangement” in the form of a vent on bandage 14. (*See* Part VIII.B.1.ii, *supra*). Although not depicted, Risk explains that bandage 14 is “in communication with the atmosphere, and air enters interior region 866 through bandage 14, line 20, and inlet port.” (EX1003, 14:63-15:1, Fig. 27).

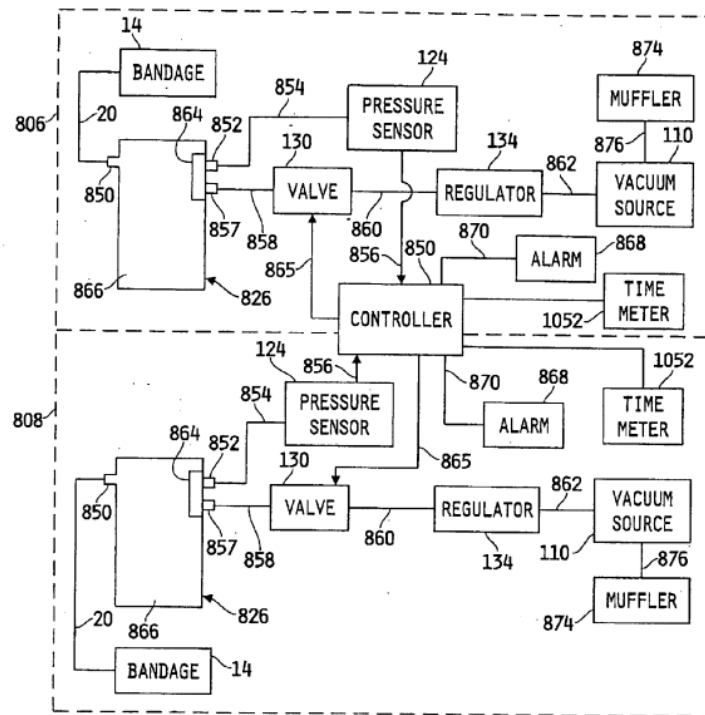
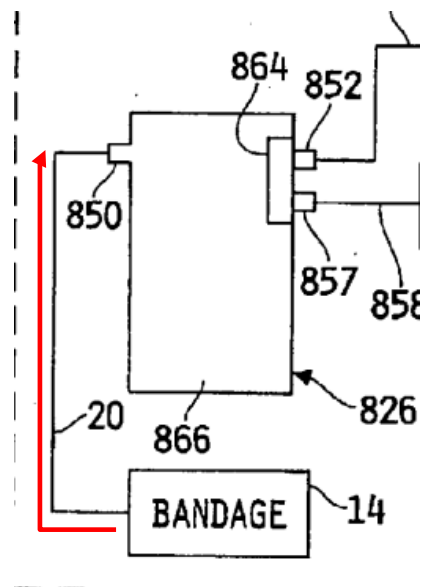


FIG. 27

A POSITA would have understood that this flow of ambient air is upstream of the vacuum source, as depicted below:



(*Id.* (excerpted and annotated); see also EX1002 ¶150).

Combination of Risk and Watson: Risk teaches the use of a “flow restrictor” in other portions of the vacuum system (e.g., Risk discloses proportional valve 130 with flow orifice 132 that “selectively dilates or constricts, thereby controlling the negative pressure level”). (EX1003, 7:43-47). The flow orifice, however, is not part of the bandage vent (i.e., venting arrangement). Although Risk discloses a flow orifice in one part of the system, a POSITA would have known to also include a flow restrictor in conjunction with the bandage vent to enable and control the negative pressure being applied to the wound during treatment, as explained below. (EX1002 ¶¶99-101).

Watson discloses the claimed “flow restrictor” on the bandage that restricts the flow of ambient air entering the system. Watson teaches that its bandage includes “a semi-permeable” cover which “allows air to pass through it”. (EX1004, 3:24-37). Watson explains that the semi-permeable material on the wound cover “allows the wound to breathe while protecting the wound from undesirable substances such as bacteria, viruses, or fluids.” (*Id.*, 1:16-24). A POSITA would have understood that this semi-permeable cover taught by Watson restricts and controls the flow of ambient air into the wound site. (EX1002 ¶¶152-153). Moreover, a POSITA would have considered Watson’s semi-permeable cover to be a “flow restrictor” based on the plain and ordinary meaning of that term as it is used in the ’534 patent. (*Id.* ¶153 (explaining “the semi-permeable material on a wound cover is akin to open cell foam

[as disclosed in the patent] that restricts and controls the flow of ambient air into the wound and, ultimately, the vacuum system”)).

When the semi-permeable cover (i.e., “flow restrictor”) of Watson is combined with the bandage vent (i.e., “venting arrangement”) of Risk the result is a venting arrangement comprising a flow restrictor that restricts the flow of ambient air through the venting arrangement and, thereby, provides a controlled flow of ambient air into the vacuum system of Risk, upstream of the vacuum source. (*See also* EX1002 ¶¶149-155). A POSITA would have been motivated to combine the teachings of Risk and Watson for the reasons discussed below.

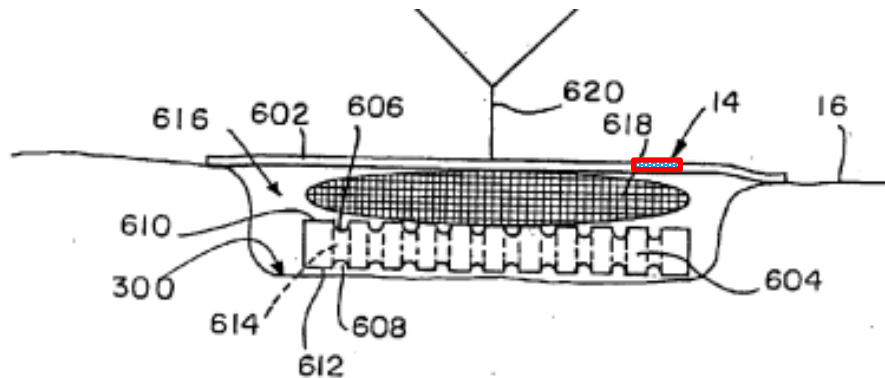
Motivation to Combine Risk and Watson: A POSITA would have been motivated to combine Risk with Watson, predictably resulting in a negative wound pressure therapy system with a bandage vent comprising a semi-permeable wound cover material that permits, yet restricts, the flow of ambient air into the wound site to control the amount of pressure applied to the wound while allowing the wound to breathe and protecting the wound from atmosphere contaminants. (EX1002 ¶¶103-105).

Risk and Watson are within the same field of negative pressure wound therapy systems. (EX1003-1004). Additionally, they both disclose “semi-permeable” or “semi-occlusive” wound cover material to protect the wound and promote healing. (EX1003, 11:14-20; EX1004, 1:16-24, 3:24-37, 8:16-19). Prior to 2005, it was

known to use semi-permeable wound covers, like that of Watson, to restrict the flow of contaminants and ambient air entering the wound. (*E.g.*, EX1029, 405-406 (using semi-permeable materials prevent bacterial contaminants from entering a wound); EX1030, 1:41-52 (disclosing a “vented wound dressing” that is air permeable to limit bacteria and promote healing); EX1024, 9:46-52 (teaching a gas-permeable wound cover that allows the wound to breathe and negative pressure levels to be maintained)). Along with its teachings of a semi-permeable wound cover, Watson provides examples of the types of semi-permeable wound cover materials (such as Gore-Tex™) which were available prior the '534 patent's date of invention. A POSITA would have been aware of these references and materials which were commonly used prior to 2005. (EX1002 ¶¶106-107).

A POSITA would have thus found it obvious to implement Watson's semi-permeable wound cover with Risk's bandage vent using these well-known prior art elements and methods to achieve predictable results. (*Id.* ¶¶106-113). In fact, Watson explicitly teaches that its semi-permeable cover is used in an NPWT system and discloses how a suction member is installed beneath the semi-permeable cover. (EX1004, 3:24-37, Fig. 20.) And Risk explicitly suggests using a semi-occlusive wound cover to accomplish the objectives outlined in Watson which would have further motivated a POSITA to make this combination. (EX1003, 11:16-20; EX1002 ¶¶114-117).

A POSITA would also have found the combination of Risk and Watson obvious to try given the limited permeability options for wound covers (non-permeable, semi-permeable, or open to the atmosphere). (EX1002 ¶¶118-122). A POSITA would have recognized the benefits of using a semi-permeable material in conjunction with a bandage vent to filter contaminants from the atmosphere while allowing the wound to breathe, as was known in the prior art. (EX1002 ¶121). A POSITA would have expected success with this combination, resulting in a bandage that admits ambient air into the wound to control negative pressure while still protecting the wound from outside contaminants. (*Id.* ¶¶121, 123-126). The proposed combination would have been easy to manufacture by adding the semi-permeable material of Watson to the vented portion of Risk's bandage, as shown below:



(EX1002 ¶124 (annotating Fig. 9 of Risk to include the disclosed bandage vent in red and semi-permeable material of Watson in blue within cover film 602))).

A POSITA would have been motivated to implement this semi-permeable cover into a system, like Risk's, which incorporates a bandage vent to admit ambient air into the system. (EX1002 ¶113).

Thus, Risk in view of Watson renders element 1[d] obvious.

vi. Element 1[e]

Risk discloses “the controller configured for controlling operation of the vacuum source while providing venting of the vacuum source via said venting arrangement to provide a desired level of said negative pressure in said confined volume.” As explained for element 1[a], Risk teaches a controller that “controls apparatus 2” which is the vacuum system, including vacuum source 110. (*See* Part VIII.B.1.ii, *supra*; EX1003, 5:22-25). Specifically, controller 50 “provides input for the . . . motors” which a POSITA would have understood to include controlling the operation of the “single 12VDC brushless motor 138 [that] drive[s] the [vacuum] pump.” (EX1003, 8:13-20; EX1002 ¶156).

As explained regarding element 1[d], Risk teaches that the venting arrangement (i.e., bandage vent) vents the vacuum system to the atmosphere to help control the amount of negative pressure being applied. A POSITA would have understood that the controller would control the system while the system is being vented because the bandage vent is constantly venting the system to the atmosphere, regardless of whether the pump is running. (EX1002 ¶157).

Thus, Risk teaches element 1[e]. In sum, Risk in view of Watson renders obvious claim 1.

2. Claim 2

Risk in view of Watson discloses “[t]he vacuum system according to claim 1, wherein said flow restrictor is provided in any one of the enclosure or the tube.” As explained above, Risk in view of Watson renders claim 1 obvious. As explained regarding element 1[d], Watson teaches a flow restrictor (a semi-permeable cover) that is combined with Risk’s venting arrangement (bandage vent) on the enclosure (bandage). Therefore, in the combined system of Risk and Watson, the flow restrictor (semi-permeable cover) is in the enclosure (bandage). A POSITA would have been motivated to combine Risk and Watson for the reasons discussed regarding element 1[d].

Thus, Risk in view of Watson renders obvious claim 2.

3. Claim 3

Risk in view of Watson discloses “[t]he vacuum system according to claim 1, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.” As explained above, Risk in view of Watson renders claim 1 obvious.

Additionally, Risk teaches a “pressure sensor 124” that “measures that negative pressure that is present through canister 26.” (EX1003, 7:33-39, Fig. 32).

A POSITA would have understood that this sensor enables determination of the level of negative pressure in the confined volume because Risk teaches that “the vacuum pump 110 creates the negative pressure that is present through the canister and underneath bandage 14 at the wound.” (EX1002 ¶164 (citing EX1003, 1:44-48, 7:30-31, 14:15-18)). A POSITA would have also understood that the pressure sensor enables the controller to determine whether the negative pressure is at the desired caregiver-defined level. (EX1002 ¶165).

Thus, Risk in view of Watson renders obvious claim 3.

4. Claim 4

Risk in view of Watson discloses “[t]he vacuum system according to claim 1, further comprising a waste container in fluid communication with said vacuum source.” As explained above, Risk in view of Watson renders claim 1 obvious. Risk also teaches “waste canister 26,” which is coupled to the bandage and vacuum source 110, and used to collect exudate removed from the wound. (EX1003, 4:38-40). Risk states that the canister is connected to vacuum source 110 via connector 416 which “is in communication with line 126 and ultimately with pump 110” (*id.*, 9:66-10:11) as shown below:

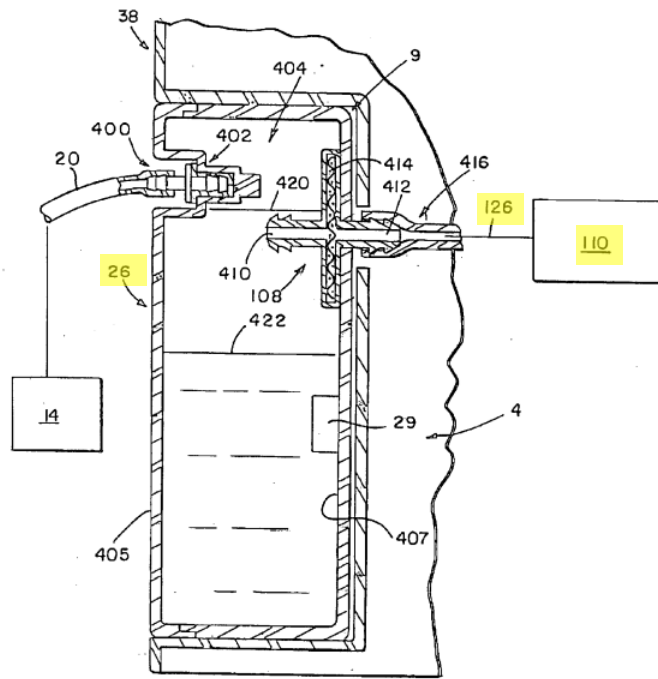


FIG. 6

(*Id.*, Fig. 6 (annotated)). A POSITA would have understood these disclosures to mean that waste canister 26 is in fluid communication with vacuum source 110, which draws ambient air therethrough. (EX1002 ¶168).

Thus, Risk in view of Watson renders obvious claim 4.

5. Claim 5

Risk in view of Watson discloses “[t]he vacuum system according to claim 1, wherein said vacuum source comprises a vacuum pump driven by a motor.” As explained above, Risk in view of Watson renders claim 1 obvious. Risk also teaches that “vacuum pump 110 is mounted on the end of a single 12VDC brushless motor 138 to drive the pump.” (EX1003, 8:13-7, Fig. 2; EX1002 ¶171).

Thus, Risk in view of Watson renders obvious claim 5.

6. Claim 9

Risk in view of Watson discloses “[t]he 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.” As explained above, Risk in view of Watson renders claim 1 obvious.

Additionally, as explained regarding claim 1, Risk discloses a bandage vent (i.e., venting arrangement) that allows ambient air to enter the area beneath the bandage. A POSITA would have understood that this bandage vent is constantly open to the atmosphere, thereby allowing ambient air to enter the wound site regardless of whether the vacuum pump is running. (EX1002 ¶174). And, a POSITA would have understood that when the vacuum pump is not operating, and suction is not being applied to the wound site, the bandage vent allows ambient pressure to be restored in the confined volume under the bandage. (*Id.*).

Thus, Risk in view of Watson renders obvious claim 9.

7. Claim 10

Risk in view of Watson discloses “[t]he 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.” As explained above, Risk in view of Watson renders claim 1 obvious. And, Risk teaches a bandage vent which a POSITA would

have understood to be an “orifice”. (EX1002 ¶178 (also noting that the venting arrangement comprises a flow restrictor which, in this case, is the semi-permeable cover taught by Watson which a POSITA would consider to be a “porous body”))).

Thus, Risk in view of Watson renders claim 10 obvious.

8. Claim 19

Claim 19 is obvious over Risk in view of Watson.

i. Claim 19, preamble

To the extent the preamble is limiting, it is taught by Risk. The preamble recites “A method for applying negative pressure to a wound, comprising.” Risk teaches a method of operating the disclosed NPWT apparatus, including teaching a “caregiver” to operate the system, how the device functions, and how to control it. (EX1003, 11:36-43; EX1002 ¶182).

Thus, Risk teaches the preamble of claim 19.

ii. Element 19[a]

Element 19[a] is substantively identical to elements 1[pre] and 1[a]. Thus, for the reasons stated above regarding elements 1[pre] and 1[a], Risk teaches element 19[a].

iii. Element 19[b]

Element 19[b] is identical to element 1[b]. Thus, for the reasons stated above regarding element 1[b], Risk teaches element 19[b].

iv. Element 19[c]

Element 19[c] is identical to element 1[c]. Thus, for the reasons stated above regarding element 1[c], Risk teaches element 19[c].

v. Element 19[d]

Element 19[d] is substantively identical to element 1[d]. Thus, for the reasons stated above regarding element 1[d], Risk in view of Watson renders obvious element 19[d]. A POSITA would have been motivated to combine Risk and Watson for the reasons discussed regarding element 1[d].

vi. Element 19[e]

Element 19[e] is substantively identical to element 1[e]. Thus, for the reasons stated above regarding element 1[e], Risk teaches element 19[e].

In sum, Risk in view of Watson renders obvious claim 19.

9. Claim 22

Claim 22 is substantively identical to claim 10 and, as explained above, Risk teaches claim 10. Additionally, as explained above, Risk and Watson render claim 19 obvious. Thus, for the reasons stated above regarding claims 10 and 19, Risk in view of Watson renders obvious claim 22.

C. Ground 2: Obviousness of Claims 6-8, 20, and 21 Based on Risk in View of Watson and Lina

1. Claim 6

Claim 6 is obvious over Risk in view of Watson and Lina.

i. Claim 6, preamble

To the extent the preamble is limiting, it is anticipated by Risk and Watson. The preamble recites “The vacuum system according to claim 5.” As explained above, Risk and Watson render claim 5 obvious and, therefore, render obvious the preamble of claim 6.

ii. Element 6[a]

Risk discloses “said motor is an electric motor”. Risk specifically discloses a 12VDC brushless motor that drives the vacuum pump as “electric motor 138.” (EX1003, 8:29-30). Additionally, Risk explains that the controller and systems within the NPWT system’s housing can be plugged into a wall socket and are driven by electric power. (*Id.*, 5:34-39; EX1002 ¶223).

Thus, Risk teaches element 6[a].

iii. Element 6[b]

Risk in view of Lina discloses “said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume”. As explained above regarding element 1[e] in Ground 1, Risk teaches a controller 50 that controls the electric motor that drives the pump. Additionally, Risk teaches that the controller controls the proportional valve and flow orifice to adjust the level of negative pressure applied to the wound. (*Id.*, 7:30-42). However, Risk does not

explicitly teach that the controller controls the pump's motor to modulate the negative pressure applied at the wound.

Combination of Risk and Lina: While Risk teaches a controller that selectively opens and closes a flow orifice to adjust the level of pressure, Lina teaches a controller that instead controls the speed of the vacuum pump to do the same. (EX1005, 12:41-49). Lina explicitly discloses a microcontroller (i.e., controller) “to control the speed of pump motor 83” that compares the sensed pressure to the desired pressure and adjusts the pump speed accordingly. (*Id.*, 13:20-31). When combined with the NPWT system of Risk, Lina's microcontroller's functionality thereby controls the operation of the electric motor taught by Risk to provide the desired level of negative pressure within the system and at the enclosure.

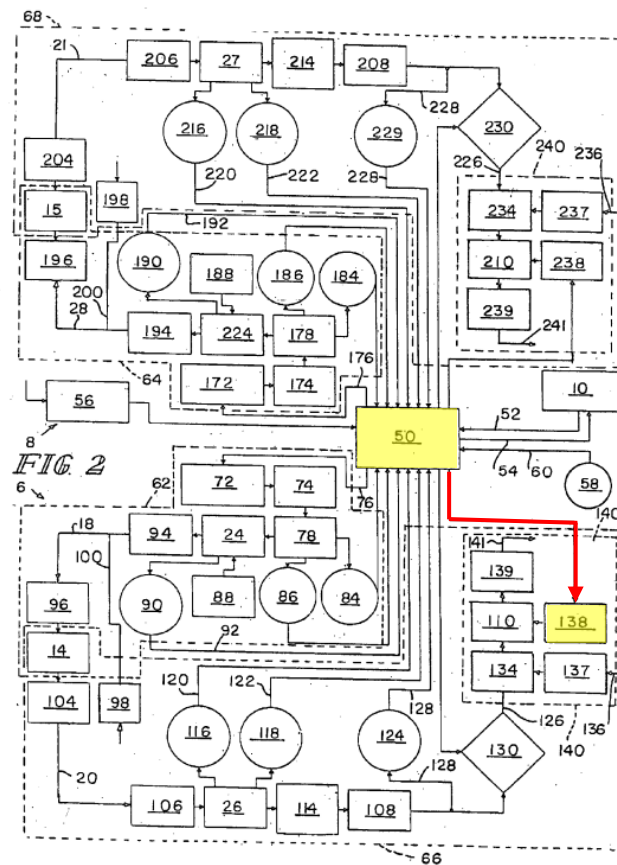
Motivation to Combine Risk and Lina: A POSITA would have been motivated to combine Risk's NPWT system and controller with the teachings of Lina, predictably resulting in a system with a controller that directly controls the speed of the electric motor driving the pump to adjust the level of negative pressure as desired. (EX1002 ¶226). Risk and Lina both teach NPWT systems that are operated by a controller and utilize electric motors to drive the vacuum pump. (EX1003; EX1005).

A POSITA would have found it obvious to modify the NPWT system of Risk to control the speed of the pump's motor based on well-known prior art teachings

and methods. (EX1002 ¶¶202-207). Prior to 2005, it was well-established in the art to control the speed of a pump's motor to adjust the pressure level in an NPWT system. (E.g., EX1006, 2:15-21 (microprocessor controls the pump speed to adjust the level of suction); EX1031, 7:53-56 (microcontroller controls the speed of the vacuum pump to alter the level of suction); EX1032, 3:65-4:30 (voltage regulator adjusts the voltage applied to the pump motor)). In-line with these teachings, Lina discloses a microcontroller 72 that controls the speed of, or voltage received by, pump motor 83 to adjust the level of negative pressure within the system. (EX1005, 13:20-36). A POSITA would have found the combination of Risk and Lina obvious based on these well-known prior art elements. (EX1002 ¶207). The proposed combination would predictably result in the NPWT system of Risk with a controller that is able to control the pressure at the wound by adjusting the speed of the pump, instead of adjusting the proportional valve. (*Id.*).

Additionally, a POSITA would have found it obvious to try combining Risk and Lina as there are a limited number of ways to adjust the level of negative pressure within an NPWT system: controlling the level of air brought into the system (e.g., through a valve) or controlling the vacuum level generated by the pump. (*Id.* ¶¶209-210 (also explaining a POSITA would have tried different types of controller functionalities to determine which was the most effective)). Because of the two known ways to adjust the level of pressure, a POSITA would have found it obvious

to simply substitute one known element (controlling pump vacuum level) for another (controlling air flow). (*Id.* ¶¶214-215 (noting “the arrangement contemplated by Lina is a much simpler solution, eliminating the need for the proportional valve”)). A POSITA also would have expected the combination to be successful because Risk teaches that the controller is operably connected to the electric motor that drives the vacuum pump:



(EX1003, Fig. 2 (annotated)). Accordingly, a POSITA would have been motivated to combine Risk and Lina and expected success in doing so. A POSITA would have

understood that the addition of Watson would not have affected the motivation to combine Risk and Lina. (EX1002 ¶201).

Thus, Risk in view of Watson and in further view of Lina renders obvious claim 6.

2. Claim 7

Risk in view of Watson and Lina discloses “[t]he 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.” As explained above, Risk in view of Watson and Lina renders claim 6 obvious.

Lina teaches that the controller controls the voltage of the pump motor to control the level of negative pressure applied at the wound site. (EX1005, 13:35-41). Specifically, Lina discloses “[m]icrocontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83.” (*Id.*). Lina also explains that controlling the pump speed drives the suction from the pump: “microcontroller 72 activates pump motor 83, which, in turn, drives vacuum pump 84 to begin removal of air from canister.” (*Id.*, 12:47-49). A POSITA would have understood that, by adjusting the voltage received by the pump motor, the controller is necessarily controlling the amount of negative pressure applied to the volume under the enclosure. (EX1002 ¶232).

A POSITA would have been motivated to combine the teachings of Lina with Risk for the reasons explained regarding element 6[b]. Thus, Risk in view of Watson and in further view of Lina renders obvious claim 7.

3. Claim 8

Risk in view of Watson and Lina discloses “[t]he 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.” As explained above, Risk in view of Watson and Lina renders claim 6 obvious.

A POSITA would have found it obvious, based on the teachings of Lina, to control the torque of the pump motor to adjust the level of negative pressure. (EX1002 ¶¶236-237 (explaining that the voltage could be continuously adjusted which would necessarily involve controlling the amperage to the motor and therefore the torque it applies to the pump)). A POSITA would have understood the speed of a motor can only be controlled in a limited number of ways and thus found it obvious to control the torque via the amperage applied. (*Id.*). Additionally, a POSITA would have known that the torque of a brushless motor, such as the 12VDC brushless motor disclosed in Risk, is controlled by the amperage applied to the motor. (*Id.* ¶212).

A POSITA would have been motivated to combine the teachings of Lina with Risk for the reasons explained regarding element 6[b]. Thus, Risk in view of Watson and Lina renders obvious claim 8.

4. Claim 20

Risk in view of Watson and in further view of Lina renders obvious claim 20.

i. Claim 20, preamble

To the extent the preamble is limiting, it is disclosed and rendered obvious by Risk in view of Watson. The preamble recites “The method according to claim 19.” As explained in Ground 1, Risk and Watson render claim 19 obvious. A POSITA would have been motivated to combine Risk and Watson for the reasons explained regarding element 1[d] in Ground 1. Therefore, Risk in view of Watson renders obvious the preamble of claim 20.

ii. Element 20[a]

Element 20[a] is substantively identical to claim 5 and element 6[a], and as explained above, Risk teaches an electric motor. (*See* Parts VIII.B.5, VIII.C.1.ii, *supra*). Thus, for the reasons stated above regarding claim 5 (in Ground 1) and element 6[a], Risk teaches element 20[a].

iii. Element 20[b]

Element 20[b] is substantively identical to element 6[b], and as explained above, Risk in view of Lina renders element 6[b] obvious. Thus, for the reasons stated above regarding element 6[b], Risk in view of Lina renders obvious element 20[b]. A POSITA would have been motivated to combine Risk and Lina for the reasons explained regarding element 6[b].

Thus, Risk in view of Watson and in further view of Lina renders obvious claim 20.

5. Claim 21

Claim 21 is substantively identical to claims 7 and 8 and, as explained above, Risk in view of Lina renders claims 7 and 8 obvious. A POSITA would have been motivated to combine Risk and Watson for the reasons discussed regarding element 1[d] in Ground 1. Additionally, as explained above, Risk in view of Watson and Lina renders obvious claim 20. Thus, for the reasons stated above regarding claims 7, 8, and 20, Risk in view of Watson and in further view of Lina renders obvious claim 21.

D. Ground 3: Anticipation of Claims 1-6, 9-15, 17-20, and 22 By Hunt

1. Claim 1

Claim 1 is anticipated by Hunt.

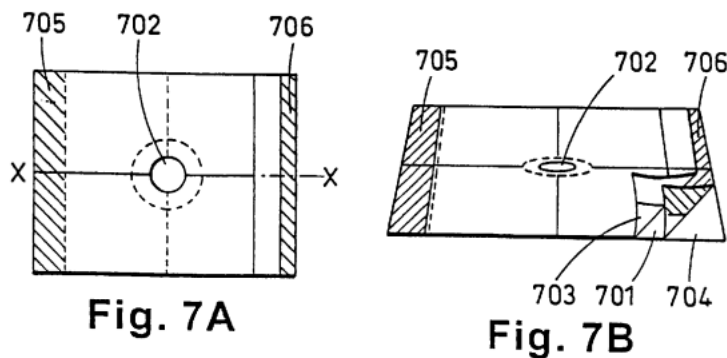
i. Claim 1, preamble

To the extent the preamble is limiting, it is anticipated by Hunt. The preamble recites “A vacuum system for applying negative pressure to a wound, the vacuum system comprising.” Hunt teaches a “therapeutic apparatus for stimulating the healing of superficial wounds in a person” which applies negative pressure via suction “to the wound site.” (EX1006, 1:45-50, 3:59-61; EX1002 ¶254).

Thus, Hunt teaches the preamble of claim 1.

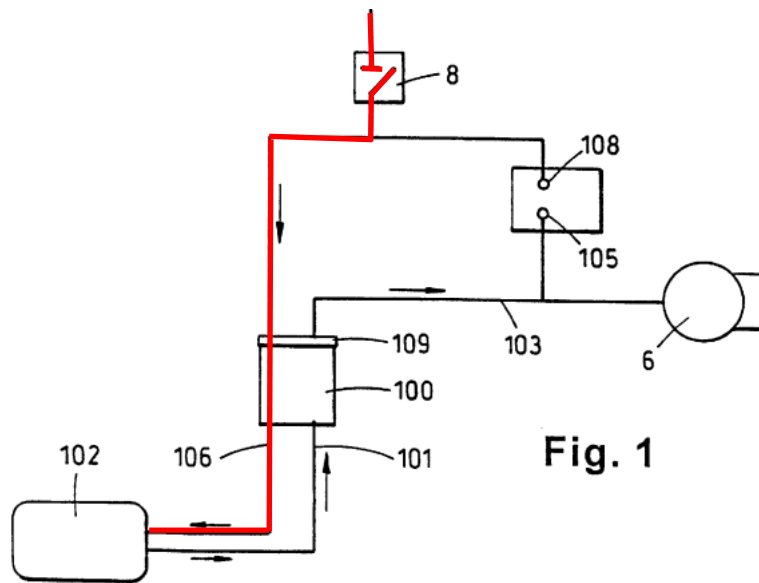
ii. Element 1[a]

Hunt teaches “an enclosure, a venting arrangement, a tube, a vacuum source, and a controller.” Hunt teaches a porous wound dressing 102 that is “pressed onto the wound” and surgical drape, comprising polyurethane film layer 701, which is “adhered to the patient’s skin around the wound site.” (EX1006, 5:19-38). The drape is depicted in Figures 7A and 7B:



A POSITA would have understood the wound dressing and surgical drape to correspond to the claimed “enclosure.” (EX1002 ¶¶257-259).

Hunt discloses a tube (tube 106) which is connected to the enclosure and to pressure relief valve 8, as shown in Figure 1 below:



(EX1006, Fig. 1 (annotated)). Pressure relief valve 8 admits ambient air into tube 106 and, thereby, vents the vacuum system. (*Id.*, 4:17-34). A POSITA would have understood tube 106 and pressure relief valve to be a “venting arrangement” under the plain and ordinary meaning of that term in the ’534 patent. (EX1002 ¶¶260-261 (explaining that the valve “has an orifice that allows ambient air to enter the tube . . .”). In one embodiment, Hunt teaches combining tubes 106 and 101 into a single, multi-partitioned tube. (EX1006, 4:34-39). A POSITA would have understood this single tube connected to pressure relief valve 8 to also be a venting arrangement for the same reasons. (EX1002 ¶262).

As shown in Figure 1, Hunt discloses a suction tube (101) connecting the enclosure (102) to a waste canister (100) and then to vacuum pump (6):

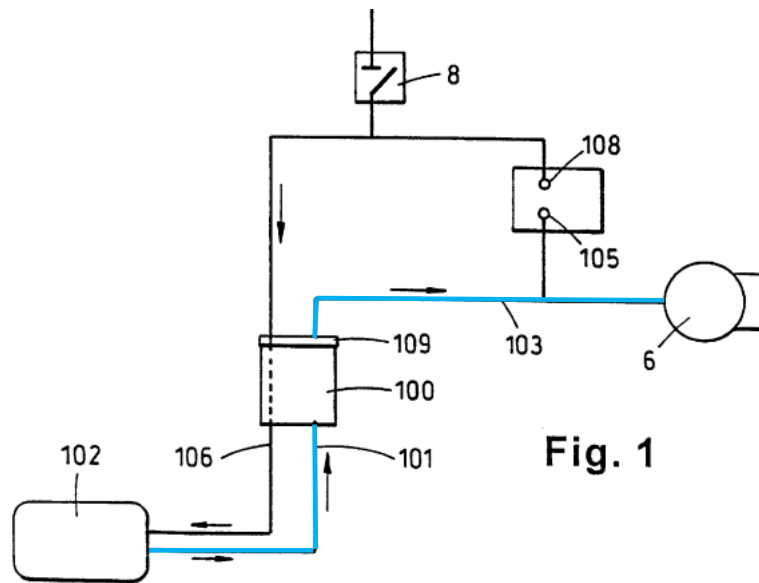


Fig. 1

(EX1006, Fig. 1 (annotated)). Tube 101 applies negative pressure to the wound site under the enclosure. (*Id.*, 3:31-61, 4:43-45; *see also* EX1002 ¶264). Hunt also teaches “it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister”. (EX1006, 4:34-39). Thus, Hunt teaches a tube.

Hunt also teaches “suction pump 6” which applies negative pressure to the wound site. (*Id.*, 3:32-33, 3:60-4:1). Thus, suction pump 6 corresponds to the claimed “vacuum source.” (*See also* EX1002 ¶¶267-268).

Hunt further discloses a microprocessor 4 that is “programmed to maintain such [negative] pressure within a predetermined range.” (EX1006, 2:15-18). A POSITA would have understood microprocessor 4 to be a “controller”. (EX1002 ¶¶269-270).

Thus, Hunt teaches element 1[a].

iii. Element 1[b]

Hunt teaches “the enclosure being attachable to a periphery of the wound so as to define a confined volume.” As explained regarding element 1[a], Hunt teaches a porous wound dressing and surgical drape that overlays the wound which correspond to the claimed “enclosure”.

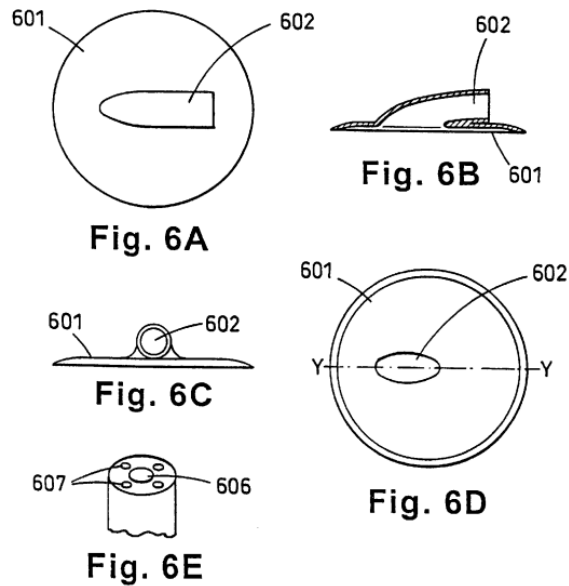
The surgical drape is “adhered to the patient’s skin around the wound site while, at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so an airtight cavity is formed around the wound.” (EX1006, 5:27-38). A POSITA would have understood these disclosures to mean that the surgical drape and wound dressing are attachable to the patient’s skin and define a confined a volume therein. (EX1002 ¶¶273-274).

Thus, Hunt teaches element 1[b].

iv. Element 1[c]

Hunt teaches “the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be seletively created in said volume.” As explained regarding element 1[a], Hunt teaches an enclosure, vaccum source, and tube that provide negative pressure to a wound site.

The wound dressing and surgical drape of Hunt (i.e., “enclosure”) include a “connector for attaching the multi-lumen tube at the wound site,” as shown in Figures 6A-6D:



(EX1006, 2:27-28, Figs. 6A-6D). Hunt teaches that the spout on the connector is either “sized to accept, as a closely sliding fit, the end of a multi-lumen tube” or the tube can be passed through the spout into the wound dressing. (*Id.*, 5:23-26). The surgical drape is “used to secure the connector, lumen and dressing.” (*Id.*, 5:27-28). A POSITA would have understood that spout 602 which connects the tube to the surgical drape and wound dressing (i.e., enclosure) corresponds to the claimed “enclosure outlet”. (EX1002 ¶¶114-115).

A POSITA would have understood that the tube which is connected to this enclosure outlet (tube 101) applies suction carried from tube 103 which is connected to the vacuum source. (EX1002 ¶279; EX1006, 3:60-61 (“Suction is applied to the wound site via the canister by a tube 103, connected to pump 6”)).

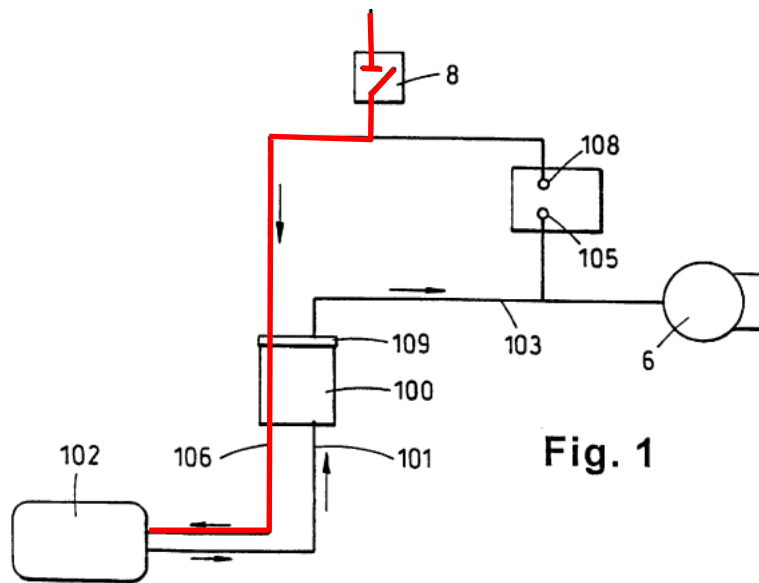
Thus, Hunt teaches element 1[c].

v. Element 1[d]

Hunt 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 vacuum system upstream of the vacuum source.” As explained regarding element 1[a], Hunt teaches a “venting arrangement” consisting of tube 106 and pressure relief valve 8.

A POSITA would have understood that pressure relief valve 8—which is part of the venting arrangement—is a “flow restrictor” under the plain and ordinary meaning of that term. (EX1002 ¶¶281, 284-286). “[P]ressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly” by opening the valve for a specified period of time. (EX1006, 4:17-28). A POSITA would have known that pressure relief valve 8 could fully restrict the flow of ambient air through tube 106 by closing the valve, or partially restrict that flow by utilizing intermediate positions between open and closed. (EX1002 ¶286 (“that the valve can be opened and closed [] creates an average restriction over time” and “the valve could have intermediate positions between open and closed to vary the resistance.”)).

As shown in Figure 1, pressure relief valve 8 opens to allow ambient air into the valve and tube 106 (i.e., the venting arrangement) which then flows into the system:



(EX1006, Fig. 1 (annotated, with the original black arrows indicating the direction of airflow)). Ambient air enters tube 106 through pressure relief valve 8 and flows through the system towards the vacuum source (pump 6). (EX1002 ¶282).

Thus, Hunt teaches element 1[d].

vi. Element 1[e]

Hunt teaches “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.” As explained regarding element 1[a], Hunt teaches microprocessor 4 which corresponds to the claimed “controller”.

Hunt specifically discloses that the microprocessor “is programmed to maintain such pressure within a predetermined range” and is controlled by a user who sets the desired pressure. (EX1006, 2:15-18, 3:11-14). A POSITA would have

understood that the microprocessor (i.e., controller) necessarily controls operation of the vacuum source. (EX1002 ¶289).

Also, as explained regarding elements 1[a] and 1[d], Hunt teaches a venting arrangement that admits ambient air into the vacuum system. The microprocessor in Hunt also controls the pressure relief valve 8—which is part of the venting arrangement—to open or close to affect the level of pressure at the wound site. (EX1006, 4:20-24 (discussing intermittent suction)). A POSITA would have understood that running the vacuum pump while the relief valve is not fully closed allows the system to reach any ideal equalized pressure within the pump’s capacity. (EX1002 ¶292 (discussing “pulse modulating” of the pump or valve)). Thus, a POSITA would have understood that the controller in Hunt is controlling operation of the vacuum source while providing venting of the vacuum system via the venting arrangement to provide a desired amount of negative pressure at the wound site. (*Id.*, ¶¶291-292). The “wound site” in Hunt corresponds to the confined volume of the enclosure. (*See* Part VIII.D.1.iii, *supra*).

Thus, Hunt teaches element 1[e]. In sum, Hunt teaches claim 1.

2. Claim 2

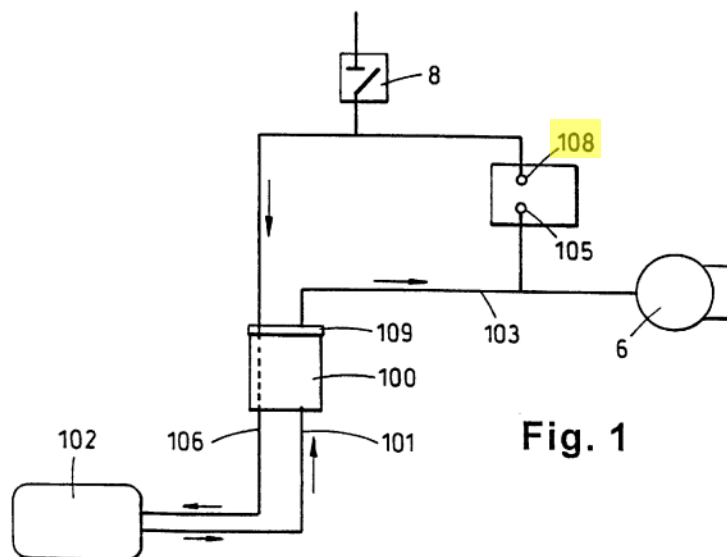
Hunt teaches “[t]he vacuum system according to claim 1, wherein said flow restrictor is provided in any one of the enclosure or the tube.” As explained above,



Thus, Hunt teaches claim 2.

3. Claim 3

Hunt teaches “[t]he vacuum system according to claim 1, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.” As explained above, Hunt teaches claim 1. Hunt also teaches a pressure transducer 108 that “measures or monitors” the level of negative pressure within the confined volume at the wound site via tube 106. (EX1006, 3:66-4:1). A POSITA would have understood that the pressure transducer 108 is a sensor that enables determination of the level of negative pressure because the pressure at the transducer when the valve is closed would be the same as the pressure at the wound site. (EX1002 ¶300). Pressure transducer 108 is attached to pressure sensing tube 106 as shown below:



(EX1006, Fig. 1 (annotated)).

Thus, Hunt teaches claim 3.

4. Claim 4

Hunt teaches “[t]he vacuum system according to claim 1, further comprising a waste container in fluid communication with said vacuum source.” As explained above, Hunt teaches claim 1. Additionally, Hunt teaches a “canister [100] for containing fluids drawn from the wound by said pump” which constitutes a waste canister. (EX1006, 1:49-50). Canister 100 is connected to tube 103 which is connected to the vacuum source (pump 6). (*Id.*, 3:33-35, 3:60-61). A POSITA would have understood that the waste canister of Hunt is in fluid communication with the vacuum source. (EX1002 ¶304).

Thus, Hunt teaches claim 4.

5. Claim 5

Hunt teaches “[t]he vacuum system according to claim 1, wherein said vacuum source comprises a vacuum pump driven by a motor.” As explained above, Hunt teaches claim 1. Hunt also discloses: “suction pump is conveniently driven by an electric motor.” (EX1006, 1:61-62; *see also id.*, 3:32-33 (“suction pump 6 with associated electric motor 6A”); EX1002 ¶307).

Thus, Hunt teaches claim 5.

6. Claim 6

Claim 6 is anticipated by Hunt.

i. Claim 6, preamble

To the extent the preamble is limiting, it is anticipated by Hunt. The preamble recites “The vacuum system according to claim 5.” As explained above, Hunt teaches claim 5 and, for the same reasons, teaches the preamble of claim 6.

ii. Element 6[a]

Hunt teaches “said motor is an electric motor.” As explained regarding claim 5, Hunt discloses “suction pump is conveniently driven by an electric motor.” (EX1006, 1:61-62). Thus, Hunt teaches element 6[a].

iii. Element 6[b]

Hunt teaches “said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.” Hunt discloses that the microprocessor (i.e., “controller”) controls the vacuum pump to maintain the desired level of negative pressure, including “by, for example, signaling the pump to increase its speed.” (*Id.*, 2:15-21). As noted above regarding element 6[a], the pump in Hunt is driven by an electric motor. A POSITA would have understood that the controller in Hunt necessarily controls the pump’s electric motor to provide the desired level of negative pressure at the wound site. (EX1002 ¶¶315-317).

Thus, Hunt teaches element 6[b]. In sum, Hunt teaches claim 6.

7. Claim 9

Hunt teaches “[t]he vacuum system according to claim 1, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said pump is not operating.” As explained above, Hunt teaches claim 1. Also as explained regarding claim 1, Hunt teaches a venting arrangement (tube 106 and pressure relief valve 8) that admits ambient air into the system when the valve is open. Hunt also discloses “pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly.” (EX1006, 4:17-28). And “when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from the atmosphere.” (*Id.*).

A POSITA would have understood that the system disclosed in Hunt, therefore, allows ambient pressure to be restored in the confined volume at the wound site via the open pressure relief valve 8 and tube 106 when the pump is turned off. (EX1002 ¶¶320-321). Thus, Hunt teaches claim 9.

8. Claim 10

Hunt teaches “[t]he 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.” As explained above, Hunt teaches claim 1 and Hunt also teaches a venting arrangement comprising a pressure relief valve and tube. A POSITA would have understood the valve has an orifice to admit ambient air. (EX1002 ¶324 (also

noting the opening in the valve constitutes a bleeding hole)). Thus, Hunt teaches claim 10.

9. Claim 11

Claim 11 is anticipated by Hunt.

i. Claim 11, preamble

To the extent the preamble is limiting, it is anticipated by Hunt. The preamble of claim 11 is substantively identical to the preamble of claim 1. Thus, for the reasons stated above regarding the preamble of claim 1, Hunt teaches the preamble of claim 11.

ii. Element 11[a]

Element 11[a] is identical to element 1[a]. Thus, for the reasons stated above regarding element 1[a], Hunt teaches element 11[a].

iii. Element 11[b]

Element 11[b] is identical to element 1[b]. Thus, for the reasons stated above regarding element 1[b], Hunt teaches element 11[b].

iv. Element 11[c]

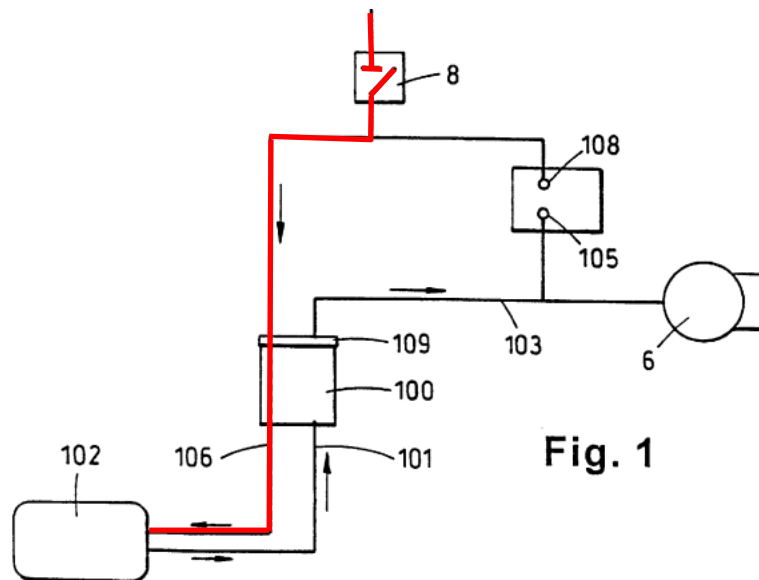
Element 11[c] is identical to element 1[c]. Thus, for the reasons stated above regarding element 1[c], Hunt teaches element 11[c].

v. Element 11[d]

Hunt teaches “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.” As explained regarding element 1[d], Hunt teaches a venting arrangement comprising a flow restrictor that restricts flow of ambient air through the venting arrangement, thereby providing a controlled flow of ambient air into the system.

The venting arrangement of Hunt (tube 106 and pressure relief valve 8) is located outside of the enclosure (wound dressing 102 and surgical drape). As shown below, pressure relief valve 8 admits ambient air into tube 106:



(EX1006, Fig. 1 (annotated)). As previously explained, Hunt also teaches that tube 106 can be combined with tube 101 to make a multi-partitioned, single tube, partially depicted in Figure 5F:

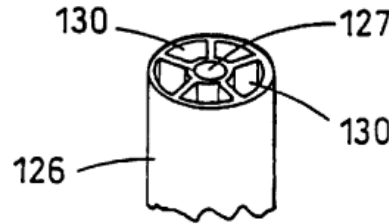


Fig. 5F

Thus, Hunt discloses that its venting arrangement allows ambient air to enter the tube.

Accordingly, Hunt teaches element 11[d].

vi. Element 11[e]

Hunt teaches “said controlled flow of ambient air entering said tube via said venting arrangement without entering said enclosure.” As explained immediately above, the pressure relief valve 8 allows a controlled flow of ambient air into tube 106 (which may be combined with tube 101). (*See also* Part VIII.D.1.v, *supra*.)

A POSITA would have understood that ambient air coming in through pressure relief valve 8 flows from tube 106 into the suction tube (tube 101) without entering the enclosure (surgical drape and wound dressing 102). (EX1002 ¶342). The multi-partitioned tube, including tubes 106 and 101, is connected to the wound dressing via connector 602 as shown below:

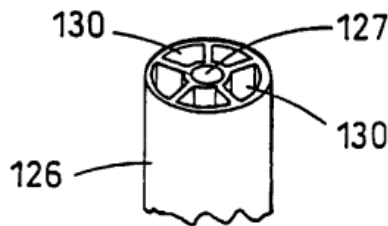


Fig. 5F

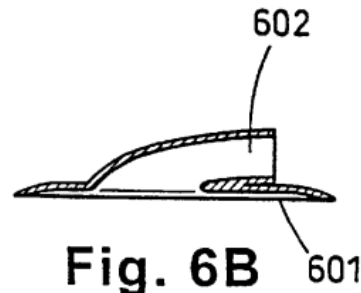


Fig. 6B

(EX1006, Figs. 5F, 6B). A POSITA would have also understood that the multi-partitioned tube, when connected to the connector, could be spaced apart from the wound dressing itself. (EX1002 ¶342). Accordingly, a POSITA would have known that ambient air would exit tube 106 (conduit 130 in the multi-partitioned tube) and enter tube 101 (central conduit 127 in the multi-partitioned tube) and flow towards the waste canister and vacuum source without entering the enclosure. (*Id.* (see Figure depicting airflow)).

Thus, Hunt teaches element 11[e].

vii. Element 11[f]

Element 11[f] is substantively identical to element 1[e]. Thus, for the reasons stated regarding element 1[e], Hunt teaches element 11[f]. Additionally, as explained regarding elements 11[d]-[e], Hunt discloses a venting arrangement that vents the tube by admitting ambient air into pressure relief valve 8 into tube 106 which flows into suction tube 101. Thus, Hunt teaches element 11[f].

In sum, Hunt teaches claim 11.

10. Claim 12

Claim 12 is substantively identical to claim 3, and as explained above, Hunt teaches claim 3. Additionally, as explained above, Hunt teaches claim 11. Thus, for the reasons stated regarding claims 3 and 11, Hunt teaches claim 12.

11. Claim 13

Claim 13 is substantively identical to claim 4 and, as explained above, Hunt teaches claim 4. Additionally, as explained above, Hunt teaches claim 11. Thus, for the reasons stated regarding claims 4 and 11, Hunt teaches claim 13.

12. Claim 14

Claim 14 is substantively identical to claim 5 and, as explained above, Hunt teaches claim 5. Additionally, as explained above, Hunt teaches claim 11. Thus, for the reasons stated above regarding claims 5 and 11, Hunt teaches claim 14.

13. Claim 15

Claim 15 is substantively identical to claim 6 and, as explained above, Hunt teaches claim 6. Additionally, as explained above, Hunt teaches claim 14. Thus, for the reasons stated regarding claims 6 and 14, Hunt teaches claim 15.

14. Claim 17

Claim 17 is substantively identical to claim 9 and, as explained above, Hunt teaches claim 9. Additionally, as explained above, Hunt teaches claim 11. Thus, for the reasons stated regarding claims 9 and 11, Hunt teaches claim 17.

15. Claim 18

Claim 18 is substantively identical to claim 10 and, as explained above, Hunt teaches claim 10. Additionally, as explained above, Hunt teaches claim 11. Thus, for the reasons stated above regarding claims 10 and 11, Hunt teaches claim 18.

16. Claim 19

Claim 19 is anticipated by Hunt.

i. Claim 19, preamble

To the extent the preamble is limiting, it is anticipated by Hunt. The preamble recites “A method for applying negative pressure to a wound, comprising.” Hunt teaches an NPWT system, including a “method of operation of the apparatus [which] can be appreciated by the schematic layout in FIG. 1.” (EX1006, 3:57-58; EX1002 ¶359).

Thus, Hunt teaches the preamble of claim 19.

ii. Element 19[a]

Element 19[a] is substantively identical to elements 1[pre] and 1[a]. Thus, for the reasons stated regarding elements 1[pre] and 1[a], Hunt teaches element 19[a].

iii. Element 19[b]

Element 19[b] is identical to element 1[b]. Thus, for the reasons stated regarding element 1[b], Hunt teaches element 19[b].

iv. Element 19[c]

Element 19[c] is identical to element 1[c]. Thus, for the reasons stated regarding element 1[c], Hunt teaches element 19[c].

v. Element 19[d]

Element 19[d] is substantively identical to element 1[d]. Thus, for the reasons stated regarding element 1[d], Hunt teaches element 19[d].

vi. Element 19[e]

Element 19[e] is substantively identical to element 1[e]. Thus, for the reasons stated regarding element 1[e], Hunt teaches element 19[e].

In sum, Hunt teaches claim 19.

17. Claim 20

Claim 20 is anticipated by Hunt.

i. Claim 20, preamble

To the extent the preamble is limiting, it is anticipated by Hunt. The preamble recites “The method according to claim 19.” As explained above, Hunt teaches claim 19 and, therefore, teaches the preamble of claim 20.

ii. Element 20[a]

Element 20[a] is substantively identical to claim 5 and element 6[a]. Thus, for the reasons stated regarding claim 5 and element 6[a], Hunt teaches element 20[a].

iii. Element 20[b]

Element 20[b] is substantively identical to element 6[b]. Thus, for the reasons stated regarding element 6[b], Hunt teaches element 20[b].

Thus, Hunt teaches claim 20.

18. Claim 22

Claim 22 is substantively identical to claim 10 and, as explained above, Hunt teaches claim 10. Additionally, as explained above, Hunt teaches claim 19. Thus, for the reasons stated regarding claims 10 and 19, Hunt teaches claim 22.

E. Ground 4: Obviousness of Claims 7-8, 16, and 21 Based on Hunt in View of Lina

1. Claim 7

Hunt in view of Lina discloses “[t]he 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.” As explained in Ground 3, Hunt teaches claim 6. Hunt also teaches a microprocessor (i.e., controller) that controls the speed of pump 6 with electric motor. (EX1006, 1:61-62, 2:15-21). Hunt does not explicitly teach that the microprocessor controls the current or voltage of said motor.

Combination of Hunt and Lina: As explained in Ground 2 regarding claim 7, Lina teaches that the controller controls the voltage received by the pump motor.

(*See, e.g.,* EX1005, 13:35-41). Thus, for the reasons above and those stated regarding claim 7 in Ground 2, Hunt in view of Lina renders obvious claim 7.

Motivation to Combine Hunt and Lina: A POSITA would have been motivated to implement Lina’s microcontroller that controls the voltage of the pump motor with Hunt’s NPWT system. (EX1002 ¶385). The motivation to combine Hunt and Lina is similar to the motivation to combine Risk and Lina, as explained in Ground 2.

Hunt and Lina both teach NPWT systems that utilize a controller to operate a vacuum pump, including controlling the speed of the pump. (EX1006, EX1005). This combination would involve well-known prior art elements and methods to achieve a predictable result: a controller that directly controls the voltage applied to the pump’s motor. (EX1002 ¶¶387-390). Prior to 2005, it was understood in the art to control the voltage applied to an NPWT system’s pump motor to adjust the level of negative pressure applied at the wound. (*Id.* ¶387; *see also* EX1005, 13:35-36 (microcontroller varies “the amount of voltage received by pump motor”); EX1032, 3:65-4:30 (using a voltage regulator to adjust the pump motor speed)). A POSITA would have known adding this functionality to Hunt’s system would predictably result in the controller’s ability to variably adjust the level of suction applied to the wound. (EX1002 ¶389).

The combination of Hunt and Lina would have been obvious to try. Both teach that the controller controls the speed of the pump, which can only be done in a limited number of ways. (*Id.* ¶392 (adjusting electric current, voltage, or frequency and duration of current or voltage)). A POSITA would have been motivated to try adjusting the speed of the pump in different ways to see which was easiest to control and utilize in Hunt’s disclosed system. (*Id.* ¶393).

A POSITA would have expected success in making the proposed combination. (*Id.* ¶395). Hunt’s microprocessor is already configured to operate the pump motor, thus, a POSITA would have found it simple to modify the controller to directly control the voltage applied to the pump in order to modulate the level of negative pressure within the system. (*Id.*).

Thus, Hunt in view of Lina renders obvious claim 7.

2. Claim 8

Hunt in view of Lina discloses and renders obvious “[t]he 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.” As explained in Ground 3 above, Hunt teaches claim 6.

Combination of Hunt and Lina: As explained in Ground 2 regarding claim 8, based on the teachings of Lina, a POSITA would have found it obvious to control the torque of the motor to adjust the level of negative pressure instead of only

controlling the voltage. (See Part VIII.C.3, *supra*; EX1002 ¶402). A POSITA would have been motivated to combine Hunt and Lina for the reasons explained above regarding claim 7.

Thus, Hunt in view of Lina renders obvious claim 8.

3. Claim 16

Hunt in view of Lina discloses “[t]he 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.” As explained in Ground 3, Hunt teaches claim 15. Claim 16 is substantively identical to claims 7 and 8. Thus, for the reasons stated regarding claims 7 and 8, Hunt in view of Lina renders claim 16 obvious. A POSITA would have been motivated to combine Hunt and Lina for the same reasons as explained regarding claim 7.

4. Claim 21

Hunt in view of Lina discloses “[t]he 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 create said level of said negative pressure in said confined volume.” As explained in Ground 3, Hunt teaches claim 20. Claim 21 is substantively identical to claim 16. Thus, for the reasons stated above regarding claim 16, Hunt in view of Lina renders claim 21 obvious. A POSITA would have

been motivated to combine Hunt and Lina for the same reasons as explained regarding claim 7.

F. Ground 5: Obviousness of Claims 11-18 Based on Hunt in View of Lina and Dolliver

1. Claim 11

Claim 11 is obvious over Hunt in view of Dolliver.

i. Claim 11, preamble

As explained in Ground 3, Hunt teaches the preamble of claim 11.

ii. Element 11[a]

As explained in Ground 3, Hunt teaches element 11[a]. Alternatively, to the extent Hunt does not explicitly teach a “venting arrangement” that allows air into the tube without entering the enclosure, a POSITA would have been motivated to combine Hunt with Dolliver, which teaches a “venting arrangement” within the suction tube between the enclosure and vacuum source.

Combination of Hunt and Dolliver: As explained regarding claim 11 in Ground 3 above, Hunt discloses tube 106 and pressure relief valve 8 (i.e., venting arrangement), which admit ambient air into the system that flows towards the canister. Dolliver also teaches a “venting arrangement” including “vent valve 119” located on the suction tube between the enclosure and pump. (EX1007, [0007]; *see also id.* Fig. 1).

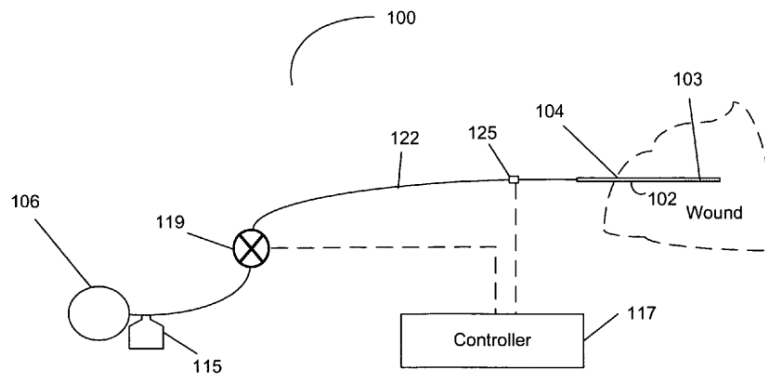


Fig. 1

The “vent valve” admits ambient air into the suction tube which affects the level of negative pressure applied at the wound site. (*Id.*, [0029]). A POSITA would have understood this “vent valve” and tube 101, in the combined system of Hunt and Dolliver, to be a venting arrangement as the valve is an orifice that admits ambient air into the tube. (EX1002 ¶442).

Motivation to Combine Hunt and Dolliver: A POSITA would have been motivated to combine the NPWT system of Hunt with the vent valve of Dolliver, located on the suction tube between the wound site and vacuum pump. (EX1002 ¶¶418-419). Hunt and Dolliver both teach negative pressure wound drainage systems that utilize valves to control the level of suction applied. (EX1006; EX1007).

Before 2005, based on the teachings in the prior art, a POSITA would have been aware that valves open to the atmosphere can be used in NPWT systems to alter the level of suction. (EX1002 ¶420; *see also* EX1005, 12:56-58; EX1003, 7:43-47; EX1006, 4:17-24; EX1007, [0029]). Modifying Hunt’s system to include the vent

valve of Dolliver, therefore, would have been a combination of known prior art elements using known methods. (EX1002 ¶425 (also explaining pressure valve 8 on tube 106 could be replaced with vent valve 119 on tube 101); *see also* EX1003, 7:43-47, 8:2-5 (using two different kinds of valves or ports to admit ambient air into the system)). The proposed combination is depicted in the exemplary system below:

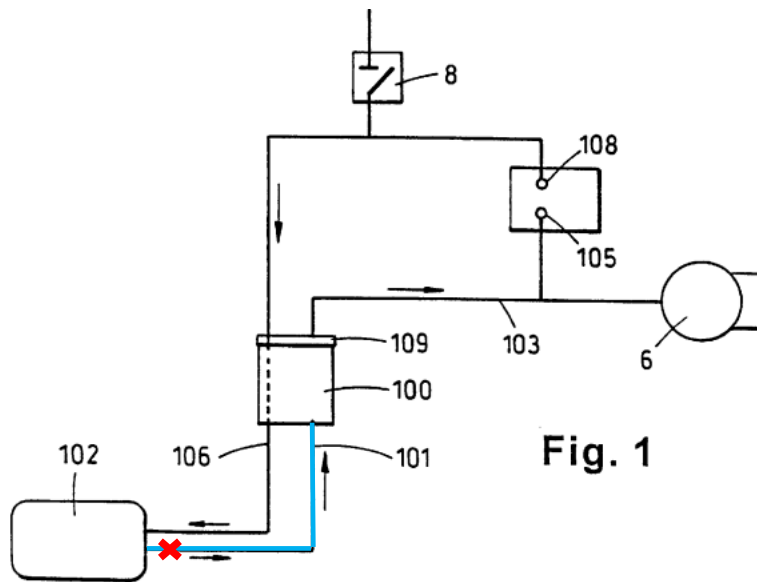


Fig. 1

(EX1006, Fig. 1 (annotated to include vent valve 119 (in red) of Dolliver on suction tube 101 (in blue)). The location of the vent valve 119 is for illustrative purposes only. A POSITA would have known to optimize the location of the vent valve. (EX1002 ¶425). With this combination, a POSITA would have expected the predictable result of providing additional control over the level of negative pressure applied to the wound site 102. (*Id.* ¶426). And, as Dolliver explains, adding the vent valve to the suction tube helps to prevent clogs in the tube when exudate is removed from the wound. (EX1007, [0005]-[0006]).

Modifying Hunt's system to include Dolliver's vent valve would have been obvious to try given the limited number of ways to control negative pressure within the vacuum system and prevent clogs within the suction tube. (EX1002 ¶428). A POSITA would have known, especially based on the teachings of the prior art, to use an orifice or opening of some kind to allow ambient air into the tube. (*Id.*). Moreover, numerous prior art references prior to 2005 taught the use of valves to do just that. (*See e.g.*, EX1003, EX1005-1007). It would have been obvious to a POSITA to try adding a valve to suction tube 101—along with pressure relief valve in tube 106—to provide further control over the level of negative pressure. (EX1002 ¶¶430-432; *see also* EX1003, 7:43-47, 8:2-5 (disclosing more than one opening to admit ambient air at different points in the system)). A POSITA would have expected this combination to be successful in light of Hunt's and Dolliver's teachings of controlling the valve (via a controller) to selectively open or close to adjust the level of suction. (EX1006, 4:17-33; EX1007, [0031]).

Thus, Hunt in view of Dolliver renders obvious element 11[a].

iii. Element 11[b]

Element 11[b] is identical to element 1[b]. Thus, for the reasons stated in Ground 3 regarding element 1[b], Hunt teaches element 11[b].

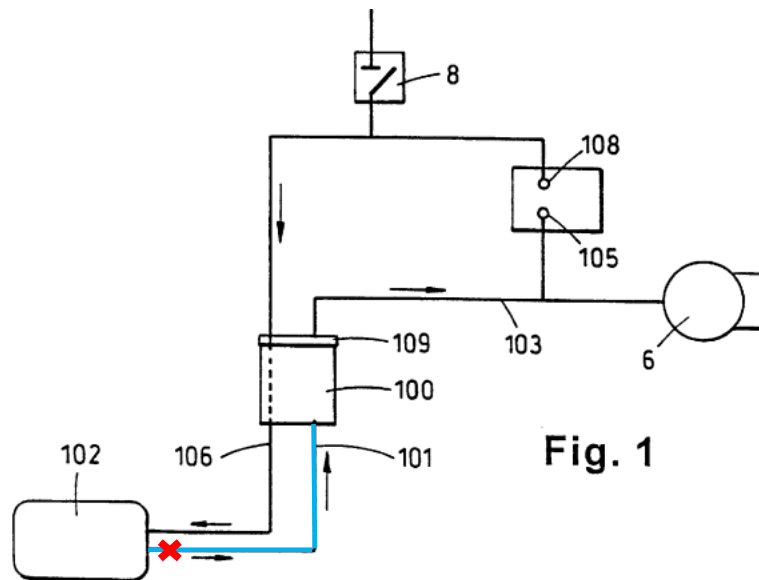
iv. Element 11[c]

Element 11[c] is identical to element 1[c]. Thus, for the reasons stated in Ground 3 regarding element 1[c], Hunt teaches element 11[c].

v. Element 11[d]

Hunt in view of Dolliver discloses “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.” As explained regarding element 11[a] above, Dolliver teaches a “vent valve” that corresponds to the claimed venting arrangement.

The venting arrangement within the combined system of Hunt and Dolliver, as shown below, includes a vent valve on the suction tube 101 which is located outside the enclosure (i.e., wound dressing 102 and surgical drape):



(EX1006, Fig. 1 (annotated)). Vent valve 119 (shown in red in Fig. 1 above) “selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere thereby decreasing the amount of suction applied . . .” (EX1007, [0029]). Ambient air necessarily enters the tube (i.e., suction tube 101) when vent valve 119 is open. (EX1002 ¶451).

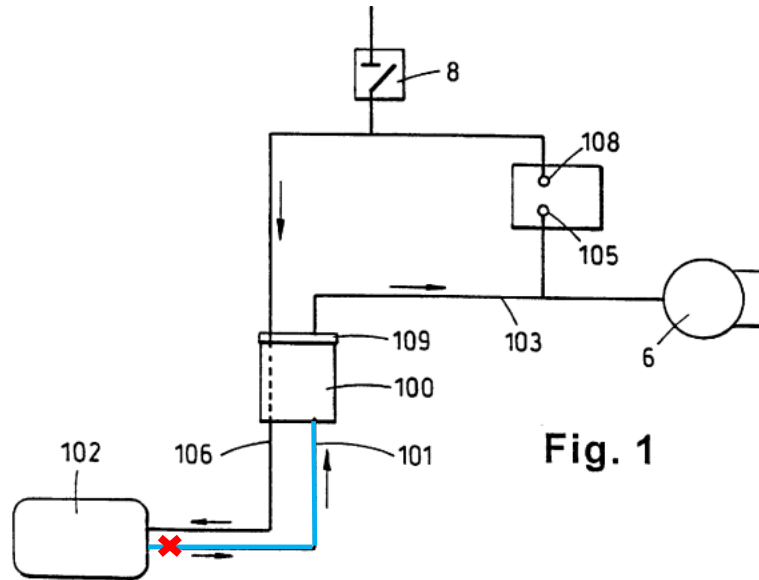
Dolliver also teaches a “flow restrictor” within vent valve 119 in the form of a “filter, such as but not limited to a bacterial filter.” (EX1007, [0029]). A POSITA would have understood that this filter necessarily restricts the flow of ambient air through vent valve 119 (i.e., the venting arrangement) when air is admitted into the tube. (EX1002 ¶¶450-451 (describing a filter as a “porous material” that restricts the flow of air therethrough)). A POSITA would have been motivated to combine the teachings of Hunt and Dolliver for the reasons explained regarding element 11[a].

Thus, Hunt in view of Dolliver renders obvious element 11[d].

vi. Element 11[e]

Hunt in view of Dolliver discloses “said controlled flow of ambient air entering said tube via said venting arrangement without entering said enclosure.” As explained regarding element 11[d], Hunt in view of Dolliver teaches a vent valve with filter that admits a controlled flow of ambient air into suction tube 101. A POSITA would have understood that the ambient air that enters the tube via vent valve 119 does not flow into the enclosure; rather, it flows upstream towards canister

100. (EX1002 ¶454). When the vacuum pump is applying negative pressure to the wound, the airflow in suction tube 101—as indicated by the black arrows in Figure 1 below—flows upstream towards canister 100:



(EX1006, Fig. 1 (annotated); EX1002 ¶454). A POSITA would have been motivated to combine Hunt and Dolliver for the reasons explained regarding element 11[a] above.

Thus, Hunt in view of Dolliver renders element 11[e] obvious.

vii. Element 11[f]

Element 11[f] is substantively identical to element 1[e]. Thus, for the reasons stated in Ground 3 regarding element 1[e], Hunt teaches element 11[f].

A POSITA would have understood Hunt’s controller to maintain its control over the vacuum source, even with the addition of Dolliver’s vent valve. (EX1002 ¶457). Like Hunt, Dolliver teaches that its vent valve “selectively opens (fully or

partially) to allow [the tube] to vent to the atmosphere, thereby decreasing the amount of suction applied.” (EX1007, [0029]). A POSITA would have understood that, in the combined Hunt-Dolliver system, Hunt’s controller controls the application of suction by the vacuum source while tube 101 is being vented through vent valve 119 (i.e., the venting arrangement). (EX1002 ¶458). A POSITA would have been motivated to combine Hunt and Dolliver for the reasons explained regarding element 11[a].

Thus, Hunt in view of Dolliver renders obvious element 11[f].

In sum, Hunt in view of Dolliver renders obvious claim 11.

2. Claim 12

Claim 12 is substantively identical to claim 3 and as explained in Ground 3, Hunt teaches claim 3. Additionally, as explained above, Hunt in view of Dolliver renders obvious claim 11. Thus, for the reasons stated regarding claims 3 and 11, Hunt in view of Dolliver renders obvious claim 12.

3. Claim 13

Claim 13 is substantively identical to claim 4 and, as explained in Ground 3, Hunt teaches claim 4. Additionally, as explained above, Hunt in view of Dolliver renders obvious claim 11. Thus, for the reasons stated regarding claims 4 and 11, Hunt in view of Dolliver renders obvious claim 13.

4. Claim 14

Claim 14 is substantively identical to claim 5 and, as explained in Ground 3, Hunt teaches claim 5. Additionally, as explained above, Hunt in view of Dolliver renders obvious claim 11. Thus, for the reasons stated regarding claims 5 and 11, Hunt in view of Dolliver renders obvious claim 14.

5. Claim 15

Claim 15 is substantively identical to claim 6 and, as explained in Ground 3, Hunt teaches claim 6. Additionally, as explained above, Hunt in view of Dolliver renders obvious claim 14. Thus, for the reasons stated regarding claims 6 and 14, Hunt in view of Dolliver renders obvious claim 15.

6. Claim 16

Claim 16 is substantively identical to claims 7 and 8, and as explained in Ground 4, Hunt in view of Lina renders obvious claims 7 and 8. Additionally, as explained above, Hunt in view of Dolliver renders obvious claim 15. Thus, for the reasons stated regarding claims 7, 8, and 15, Hunt in view of Dolliver and in further view of Lina renders obvious claim 16.

7. Claim 17

Hunt in view of Dolliver discloses “[t]he 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.” As explained above, Hunt in view of Dolliver renders obvious claim 11.

A POSITA would have understood that, when the vacuum pump of Hunt is turned on, the vent valve of Dolliver (in the combined Hunt-Dolliver system) is open and “vents to the atmosphere” to “decreas[e] the amount of suction applied” to the wound site. (EX1002 ¶472; EX1007, [0029]). A POSITA would have also understood that, when the pump is turned off and not operating, vent valve 119 admits ambient air into the system and restores ambient pressure at the wound site. (EX1002 ¶¶471-473). A POSITA would have been motivated to combine Hunt and Dolliver for the reasons explained regarding element 11[a].

Thus, Hunt in view of Dolliver renders obvious claim 17.

8. Claim 18

Hunt in view of Dolliver discloses “[t]he 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.” As explained above, Hunt in view of Dolliver renders obvious claim 11.

Also as explained regarding claim 11, the venting arrangement within the combined Hunt-Dolliver system includes a vent valve that admits ambient air into the suction tube. A POSITA would have understood the vent valve to constitute an

orifice or a bleeding hole. (EX1002 ¶476). A POSITA would have been motivated to combine Hunt and Dolliver for the reasons explained regarding element 11[a].

Thus, Hunt in view of Dolliver renders obvious claim 18.

IX. SECONDARY CONSIDERATIONS

Patent Owner has not identified any evidence of secondary indicia of non-obviousness for the '534 patent. Accordingly, there is no objective evidence of non-obviousness that might warrant a finding that the Challenged Claims are patentable. (EX1002 ¶¶478-479). Should Patent Owner identify any evidence of non-obviousness in response to this Petition, Petitioners reserve the right to respond in their Reply.

X. CONCLUSION

Petitioners respectfully request institution of review on claims 1-22 and a finding that they are unpatentable.

Respectfully submitted,

/Erik B. Milch/

Erik B. Milch (Reg. No. 42,887)
Proskauer Rose LLP
1001 Pennsylvania Ave., NW
Suite 600
Washington, DC 20004
Tel: (202) 416-6800
emilch@proskauer.com

Dated: June 21, 2024

Attorney for Petitioners Medela LLC and Medela AG

Petition for *Inter Partes* Review of
U.S. Patent No. 8,858,534 B2

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I hereby certify that on June 21, 2024, I caused a complete copy of this Petition for *Inter Partes* Review of U.S. Patent No. 8,858,534 and all exhibits, to be served on the Patent Owner of the subject Patent as follows:

Erik Lund
1850 Towers Crescent Plaza,
Suite 550,
Tysons, VA 22182

/Erik B. Milch/
Erik B. Milch (Reg. No. 42,887)

CERTIFICATE OF COMPLIANCE

Petitioners Medela LLC and Medela AG certify:

1. This Petition complies with the type-volume limitations of 37 C.F.R. § 42.24(a)(1)(i) and contains 13,940 words, excluding the portions of the Petition exempted by 37 C.F.R. § 42.24(a)(1); and

2. This Petition complies with the typeface and style requirements of 37 C.F.R. §§ 42.6(a)(2)(ii), 42.6(a)(2)(iii) and has been prepared in proportionally spaced, 14-point Times New Roman font using Microsoft Word Version 2308 (2024).

/Erik B. Milch/

Erik B. Milch (Reg. No. 42,887)