

Petition for *Inter Partes* Review of
U.S. Patent No. 8,506,554

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. IPR2024-01075

U.S. Patent No. 8,506,554 B2

PCT Filing Date: July 24, 2005

Issue Date: August 13, 2013

Title: WOUND CLOSURE AND DRAINAGE SYSTEM

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,506,554 B2**

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List of Exhibits

Exhibit No.	Description of Document
1001	U.S. Patent No. 8,506,554 B2 to Carmeli Adahan (Application filed July 24, 2005, issued August 13, 2013)
1002	Declaration of John M. Collins, Ph.D
1003	U.S. Patent No. 6,142,982 to Kenneth William Hunt, et al. (Application filed May 13, 1998, issued November 7, 2000)
1004	U.S. Patent No. 6,648,862 to Richard Watson (Application filed November 20, 2001, issued November 18, 2003)
1005	U.S. Patent Application Publication No. US 2005/0192548 to Phillip B. Dolliver, et al. (Application filed February 26, 2004, published September 1, 2005)
1006	Complaint, <i>M.E.A.C. Engineering Ltd. v. Medela LLC, et al.</i> , Case No. 1:23-cv-14045 (N.D. Ill.)
1007	U.S. Patent No. 8,858,534 B2 to Carmeli Adahan (Application filed June 14, 2013, issued October 14, 2014)
1008	File History of U.S. Patent No. 8,506,554
1009	File History of U.S. Patent No. 8,858,534
1010	Northern District of Illinois Time-to-Trial Statistics, Lex Machina, available at https://law.lexmachina.com/court/ilnd/cases?pending-from=2009-01-01&filters=true&view=analytics&tab=timing&cols=475 (last accessed May 30, 2024)
1011	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.)

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Exhibit No.	Description of Document
1012	Christine Miller, “The History of Negative Pressure Wound Therapy (NPWT): From ‘Lip Service’ to the Modern Vacuum System,” J. Am. Coll. Clin. Wound Spec. 4: 61-62 (2014)
1013	U.S. Patent No. 1,889,425 to George L. Sorenson (Application filed March 2, 1931, issued November 29, 1932)
1014	U.S. Patent No. 3,026,874 to R.C. Stevens (Application filed November 6, 1959, issued March 27, 1962)
1015	U.S. Patent No. 4,569,674 to Earl G. Phillips, et al. (Application filed August 3, 1982, issued February 11, 1986)
1016	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,” Annals of Plastic Surgery, Vol. 38, No. 6 (June 1997)
1017	U.S. Patent No. 6,764,462 to James R. Risk, et al. (Application filed May 31, 2002, issued July 20, 2004)
1018	U.S. Patent No. 6,695,823 to Cesar Z. Lina, et al. (Application filed April 7, 2000, issued February 24, 2004)
1019	U.S. Patent No. 7,678,102 to Keith Patrick Heaton (PCT Application filed November 8, 2008, issued March 16, 2010)
1020	U.S. Patent No. 6,071,267 to David S. Zamierowski (Application filed February 6, 1998, issued June 6, 2000)
1021	U.S. Patent No. 5,735,833 to Daniel H. Olson (Application filed December 11, 1996, issued April 7, 1998)
1022	U.S. Patent Publication No. 2003/0125649 to Laura Janet McIntosh, et al. (Application filed October 29, 2002, published July 3, 2003)
1023	U.S. Patent No. 7,708,724 to Richard Scott Weston (Application filed April 4, 2005, issued May 4, 2010)

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Exhibit No.	Description of Document
1024	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)
1025	U.S. Patent No. 6,241,739 to Stephen H. Waldron (Application filed November 12, 1999, issued June 5, 2001)
1026	U.S. Patent No. 6,045,516 to James Phelan (Application filed December 18, 1998, issued April 4, 2000)
1027	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)
1028	’554 Patent Claim Listing
1029	U.S. Patent No. 3,841,331 to Joseph R. Wilder, et al. (Application filed on November 17, 1972, issued on October 15, 1974)

I. INTRODUCTION

Petitioners Medela LLC and Medela AG respectfully submit this Petition for *Inter Partes* Review of claims 12-17, 26, and 27 (the “Challenged Claims”) of U.S. Patent No. 8,506,554 (the “’554 patent”) (EX1001). Petitioner requests 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 ’554 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. (EX1006). There are three other related cases involving Patent Owner and the ’554 patent: (1) *MEAC Engineering LTD v. Solvntum 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

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4, 2023, and January 12, 2024, respectively. Solventum Corp. filed an *inter partes* review proceeding challenging claims 12-17 and 26-27 of the '554 Patent on June 5, 2024. PTAB-IPR2024-01001.

Petitioners have concurrently filed a petition for *Inter Partes* review of a related patent—U.S. Patent No. 8,858,534 (the “'534 patent”) (EX1007)—also asserted in the pending litigation: IPR2024-01076.

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

Petitioners provide the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
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	New York, NY 10036 Tel: (212) 969-3000
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D. Service Information under § 42.8(b)(4)

This Petition is being served by Federal Express to the attorney of record for the '554 patent, Erik Lund, 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 8 claims, with a \$41,500 payment.

IV. REQUIREMENTS UNDER 37 CFR §§ 42.104 AND 42.108

A. Grounds for Standing

Petitioners certify the '554 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 12-17, 26, and 27 based on:

Ground	'554 Patent Claims	Basis for Challenge	Application of Prior Art
1	12, 13, 16, 26, 27	35 U.S.C. § 102	Hunt
2	14, 15	35 U.S.C. § 103	Hunt in view of Watson

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Ground	'554 Patent Claims	Basis for Challenge	Application of Prior Art
3	12, 13, 16, 17, 26, 27	35 U.S.C. § 103	Hunt in view of Dolliver
4	14, 15	35 U.S.C. § 103	Hunt in view of Dolliver and Watson

Submitted with this Petition is a 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 an Election/Restriction requiring that applicant elect a single invention, noting that certain claims were drawn to: (1) a vacuum system and method; (2) an enclosure; (3) a disposable assembly; and (4) another vacuum system. (EX1008 at 1045-1048). In response, the applicant elected the second group containing claims “drawn to an enclosure for draining an open wound.” (*Id.* at 972-974). On October 14, 2010, the examiner issued a Non-Final Rejection under 35 U.S.C. §§ 102 and 103 finding the claims anticipated by Lerman. (*Id.* at 954-961). In response, applicant amended the claims to require “applying negative pressure” through an enclosure attachable to a tube that comprises a “venting arrangement, outside of said enclosure, such that

ambient air can enter said tube via said venting arrangement” to traverse the rejection over Lerman. (*Id.* at 620-639).

On April 20, 2011, the examiner issued a Final Rejection on new grounds, concluding the amended claims were invalid under 35 U.S.C. §§ 102 and 103 over Lockwood and/or over Lockwood in view of Argenta et al. (*Id.* at 575-584). Applicant then submitted a Request for Continued Examination, amending the claims to require ambient air to “flow to said vacuum source without entering said enclosure.” (*Id.* at 485-506). Applicant argued that “Lockwood *teaches away* from the claimed subject matter” and ambient air in Lockwood “**has to flow over the wound**” within the enclosure. (*Id.* at 498 (emphasis in original)). In contrast, applicant argued, the amended claims require that “air sucked in through the venting arrangement goes **directly** to the pump under suction *without passing through the enclosure*, and tends to dislodge any blockage in the tube, if present there.” (*Id.* (emphasis in original)).

On October 11, 2011, the examiner issued a Non-Final Rejection of the amended claims. (*Id.* at 429). The examiner withdrew the rejection over Lockwood under 35 U.S.C. § 102 based on applicant’s amendments, however, rejected the amended claims over Lockwood in view of Leffler and Argenta under 35 U.S.C. § 103 because Leffler discloses “a venting arrangement outside of the wound area allowing the flow to the vacuum source without entering the wound area.” (*Id.* at

432-438). Applicant argued in response that the invention of Leffler “would destroy the operation of Lockwood’s device” and, therefore, would not be combined with Lockwood. (*Id.* at 394-418). Although the examiner found this argument persuasive, the examiner still found the claims unpatentable over Argenta in view of Leffler. (*Id.* at 349-355). During a telephonic interview, applicant and examiner agreed to add a claim limitation of “comprising a calibrated orifice to restrict flow through the venting arrangement located outside said enclosure.” (*Id.* at 319). Taking this amendment into account, the examiner found the claims in condition for allowance. (*Id.* at 320-323).

Applicant then amended the claims again, removing examiner’s amendment and adding a “flow restrictor.” (*Id.* at 299-309). On July 24, 2013, the examiner filed an issue notification for the amended claims. (*Id.* at 48). Several certificates of correction were requested after issuance.

The prior art references identified in this Petition were never discussed nor analyzed during prosecution of the ’554 patent,¹ however, some were disclosed to the Patent Office. Dolliver and Watson were disclosed along with certain patents and publications that are related to Hunt. None of the other cited prior art references,

¹ The identified references were also never discussed nor analyzed during prosecution of the related ’534 patent. EX1009.

discussed in this Petition to evidence the state of the art at the time of invention, were discussed nor 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 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. (EX1010). 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 '554 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 system that is identified in its counterclaims. (EX1011 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.** Petitioners acknowledge that 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 '554 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 '554 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 a wound. In fact, such techniques date back to humans sucking on wounds to remove contaminants. (EX1012 at 1; EX1002 ¶39).

As early as the 1930s, the manipulation of pressure levels of suction devices was known. (EX1013; EX1002 ¶40). Vacuum-assisted drainage was in use by 1960

(EX1014), and by the 1980s, the use of negative pressure devices was common. (EX1015 at 1:14-17; EX1002 ¶40).

The more recent types of devices were invented in the 1990s by a group at Wake Forest University. (EX1016; 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, EX1017-1020; 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.” (EX1019 at 1:4-14; EX1002 ¶43). Controllers and sensors were used to modulate the level of negative pressure in the system. (EX1003; EX1005; EX1017; EX1018; EX1002 ¶43).

B. The Role of Ambient Air in NPWT Systems

One of the dangers of NPWT devices is the use of 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. (EX1017; EX1020-1023; EX1002 ¶46). Others disclose an air opening on the tubing connecting the wound cover to the vacuum source. (EX1014; EX1017; EX1024; 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. (EX1025-1027; 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 is shown in U.S. Patent. 6,695,823 to Cesar Z. Lina, et al. (EX1018, Fig. 1 (orifice 86); EX1002 ¶48).

VI. OVERVIEW OF THE '554 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, conversely, additional practical experience could compensate for less education. (EX1002 ¶69).

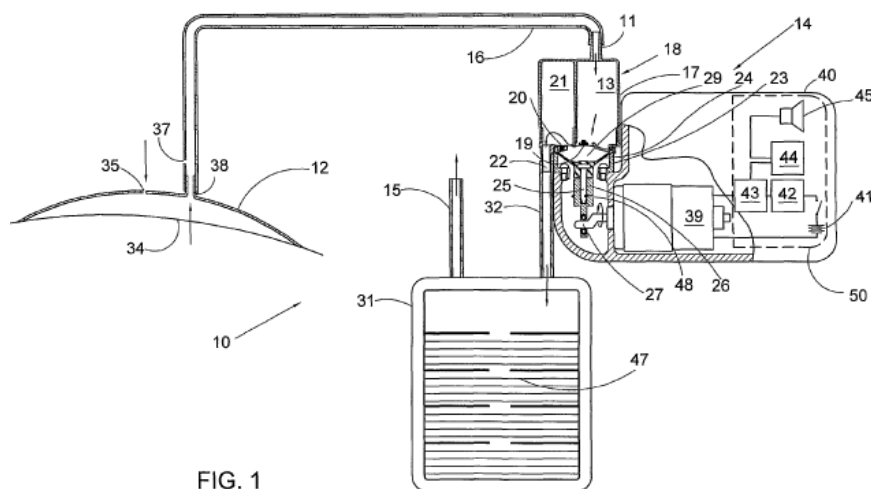
B. Priority Date

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 '554 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 to allow liquids drawn from the wound to be deposited in the waste container. (*Id.*, 2:41-44, 3:18-24). The specification also teaches “bleeding orifice 35 is provided within the enclosure 12, or adjacent to it as a tube orifice 37 (i.e. venting arrangement), allowing air to flow into and through suction tube 16.” (*Id.*, 4:28-31). 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.*, 4:41-46). The specification further teaches that “the pump unit is disposed of after use, together with the tubing connected to it, as well as the waste bag connected, with its content, and with the wound closure which may be connected to the pump unit via the tube.” (*Id.*, 3:20-24).

D. The Challenged Claims

This Petition challenges claims 12-17, 26, and 27 of the ’554 patent.

E. Claim Listing

Exhibit 1028 is a claim listing enumerating each challenged 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 for this Petition 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 '554 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 OBVIOUS

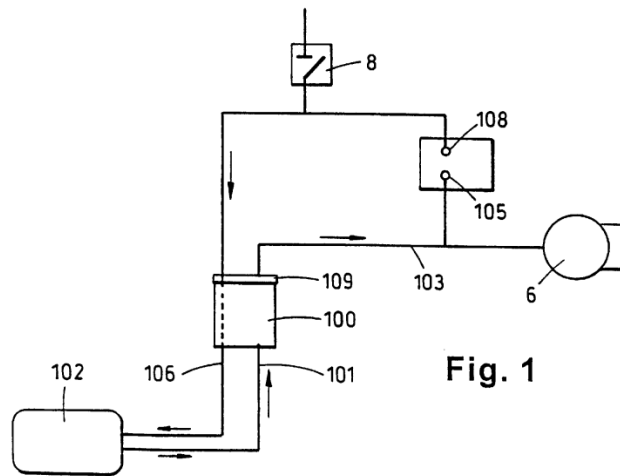
As detailed below, claims 12-17, 26, and 27 of the '554 patent are anticipated by and/or obvious in view of the identified prior art.

A. Summary and Date Qualification of the Prior Art

1. Hunt (Ex. 1003)

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. (EX1003, Abstract; *see also id.*, 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 begin applied to the wound. (*Id.*, 1:55-63, 4:9-16).

2. Watson (Ex. 1004)

U.S. Patent No. 6,648,862 to Richard Watson ("Watson") is a patent entitled "Personally Portable Vacuum Desiccator," filed November 20, 2001, issued November 18, 2003, and qualifies as prior art under 35 U.S.C. §§ 102(a), (b), and (e) (pre-AIA).

Watson discloses a portable vacuum system which applies low pressure to a wound to remove fluid which is collected in a trap. (EX1004 at Abstract, 2:24-28; *see also id.* at Fig. 1).

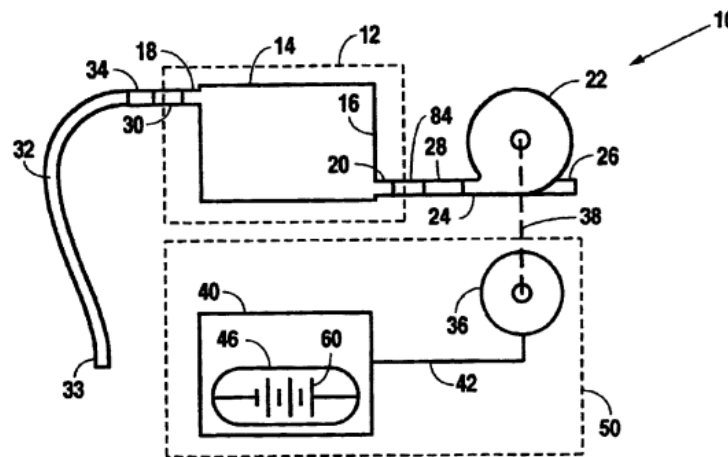


Fig. 1

Watson also teaches that certain components within the vacuum desiccator system, which contact the removed wound fluid, are disposable. (*Id.* at 2:28-32, 4:17-22). The system of Watson includes wound dressing, tubing, a desiccator cartridge for waste, a pump, a motor, and an electrical control unit. (*Id.* at 4:43-52, 2:35-36, 3:63-65, 5:48-55, 6:8-15).

3. Dolliver (Ex. 1005)

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 drain catheter that applies suction to the wound. (EX1005, Abstract; *see also id.*, Fig. 1).

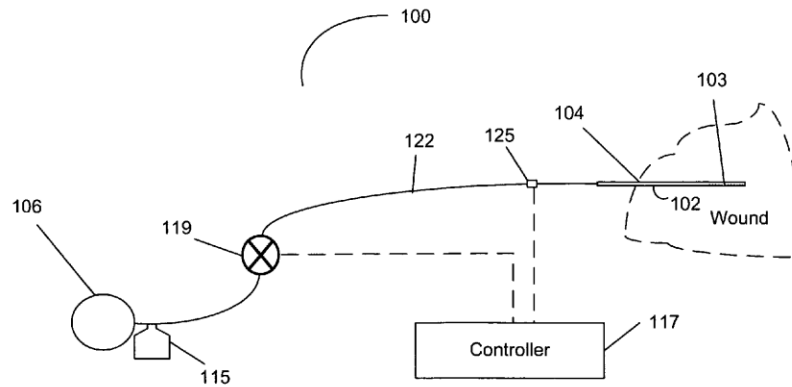


Fig. 1

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: Anticipation of Claims 12, 13, 16, 26, and 27 By Hunt

1. Claim 12

Claim 12 is anticipated by Hunt.

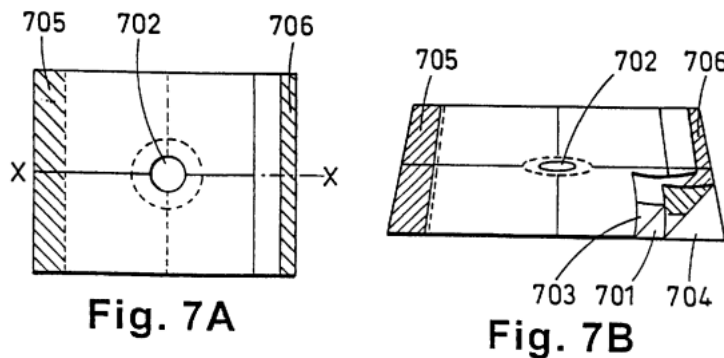
i. Claim 12, Preamble

To the extent the preamble is limiting, it is taught 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”. (EX1003, 1:45-50, 3:59-61).

Thus, Hunt teaches the preamble of claim 12.

ii. Element 12[a]

Hunt teaches “an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume.” 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.” (*Id.*, 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 ¶¶93-95).

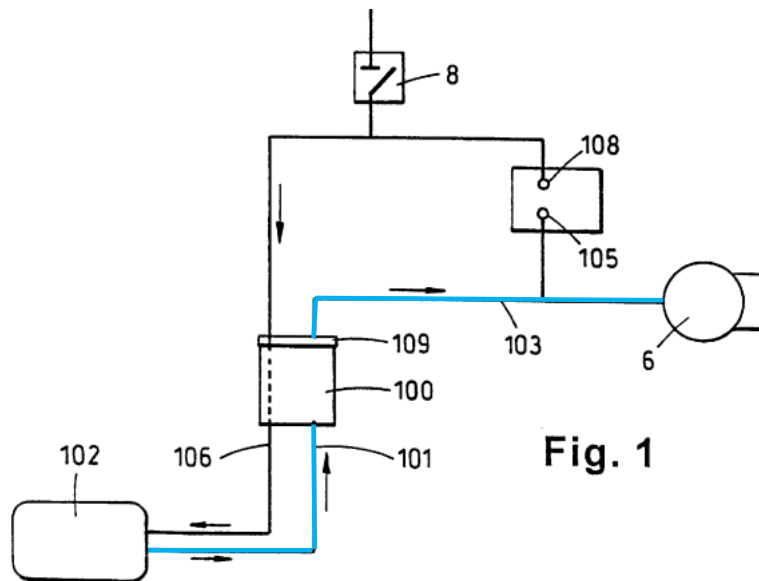
The surgical drape is “adhered to the patient’s skin around the wound site while, at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an airtight cavity is formed around the wound.” (EX1003, 5:27-38). A POSITA would have understood 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 ¶¶98-99).

Hunt also teaches “suction pump 6” which applies negative pressure to the wound site. (EX1003, 3:32-33, 3:60-4:1). Thus, suction pump 6 corresponds to the claimed “vacuum source.” (*See also* EX1002 ¶¶96-97).

Thus, Hunt teaches element 12[a].

iii. Element 12[b]

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



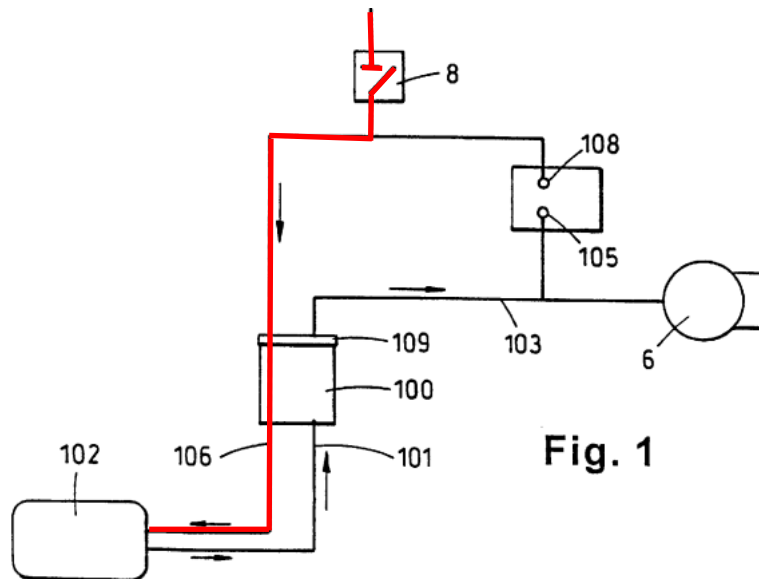
(EX1003, Fig. 1 (annotated)). Tube 101 applies negative pressure to the wound site under the enclosure. (*Id.*, 3:31-61, 4:43-45; *see also* EX1002 ¶102 (explaining the operative connection between tube 103 and tube 101 which apply suction to the wound dressing)). Hunt also teaches “it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister”. (EX1003, 4:34-39

(describing combining tubes 106 and 101—as shown in Figure 1 above—into a single, multi-partitioned tube)).

Thus, Hunt teaches element 12[b].

iv. Element 12[c]

Hunt teaches “a venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement.” Hunt discloses a tube (tube 106) which is connected to the enclosure and to pressure relief valve 8, as shown in Figure 1 below:



(EX1003, 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 ’554 patent. (EX1002 ¶¶106-107 (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. (EX1003, 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 ¶108).

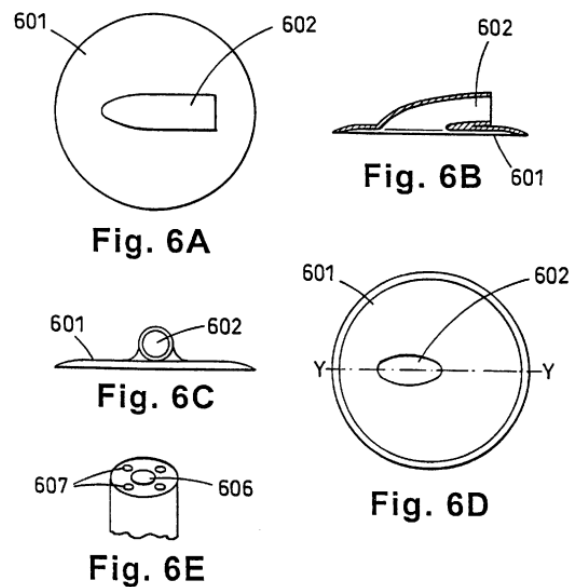
A POSITA would have also understood that pressure relief valve 8—which is part of the venting arrangement—is a “flow restrictor” under the plain and ordinary meaning of that term. (*Id.* ¶¶110-111). “[P]ressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly” by opening the valve for a specified period of time. (EX1003, 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 ¶111 (“that the valve can at least 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”)).

Thus, Hunt teaches element 12[c].

v. Element 12[d]

Hunt teaches “the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be created in said volume.” As explained regarding elements 12[a] and [b] above, Hunt teaches an enclosure, vacuum 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:



(EX1003, 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, alternatively, the tube can be passed through the spout into the wound dressing (i.e., through the enclosure outlet). (*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 the 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).

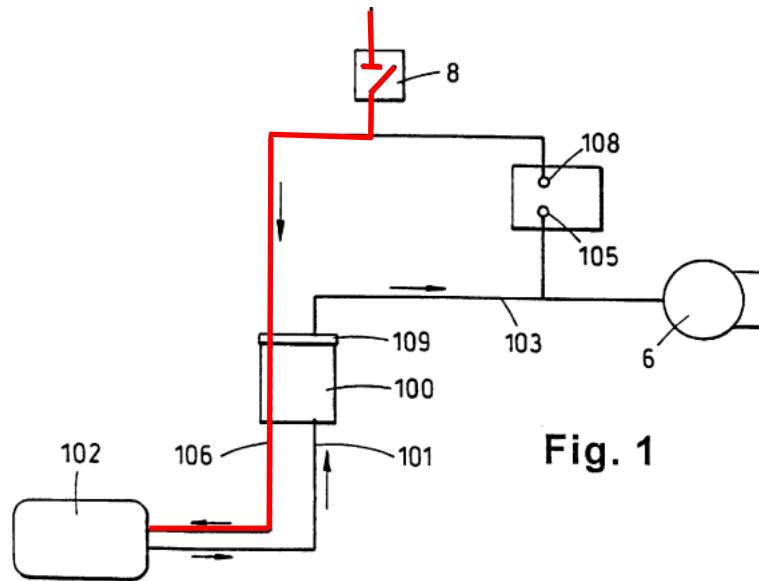
A POSITA would have understood that the tube which is connected to this enclosure outlet (tube 101) applies suction carried from tube 103 which is connected to the vacuum source. (EX1002 ¶116; *see also* EX1003, 3:60-61 (“Suction is applied to the wound site via the canister by a tube 103, connected to pump 6”). The suction creates a negative pressure in the volume of the enclosure. (EX1002 ¶116).

Thus, Hunt teaches element 12[d].

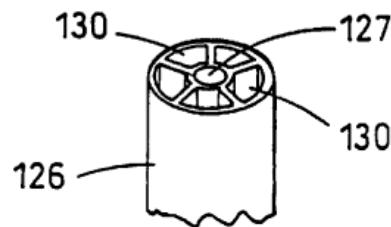
vi. Element 12[e]

Hunt teaches “said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure”. As explained regarding element 12[c], Hunt teaches a venting arrangement which comprises tube 106 and pressure relief valve 8.

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:



(EX1003, 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:



(*Id.*, Fig. 5F). Thus, Hunt discloses that its venting arrangement is located outside the enclosure and allows ambient air to enter the tube.

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 ¶121).

The multi-partitioned tube, including tubes 106 and 101, is connected to the wound dressing via connector 602 as shown below:

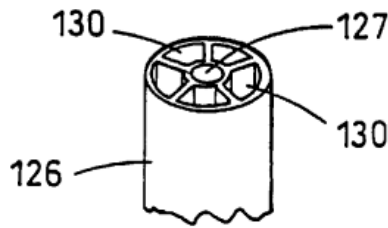


Fig. 5F

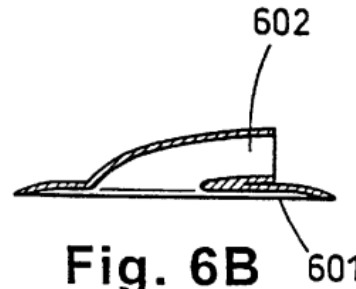
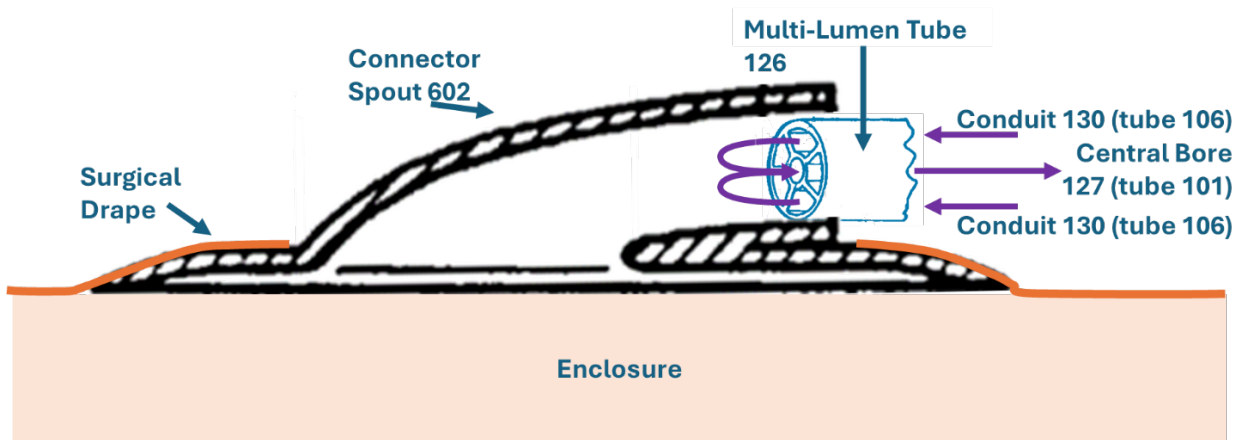


Fig. 6B

(EX1003, 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 ¶121). Accordingly, a POSITA would have known that ambient air would exit tube 106 (or conduit 130 in the multi-partitioned tube) and enter tube 101 (or central conduit 127 in the multi-partitioned tube) and flow towards the waste canister and vacuum source without entering the enclosure, as depicted below:



(*Id.*).

Thus, Hunt teaches element 12[e].

vii. Element 12[f]

Hunt teaches “a waste container in fluid communication with said vacuum source.” Hunt teaches a “canister [100] for containing fluids drawn from the wound by said pump” which constitutes a waste canister. (EX1003, 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, then, that the waste canister of Hunt is in fluid communication with the vacuum source. (EX1002 ¶124).

Thus, Hunt teaches element 12[f]. In sum, Hunt teaches claim 12.

2. Claim 13

Claim 13 is anticipated by Hunt.

i. Claim 13, preamble

To the extent the preamble is limiting, it is anticipated by Hunt. The preamble recites “The vacuum system of claim 12.” As explained above, Hunt teaches claim 12 and, therefore, for the same reasons teaches the preamble of claim 13.

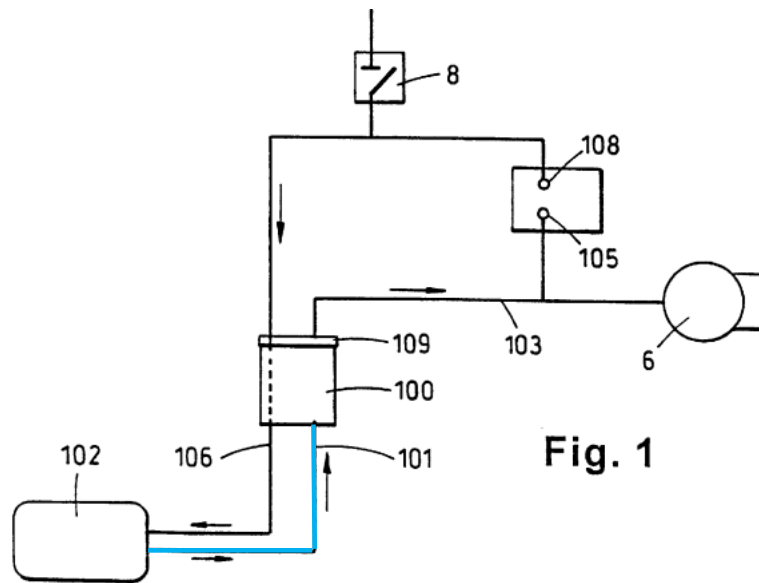
ii. Element 13[a]

Hunt teaches “wherein said vacuum system further operates to drain the wound from fluids exuded therefrom.” As explained regarding element 12[f], Hunt teaches canister 100 “for containing fluids drawn from the wound.” (EX1003, Abstract). A POSITA would have recognized that the vacuum system of Hunt operates to drain the wound from fluids, which is deposited in canister 100. (EX1002 ¶131).

Thus, Hunt teaches element 13[a].

iii. Element 13[b]

Hunt teaches “wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of negative pressure.” As explained regarding element 12[e], in Hunt, ambient air enters the tube (i.e., multi-partitioned tube) via the venting arrangement (tube 106 and pressure relief valve 8) and flows towards the vacuum pump when negative pressure is applied. Figure 1 includes arrows indicating the direction of air flow within the system:



(EX1003, Fig. 1 (annotated to indicate the path traveled by the exuded liquids and ambient air)). A POSITA would have understood that the fluids removed from the wound during negative pressure treatment would necessarily flow with ambient air in the multi-partitioned tube towards canister 100. (EX1002 ¶¶134-136).

Thus, Hunt teaches element 13[b].

iv. Element 13[c]

Hunt teaches “and facilitates draining of the exuded fluids to said waste canister”. As explained regarding elements 12[f] and 13[a]-[b], the system of Hunt applies negative pressure to remove fluids from a wound which, along with ambient air, travel towards canister 100 where the fluids are deposited. A POSITA would have recognized that the application of suction and ambient air admitted through the venting arrangement facilitate the movement of fluids exuded from the wound towards the waste canister. (EX1002 ¶138).

Thus, Hunt teaches element 13[c]. In sum, Hunt teaches claim 13.

3. Claim 16

Hunt teaches “The vacuum system according to claim 12, wherein said venting arrangement comprises one or more bleeding holes.” As explained above, Hunt teaches claim 12 and also teaches a venting arrangement that comprises tube 106 and a pressure relief valve 8. A POSITA would have understood pressure relief valve 8 to have a bleeding hole—based on the plain and ordinary meaning of that term—where it opens and allows ambient air to enter tube 106. (*Id.* ¶¶141-142).

Thus, Hunt teaches claim 16.

4. Claim 26

Hunt teaches “The vacuum system according to claim 12, wherein the venting arrangement is a tube orifice.” As explained above, Hunt teaches claim 12 and Hunt also teaches a venting arrangement comprising a pressure relief valve 8 and tube 106. A POSITA would have understood that pressure relief valve 8 has an opening to admit ambient air into tube 106. (EX1002 ¶145). A POSITA would have also recognized that the opening in pressure relief valve 8 (which exposes the lumen of tube 106 to the atmosphere) is a tube orifice, under the plain and ordinary meaning of that term. (EX1002 ¶145).

Thus, Hunt teaches claim 26.

5. Claim 27

Hunt teaches “The vacuum system according to claim 26, said orifice having a smaller opening than a cross-section of the tube.” As explained above, Hunt teaches claim 26 and teaches a tube orifice. A POSITA would have understood that the opening (i.e., tube orifice) in pressure relief valve 8 would necessarily be smaller than the cross-section of the multi-partitioned tube in certain positions between open and closed. (EX1002 ¶147).

Thus, Hunt teaches claim 27.

C. Ground 2: Obviousness of Claims 14 and 15 Based on Hunt in View of Watson

1. Claim 14

To the extent Hunt does not explicitly teach the disposable and detachable components recited in claim 14, a POSITA would have been motivated to combine Hunt with Watson, which teaches that the components of the vacuum system which come into contact with wound exudate are removable and disposable.

i. Claim 14, preamble

To the extent the preamble is limiting, it is anticipated by Hunt. The preamble recites “The vacuum system of claim 12.” As explained in Ground 1, Hunt teaches claim 12 and, therefore, for the same reasons teaches the preamble of claim 14.

ii. Element 14[a]

Hunt in view of Watson discloses “wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit.”

Combination of Hunt and Watson: As explained in Ground 1, Hunt teaches a vacuum source including a pump (pump 6) and Hunt also teaches a drive unit (electric motor) which drives the pump. (EX1003, 1:61-63). Watson similarly teaches a “vacuum pump member” which is connected to “electric motive 36” which drives the pump. (EX1004, 2:49-53, 3:57-65, Fig. 1).

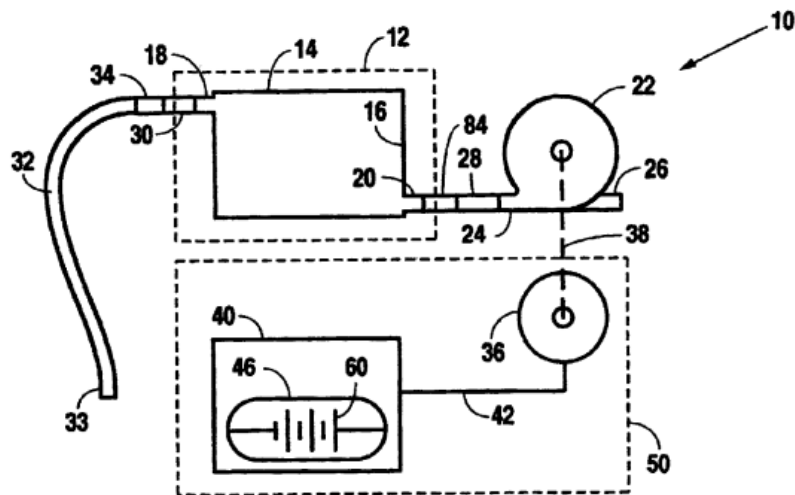


Fig. 1

A POSITA would have understood the vacuum pump member to correspond to the claimed “pump unit” and electric motive (or motor) to correspond to the claimed drive unit. (EX1002 ¶183).

Watson also teaches that the vacuum pump member is “mechanically” or magnetically coupled” to, and “readily separable” from, the electric motive. (EX1004, 3:57-65). In an embodiment, Watson discloses that the vacuum pump member is integrated with the desiccator cartridge (i.e., waste container) which is “simply attached to the housing” containing the electric motive. (*Id.*, 4:26-29, Figs. 1, 4; *see also id.*, 3:59-65 (explaining this embodiment is “particularly useful” so the components are readily separable)). A POSITA reading Watson would have recognized that the vacuum unit is, therefore, detachably attached to the drive unit, based on the plain and ordinary meaning of that term. (EX1002 ¶¶184-186).

Additionally, Watson teaches that the pump unit (i.e., vacuum pump member) is disposable. As explained above, in an embodiment of Watson “the vacuum pump member and the desiccator cartridge are integrated together as a unit.” (EX1004, 3:64-65). Watson also states:

In a preferred embodiment of the vacuum desiccator 10, all of the components in gas/liquid flow communication are replaceable. This allows the components of the device that are exposed to contact with the wound fluids to be separable from the other components of the device to facilitate cleaning or disposal of contaminated components. . . . This feature may be useful where the desiccator cartridge and vacuum pump head are combined as a single integrated unit.

(*Id.*, 7:16-32). And Watson discloses the “vacuum pump member or pump head is connected in gas flow communication with the interior chamber of the trap.” (*Id.*, 2:49-52). A POSITA would have understood that the vacuum pump member (i.e.,

pump unit) is disposable along with the desiccator cartridge and all components coming into contact with wound fluid, especially in the preferred embodiment where the pump unit and desiccator cartridge are integrated together as a unit. (EX1002 ¶¶185-186). A POSITA would have also understood, based on the disclosures of Watson, that the drive unit (i.e., electric motive) is non-disposable under the plain and ordinary meaning of that term as it is part of the housing, not the disposable unit, and does not come into contact with wound fluid. (*Id.* ¶187).

Motivation to Combine Hunt and Watson: A POSITA would have been motivated to combine the NPWT system of Hunt with the disposable and detachable components of Watson. (EX1002, ¶¶154-178). Hunt and Watson both teach portable wound therapy vacuum systems that utilize pumps and waste containers to remove fluid from a wound. (*See generally* EX1003; EX1004).

Before 2005, based on the teachings in the prior art, a POSITA would have been aware that disposable and detachable components could be used in NPWT systems to facilitate replacement of those components which are contaminated by wound fluid. (EX1002 ¶¶159-167; *see also* EX1029, 1:64-67, 3:59-65 (teaching “the entire assembly may be discarded after first detaching the syringe from the driver fittings,” including the waste container, tubing, and pump); EX1018, Abstract, 2:46-49, 3:19-21 (disclosing a “disposable wound fluids canister and porous pad” which is “removed . . . , disposed of, and replaced” to “protect the wound closure

apparatus from contamination”); EX1005, [0033] (disclosing a “disposable set” of components including the tubing which contacts wound fluid); EX1017, 4:39-43, 5:1-4, 7:8-10 (teaching that waste canister, which “snaps into” the housing, is “discarded when filled and replaced”); *see also* EX1004, 4:17-22). Hunt also teaches a disposable waste canister “removably mounted within the housing, e.g. by means of a latch or release mechanism, so that the canister can be readily removed and replaced when full.” (EX1003, 1:67-2:3). Modifying Hunt’s system to include the disposable and detachable components of Watson, therefore, would have been a combination of known prior art elements using known methods, predictably resulting in a system with components that can be readily detached and replaced. (EX1002 ¶¶159-167). And, as Watson explains, providing disposable components avoids contamination from wound fluid within the vacuum system. (EX1004, 2:28-32, 4:17-22, 7:21-23).

A POSITA would have been further motivated to implement the disposable components of Watson’s system into Hunt’s NPWT system because Watson expressly suggests improving the portable wound therapy device disclosed in Hunt. (EX1002 ¶¶168-170). Watson stated that Hunt’s fluid reservoir is “subject to slouching” and could “adversely affect the function of the Hunt apparatus if the fluid prematurely enters an inappropriate pathway (the outlet end of the canister).”

(EX1004, 1:64-2:2). Thus, a POSITA reading Watson would have been motivated to improve Hunt's system through Watson's teachings. (EX1002 ¶¶168, 170).

Modifying Hunt's system to include Watson's disposable components would also have been obvious to try given the limited number of ways to remove wound exudate and contaminants from an NPWT system. (EX1002 ¶¶172-175). A POSITA would have known, especially based on the teachings of the prior art, to try either using parts that can be easily removed and cleaned, easily cleaned in place, or easily removed and disposable. (*Id.*). Moreover, numerous prior art references prior to 2005 taught the use of detachable and disposable components for that purpose. (*See e.g.*, EX1004; EX1018; EX1029). It would have been obvious to a POSITA to try a different design choice, such as implementing the disposable and detachable components of Watson—including the disposable bandage, tubing, desiccator cartridge, and pump unit—in Hunt's system. (EX1002 ¶¶174-175).

A POSITA would have expected this combination to be successful in light of Hunt's disclosures as the use of disposable components would not have altered the system's functionality since those same components are disclosed in Hunt. (EX1002 ¶177). A POSITA would have recognized that manufacturing the same components disclosed in Hunt with disposable materials would have been a simple modification. (*Id.*). And, as Hunt already teaches a POSITA how to simply attach certain components (such as canister 100) to the housing using a "latch or release

mechanism,” a POSITA would have found it obvious and been motivated to use a similar latch or release mechanism for the other components which are removable and replaceable. (*Id.*; EX1003, 1:67-2:3).

Thus, Hunt in view of Watson renders obvious element 14[a].

iii. Element 14[b]

Hunt discloses “said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements.”

A POSITA would have recognized that the enclosure in Hunt (i.e., porous dressing and surgical drape) would be disposed after use and exposure to a patient’s wound. (EX1002 ¶189). Hunt also specifically teaches that canister 100 is “removably mounted within the housing, e.g. by means of a latch or release mechanism, so that the canister can be readily removed and replaced when full”. (EX1003, 1:67-2:3). Accordingly, a POSITA would have understood the enclosure, tubing, and waste container (which come into contact with ambient air after entering the system via the venting arrangement) in Hunt to be disposable. (EX1002 ¶¶189-190).

To the extent Hunt does not explicitly disclose element 14[b], Hunt in view of Watson discloses this limitation. As explained above, Hunt teaches that canister 100 (i.e., the waste container) is “readily removed and replaced,” which a POSITA

would have understood to mean disposable under the plain and ordinary meaning of that term. (EX1002 ¶190). Likewise, Watson teaches a desiccator cartridge (i.e., waste container) that is “removable . . . and separately disposable”. (EX1004, 3:18-19). Watson also teaches that “all of the components in gas/liquid flow communication are replaceable”. (*Id.*, 7:16-18). This includes a “delivery tube 32” and “occlusive dressing” (i.e., an enclosure) which necessarily contact wound fluid. (*Id.*, 6:16-20; EX1002 ¶191).

As explained in Ground 1, the venting arrangement of Hunt (i.e., tube 106 and pressure relief valve 8), in the single multi-partitioned tube, admits ambient air into the tube which flows to canister 100 with wound exudate. Thus, in the combined Hunt-Watson system, the components of the system which come into contact with ambient air admitted through the venting arrangement are also disposable, including the tubing and waste canister. (EX1002 ¶191). As explained previously, Watson teaches that the components which come into contact with wound fluid are all disposable, therefore, the enclosure is also disposable. (EX1004, 6:16-20, 7:16-18). And, as explained regarding element 14[a], the vacuum pump member (i.e., pump unit) is disposable, especially when integrated with the desiccator cartridge in the preferred embodiment of Watson. (*See* Part VIII.C.1.ii, *supra*). A POSITA would have been motivated to combine the teachings of Hunt and Watson for the reasons explained regarding element 14[a] above.

Thus, Hunt alone and/or Hunt in view of Watson teaches and renders obvious element 14[b].

iv. Element 14[c]

Hunt teaches “said drained liquids may be disposed of together with said disposable elements.” Hunt teaches canister 100 is “removably mounted within the housing, e.g. by means of a latch or release mechanism, so that the canister can be readily removed and replaced when full.” (EX1003, 1:67-2:3). A POSITA reading Hunt would have recognized that drained liquids from the wound within the canister would be disposed of together with the canister. (EX1002 ¶193).

To the extent Hunt does not explicitly teach element 14[c], Hunt in view of Watson discloses this limitation. Watson teaches a desiccator cartridge (i.e., waste container) that is used to hold wound fluid and “[w]hen the amount of moisture retained approaches saturation . . . the desiccator cartridge may [] be removed and disposed of”. (EX1004, 7:1-5, 2:35-48). A POSITA reading Watson would have understood that the drained liquids from the wound and contained within the desiccator cartridge would be thrown away along with the disposable desiccator cartridge. (EX1002 ¶194). A POSITA would have been motivated to combine the teachings of Hunt and Watson for the reasons explained regarding element 14[a] above.

Thus, Hunt alone and/or Hunt in view of Watson teaches and renders obvious element 14[c]. In sum, Hunt in view of Watson renders obvious claim 14.

2. Claim 15

Hunt in view of Watson discloses “The vacuum system according to claim 14, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.” As explained above, Hunt in view of Watson renders obvious claim 14.

A POSITA would have understood the “readily separable” pump unit of Watson to be adapted for attaching and detaching by simple hand manipulations based on the plain and ordinary meaning of the claim terms. (EX1002 ¶¶197-198; EX1004, 3:57-65). Watson teaches that the vacuum pump member (i.e., pump unit) can be “mechanically coupled” or “magnetically coupled” to the electric motive 36 (i.e., drive unit). (EX1004, 3:57-65). A POSITA would have understood this to mean a simple hand manipulation could be used to attach or detach the pump and drive unit. (EX1002 ¶¶197-198). Moreover, Watson does not teach the use of tools or a specific method of manufacture to couple the vacuum pump member with the motor; thus, a POSITA would have recognized only a simple hand manipulation would be required to attach and detach the two units. (*Id.* ¶198; EX1004, 4:26-29 (the pump member is “simply attached to the housing”), Fig. 1). A POSITA would have been

motivated to combine the teachings of Hunt and Watson for the reasons explained regarding element 14[a] above.

Thus, Hunt in view of Watson renders obvious claim 15.

D. Ground 3: Obviousness of Claims 12, 13, 16, 17, 26, and 27 Based on Hunt in View of Dolliver

1. Claim 12

Claim 12 is obvious over Hunt in view of Dolliver.

i. Claim 12, Preamble

As explained in Ground 1, Hunt teaches the preamble of claim 12.

ii. Element 12[a]

As explained in Ground 1, Hunt teaches element 12[a].

iii. Element 12[b]

As explained in Ground 1, Hunt teaches element 12[b].

iv. Element 12[c]

As explained in Ground 1, Hunt teaches element 12[c]. 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: Hunt in view of Dolliver discloses “a venting arrangement comprising a flow restrictor to restrict flow through said

venting arrangement.” As explained regarding claim 12 in Ground 1 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. (EX1005, [0007]; *see also id.* Fig. 1).

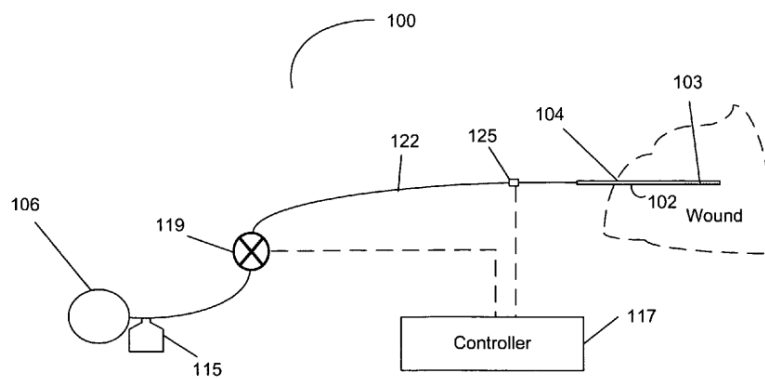


Fig. 1

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 vacuum system. (EX1002 ¶229).

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.” (EX1005, [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 ¶230 (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 below.

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 ¶¶206-222). Hunt and Dolliver both teach negative pressure wound drainage systems that utilize valves to control the level of suction applied. (*See generally*, EX1003; EX1005).

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 ¶¶207-212 (also explaining pressure valve 8 on tube 106 could be replaced with vent valve 119 on tube 101); *see also* EX1003, 4:17-24; EX1018, 12:56-58; EX1017, 7:43-47; EX1005, [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. (*Id.* ¶¶207-213; *see also* EX1017, 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:

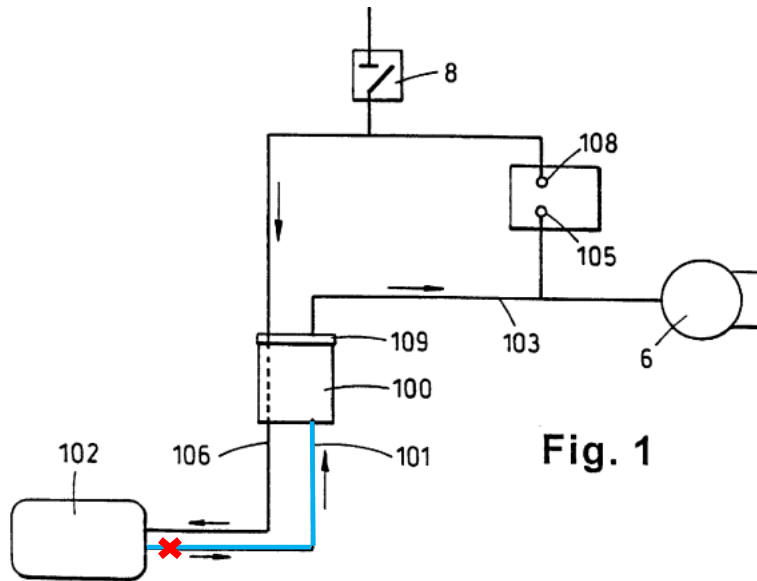


Fig. 1

(EX1003, Fig. 1 (annotated to include vent valve 119 (in red) of Dolliver on suction tube 101 (in blue) of Hunt). 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 ¶212). 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.* ¶213). 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. (EX1005, [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 ¶¶214-218). 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; EX1017; EX1018; EX1002 ¶219). 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 ¶¶214-218; *see also* EX1017, 7:43-47, 8:2-5 (disclosing more than one opening to the atmosphere 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. (EX1003, 4:17-33; EX1005, [0031]; EX1002 ¶¶220-221).

Thus, Hunt in view of Dolliver renders obvious element 12[c].

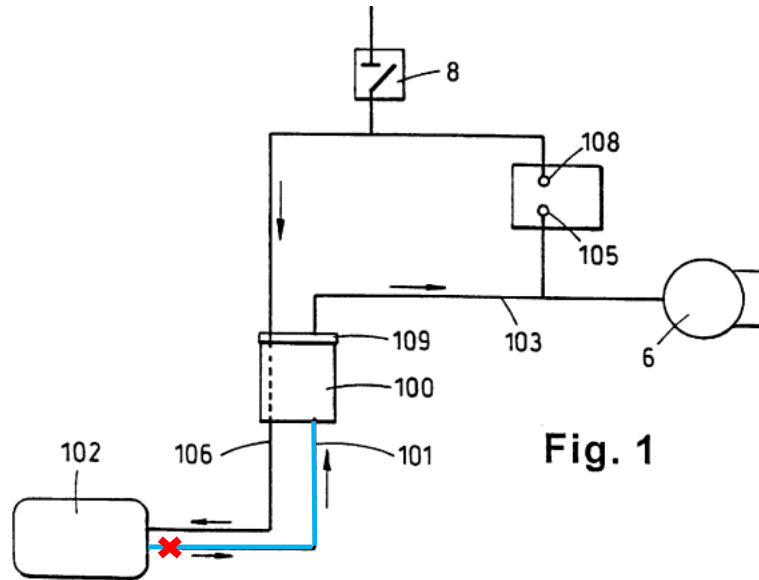
v. Element 12[d]

As explained in Ground 1, Hunt teaches element 12[d].

vi. Element 12[e]

As explained in Ground 1, Hunt teaches element 12[e]. Alternatively, Hunt in view of Dolliver discloses “said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure.” As explained regarding element 12[c], the combined system of Hunt and Dolliver teaches a venting arrangement including tube 101 and vent valve 119.

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):



(EX1003, 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” (EX1005, [0029]). Ambient air necessarily enters the tube (i.e., suction tube 101) when vent valve 119 is open. (See EX1003, Fig.1 (annotated above); EX1002 ¶¶234-235).

A POSITA would have understood that the ambient air that enters tube 101 via vent valve 119 does not flow into the enclosure; rather, it flows towards canister 100. (EX1002 ¶235). When the vacuum pump is applying negative pressure to the wound, the airflow in suction tube 101—as indicated by the black arrows adjacent tube 101 in Figure 1 below—flows towards canister 100:

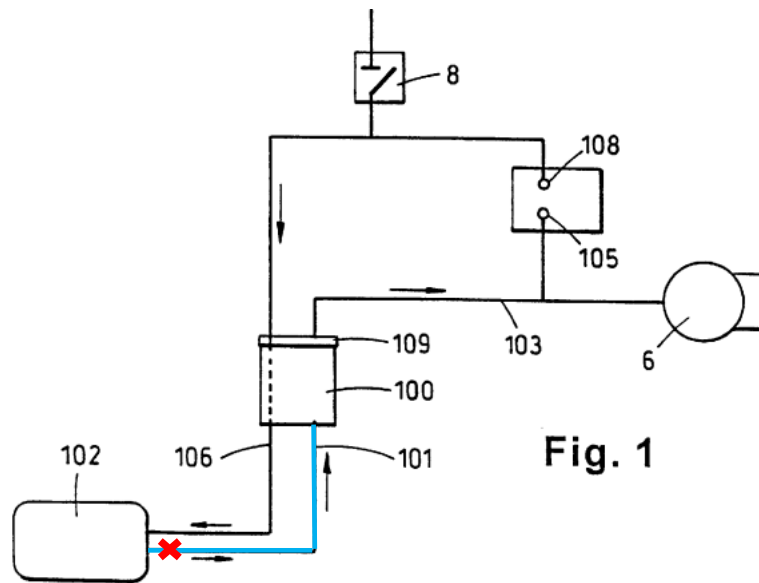


Fig. 1

(EX1002 ¶235; EX1003 [Hunt], Fig. 1 (annotated)). A POSITA would have been motivated to combine Hunt and Dolliver for the reasons explained regarding element 12[c] above.

Thus, Hunt in view of Dolliver renders obvious element 12[e].

vii. Element 12[f]

As explained in Ground 1, Hunt teaches element 12[f]. In sum, Hunt in view of Dolliver renders obvious claim 12.

2. Claim 13

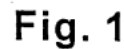
Claim 13 is obvious over Hunt in view of Dolliver.

i. Claim 13, preamble

To the extent the preamble is limiting, it is rendered obvious by Hunt in view of Dolliver. The preamble recites “The vacuum system of claim 12.” As explained

As explained in Ground 1, Hunt teaches element 13[a].

As explained in Ground 1, Hunt teaches element 13[b]. Alternatively, Hunt in view of Dolliver discloses “wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of negative pressure.” As explained regarding element 12[e], in the combined system of Hunt and Dolliver, ambient air enters tube 101 via the vent valve 119 and flows towards the canister when negative pressure is applied. Figure 1 includes arrows indicating the direction of air flow within the system:



(EX1003, Fig. 1 (annotated to indicate the path traveled by the exuded liquids and ambient air)). A POSITA would have understood that the fluids removed from the wound during negative pressure treatment would necessarily flow with ambient air in tube 101 towards canister 100. (EX1002 ¶¶243-244).

Thus, Hunt in view of Dolliver renders obvious element 13[b].

iv. Element 13[c]

As explained in Ground 1, Hunt teaches element 13[c]. Alternatively, Hunt in view of Dolliver discloses “and facilitates draining of the exuded fluids to said waste canister”. As explained regarding elements 12[f] and 13[a]-[b], the combined system of Hunt and Dolliver applies negative pressure to remove fluids from a wound which, along with ambient air, travel towards canister 100 where the fluids are deposited. A POSITA would have recognized that the application of suction and ambient air admitted through the venting arrangement facilitates the movement of fluids exuded from the wound towards the waste canister. (EX1002, ¶¶246-247).

Thus, Hunt in view of Dolliver renders obvious element 13[c]. In sum, Hunt in view of Dolliver renders obvious claim 13.

3. Claim 16

Hunt in view of Dolliver discloses “The vacuum system according to claim 12, wherein said venting arrangement comprises one or more bleeding holes.” As explained above, Hunt in view of Dolliver renders obvious claim 12 and discloses a

venting arrangement that comprising tube 101 and vent valve 119. A POSITA would have understood vent valve 119 to have a bleeding hole—based on the plain and ordinary meaning of that term—where it opens and allows ambient air to enter tube 101. (EX1002 ¶251).

Thus, Hunt in view of Dolliver renders obvious claim 16.

4. Claim 17

Hunt in view of Dolliver discloses “The vacuum system according to claim 12, wherein said venting arrangement is provided in the form of a porous body.” As explained regarding claim 12, Dolliver teaches a filter within vent valve 119 (i.e., within the venting arrangement). (*See also* EX1005, [0029]). A POSITA would have understood this filter to be made of a “porous material” which corresponds to a porous body. (EX1002 ¶254).

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

5. Claim 26

Hunt in view of Dolliver discloses “The vacuum system according to claim 12, wherein the venting arrangement is a tube orifice.” As explained above, Hunt in view of Dolliver renders obvious claim 12 and Dolliver teaches a venting arrangement comprising a vent valve 119 and tube 101. A POSITA would have understood that vent valve 119 has an opening constituting an “orifice” to admit ambient air. (EX1002 ¶257). A POSITA would have also recognized that because

vent valve 119 exposes the lumen of tube 101 to the atmosphere, the opening would be a tube orifice based on the plain and ordinary meaning of that term. (*Id.*).

Thus, Hunt in view of Dolliver renders obvious claim 26.

6. Claim 27

Hunt in view of Dolliver discloses “The vacuum system according to claim 26, said orifice having a smaller opening than a cross-section of the tube.” As explained above, Hunt and Dolliver render obvious claim 26 and teach a tube orifice. A POSITA would have understood that the opening within vent valve 119 (i.e., tube orifice) is necessarily smaller than the cross-section of tube 101 in certain positions between fully open and closed. (EX1002 ¶259).

Thus, Hunt in view of Dolliver renders obvious claim 27.

E. Ground 4: Obviousness of Claims 14 and 15 Based on Hunt in View of Dolliver and Watson

1. Claim 14

To the extent Hunt and Dolliver do not explicitly teach the disposable and detachable components recited in claim 14, a POSITA would have been motivated to combine Hunt and Dolliver with Watson, which teaches that the components of the vacuum system which come into contact with wound exudate are removable and disposable as explained in Ground 2.

i. Claim 14, preamble

To the extent the preamble is limiting, it is rendered obvious by Hunt and Dolliver. The preamble recites “The vacuum system of claim 12.” As explained in Ground 3, Hunt in view of Dolliver renders obvious claim 12 and, therefore, for the same reasons renders obvious the preamble of claim 14.

ii. Element 14[a]

Hunt in view Dolliver and in further view of Watson discloses “wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit.”

Combination of Hunt, Watson, and Dolliver: As explained in Ground 2, Watson teaches a disposable pump unit (i.e., vacuum pump member) that is detachably attached to a non-disposable drive unit (i.e., electric motive 36). Thus, for the reasons above and those stated regarding element 14[a] in Ground 2, Hunt in view of Dolliver and Watson renders obvious element 14[a].

Motivation to Combine Hunt, Dolliver, and Watson: A POSITA would have been motivated to combine the NPWT system of Hunt with the disposable and detachable components of Watson as explained in Ground 2. The inclusion of Dolliver in this combination does not change the analysis. (EX1002, ¶¶264-266).

Thus, Hunt in view of Dolliver and Watson renders obvious element 14[a].

iii. Element 14[b]

As explained in Ground 2, Hunt and/or Watson teaches and renders obvious element 14[b]. A POSITA would have been motivated to combine the NPWT system of Hunt with Watson and Dolliver for the reasons explained above. Thus, Hunt in view of Dolliver and Watson renders obvious element 14[b].

iv. Element 14[c]

As explained in Ground 2, Hunt and/or Watson teaches and renders obvious element 14[c]. A POSITA would have been motivated to combine the NPWT system of Hunt with Watson and Dolliver for the reasons explained above. Thus, Hunt in view of Dolliver and Watson renders obvious element 14[c]. In sum, Hunt in view of Dolliver and Watson renders obvious claim 14.

2. Claim 15

As explained in Ground 2, Watson teaches claim 15. A POSITA would have been motivated to combine the NPWT system of Hunt with Watson and Dolliver for the reasons explained above. Thus, Hunt in view of Dolliver and Watson renders obvious claim 15.

IX. SECONDARY CONSIDERATIONS

Patent Owner has not identified any evidence of secondary indicia of non-obviousness for the '554 patent. Accordingly, there is no objective evidence of non-obviousness that might warrant a finding that the Challenged Claims are patentable.

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(EX1002 ¶¶285-286). 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 12-17, 26, and 27 and a finding that they are unpatentable.

Respectfully submitted,

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Dated: June 21, 2024

Attorney for Petitioners Medela LLC and Medela AG

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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. 8,506,554, 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 9,455 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)