

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDELA LLC and MEDELA AG,  
Petitioners

v.

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

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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

**DECLARATION OF JOHN M. COLLINS, PH.D.**

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Petition for *Inter Partes* Review of  
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Exhibit 1002  
I, John M. Collins, declare as follows:

1. My name is John M. Collins. I am the current Director of Innovation Platforms for CIMIT: Consortia for Improving Medicine with Innovation and Technology based at Massachusetts General Hospital in Boston, Massachusetts.

2. I have prepared this report as an expert witness retained by Medela, LLC and Medela AG. In this report I give my opinion as to the validity of the claims of U.S. Patent No. 8,506,554 (the “’554 Patent”).

3. This report contains statements of my opinions formed as of the present date and the reasoning for those opinions. As this case progresses, I may offer additional opinions based on my review of materials, opinions, and/or testimony of other expert witnesses. I make this declaration based upon my personal knowledge and, if called upon to testify, I would competently testify thereto.

## **I. BACKGROUND AND QUALIFICATIONS**

### **A. Relevant Experience and Qualifications**

4. Below, I have summarized my educational background, career history, publications, and other relevant qualifications. My full curriculum vitae is attached as **Appendix A** to this declaration.

5. I have over 40 years of product design and product development expertise covering a wide range of industries and products, including consumer, industrial, and medical products and devices. Over that time, I have had a consistent

focus on medical devices and technologies. I have been responsible for all aspects of product's development, including defining the need in the market as well as the requirements, user interface, overall look and feel (industrial design), construction design (design for manufacturing, etc.), and performance/functionality validation. In addition to doing engineering work, including technology assessment and planning, my responsibilities have included assembling and managing teams to develop new products.

6. I received my B.S. Science in 1980 in mechanical engineering from Rensselaer Polytechnic Institute, and my M.S. in 1982 and Ph.D. in 1988 in mechanical engineering from Massachusetts Institute of Technology ("MIT"). At MIT, my academic work was in mechanical engineering with a concentration on biomedical applications of fluid dynamics, including heat/mass transfer. My Ph.D. and M.S. thesis projects applied these principles to pulmonary dynamics.

7. Since 2008 I have been employed at the Consortia for Improving Medicine with Innovation and Technology ("CIMIT"), an operating unit within Massachusetts General Hospital. Founded by Massachusetts General Hospital, Brigham and Women's Hospital, Charles Stark Draper Laboratory and Massachusetts Institute of Technology, CIMIT is a consortium of thirteen of the greater Boston area's premier clinical, research, and academic institutions, including

the Harvard Medical School and its teaching hospitals, along with a growing list of national and international affiliates. See [www.CIMIT.org](http://www.CIMIT.org).

8. CIMIT's mission is to improve patient care by facilitating collaboration among clinicians, academics, engineers, and entrepreneurs to catalyze the discovery, development, and implementation of innovative technologies and procedures/systems that improve patient care. For most of my tenure, I have been responsible for ensuring CIMIT's "Finding, Funding, Facilitating, and Following" functions are effective. In addition, I worked on supporting teams of clinicians, engineers, and entrepreneurs in start-ups or emerging from academic labs in the commercialization of healthcare technologies. I am now focused on using these experiences to develop and define CIMIT's web-based platforms to scale the support available to innovators. These include a secure, interactive platform for teams to apply for funding called CoLab. See <https://www.cimit.net/web/cimit-colab/cimit-colab>. It also includes a novel way to plan, track, and display a project's maturity as well as provide guidance on how to execute tasks. See [www.GAITS.org](http://www.GAITS.org). In addition, I manage CIMIT's Commercialization Readiness Assessment and Accelerator for Solutions in Healthcare ("CRAASH") program which supports teams to commercialize promising healthcare innovations. See: <https://www.craash.org>.

9. A recent example of the use of these platforms to support innovation is in CIMIT's work as the coordinating center for the National Institutes of Health's Rapid Acceleration of Diagnostics Technology ("RADx Tech") initiative. This \$500M-plus initiative was highly successful in speeding innovation in the development and deployment of Point of Care ("POC") testing technologies capable of testing millions of Americans for the presence of the SARS-CoV-2 virus and help stop the spread of COVID. A paper describing the use of these platforms is available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8112669/>.

10. Also, since 2008, I have been the Chief Technology and Innovation Officer of Reed Collins LLC. In this role, I provide consulting services on technology, intellectual property, commercialization, and business development and serve on review, steering, and advisory boards for non-profit organizations that support healthcare innovation. Examples include the Scientific Advisory Board for the Massachusetts Life Science Center, the Strategic and Industry Partnerships Programme Oversight Group at the Oxford Academic Life Science Network, and Howard University. I also consult for and provide expert technical opinions in patent-related matters, including patent infringement disputes.

11. Prior to 2008, I held various positions at technology and product development companies. From 1982 to 1986, after receiving my M.S. degree at MIT,

I worked at Booz, Allen & Hamilton, where I developed automotive, consumer, and industrial products. Examples include GE's under-counter coffee maker, GM's hydraulic systems for automotive anti-lock brakes, Engelhard's coating and drying system for catalytic converters, Rubbermaid's ergonomic table, and the Regina rug scrubber.

12. After completing my Ph.D. in 1988, I joined Arthur D. Little, Inc. ("ADL"). I joined ADL as a design engineer and helped form its medical products business. I progressed from being a design engineer to being responsible for the Technology and Innovation ("T&I") Directorate at ADL, with more than 250 staff. From the resources of ADL's T&I, I helped form TIAX LLC, a privately held technology transformation company focused on advancing and developing technologies for commercialization in several core technology areas, including medical devices and products, clean energy and material, appliances and HVAC systems, and enhanced security.

13. I have worked on a wide range of medical products over my career, including:

- Devices which use vacuum to remove bodily fluids, applications include:
  - Female external catheter for urine incontinence;
  - Chest drainage to remove air, fluid, or pus from the intrathoracic space.

- Pumps for medical fluids, applications include:
  - Blood pumps, both extra-corporeal and intra-aortic;
  - Micro-surgical eye irrigation pumps operating in either pressure or volumetric control mode;
  - Orthopedic lavage pumps;
  - Ambulatory drug infusion pumps.
- Medical fluid handling systems, applications include:
  - High frequency ventilation system for neonates;
  - Intraosseous infusion needles;
  - Blood and IV fluid warmers along with the associated containers;
  - Aerosol drug delivery systems.
- Minimally invasive surgical devices and systems, applications include:
  - Access (cutting) devices called trocars with automated safety covers as well as universal seals;
  - Surgical clip appliers;
  - Surgical ligate & divide absorbable clip appliers (which collected, cut, and clipped tissue);
  - Arthroscopic shaver blades;
  - Neurological and vascular surgical navigation systems.

14. I have also worked in consumer and industrial products that involve managing fluid systems, including: the “Regina Steemer” home rug scrubber with soap/liquid mixing and dispensing along with vacuum pick-up and the first GE undercounter coffee maker.

15. I am a named inventor on over 20 United States patents, in addition to foreign counterparts, on products and manufacturing processes. Many of these patents are directed to technologies relating to medical devices. A complete list of

my patents is set forth in my curriculum vitae (Appendix A), which I incorporate here by reference.

16. I have over 27 years of experience consulting for and testifying as an independent technical expert witness in patent infringement and related disputes, including disputes involving mechanical, electro-mechanical, and thermo-fluid medical devices.

### **1. Compensation**

17. For my efforts in connection with preparing this declaration, I have been compensated at the rate of \$450 per hour. My compensation is not contingent on the results of this, or any other, proceeding relating to the '554 Patent.

### **2. Materials and Information Considered**

18. I have considered a variety of information from various sources in forming the opinions contained in this declaration. I have reviewed and considered each of the exhibits listed below in forming my opinions:

| <b>Exhibit No.</b> | <b>Description of Document</b>                                                                                      |
|--------------------|---------------------------------------------------------------------------------------------------------------------|
| <b>1001</b>        | U.S. Patent No. 8,506,554 B2 to Carmeli Adahan (Application filed July 24, 2005, issued August 13, 2013)            |
| <b>1003</b>        | U.S. Patent No. 6,142,982 to Kenneth William Hunt, et al. (Application filed May 13, 1998, issued November 7, 2000) |

Petition for *Inter Partes* Review of  
U.S. Patent No. 8,506,554 B2  
Exhibit 1002

| <b>Exhibit No.</b> | <b>Description of Document</b>                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1004</b>        | U.S. Patent No. 6,648,862 to Richard Watson (Application filed November 20, 2001, issued November 18, 2003)                                                                                                                                                                                                                                                                                          |
| <b>1005</b>        | U.S. Patent Application Publication No. US 2005/0192548 to Phillip B. Dolliver, et al. (Application filed February 26, 2004, published September 1, 2005)                                                                                                                                                                                                                                            |
| <b>1006</b>        | Complaint, <i>M.E.A.C. Engineering Ltd. v. Medela LLC, et al.</i> , Case No. 1:23-cv-14045 (N.D. Ill.)                                                                                                                                                                                                                                                                                               |
| <b>1007</b>        | U.S. Patent No. 8,858,534 B2 to Carmeli Adahan (Application filed June 14, 2013, issued October 14, 2014)                                                                                                                                                                                                                                                                                            |
| <b>1008</b>        | File History of U.S. Patent No. 8,506,554                                                                                                                                                                                                                                                                                                                                                            |
| <b>1009</b>        | File History of U.S. Patent No. 8,858,534                                                                                                                                                                                                                                                                                                                                                            |
| <b>1010</b>        | Northern District of Illinois Time-to-Trial Statistics, Lex Machina, available at <a href="https://law.lexmachina.com/court/ilnd/cases?pending-from=2009-01-01&amp;filters=true&amp;view=analytics&amp;tab=timing&amp;cols=475">https://law.lexmachina.com/court/ilnd/cases?pending-from=2009-01-01&amp;filters=true&amp;view=analytics&amp;tab=timing&amp;cols=475</a> (last accessed May 30, 2024) |
| <b>1011</b>        | 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.)                                                                                                                                                                                                                                                                         |
| <b>1012</b>        | 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)                                                                                                                                                                                                                            |
| <b>1013</b>        | U.S. Patent No. 1,889,425 to George L. Sorenson (Application filed March 2, 1931, issued November 29, 1932)                                                                                                                                                                                                                                                                                          |
| <b>1014</b>        | U.S. Patent No. 3,026,874 to R.C. Stevens (Application filed November 6, 1959, issued March 27, 1962)                                                                                                                                                                                                                                                                                                |

Petition for *Inter Partes* Review of  
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| <b>Exhibit No.</b> | <b>Description of Document</b>                                                                                                                                                                                                                           |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1015</b>        | U.S. Patent No. 4,569,674 to Earl G. Phillips, et al. (Application filed August 3, 1982, issued February 11, 1986)                                                                                                                                       |
| <b>1016</b>        | 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) |
| <b>1017</b>        | U.S. Patent No. 6,764,462 to James R. Risk, et al. (Application filed May 31, 2002, issued July 20, 2004)                                                                                                                                                |
| <b>1018</b>        | U.S. Patent No. 6,695,823 to Cesar Z. Lina, et al. (Application filed April 7, 2000, issued February 24, 2004)                                                                                                                                           |
| <b>1019</b>        | U.S. Patent No. 7,678,102 to Keith Patrick Heaton (PCT Application filed November 8, 2008, issued March 16, 2010)                                                                                                                                        |
| <b>1020</b>        | U.S. Patent No. 6,071,267 to David S. Zamierowski (Application filed February 6, 1998, issued June 6, 2000)                                                                                                                                              |
| <b>1021</b>        | U.S. Patent No. 5,735,833 to Daniel H. Olson (Application filed December 11, 1996, issued April 7, 1998)                                                                                                                                                 |
| <b>1022</b>        | U.S. Patent Publication No. 2003/0125649 to Laura Janet McIntosh, et al. (Application filed October 29, 2002, published July 3, 2003)                                                                                                                    |
| <b>1023</b>        | U.S. Patent No. 7,708,724 to Richard Scott Weston (Application filed April 4, 2005, issued May 4, 2010)                                                                                                                                                  |
| <b>1024</b>        | Richard F. Edlich, et al., “Evaluation of a New, Improved Surgical Drainage System,” <i>Dep’t Plastic Surgery, U. of Va., New Instruments</i> , Vol. 149 (February 1995)                                                                                 |
| <b>1025</b>        | U.S. Patent No. 6,241,739 to Stephen H. Waldron (Application filed November 12, 1999, issued June 5, 2001)                                                                                                                                               |

| <b>Exhibit No.</b> | <b>Description of Document</b>                                                                                                                             |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1026</b>        | U.S. Patent No. 6,045,516 to James Phelan (Application filed December 18, 1998, issued April 4, 2000)                                                      |
| <b>1027</b>        | 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) |
| <b>1028</b>        | '554 Patent Claim Listing                                                                                                                                  |
| <b>1029</b>        | U.S. Patent No. 3,841,331 to Joseph R. Wilder, et al. (Application filed on November 17, 1972, issued on October 15, 1974)                                 |

## **II. STATEMENT OF LEGAL PRINCIPLES**

19. I am not an attorney. In forming my opinions in this declaration, I applied relevant legal principles provided and explained to me by counsel, which are summarized below. The below legal principles represent my understanding of the law that I have applied in forming my opinions in this declaration.

### **A. Claim Construction**

20. I have been informed by counsel that a purpose of claim construction is to determine what a person of ordinary skill in the art would have understood the claim terms to mean. I further understand that claim terms are generally given their ordinary and customary meaning, which is how a person of ordinary skill in the art (a “POSITA”) at the time of invention would have understood the claim terms. The time of the invention is the effective filing date of the patent application. Also, a

person of ordinary skill in the art is deemed to read a claim term within the context of the claim and within the context of the entire patent, including the specification.

I am informed that the patent specification may be highly relevant to the claim construction and has been described as the single best guide to the meaning of a disputed claim term. The patent specification usually provides the best context for understanding the meaning of terms that do have a customary meaning within the art. I understand that the “plain and ordinary meaning” or *Phillips* standard is applicable in these proceedings.

21. I am also informed that other claims within the patent can provide information as to a claim term meaning. Claim terms are normally used consistently throughout the patent, thus, the usage of a term in one claim can shed light on the meaning of that same term in other claims. I understand that differences among claims can also provide guidance to determine the meaning of claim terms.

22. I am further informed that the prosecution history of the patent can inform the meaning of claim language. The prosecution history helps explain how the inventors understood their invention and whether the invention was limited during prosecution, narrowing the claim scope. Extrinsic evidence, such as expert testimony, may also be consulted when properly construing claim terms.

23. I discuss issues of claim construction specific to the '554 Patent in Part VI.

**B. Anticipation**

24. I have been informed by counsel that under 35 U.S.C. § 102 (pre-AIA, before March 16, 2013), a patent claim may be invalid if it lacks novelty over the prior art, a concept known as “anticipation.” I also understand that a prior art reference anticipates a patent claim, therefore rendering it invalid, if all the elements of the challenged claim are disclosed within the prior art reference. I am informed that the disclosure within the prior art reference may be explicit or inherent, meaning it is necessarily present or implicitly present. I understand that the prior art reference need not use the same words as the challenged patent claim, however, all the requirements of the claim must be disclosed such that a POSITA could make and use the claimed subject matter.

25. I understand that 35 U.S.C. § 102 defines what is available for use as a prior art reference to a patent claim.

26. Under 35 U.S.C. § 102(a) (pre-AIA), a challenged patent claim is anticipated if it was known or used by others in the United States, or patented or described in a printed publication in the United States or in a foreign country, before the invention by the applicant for the patent.

27. Under 35 U.S.C. § 102(b) (pre-AIA), a challenged patent claim is anticipated if it was patented or described in a printed publication in the United States or a foreign country or in public use or on sale in the United States more than one year prior to the date of application for patent in the United States.

28. Under 35 U.S.C. § 102(e) (pre-AIA), a challenged patent claim is anticipated if: (1) it was described in a patent application, published under § 122(b), by another filed in the United States before the invention by the patent applicant; or (2) a patent granted on an patent application filed by another in the United States before the invention by the patent applicant, except that an international application filed under the treaty defined in § 351(a) has the effect of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in English.

29. I further understand that the invention date of a patent or prior art reference is generally the filing date of that application. However, I understand that a patent or prior art reference may be granted an earlier effective filing date if it properly claims priority to an earlier patent application.

30. I understand that when a challenged claim covers several structures, either generically or as alternatives, the claim is deemed anticipated if any of the structures within the scope of the claim is found in the prior art reference.

31. I understand that when a challenged claim requires a selection of an element from a list of alternatives, the prior art teaches the element if one of the alternatives is taught by the prior art.

**C. Obviousness**

32. I have been informed by counsel that under 35 U.S.C. § 103 (pre-AIA, before March 16, 2013), a patent claim may be rendered invalid as obvious if, when the invention was made, the subject matter of the claim, considered as a whole, would have been obvious to a person of ordinary skill in the art. I have also been advised by counsel that this pre-AIA rule applies to the claims of the '554 Patent because it claims priority to a PCT application filed prior to March 16, 2013.

33. Counsel has advised me that the following factors should be considered when analyzing obviousness: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims; and (3) the level of ordinary skill in the pertinent art. I understand further factors ("secondary considerations") may indicate non-obviousness. These factors include: commercial success, unexpected results, long felt but unresolved need, industry acclaim, simultaneous invention, copying by others, skepticism by experts in the field, and failure of others. I also understand that these secondary considerations should share a nexus with the claimed invention.

34. I understand that a POSITA is assumed to have knowledge of all prior art. A POSITA can combine different prior art references based on the teachings of those references, the general knowledge present in the art, or their common sense. I further understand that a motivation to combine references may be implicit in the prior art, and there is no requirement that there be an actual or explicit teaching to combine two references. Counsel has explained that one may take into account inferences and creative steps that a person of ordinary skill in the art would employ to combine the known elements in the prior art in the manner claimed by the challenged patent. I understand that one should avoid hindsight bias and *ex post* reasoning when performing an obviousness analysis; however, this does not mean a POSITA must ignore common sense.

35. I am informed that neither the particular motivation for the patent nor the stated purpose of the patentee is controlling when determining obviousness. The main inquiry relates to the objective reach of the claims and if those claims extend to something obvious. If so, the entire patent claim is invalid.

36. I understand a patent may be found invalid by obviousness if, at the time of invention, there was a known problem for which there was an obvious solution encompassed by the patent's claims. I further understand a motivation to combine various prior art references to solve such a problem may come from a

variety of sources, including market demand, academic papers, or scientific literature. I am informed that a need or problem within the field at the time of invention may also provide a reason to combine prior art references and render a patent claim obvious. Familiar items may have obvious uses beyond their primary purpose and a POSITA would be able to fit the teachings of multiple prior art references together like the pieces of a puzzle. I understand that a POSITA is also a person of at least ordinary creativity. Additionally, when there is a design need or market pressure to solve a problem with a finite number of identified, predictable solutions, a POSITA has good reason to pursue the known options within his or her technical abilities. If these finite number of predictable solutions lead to the anticipated success, I understand that the invention is likely the product of ordinary skill and common sense, and not any sort of innovation. I am informed that the fact that a combination was obvious to try may also show that it was obvious and invalid. I understand that if a patent claims a combination of familiar elements according to known methods, that combination is likely to be obvious when it does nothing more than yield predictable results. Thus, if a POSITA can implement a predictable variation, a claimed invention is likely obvious. I understand that combining embodiments disclosed near each other within a prior art reference would not ordinarily require a great leap of inventiveness.

37. Counsel has also advised me that obviousness may be shown by demonstrating that it would have been obvious to modify what is taught in a single piece of prior art to create the patented invention. I understand obviousness may be shown by demonstrating that it would have been obvious to combine the teachings of more than one item of prior art. I have been advised by counsel that a claimed invention may be obvious if some teaching, suggestion, or motivation exists that would have led a person of ordinary skill in the art to combine the invalidating references. Additionally, I am informed that this suggestion or motivation may come from within the knowledge of a POSITA, or from sources such as explicit statements in the prior art, but such explicit statements are not required. Alternatively, any need or problem known in the field at the time and addressed by the patent may provide a reason for combining elements of the prior art. I am advised by counsel that when there is a design need or market pressure, and there are a finite number of predictable solutions, a person of ordinary skill may be motivated to apply common sense and his or her skill to combine the known options to solve the problem.

38. Counsel has advised me that the following are examples of approaches and rationales that may be considered in determining whether a piece of prior art could have been combined with other prior art or with other information within the knowledge of a person having ordinary skill in the art:

- a. some teaching, motivation, or suggestion in the prior art that would have led a person of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention;
- b. known work in one field of endeavor may prompt variations of it for use in the same, or different, field based on design incentives or other market forces if the variations would have been predictable to a POSITA;
- c. combining prior art elements according to known methods to yield predictable results;
- d. applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
- e. applying a technique or approach that would have been “obvious to try” (choosing from a finite number of identified, predictable solutions with a reasonable expectation of success);
- f. simple substitution of one known element for another to obtain predictable results; or
- g. use of a known technique to improve similar products, devices, or methods in the same way.

### **III. RELEVANT TECHNOLOGICAL BACKGROUND**

#### **A. The Use of Negative Pressure in Medical Devices to Treat and Heal Wounds**

39. Negative pressure wound therapy (“NPWT”) is a method to help promote healing of human wounds by applying suction (or negative pressure) to an open wound. Also called Vacuum-Assisted Closure (“VAC”), NPWT can accelerate the healing process by promoting blood flow and removing excess fluids and contaminants (i.e., exudate) from a wound. NPWT is a well-known technique, with roots dating back to early civilization. The concept of using even just a human mouth to create suction to remove poison, for example, from a wound was widely utilized by the Romans. Ex. 1012 at 1. The application of cups in which a vacuum is created, or “cupping” techniques, were also used in wound healing to remove fluids and/or exudate from various types of wounds. *Id.* at 2; Ex. 1022 at [0005].

40. With technological improvements over time, these rudimentary suction approaches morphed into vacuum-assisted removal of exudate. In the 1930s, medical professionals used basic suction devices that they could control with their finger to modulate the suction to remove fluid from a patient’s body. Ex. 1013. By 1960, doctors were using vacuum-assisted drainage devices to remove exudate. Ex. 1014. And by the 1980s, it had “long been known to drain unwanted liquid from a wound

by means of a tube connected to a closed container, the interior of which is under a partial vacuum, that is, subatmospheric or negative pressure.” Ex. 1015 at 1:14-17.

41. Modern-day NPWT devices were introduced in the United States in the 1990s. Inventors Louis C. Argenta and Michael J. Morykwas at Wake Forest University School of Medicine developed a mechanical vacuum pump that worked with tubing and foam to apply suction and remove exudate from an enclosed wound. Ex. 1016. Argenta and Morykwas introduced vacuum assistance to apply sub-atmospheric pressure to open wounds through an open-cell foam dressing within the wound cavity. Their system applied negative pressure to the wound through the foam dressing, removing exudate and contaminants from the wound, to promote healing and allowing the wound to close. Argenta and Morykwas found this technique reduced chronic edema and improved blood flow at the wound bed. *Id.*

42. A company known as Kinetic Concepts, Inc. (“KCI”) picked up on this invention and commercialized a product, the “V.A.C.” system, which applied negative pressure to an open wound to promote healing. The system included open-cell polyurethane foam dressing to cover and seal the wound, an evacuation tube for the removal of exudate connected to the foam, a canister to collect the exudate, and an adjustable vacuum pump generating negative pressures between 50 and 200 mm Hg. V.A.C. ATS User Manual, <https://www.wondbedekkers.nl/vacuum/VAC-ats->

[manual.pdf](#). Over time, KCI released different iterations of the VAC system along with numerous other medical device companies who have recognized the efficiencies in wound healing through NPWT devices.

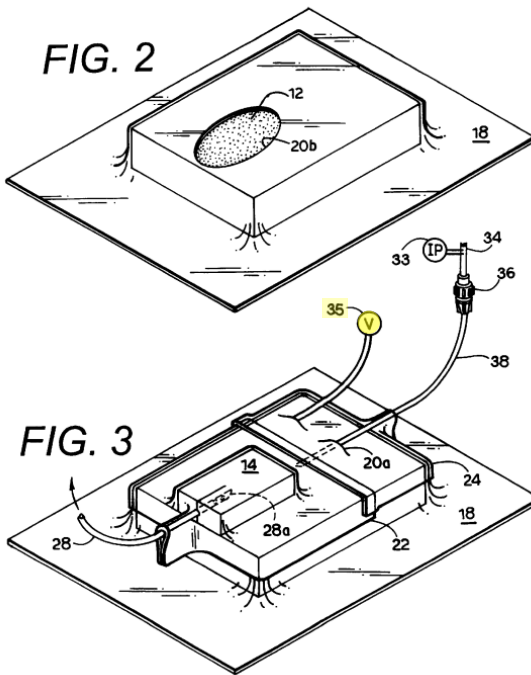
43. Numerous patents regarding NPWT, predating the '554 Patent, have acknowledged that these devices were well-known in the art by the late 1990s and early 2000s. Exs. 1003, 1017-1020. For example, as of 2000, NPWT was “accepted as a highly effective way of improving the rate of healing patients suffering from pressure sores, ulcers, partial thickness burns and wounds that fail to heal quickly after an operation.” Ex. 1019 at 1:4-14. Additionally, it was standard to include a controller within the NPWT device to control the vacuum pump and sensors and allow for intermittent or continuous wound therapy. Exs. 1003, 1005, 1017, 1018.

**B. Introduction of Ambient Air is Required in Negative Pressure Wound Therapy Devices**

44. NPWT devices must be open to the atmosphere in some manner to control the amount of negative pressure that is being applied and to relieve it and so that the wound cover can be removed. In wound therapy, specifically, care must be taken to ensure that the amount of negative pressure does not exceed a threshold level that could result in severe damage to the patient’s body. In addition, NPWT often involves cycling the vacuum level to optimize wound healing by intermittently applying negative pressure to the wound site at varying levels.

45. Accordingly, NPWT devices include some kind of vent, valve, or other opening to allow ambient air into the system. Introducing ambient air to the system can serve multiple purposes, including: regulating the negative pressure introduced to the wound, restoring ambient pressure when the vacuum is turned off, allowing air into the wound so it can breathe, and de-clogging any blockages in the exudate removal tube.

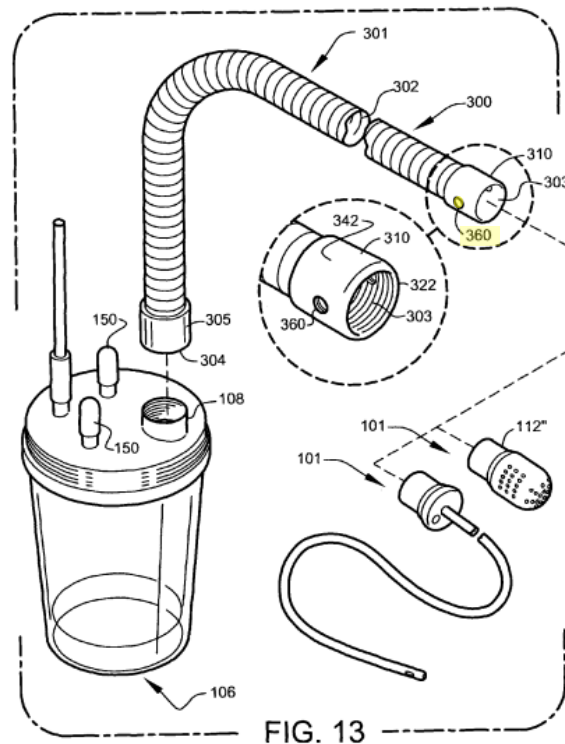
46. While NPWT systems have an opening through which ambient air can enter, systems developed in the late 1990s and early 2000s included these openings in different locations within the system. Some NPWT inventors chose to put a vent directly on the wound cover. Ex. 1017, 1020, 1022, 1023. This exposes the wound to ambient air to release pressure as needed (Ex. 1022 at [0040]) and allows the wound to breathe (Ex. 1023 at 9:46-52). An example of a vent included with a wound cover is depicted in U.S. Patent No. 6,071,267 to David S. Zamierowski:



Ex. 1020 at Fig. 3 (highlighting added to show vent – “v” 35). *See also id.* at col. 6, 9-11 (“Other fluid supply corrections include an injection port 33 connected to the tubing 34 and a vent 35 connected to the primary fluid transfer element 12.”).

47. Another common location for an air opening in NPWT devices is on the tubing connecting the wound cover to the vacuum source. In some cases, NPWT devices include a second tube—in addition to the tube used to apply suction and remove exudate from the wound—which allows ambient air into the system and to flow to the wound. Ex. 1014, 1017, 1024. In other cases, the suction tube may include a hole or orifice through the wall of the tube that allows air to enter the tube directly. Ex. 1025-1027. For example, as depicted in U.S. Patent No. 7,955,318 to

Joseph P. Schultz, et al., the opening may consist of a hole on the side of a tube to allow ambient air into the tube:



Ex. 1027 at Fig. 13 (highlighting added to indicate air opening 360).

48. A third option is to include the air opening within the housing of the vacuum system itself, near the pump. Including an air opening within the system housing allows for release of negative pressure and can assist in de-clogging any blockages within the housing. An example of an 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.:

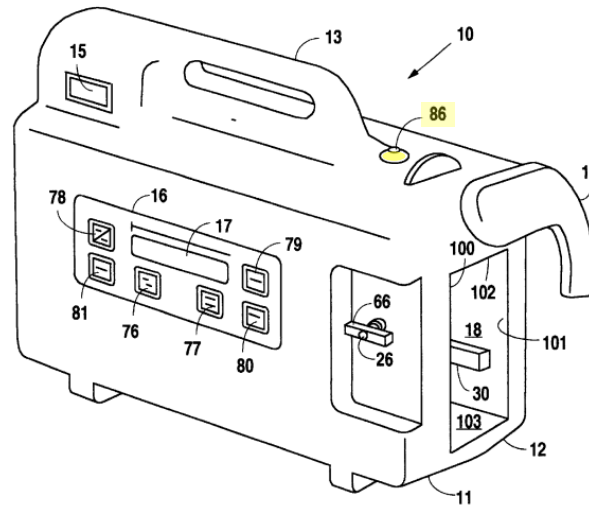


Fig. 1

Ex. 1018 at Fig. 1 (highlighting to indicate orifice 86).

49. As previously stated, these ambient air openings may take different forms (namely, vents or holes, and valves) to allow ambient air into the system. A particular inventor may choose a vent in lieu of or in addition to a valve on an NPWT system for various reasons. One of which is that a vent, which may take the form of a hole or orifice, may control the rate of air entering the system but will not block it completely (unless, of course, the operator covers the hole with his or her finger to block airflow). On the other hand, a valve can be opened or closed to allow air to flow in the system or either partially or entirely block air from flowing into the system. Valves can also include an orifice to control the flow of ambient air when

open. Regardless of which type or combination of air opening is used, NPWT systems include a variety of configurations to allow ambient air to enter the system.

#### **IV. THE '554 PATENT**

50. I understand that the '554 Patent issued on August 13, 2013 from a PCT application which was filed on July 24, 2005. Ex. 1001. I understand that Petitioners are challenging the validity of claims 12-17, 26, and 27 of the '554 Patent (the "Challenged Claims") in the Petition for *Inter Partes* Review to which this declaration will be attached. Those claims are reproduced in Ex. 1028. In rendering my opinions, I have considered all claims of the '554 Patent, the '554 Patent specification, and the '554 Patent prosecution history.

##### **A. Overview of the '554 Patent**

51. The '554 Patent relates to a vacuum system that utilizes negative pressure to drain liquids from a wound ("NPWT system"). Ex. 1001 at Abstract. The '554 Patent describes the invention as including:

[A]n enclosure sealable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids. The enclosure has an outlet connected by means of a tube to an inlet of the pump unit and the waste container is connected to an outlet of the pump unit, such that when the vacuum pump is operated the drained liquids flow through the vacuum pump. The enclosure has one or more bleeding holes provided therethrough or adjacent to its outlet so that ambient air may enter the tube and flow together with the drained liquids.

*Id.* at Abstract.

52. Figure 1 of the '554 Patent depicts the exemplary NPWT system, showing the relevant components:

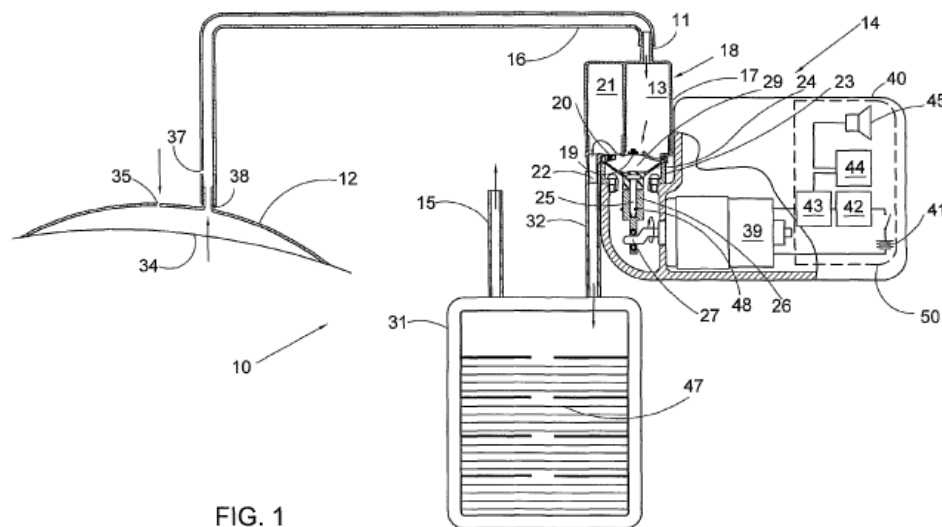


FIG. 1

53. NPWT systems were well-known at the time of the application for the '554 Patent. The specification, in fact, acknowledges that the negative pressure “method of healing (known as ‘cupping’) was exercised since the times of ancient Greek physicians until the 19th century.” *Id.* at 1:14-16. The '554 Patent specification further identifies “deficiencies” of the prior art systems, including:

- a. wound exudate may contaminate the pump or “require costly and complex methods of isolating the pump” from the use of negative pressure pump suction (*Id.* at 1:41-45);

- b. the use of a “rigid canister” which is “bulky and inconvenient” for patients who carry their containers with them (*Id.* at 1:46-49);
- c. air tight sealing of the wound “requires a pressure relief or bleed valve to produce the pressure cycling desirable to obtain accelerated wound closure” (*Id.* at 1:50-55);
- d. when negative pressure is applied to a sealed enclosure, the exudate is pushed “toward[s] the negative pressure source, through the connecting [tube], which may occlude, should the exudate coagulate” (*Id.* at 1:56-60); and
- e. monitoring negative pressure “requires the use of a vacuum transducer, gage or relief valve . . . connected to the suction tube, which is subject to contamination” (*Id.* at 1:61-67).

54. Thus, the '554 Patent purports to improve on prior art NPWT systems. The specification and claims focus on three main features.

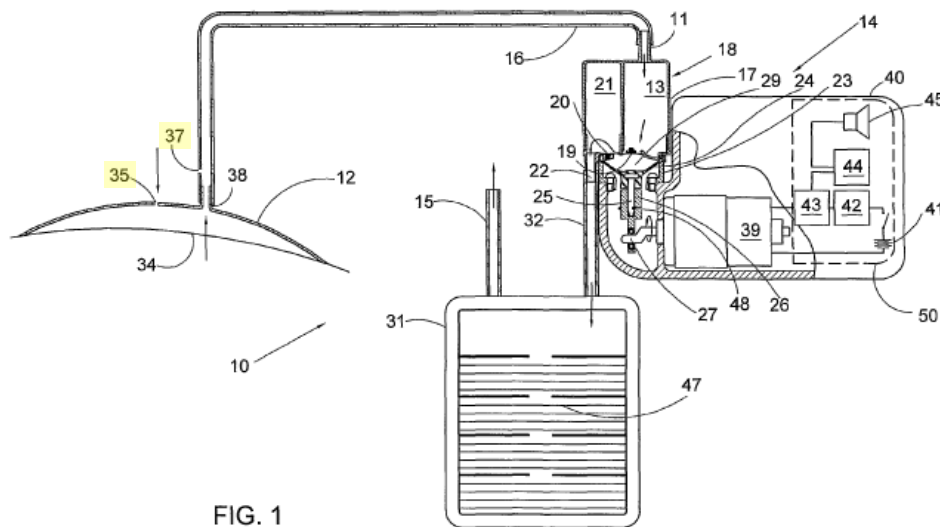
55. **Venting Arrangement with Flow Restrictor:** The independent claims of the '554 Patent require a “venting arrangement” that is located outside the enclosure and includes a flow restrictor that allows ambient air to enter the negative pressure tube and restricts the flow within the tube towards the vacuum source. *Id.* at claims 1, 12, 18. The claimed venting arrangement may comprise bleeding holes,

a porous body, or a tube orifice. *Id.* at claims 2, 3, 10, 11, 16, 17, 22-29. The specification further describes the claimed “bleeding hole”: “The bleeding hole in the enclosure may be a calibrated orifice or other flow restrictors providing for controlled flow of ambient air into the enclosure or into its outlet” or through the suction tube. *Id.* at 2:19-21, claims 4, 6, 7, 13, 14, 19. The ’554 Patent describes the bleeding hole as, for example, “a hole plugged with open cell foam or an open pore sintered metal plug, which restrict the flow, but are not susceptible to plugging as is a small orifice.” *Id.* at 2:22-24, 4:41-46.

56. One purported benefit of the claimed “venting arrangement” over the prior art is that the “bleeding hole renders the wound closure vented or non-airtight, as distinguishable from conventional wound closures.” *Id.* at 2:25-27. This allows ambient air to flow from the bleeding hole (i.e., flow restrictor) into the tube and “flow together with the exuded liquids when negative pressure is present” and prevents coagulation of exudate in the tube. *Id.* at 2:15-17, 4:29-36, claims 5, 13, 14, 19. Additionally, the venting arrangement allows ambient pressure to be maintained within the wound enclosure when the vacuum pump is not turned on. *Id.* at 2:17-18, 4:36-40, claim 6.

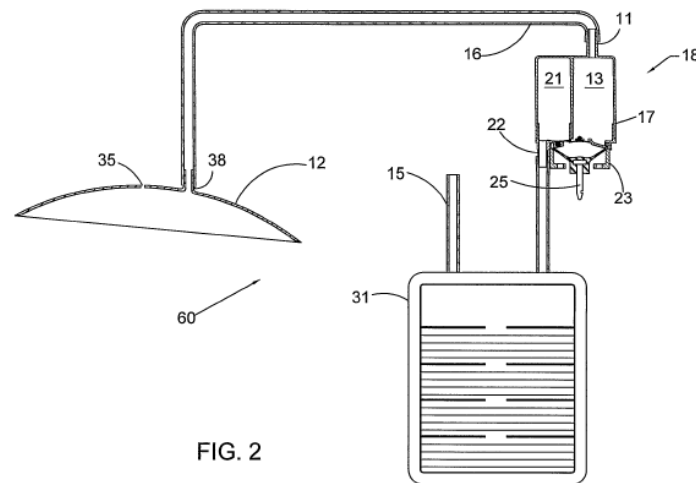
57. The ’554 Patent specification describes a bleeding orifice on the enclosure itself—which is not claimed in the ’554 Patent—and a tube orifice

adjacent to the enclosure. These orifices are depicted in Figure 1 as bleeding orifice 35 on the enclosure and tube orifice 37 adjacent to the enclosure (highlighting added):

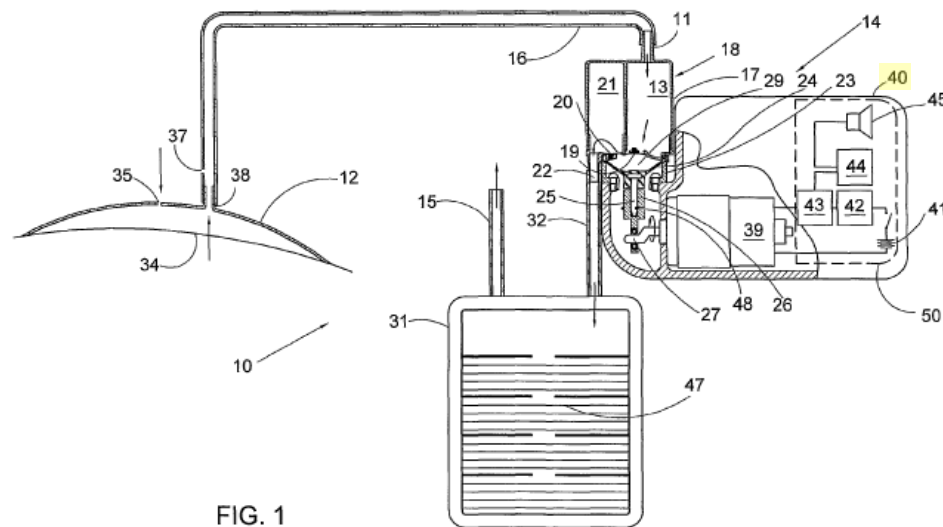


58. **Disposable Vacuum Pump with Waste Collection Bag:** A second feature that the '554 Patent purports to overcome the deficiencies in prior art NPWT systems is a disposable vacuum pump and waste collection bag that can “be adapted to be carried by an ambulatory patient.” *Id.* at 2:50-61, claims 8-11, 14, 20. The various components of the claimed invention are connectable and detachable, “[p]referably, . . . by simple hand manipulations.” *Id.* at 2:62 – 3:9, cl. 15, 21. Regarding the waste container, the '554 Patent describes that it “may contain a porous media adapted to soak up the drained liquids and may be in the form of a

collapsible or foldable bag.” *Id.* at 3:14-16. Figure 2 depicts the disposable vacuum system as disclosed in the ’554 Patent:



59. **Drive Unit:** A third feature contained within the ’554 Patent that purports to overcome deficiencies in the prior art is the drive unit that is used to maintain the amount of negative pressure within the enclosure. *Id.* at 3:25-29. The drive unit is non-disposable and provides an “indirect means . . . for controlling or monitoring the level of negative pressure applied to the wound.” *Id.* at 3:47-51, claims 8, 14, 15, 20, 21. The drive unit 40 is depicted in Figure 1 below (highlighting added):



## B. '554 Patent Prosecution History

60. I understand that the '554 Patent issued from U.S. Patent Application No. 11/989,297 (the "'297 Application") which is a national stage entry of PCT Application No. IL2005/000784. PCT IL2005/000784 was filed on July 24, 2005. I also understand that for purposes of evaluating the validity of the '554 Patent, July 24, 2005 is treated as the applicable priority date of the '554 Patent (the "Critical Date"). For purposes of this declaration, I have assumed a priority date of July 24, 2005, but I make no opinion as to the propriety of that priority date regarding the '554 Patent.

61. Based on the file history, I understand the '297 Application was filed on January 24, 2008. The Examiner issued an Office Action concerning the '297 Application on August 13, 2010. Ex. 1008 at 1043-48. The Examiner required the

applicant to restrict its claims between product and process to a single inventive concept, noting that claims in the application were directed to: (i) a vacuum system and method for draining an open wound; (ii) an enclosure for draining an open wound; (iii) a disposable assembly for draining an open wound; and (iv) a vacuum system for draining an open wound. *Id.* at 1045-48. In response, the applicant elected certain claims which were directed to an enclosure for draining an open wound. *Id.* at 972-74.

62. I understand that on October 14, 2010, the Examiner issued a non-final rejection of the '297 Application indicating two claims were anticipated by, and two claims were rendered obvious over, *Lerman* (US 5,941,859). *Id.* at 954-61. I understand that Applicant amended the claims to overcome the anticipation and obviousness rejections and added new claims. *Id.* at 620-39. Specifically, claim 11 which was rejected as anticipated by *Lerman* was amended as follows:

Petition for *Inter Partes* Review of  
U.S. Patent No. 8,506,554 B2  
Exhibit 1002

11. (currently amended) An enclosure for applying negative pressure to ~~draining an open a wound from liquids exuded therefrom~~, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable ~~by means of a tube to an inlet of~~ a vacuum pump source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, ~~wherein one or more bleeding holes are provided in the enclosure or adjacent to its outlet outside said enclosure~~, such that ambient air can enter said tube via said venting arrangement ~~and flow together with the exuded liquids under the action of the negative pressure, and the ambient pressure may be restored in said confined volume when said vacuum pump is not operating.~~

*Id.* at 621. Applicant argued “Lerman does **not** describe the claimed combination comprising ‘said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement.’” *Id.* at 631 (emphasis in original). Regarding the Examiner’s obviousness rejection, Applicant argued that “in operation of the pump, fluid is meant to flow only in one direction, i.e., from the shield to the tube, but not vice versa” which distinguished it from the purpose of Lerman. *Id.* at 634-35. Applicant further argued that the bleeding holes disclosed in Lerman are there to “provide greater air flow **towards** the suction tube, **through** the enclosed volume of the shield. This forces the ambient air to pass over the wound, and the flow of air over the wound enhances drainage of the wound.” *Id.* at 635 (emphasis in original).

63. I understand that the Examiner issued a final rejection of the '297 Application on April 20, 2011. *Id.* at 575-84. The Examiner rejected certain claims as anticipated by *Lockwood* (US 2005/0004534) and the remaining claims as being invalid for obvious over *Lockwood* alone and/or in view of *Argenta* (US 2001/0029956). *Id.* at 577-83. Based on the prosecution history, on August 22, 2011 the Applicant filed a Request for Continued Examination of the '297 Application, amending the claims yet again. *Id.* at 485-95. Claim 11 was amended to add a final element, as shown below:

11. (Currently amended) An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.

*Id.* at 489. I understand that Applicant highlighted this added claim limitation to argue that it overcame the anticipation rejection over *Lockwood*. *Id.* at 497-501. Specifically, Applicant noted:

Claim 11 currently recites the limitation of the venting arrangement (which is outside of the enclosure) is such that "*ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.*"

Thus 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.* at 497-98. Applicant specifically argued that “Lockwood ***teaches away*** from the claimed subject matter . . . ensuring that ambient air is drawn in via vent 19 **has to flow over the wound** . . .” and concluded “Lockwood teaches away from claim 11, which in contrast requires the ambient air to enter the tube via the venting arrangement and flow to the vacuum source **without entering the enclosure**.” *Id.* at 498, 501. In the prosecution history, Applicant argued that Argenta did not contain this claim element either and, therefore, could not render the claims obvious. *Id.* at 504.

64. Based on the prosecution history, on October 11, 2011, the Examiner issued a non-final rejection in response to Applicant’s Request for Continued Examination. *Id.* at 429-38. The Examiner rejected the claims as obvious over Lockwood in view of *Leffler* (US 3,516,160) and, for certain claims, in further view of Argenta. *Id.* at 432-38. The prosecution history indicates an interview between Applicant and the Examiner occurred on February 6, 2012 in which Applicant argued the combination of Lockwood and Leffler was improper. *Id.* at 427. I understand that on February 13, 2012, Applicant made amendments to the

specification and added a claim within the '297 Application, including adding a reference to “venting arrangement” within the specification:

the volume above the wound area of the body 34. A bleeding orifice 35 is provided within the enclosure 12, or adjacent to it as a tube orifice 37 (i.e. venting arrangement), allowing ambient air to flow into and through suction tube 16, rendering enclosure 12 non-air tight, or vented. This feature, unlike conventional sealed closures, provides for quick movement of

*Id.* at 395. And Applicant added a new claim limitation reciting a tube orifice:

54. (New) The vacuum system according to claim 11, wherein the venting arrangement is a tube orifice.

*Id.* at 402. In its arguments to the Examiner regarding the obviousness rejections, Applicant argued “[s]upplying the suction tube of Lockwood with the venting arrangement of Leffler would destroy the operation of Lockwood’s device and intended use thereof.” *Id.* at 405.

65. Based on the prosecution history, on June 11, 2012, the Examiner issued another non-final rejection of the '297 Application. *Id.* at 349-55. The Examiner rejected the claims as obvious over Argenta in view of Leffler. *Id.* at 351-55. In an Applicant-initiated interview, the Examiner agreed that the claims could be allowed if Applicant added the limitation: “comprising a calibrate orifice to restrict flow through the venting arrangement located outside said enclosure.” *Id.* at 347. On October 9, 2012, the Examiner issued a Notice of Allowance. *Id.* at 314-24.

66. I understand that on January 8, 2013, the Applicant amended the claims, with amendments to claim 11 shown below:

11. (Currently Amended) An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube ~~and a venting arrangement~~, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure ~~[[may]] can be selectively created~~ in said volume, ~~said tube comprising a venting arrangement comprising a calibrated orifice to restrict flow through said venting arrangement located outside said enclosure and comprising a flow restrictor[[,]]~~ such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without ~~entering having to enter~~ said enclosure.

*Id.* at 300-07. Based on the prosecution history, after another Applicant-initiated interview in which the Examiner was authorized to include “to restrict flow through said venting arrangement” and Applicant was permitted to change “calibrated orifice” to “flow restrictor” in the claims, the Examiner allowed the amended claims on April 10, 2013. *Id.* at 99-110, 61-62. Based on the prosecution history, the ’554 Patent was issued on August 13, 2013. *Id.* at 48.

### **C. The Challenged Claims**

67. This Declaration addresses claims 12-17, 26, and 27 (the “Challenged Claims”). There is one independent claim within the Challenged Claims, claim 12, which recites a vacuum system for applying negative pressure to a wound. It recites:

12. A vacuum system for applying a negative pressure to a wound, the vacuum system comprising:

an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume,

a tube,

a venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement,

the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be created in said volume,

said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure; and

a waste container in fluid communication with said vacuum source.

## **V. LEVEL OF ORDINARY SKILL IN THE ART**

68. In determining the characteristics of a person of ordinary skill in the art of the field of the '554 Patent at the time of the claimed invention (a "POSITA")<sup>1</sup>, I considered several factors, including various prior art techniques relating to negative pressure wound therapy systems, the type of problems that such techniques gave rise to, and the ease and rapidity with which innovations were made. Additionally, I considered the sophistication of the technologies involved, educational background of those in the field, and experience of those in the field at the time of invention. I

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<sup>1</sup> I considered the level of ordinary skill in the art as of July 24, 2005, the assumed Critical Date of the '554 Patent, as explained more fully above in Part IV.B.

also considered the level of education necessary to understand the '554 Patent and its claimed invention. Finally, I considered the relevant time period along with engineers in the field of vacuum pump systems, wound therapy systems, and medical device technologies.

69. Based on the above, I have concluded that a POSITA in the field of art of the '554 Patent would have had a bachelor's degree in mechanical engineering, biomedical engineering, or a similar field with at least two years of experience in research in, development of, or practice with medical pumping systems, including pressure-generating pumps. A person with less formal education, but more relevant practical experience, may also meet this standard, as may a person with more formal education but less relevant practical experience. Such a person would have been capable of understanding the '554 Patent and the prior art references discussed below. Based on my own education, training, and professional experience in the field of the claimed invention, I am familiar with the level and abilities of a POSITA at the time of the claimed invention. In 2005 I was president at TIAX LLC, where a key part of my job was hiring engineers as well as assembling and managing project teams to develop new products, many of whom would have qualified as a POSITA at the time. Accordingly, I have experience assessing the skillset required for products similar to the ones described in the '554 Patent and the prior art.

Additionally, I meet at least the minimum qualifications to be a person having ordinary skill in the art at the time of the claimed invention of the '554 Patent. My opinions herein would not change if a slightly different definition of a POSITA is adopted.

## **VI. CLAIM CONSTRUCTION FOR THE '554 PATENT**

70. In my analysis of the '554 Patent's claim terms and the prior art in this declaration, unless otherwise indicated, I have applied the plain and ordinary meaning of the claim terms in light of the specification and '554 Patent prosecution history to a person of ordinary skill in the art.

71. I understand that the Board may decide to construe certain terms of the challenged claims. Regardless of any likely construction that is ultimately applied, however, the Grounds included in the Petition are sufficient to invalidate the claims.

72. I understand that the Petitioners may take a different approach to claim construction in other proceedings, but for purposes of the Petition I understand that Petitioners believe no construction is necessary.

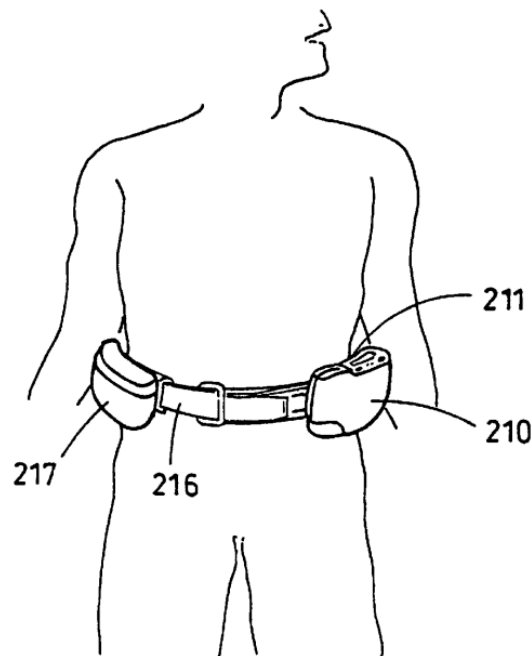
73. I have not yet formed, and do not offer, any opinion on the indefiniteness of any claims of the '554 Patent.

## VII. SUMMARY OF THE PRIOR ART

### A. Hunt (Ex. 1003)

74. U.S. Patent No. 6,142,982 to Kenneth William Hunt and Keith Patrick Heaton is an issued patent entitled “Portable Wound Treatment Apparatus” (“Hunt”). Ex. 1003. Hunt was filed on May 13, 1998 and issued on November 7, 2000. It is prior art to the ’554 Patent under 35 U.S.C. §§ 102(a), (b), and (e).

75. Hunt discloses a portable, vacuum-assisted wound treatment system with a suction pump that connects to a wound via a plurality of tubes and a canister to collect fluids drawn from the wound. *Id.* at Abstract. The portability of the patented invention in Hunt is depicted by the apparatus supported on a belt in the pictorial representation in Figure 3A:



*Id.* at Fig. 3A. Hunt explains that suction is applied to a wound which is covered by a porous dressing and connected via a tube to a waste canister. *Id.* at 3:57-62. The invention in Hunt also includes a second tube that is connected to the wound site and also to a pressure relief valve that “enables the pressure at the wound site to be brought to atmospheric pressure rapidly.” *Id.* at 3:63 – 4:1, 4:17-21.

76. The NPWT system described in Hunt includes a controller “indicating the status of the treatment being applied to the wound” and sensors to determine the level of suction. *Id.* at 1:55-63, 4:9-16. Figure 1 depicts the patented invention of Hunt, including the wound dressing (102), direction of airflow into and out of the wound (depicted by arrows), tubes (106 and 101), pressure transducers (105 and 108), canister (100), valve (8), and suction pump (6):

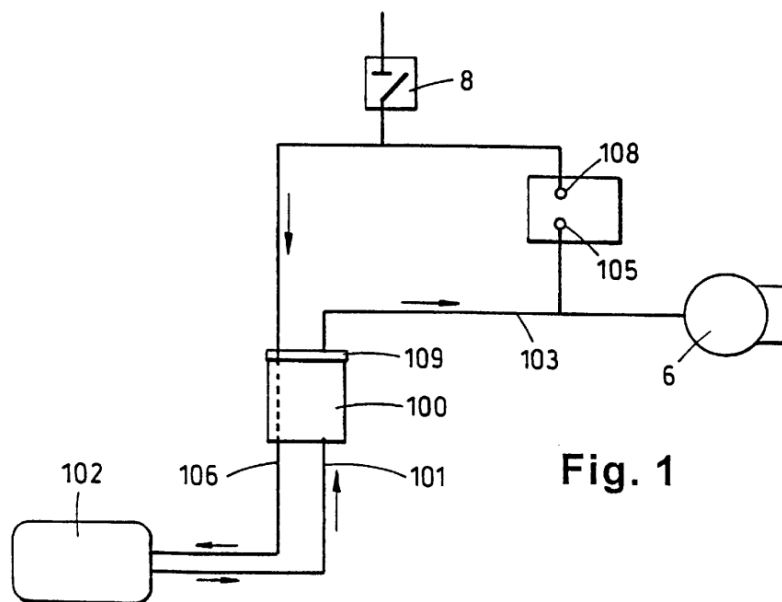


**Fig. 1**

*Id.* at Fig. 1.

**B. Dolliver (Ex. 1005)**

77. U.S. Patent Application Publication No. 2005/0192548 to Phillip B. Dolliver and Alec Bobroff is an issued patent entitled “Wound Drainage Suction Relief” (“Dolliver”). Ex. 1005. Dolliver was filed on February 26, 2004 and published on September 1, 2005. It is prior art to the ’554 Patent under 35 U.S.C. § 102(e).

78. Dolliver discloses a portable, vacuum-assisted wound drainage system connected to a suction pump that utilizes a drain catheter and conduit to draw fluid from a wound. *Id.* at Abstract. The system disclosed in Dolliver is operated by a controller that “periodically increases and decreases the application of suction at the drain catheter.” *Id.*

79. Dolliver explains that suction is applied to a wound via a drain catheter that includes a “vent valve, positioned between the drain catheter and the suction means.” *Id.* at [0007]. The suction device of Dolliver “provides a region of low pressure such that fluid is drawn...towards the suction device 106.” *Id.* at [0023]. The invention in Dolliver also includes a container that can collect fluid removed from the wound. *Id.* at [0023], [0039].

80. Like Hunt, the system described in Dolliver includes a controller that can “provide, without limitation, mechanical or electrical control signals to the suction device 106 that control the amount of suction generated by the suction device 106.” *Id.* at [0031]. Figure 1 depicts the patented invention of Dolliver, including the drain catheter (102) connected to the wound, sensor (125), conduit (122), vent valve (119), container (115), suction device (106), and controller (117):

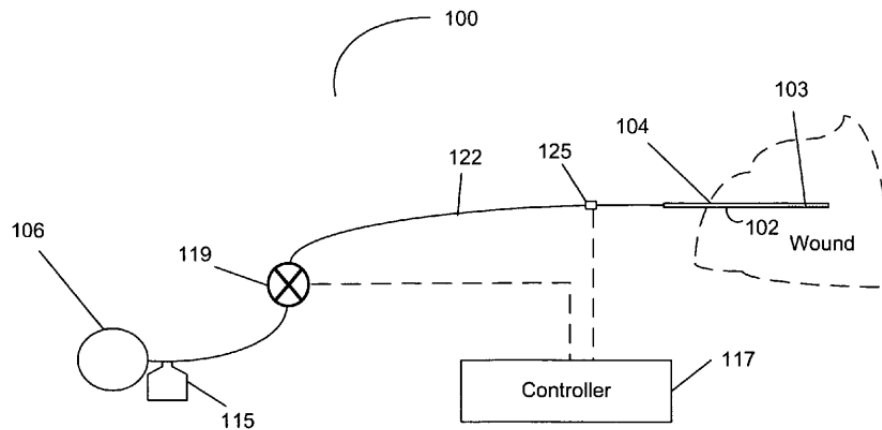


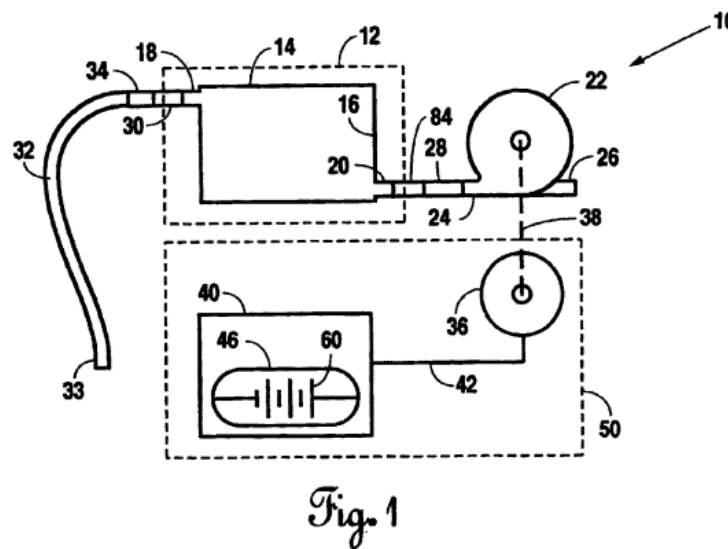
Fig. 1

*Id.* at Fig. 1.

### C. Watson (Ex. 1004)

81. U.S. Patent No. 6,648,862 to Richard Watson is an issued patent entitled “Personally Portable Vacuum Desiccator” (“Watson”). Ex. 1004. It was filed on November 20, 2001 and issued on November 18, 2003. Watson qualifies as prior art to the ’554 Patent under 35 U.S.C. §§ 102(a), (b), and (e).

82. Watson discloses a vacuum system that applies low pressure to a wound to promote healing. *Id.* at Abstract, 2:21-28, 4:43-52, Fig. 1. The disclosed system in Watson is “therapeutically useful to provide a personally portable low negative pressure source and trap for aspirating and collecting fluid exudate from a wound or incision.” *Id.* at 2:24-28. Parts of the system are also disposable and can be removed, especially after coming in contact with biological waste. *Id.* at 2:28-32; 4:17-22. Watson further discloses “an air tight dressing” and “flow delivery tube” to connect the wound site to the vacuum desiccator device. *Id.* at 4:43-52. The vacuum desiccator device is schematically depicted in Figure 1:



*Id.* at Fig. 1.

83. The vacuum system in Watson includes a “trap” that has a “desiccator cartridge” which collects exudate removed from the wound. *Id.* at 2:35-36, 3:3-21.

In an embodiment, “the vacuum pump member and the desiccator cartridge are integrated together as a unit.” *Id.* at 3:63-65. The vacuum pump is driven by “an electric motive or drive means” and “electrical control circuit.” *Id.* at 5:48-55; 6:8-15.

### **VIII. APPLICATION OF THE PRIOR ART TO THE CHALLENGED CLAIMS**

84. Based on my review and analysis of the materials cited herein, my opinions regarding the understanding of a POSITA, and my training and experience, it is my opinion that the Challenged Claims are anticipated and/or rendered obvious by the Grounds presented in this declaration. The reasons for my conclusions are explained more fully below.

| <b>Ground</b> | <b>'554 Patent Claims</b> | <b>Basis for Challenge</b> | <b>Application of Prior Art</b>     |
|---------------|---------------------------|----------------------------|-------------------------------------|
| 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              |
| 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 |

85. I am informed by counsel that each of the references cited in the above grounds qualifies as prior art to the Challenged Claims because each reference was filed and/or published before the Critical Date for the '554 Patent.

**A. Ground 1: Analysis of Claims 12, 13, 16, 26, and 27 Based on Hunt**

86. In my opinion, claims 12-16, 26, and 27 of the '554 Patent are invalid because they are anticipated by the teachings of Hunt, as detailed below.

**1. Claim 12**

87. Based on my review and for the reasons that follow, it is my opinion that claim 12 is anticipated by the teachings of Hunt.

88. I have reproduced independent claim 12 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

12[pre] A vacuum system for applying negative pressure to a wound,  
the vacuum system comprising:

[a] an enclosure and a vacuum source, the enclosure being attachable  
to the wound circumference so as to define a confined volume;

[b] a tube;

[c] a venting arrangement comprising a flow restrictor to restrict flow  
through said venting arrangement,

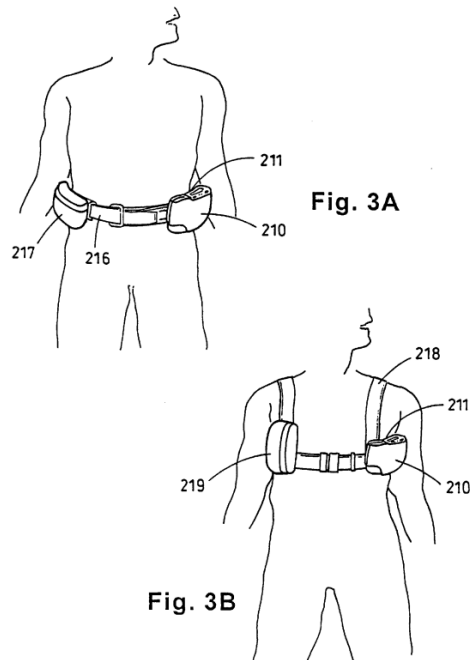
[d] the enclosure having an enclosure outlet connectable to said  
vacuum source via said tube so that negative pressure can be  
created in said volume,

- [e] said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure; and
- [f] a waste container in fluid communication with said vacuum source.

**i. Limitation 12[pre]: A vacuum system for applying negative pressure to a wound, the vacuum system comprising:**

89. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 12, it is my opinion that Hunt teaches a vacuum system for applying negative pressure to a wound.

90. Hunt discloses a “portable therapeutic apparatus for stimulating the healing of superficial wounds in a person.” Ex. 1003 at 1:45-48. Hunt further teaches that the treatment apparatus comprises “a suction pump and canister for containing fluids drawn from the wound by said pump.” *Id.* at 1:48-50. Hunt explains that suction (i.e., negative pressure) is applied “to the wound site”. *Id.* at 3:59-61. The vacuum system taught by Hunt is designed to be worn by a patient and is depicted in Figures 3A-3B:



*Id.* at Figs. 3A, 3B.

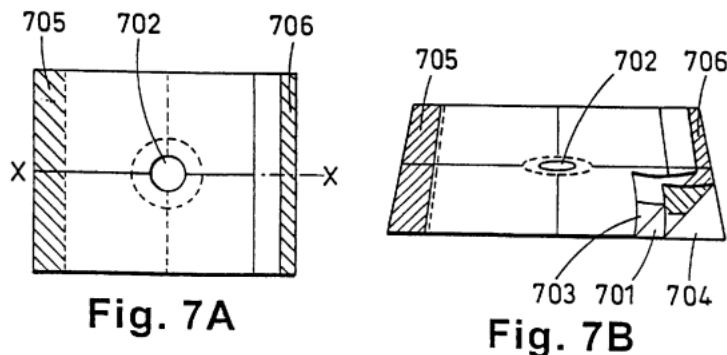
91. Accordingly, it is my opinion that Hunt teaches limitation 12[pre].

**ii. Limitation 12[a]: an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume;**

92. In my opinion, Hunt teaches limitation 12[a]. Hunt teaches an enclosure (wound dressing with surgical drape) and vacuum source (suction pump 6), and the enclosure is attachable to a wound circumference to define a confined volume therein.

93. **Enclosure:** In my opinion, Hunt teaches an enclosure. Hunt teaches that a porous wound dressing 102, cut to correspond to the size of the wound, is “pressed onto the wound”. *Id.* at 5:19-21. Additionally, Hunt teaches a multi-layer

“surgical drape” to secure and connect the dressing with the vacuum source. The surgical dressing comprises a polyurethane film layer 701 that is coated on one side with a pressure-sensitive acrylic resin adhesive to secure the dressing to the wound. The surgical drape has a hole 702 through all layers to accommodate a “spout” for fluid connection. *Id.* at 5:27-32. The surgical drape may also include an outer protective film 703, such as polyethylene, and a liner 704 that is stripped off prior to use to expose the pressure-sensitive adhesive layer. *Id.* at 5:44-46. The surgical drape is depicted in Figures 7A and 7B, as shown below:

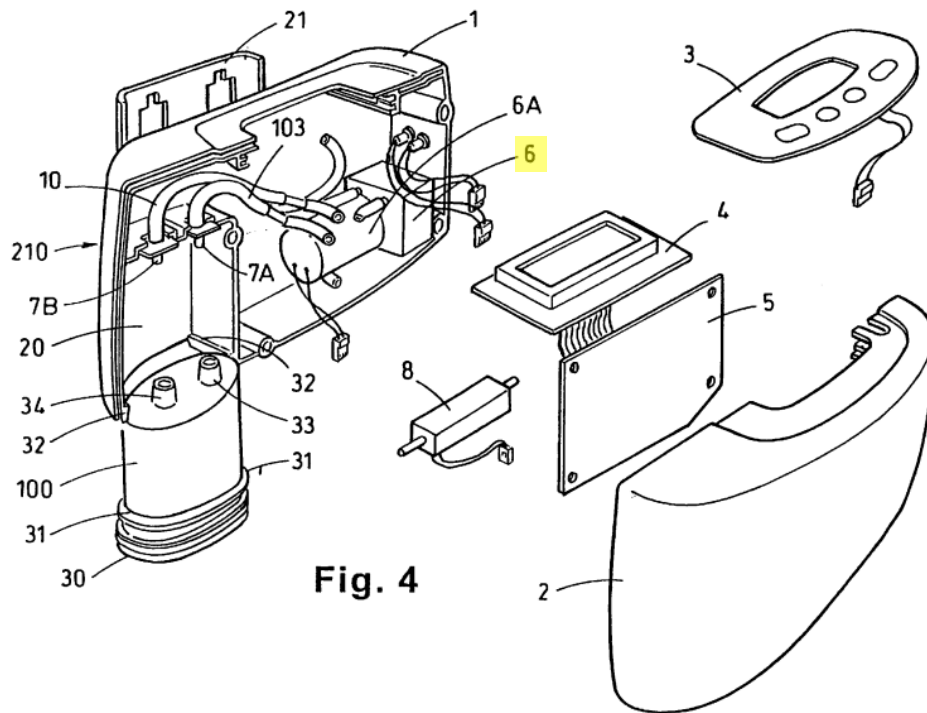


*Id.* at Figs. 7A-7B.

94. Hunt also teaches that “[f]ilm 701 has an overall size that allows it to be adhered to the patient’s skin around the wound site . . . so that an airtight cavity is formed around the wound.” *Id.* at 5:27-38.

95. Accordingly, it is my opinion that Hunt teaches the claimed “enclosure.”

96. **Vacuum Source:** In my opinion, Hunt teaches a “vacuum source.” Specifically, Hunt discloses “suction pump 6” that is run by an electric motor. *Id.* at 3:32-33. Hunt teaches “the pump 6 is a diaphragm pump but other types of pump and equivalent components to those specifically employed may be substituted.” *Id.* at 5:9-11. Suction pump 6 is depicted within the housing of Hunt’s NPWT system, shown in Figure 4 below:



*Id.* at Fig. 4 (highlighted to identify suction pump 6). Hunt also teaches that “[s]uction is applied to the wound site . . . by a tube 103, connected to the pump 6.” *Id.* at 3:60 – 4:1.

97. Accordingly, in my opinion Hunt teaches the claimed “vacuum source”.

98. Hunt also teaches that its enclosure (wound dressing 102 and surgical drape) is attachable to a wound circumference to define a confined volume. Hunt discloses the porous dressing “is cut to correspond with the extent of the wound and pressed onto the wound . . . .” *Id.* at 5:19-21. This porous wound dressing sized to fit around the wound is accompanied by a surgical drape that is “used to secure the connector, lumen, and dressing.” *Id.* at 5:27-29. Hunt further teaches that the surgical drape comprises film 701 which “has an overall size that **allows it to be 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.**” *Id.* at 5:27-38 (emphasis added). The surgical drape taught by Hunt is depicted in Figures 7A and 7B, as shown below:

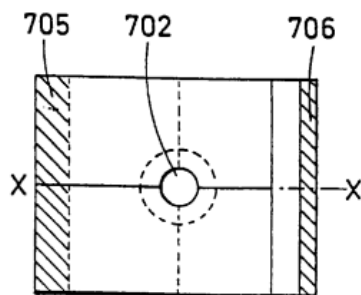


Fig. 7A

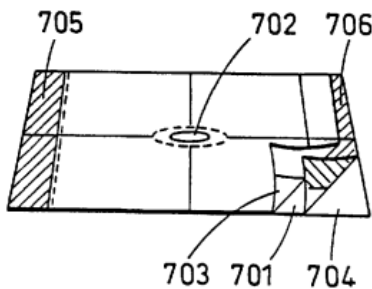


Fig. 7B

*Id.* at Figs. 7A-7B.

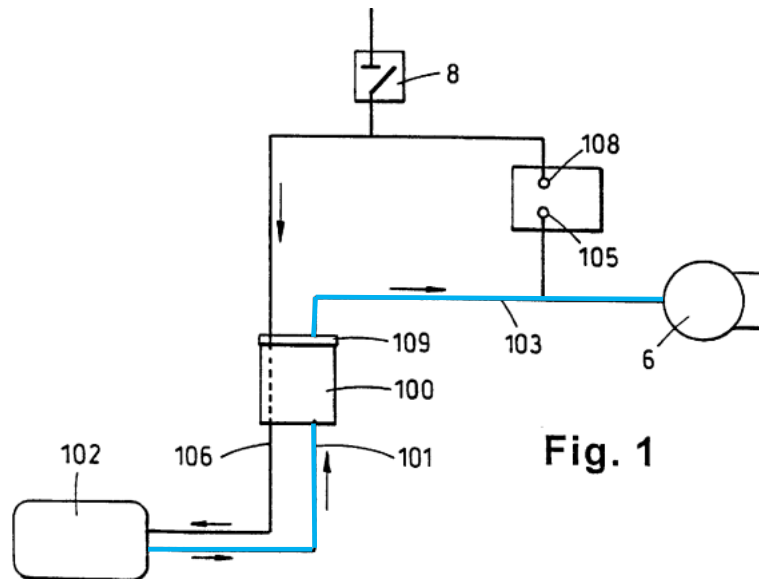
99. A POSITA would have understood that the wound dressing and surgical drape taught by Hunt defines a confined volume underneath at the wound site.

100. For the reasons stated above, in my opinion Hunt teaches limitation 12[a].

**iii. Limitation 12[b]: a tube;**

101. In my opinion, Hunt teaches limitation 12[b]. Hunt teaches a tube.

102. Hunt describes multiple tubes that run to and from the wound dressing in the disclosed NPWT system: tube 101 connects the canister to the porous wound dressing; tube 103 connects the canister to the pump which allows negative suction to be applied to the wound via the canister; and tube 106 is connected to the wound site 102 at one end, and to a pressure relief valve 8 at a second end. Specifically, Hunt explains: “[s]uction is applied to the wound site via the canister by a tube 103, connected to pump 6.” *Id.* at 3:60-61. Hunt also teaches that tube 101 operatively connects with tube 103 at the canister and applies suction to the wound dressing. *Id.* at 3:63-66; Fig. 1. The connection of the tubes is depicted in Figure 1 below:



*Id.* at Fig. 1 (annotated in blue to identify the tubes 101 and 103). Hunt teaches that the suction pump 6 is connected by a silicon rubber tube 103 to the canister 100. *Id.* at 3:31-34. Hunt also teaches that canister 100 is connected via tube 101 to porous dressing 102 at the wound site. Therefore, suction is applied to the wound site via tube 101 from the canister which is connected to the pump 6 by tube 103. *Id.* at 3:59-61. To the extent Hunt does not explicitly disclose that tube 101 is connected to a vacuum source, a POSITA would have understood that to remove exudate from the wound, tube 101 necessarily applies suction from the pump 6 applied via tube 103. *Id.* at 4:43-45. Said another way, if the tube 101 was not at least fluidically connected to the vacuum source, there would be no negative pressure in the enclosure.

103. Additionally, Hunt teaches that “it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister.” *Id.* at 4:34-39.

Hunt further explains that “tubes 103 and 101 may comprise an internal tube surrounded by an annular space represented by tube 106.” *Id.* As such, Hunt teaches that tubes 103 and 101 may have a common internal lumen to apply suction to the wound dressing from the pump.

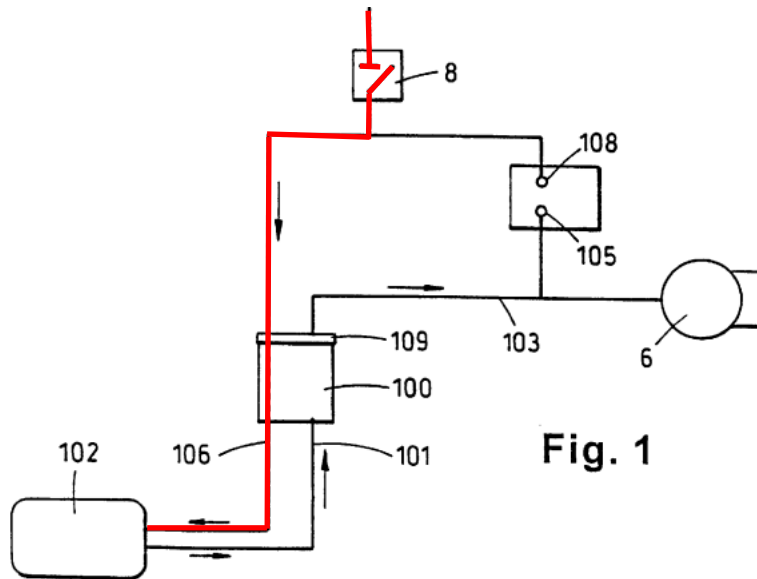
104. Accordingly, it is my opinion that Hunt teaches limitation 12[b].

**iv. Limitation 12[c]: a venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement,**

105. In my opinion, Hunt teaches limitation 12[c] because Hunt teaches that the system is vented through pressure relief valve 8 and tube 106. Pressure relief valve 8 restricts flow of ambient air through the valve itself and tube 106 as air moves through the vacuum system.

106. As explained immediately above, Hunt teaches multiple tubes running between the wound site and vacuum system: tube 101 connects the canister to the porous wound dressing; tube 103 connects the canister to the pump which allows negative suction to be applied to the wound via the canister; and tube 106 is connected to the wound site 102 at one end, and to a pressure relief valve 8 at a second end. It is also connected to a pressure transducer 108, which allows the user to measure or monitor the pressure under the confined volume at the wound site. *Id.* at 3:57 – 4:1. Hunt also teaches that by connecting the second end of tube 106 to a

pressure relief valve 8 it allows venting of the enclosure. *Id.* at 4:17-34. Tube 106 and its connection to pressure relief valve 8 is depicted in Figure 1 below:



*Id.* at Fig. 1 (tube 106 and its connection to pressure relief valve 8 annotated in red).

107. As such, a POSITA would have understood that pressure relief valve 8 and tube 106 constitute a “venting arrangement” as that term is used in the ’554 Patent. For example, the pressure relief valve 8 has an orifice that allows ambient air to enter the tube and through the tube into the volume beneath the porous dressing 102 at the wound site. I understand that any construction of “venting arrangement” includes an orifice, therefore, it is my opinion that Hunt discloses a venting arrangement.

108. Hunt also teaches that the tubes 101 and 106 may be combined into a multi-partitioned tube. Specifically, Hunt teaches: “Instead of running two separate

tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by an annular space represented by tube 106.”  
*Id.* at 4:34-39. In this embodiment, a POSITA would have understood that the multi-partitioned tube still would necessarily have a hole at a position spaced apart from the wound dressing, allowing ambient air to enter tube 106 via the opening in pressure relief valve 8 and flow into the vacuum.

109. Accordingly, it is my opinion that Hunt teaches a “venting arrangement.”

110. The venting arrangement of Hunt comprises a flow restrictor that restricts the flow of air through the venting arrangement. Hunt teaches “pressure relief valve 8” that is coupled to tube 106 as shown in Figure 1 below:

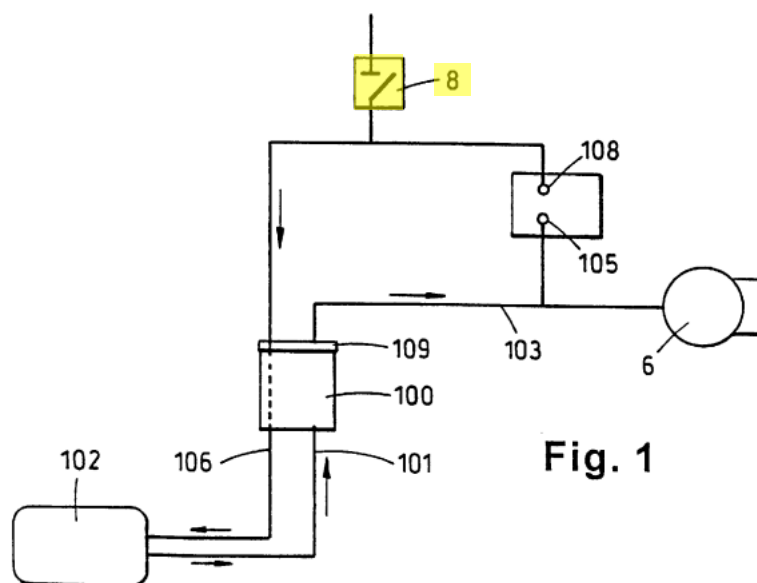


**Fig. 1**

*Id.* at Fig. 1 (highlighting added to identify pressure relief valve 8).

111. Regarding the pressure relief valve, Hunt explains:

In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow pressure to equalized at the wound site and then close to restore the suction. It will be appreciated that 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.* at 4:17-28. Under the plain and ordinary meaning of “flow restrictor,” a POSITA would have understood that Hunt’s pressure relief valve 8 can at least fully restrict the flow of ambient air through the venting arrangement (including tube 106) and controls the flow of ambient air through the valve and tube 106 into the vacuum system. Also, that the valve can at least be opened and closed which creates an average restriction over time that is less than a full restriction. A POSITA would also have known that the valve could have intermediate positions between open and closed to vary the resistance.

112. Accordingly, in my opinion Hunt teaches limitation 12[c].

- v. **Limitation 12[d]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be created in said volume;**

113. In my opinion, Hunt teaches limitation 12[d] because Hunt discloses an enclosure (wound dressing and surgical drape) that is connectable to the vacuum source (suction pump 6) via the tube (tube 101) so that negative pressure is selectively created in the volume under the enclosure.

114. As I explained above, Hunt teaches an “enclosure” through its disclosure of a wound dressing and surgical drape. In one embodiment, as taught by Hunt, “FIGS. 6A-6D show various views of a connector for attaching the multi-lumen tube at the wound site.” *Id.* at 2:27-28. Figures 6A-6D are shown below:

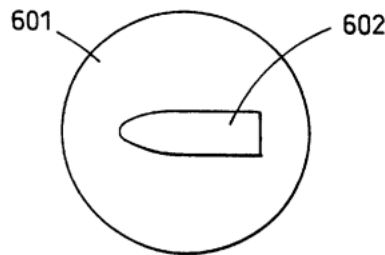


**Fig. 6A**

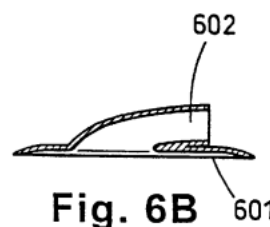


**Fig. 6B**



**Fig. 6C**

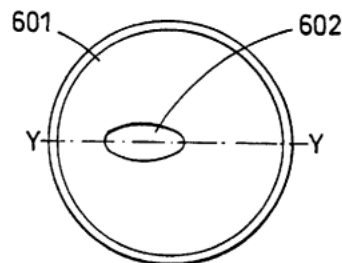


**Fig. 6D**

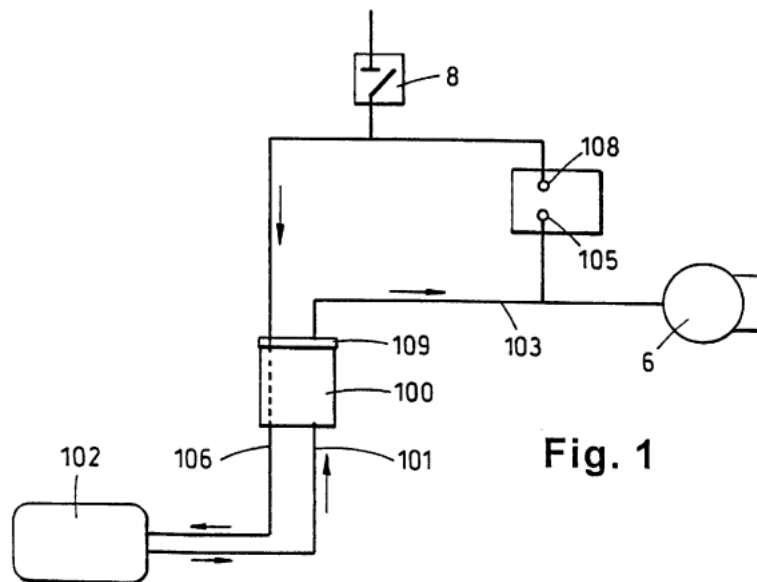


**Fig. 6E**

*Id.* at Figs. 6A-6D. Hunt further teaches that connector at the wound dressing “comprises a molded plastic disc-like cup 601 having a centrally positioned spout 602” which is “sized to accept, as a closely sliding fit, the end of a multi-lumen tube.” *Id.* at 5:16-19. Alternatively, Hunt teaches that the end of the tube “can be passed into the spout” and pressed into the wound dressing. *Id.* at 5:23-26. A POSITA would have therefore understood spout 602, part of the connector to the enclosure, to be an enclosure outlet.

115. Hunt further teaches that the surgical drape with wound dressing (corresponding to the claimed “enclosure”) “**can be used to secure the connector, lumen and dressing.**” *Id.* at 5:27-38 (emphasis added). Thus, Hunt teaches that the enclosure (wound dressing and surgical drape) has an enclosure outlet connector.

116. Hunt also teaches that “[s]uction is applied to the wound site via the canister by a tube 103, connected to pump 6.” *Id.* at 3:60-61. As explained regarding limitation 12[b] above, Hunt teaches a “tube” (tube 101) that applies the suction carried from tube 103 to the wound site. Hunt also teaches that tube 101 is connected to the porous dressing 102 at the wound. *Id.* at 3:58-60. This is shown in Figure 1 below:



*Id.* at Fig. 1.

117. Accordingly, it is my opinion that Hunt teaches limitation 12[d].

- vi. **Limitation 12[e]: said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure; and**

118. In my opinion, Hunt teaches limitation 12[e]. As explained above, Hunt teaches a venting arrangement (tube 106 and pressure relief valve 8). The venting arrangement allows ambient air to enter tube 106 through opened pressure relief valve 8, as shown below:

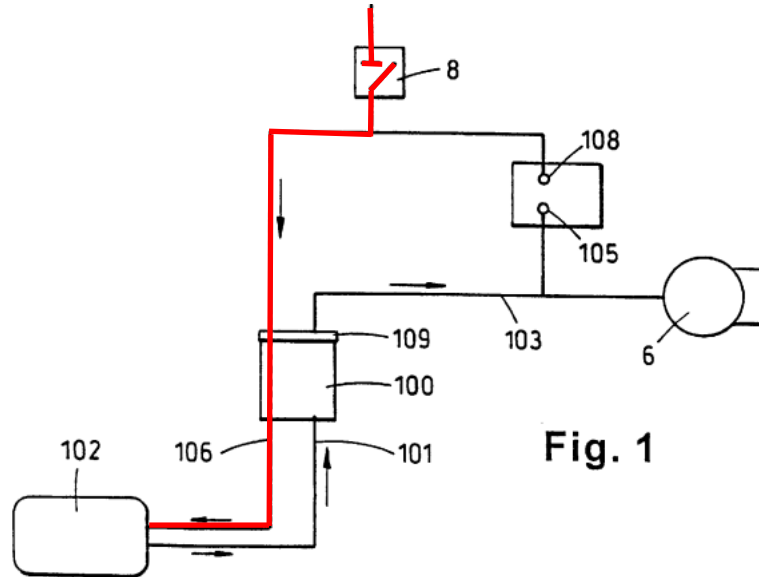


**Fig. 1**

*Id.* at Fig. 1 (ambient air in tube 106 and valve 108 annotated in red, airflow indicated by arrows within Figure 1). As shown in Figure 1, the ambient air that enters tube 106 and flows towards the wound dressing 102, is then further drawn into the vacuum system via tube 101, upstream of the vacuum source (pump 6).

119. Hunt also teaches that the tubes 101 and 106 may be combined into a multi-partitioned tube. Specifically, Hunt teaches: “Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by an annular space represented by tube 106.”

*Id.* at 4:34-39. This is depicted in Figure 5F:

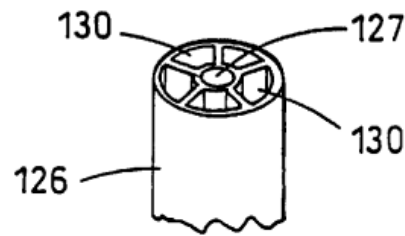


**Fig. 5F**

*Id.* at Fig. 5F. In this embodiment, a POSITA would have understood that the venting arrangement and flow restrictor (pressure relief valve 8 and tube 106) necessarily provides a controlled flow of ambient air into the multi-partitioned tube.

120. The venting arrangement of Hunt (i.e., tube 106 and pressure relief valve 8) is located outside the enclosure, as shown below:

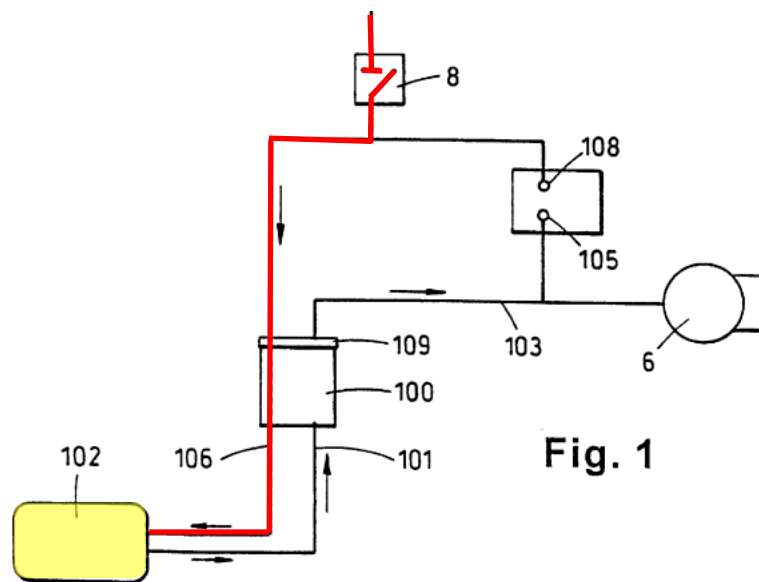
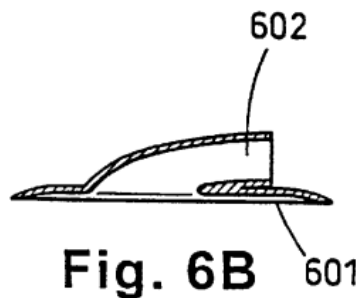


**Fig. 1**

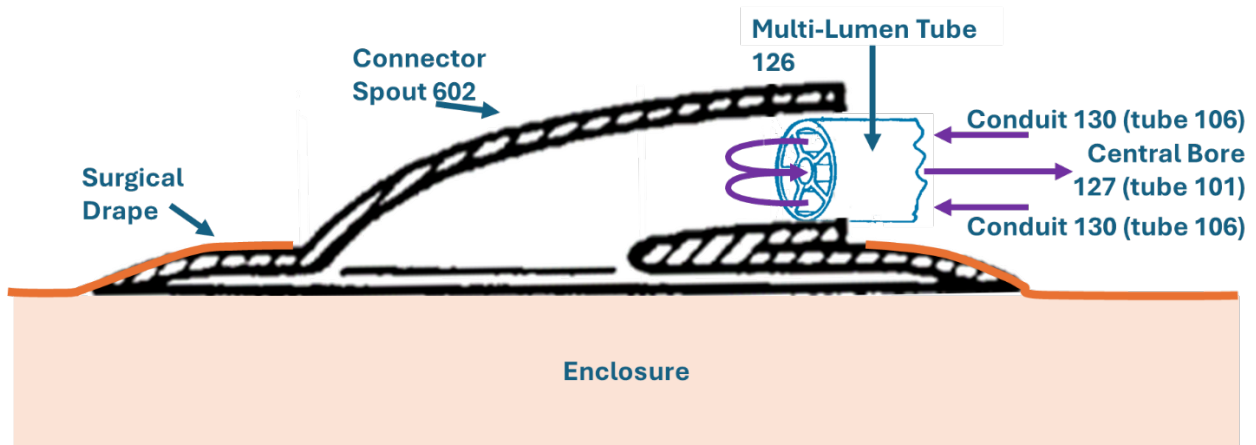
*Id.* at Fig. 1 (tube 106 and valve 108 annotated in red with wound dressing 102 annotated in yellow). The venting arrangement allows ambient air to first enter

through the orifice in pressure relief valve and flow into the vacuum system through tube 106 without entering the wound dressing 102, as detailed below.

121. As previously explained, Hunt teaches that the tubes 101 and 106 may be combined into a multi-partitioned tube. The multi-partitioned tube connects with the wound dressing, as depicted in Figure 6B:



*Id.* at Fig. 6B. In this embodiment, a POSITA would have understood that the multi-partitioned tube would necessarily have an outlet at a position spaced apart from the wound dressing in connector spout 602, allowing ambient air to exit tube 106 (the annular space surrounding the internal combined tube 101 and 103) and enter tube 101 and 103 and flow to the canister and pump. The vented flowpath at the end of tubes 106 and 101 is depicted in the illustration below that I created from Hunt Figures 5F and 6B and reflecting the surgical drape as depicted in Figure 7 with the purple lines indicating the direction of air flow:



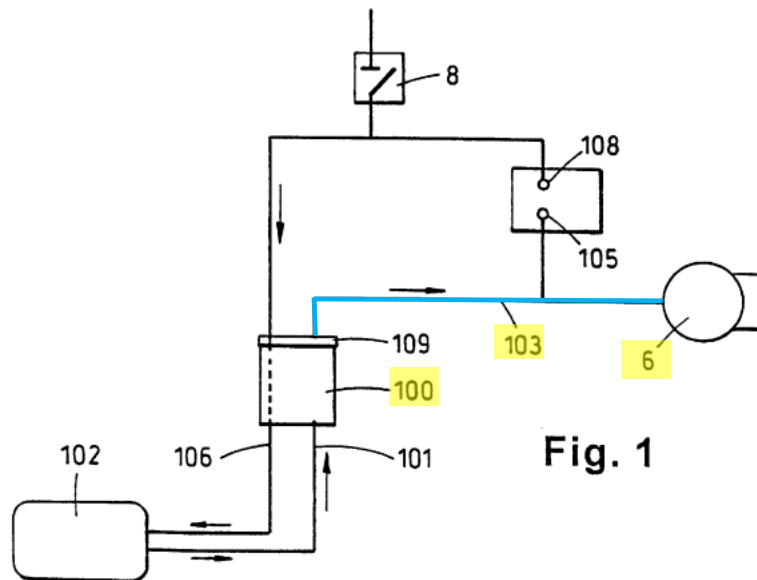
This shows that air from the atmosphere exits conduits 130 (tube 106) of the multi-partitioned tube inside the connector spout 602 and combines with any exudate to flow out through the central bore 127 (tube 101) of the multi-partitioned tube to the cannister. Based on basic principles of conservation of mass, under constant pressure conditions in the enclosure there can be no net flow into or out of the enclosure. As such, ambient air flowing from tube 106 flows into tube 101 as shown above. Of course, some air must flow into the enclosure when the pressure inside the enclosure increases (reduced vacuum) and out of the enclosure when the pressure decreases (increased vacuum). However, in use, some air will flow directly from tube 106 into tube 101 without entering the enclosure.

122. Accordingly, it is my opinion that Hunt teaches limitation 12[e].

**vii. Limitation 12[f]: a waste container in fluid communication with said vacuum source.**

123. In my opinion, Hunt teaches limitation 12[f]. Hunt discloses a “canister for containing fluids drawn from the wound by said pump.” *Id.* at 1:49-50.

124. As shown in Figure 1, Hunt teaches a canister 100 that is connected to the wound dressing via tube 101 and also connected to the pump via tube 103.



*Id.* at Fig. 1 (highlighted to identify the canister 100 and tube 103 (annotated in blue) connecting it to the vacuum pump 6). Hunt specifically teaches “the pump is connected by a silicon rubber tube 103 to a canister spigot 7A in a compartment 20 for the canister 100.” *Id.* at 3:33-35. Additionally, “[s]uction is applied to the wound site via the canister by a tube 103, connected to pump 6.” *Id.* at 3:60-61. A POSITA

would have understood that tube 103 provides fluid communication between the vacuum source and canister as it supplies the negative air pressure from the pump 6.

125. Accordingly, in my opinion Hunt teaches claim 12[f].

126. For the reasons stated above, it is my opinion that Hunt teaches all the limitations of claim 12 of the '554 Patent.

## **2. Claim 13**

127. Based on my review and for the reasons that follow, it is my opinion that claim 13 is anticipated by the teachings of Hunt.

128. I have reproduced claim 13 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

13[pre] The vacuum system of claim 12,

[a] wherein said vacuum system further operates to drain the wound  
from fluids exuded therefrom,

[b] wherein the ambient air can enter said tube via said venting  
arrangement and flow together with the exuded liquids under the  
action of the negative pressure,

[c] and facilitates draining of the exuded fluids to said waste container.

**i. Limitation 13[pre]: The vacuum system of claim 12,**

129. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 13, it is my opinion that Hunt teaches limitation 13[pre]. As I explain above, in my opinion Hunt teaches the vacuum system of claim 12. The analysis and my discussion of claim 12 is hereby incorporated by reference.

130. Accordingly, it is my opinion that Hunt teaches limitation 13[pre].

**ii. Limitation 13[a]: wherein said vacuum system further operates to drain the wound from fluids exuded therefrom,**

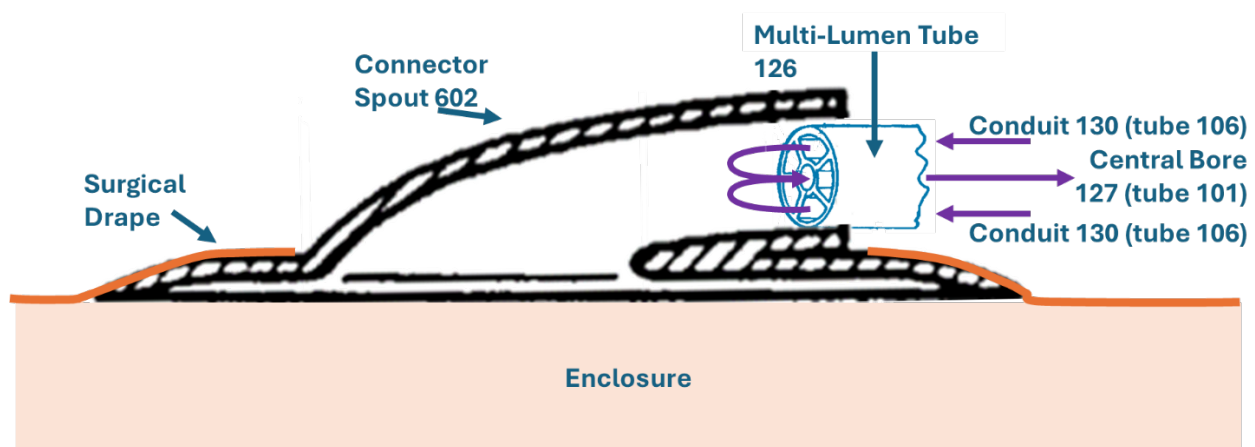
131. In my opinion, Hunt teaches limitation 13[a]. As explained above regarding limitation 12[f], Hunt discloses a waste canister that collects exudate from a wound after suction is applied. Hunt teaches “[s]uction is applied to the wound site via the canister by a tube 103, connected to pump 6.” *Id.* at 3:60-61. The canister is specifically “for containing fluids drawn from the wound.” *Id.* at Abstract. Thus, a POSITA would have understood that the vacuum system of Hunt operates to drain the wound from exuded fluids.

132. Accordingly, it is my opinion that Hunt teaches limitation 13[a].

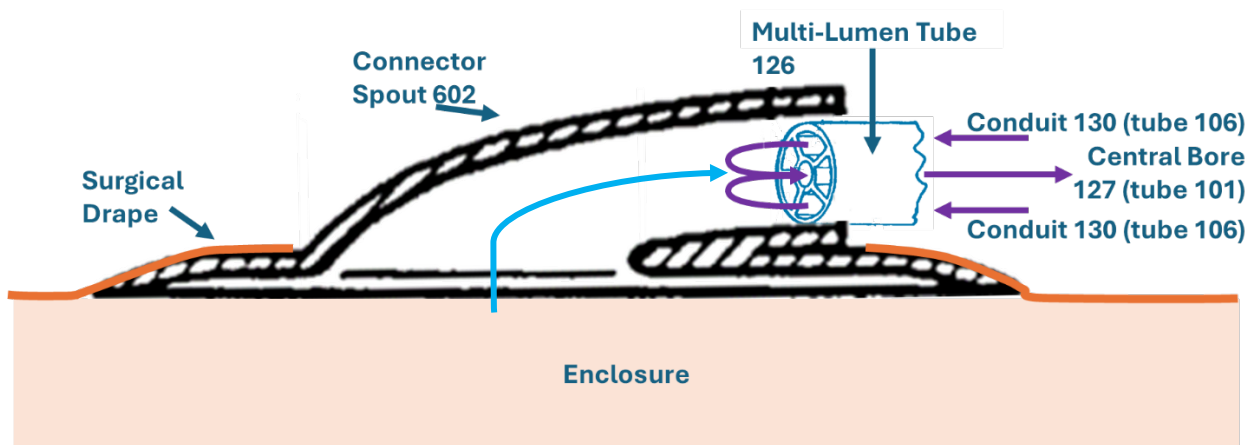
**iii. Limitation 13[b]: wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure,**

133. In my opinion, Hunt teaches limitation 13[b]. As explained above regarding limitation 12[e], Hunt teaches a venting arrangement that allows ambient air to enter the tube and flow towards the canister and vacuum pump when suction is applied.

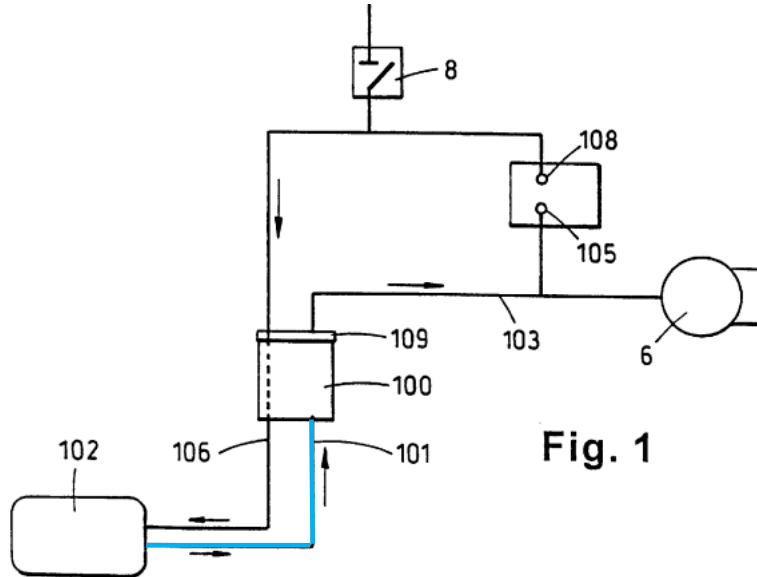
134. Also as explained above, a POSITA would have understood that the venting arrangement of Hunt (tube 106 and pressure relief valve 8) allows ambient air to enter the multi-partitioned tube and flow into tube 101 and 103 (the suction tube) and flow to the canister and vacuum pump under the application of negative pressure. The vented flowpath at the end of tubes 106 and 101 is depicted in the illustration below that I created from Hunt Figures 5F and 6B with purple lines indicating the direction of air flow:



135. Additionally, exudate, or exuded fluids, removed from the wound under the application of negative pressure that flow to the waste canister (as explained above) also enter central bore 127 (tube 101) as annotated in the blue line below:



136. A POSITA would have understood that ambient air entering tube 101 from tube 106 (the purple line above) necessarily flows together with exuded liquids from the wound (the blue line above) towards the canister and vacuum source when the pump is turned on and negative pressure is being applied. This is shown in annotated Figure 1 where the arrows indicate the airflow direction:

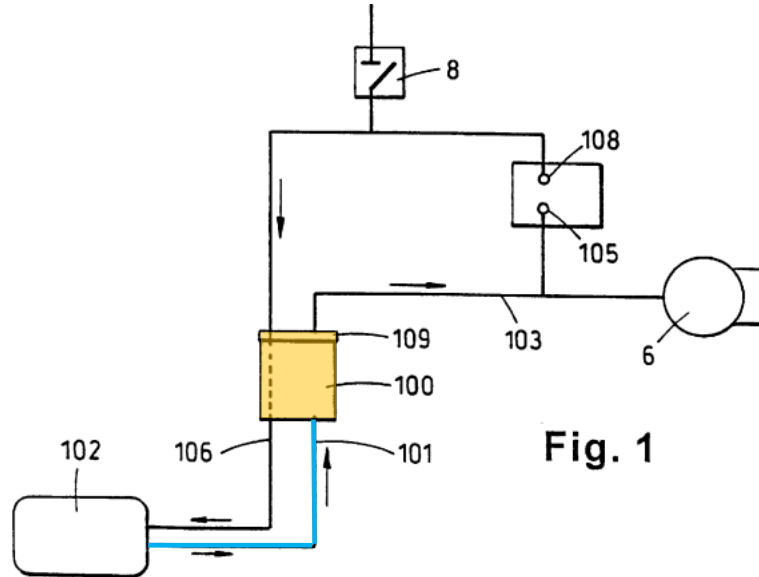


*Id.* at Fig. 1 (annotated in blue to identify the path traveled by the exuded liquids and ambient air).

137. Accordingly, it is my opinion that Hunt teaches limitation 13[b].

**iv. Limitation 13[c]: and facilitates draining of the exuded fluids to said waste container.**

138. In my opinion, Hunt teaches limitation 13[c]. As explained above regarding limitations 13[a] and 13[b], the vacuum system in Hunt uses suction to draw fluid exudate from a wound which travels with ambient air admitted through the venting arrangement towards waste container 100. A POSITA would have understood that the ambient air flows from the venting arrangement and the suction present in tube 101 (as shown in Figure 1 below) facilitate draining of the exuded fluids in tube 101 and help carry the exuded fluids to be deposited in waste canister 100.



*Id.* at Fig.1 (annotated in blue to indicate the path traveled by exuded liquids along with ambient air towards waste canister 100 annotated in yellow).

139. Accordingly, it is my opinion that Hunt teaches limitation 13[c].

140. For the reasons stated above, it is my opinion that Hunt teaches all the limitations of claim 13 of the '554 Patent.

**3. Claim 16: The vacuum system according to claim 12, wherein said venting arrangement comprises one or more bleeding holes.**

141. In my opinion, Hunt teaches claim 16. As explained above, Hunt teaches the vacuum system of claim 12. In my opinion, Hunt also teaches the additional limitations in claim 16 because the pressure relief valve 8 has a bleeding hole.

142. As I explained with regard to claim 12 above, Hunt teaches a “venting arrangement” that admits ambient air into the tube 106 via pressure relief valve 8 and flows into the balance of the vacuum system. A POSITA would have recognized that the relief valve has a bleeding hole where it opens to admit ambient air. Thus, based on the plain and ordinary meaning of the term “bleeding hole,” a POSITA would have recognized that the venting arrangement in Hunt comprises a bleeding hole.

143. Accordingly, in my opinion Hunt teaches claim 16.

**4. Claim 26: The vacuum system according to claim 12,  
wherein the venting arrangement is a tube orifice.**

144. In my opinion, Hunt teaches claim 26. As explained above, Hunt teaches the vacuum system of claim 12. In my opinion, Hunt also teaches the additional limitations in claim 26 because the venting arrangement comprising the pressure relief valve 8 and tube 106 is a tube orifice.

145. As I explained with regard to claim 12 above, Hunt teaches a “venting arrangement” that admits ambient air into the tube 106 via the relief valve and flows into the balance of the vacuum system. A POSITA would have recognized that pressure relief valve 8 has an opening which admits ambient air into tube 106. A POSITA would also have understood that the opening in pressure relief valve 8 constitutes an orifice under the plain and ordinary meaning of that term. Since the

orifice in pressure relief valve 8 exposes the lumen of tube 106 (i.e., conduit 130 within the multi-partitioned tube of Hunt) to atmosphere, a POSITA would have understood that the orifice within pressure relief valve 8 is a tube orifice.

146. Accordingly, in my opinion Hunt teaches claim 26.

**5. Claim 27: The vacuum system according to claim 26, said orifice having a smaller opening than a cross-section of the tube.**

147. In my opinion, Hunt teaches claim 27. As explained above, Hunt teaches the vacuum system of claim 26. Additionally, as explained above, the opening within pressure relief valve 8 that is used to admit ambient air into tube 106 is a tube orifice. A POSITA would have understood that this valve opening (i.e., tube orifice) in certain positions between being fully opened and fully closed would necessarily be smaller than the cross-section of the multi-partitioned tube.

148. Accordingly, in my opinion Hunt teaches claim 27.

**B. Ground 2: Analysis of Claims 14 and 15 Based on Hunt in view of Watson**

149. In my opinion, claims 14 and 15 of the '554 Patent are invalid because they are obvious over the teachings of Hunt in view of Watson, as detailed below. Hunt does not explicitly teach the disposable and detachable components of the vacuum system as recited in claims 14 and 15, however, Watson teaches those

limitations. Thus, as explained in Ground 2 below, Hunt in view of Watson renders obvious claims 14 and 15.

### **1. Overview of the Combination of Hunt and Watson**

150. Well prior to July 24, 2005, POSITAs were well-aware that certain components of NPWT systems should be detachable and disposable from the other components in the system. For example, the portions of the NPWT system which came into contact with removed fluid exudate from the wound were, thereafter, contaminated and should not be reused with another patient. Thus, prior to the Critical Date, POSITAs understood the need to have disposable enclosures, waste containers, and tubing which come into contact with human biological material. In addition, a POSITA would have understood the option to have a disposable pump if there was a reasonable chance that it would become contaminated by, for example, liquid or aerosolized exudate that passes through the pump. Moreover, a POSITA would have recognized that these components needed to be easily detachable from the systems so they could be disposed of and replaced with components to be used with the other, non-disposable components of the system.

151. Watson provides an example of this well-known practice. Watson specifically teaches “a benefit of the present invention for such applications involving biological waste is that the trap and all other components of the desiccator

device that contact the aspirated biological materials are removable from the device and are replaceable.” Ex. 1004 at 2:28-32. For example, “[t]he desiccator cartridge is removable from the vacuum desiccator and separately disposable.” *Id.* at 3:18-20. Watson teaches the use of a pump head that is integrated into the desiccator cartridge and easily separable from the motor. *Id.* at 3:55-65.

152. As I set forth below, a POSITA would have been motivated to implement Hunt’s NPWT system with Watson’s disposable pump included with Hunt’s other disposable components. Additionally, as explained below, a POSITA would have found it an obvious choice to use the disposable and detachable components of Watson to avoid the introduction of biological material between patients based on what is known in the art alone, or at the very least, based on the teachings of Watson which teaches that the pump head (the part that contacts potential contaminates) can be disposable or affixed to the motor and reused.

153. As I explain in more detail in Parts VIII.B.3-4 below, the combination of Hunt’s NPWT system with the disposable and detachable components of Watson teaches and/or renders obvious claims 14 and 15 of the ’554 Patent.

## **2. Motivation to Combine and Expectation of Success (Hunt in view of Watson)**

154. I understand that Hunt and Watson are considered to be analogous art since they both relate to wound therapy vacuum systems. In particular, Hunt

discloses “a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises . . . a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound”. Ex. 1003 at 1:46-51. Similarly, Watson teaches “a personally portable vacuum pump and moisture trapping device. . . . As a specific example, the present invention is therapeutically useful to provide a personally portable low negative pressure source and trap for aspirating and collecting fluid exudate from a wound or incision.” Ex. 1004 at 2:21-28.

155. A POSITA would have known that certain components of the vacuum system of Hunt would be disposable. In particular, a POSITA would have understood that those components which are contaminated by wound exudate would be replaced before treatment was applied to a new patient. Additionally, A POSITA would have understood that each of these individually manufactured parts were attached and can be detached from the housing, including pump 6. Moreover, Hunt specifically explains that the canister 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.” *Id.* at 1:67 – 2:3. Hunt also teaches to place a filter near the outlet of the canister to prevent liquid or solid particles from entering tube

103. *Id.* at 4:1-3. This is to prevent contamination of tube 103 and pump 6. However, if that filter is not in place, not secured properly, or has holes, the pump will be contaminated.

156. Also, during normal use, Hunt teaches that the pressure drop across the filter is not substantial. However, if the liquid in the canister reaches a level where it contacts the filter, the pressure drop across the filter is much higher and can be detected by the system as a signal that the canister is full. *Id.* at 4:9-16. A POSITA would have understood that in a body worn device, the fluid in the canister will slosh (or “slouch” as taught by Watson (Ex. 1004 at 1:67)) with movement and may prematurely contact the filter before the canister is full, particularly if the orientation of the canister does not remain upright when worn. Watson describes this as a problem with Hunt, with the potential of the fluid prematurely contacting the outlet end of the canister. *Id.* at 1:66 – 2:2. This can cause the device to stop operating and the premature replacement of the disposables. As such, a POSITA reading Hunt would have recognized the benefits of a pump unit being easily removed and replaced like the canister.

157. To the extent Hunt does not explicitly teach that the wound enclosure and waste canister are disposable and easily detachable from the remainder of the vacuum system, Watson teaches these elements. Ex. 1004. Further, Watson teaches

that the pump head (which has the potential to be contaminated) can be integrated with the disposable cartridge and easily separable from the driving motor. Watson teaches that the pump head can either be integrated in the disposable, or permanently affixed to the motor and be part of the reusable device. *Id.* at 3:55-65. The options are simple design choices. For example, Watson teaches that motor 36 and pump member 22 can be a single unit such as the miniature, oil-less is commercially available diaphragm pump from the Gast Manufacturing, Inc. series 3D 1060, model 101-1028. And, alternatively, Watson teaches that the motor shaft coupling 38 may be mechanically coupled to the vacuum pump head 22 so as to be readily separable from the pump head 22 as exemplified in FIG. 4. Watson explains that the pump head may have a shaft into which a spindled motor shaft slides. The receiver 102 in the pump shaft could use a threaded, keyed, or similar interfacing configuration. As a further alternative, the motor 36 may be magnetically coupled to the pump head 22 so as to again be readily separable. *Id.* at 8:3-28.

158. Like Hunt, Watson describes its invention as “therapeutically useful to provide a personally portable low negative pressure source and trap for aspirating and collecting fluid exudate from a wound or incision.” Ex. 1004 at 2:24-28. Watson also states: “A further benefit of the present invention for such applications involving biological waste is that the trap and all other components of the desiccator device

that contact the aspirated biological materials are removable from the device and are replaceable.” *Id.* at 2:28-32. In my opinion, a POSITA would have been motivated to combine the teachings of Hunt and Watson for several reasons.

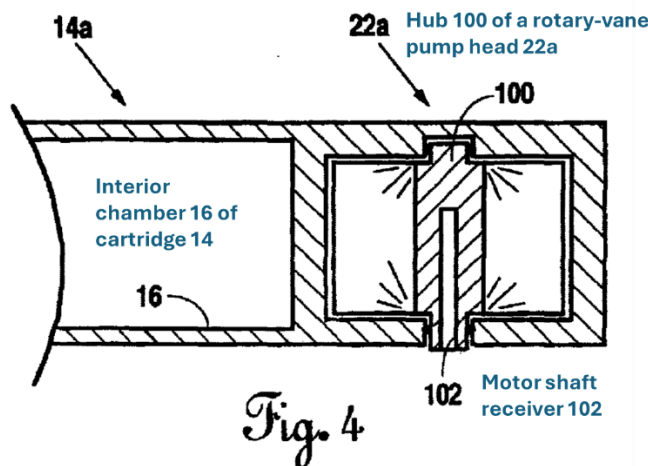
**i. Implementing the disposable components of the vacuum system which contact wound exudate based on the teachings of Watson to the NPWT system taught by Hunt would have been using well-established prior art elements according to known methods to yield predictable results.**

159. Prior to July 24, 2005, it was well-known and well-understood that certain parts of NPWT systems could be made disposable and easily detachable to avoid contamination between patients. Utilizing disposable components that could be snapped into the vacuum system and easily replaced were known and commonly used in wound treatment apparatuses at least by the early 1970s. Ex. 1029. As Watson teaches, using some disposable components in a vacuum wound treatment system is beneficial to avoid contamination. Ex. 1004 at 4:17-22. Watson specifically discloses:

The component parts of the vacuum desiccator device which are in gas/liquid flow communication are replaceable. This allows the components of the device which are exposed to contact with the wound fluids to be separable from the other components of the device to facilitate cleaning or disposal of contaminated components.

*Id.*

160. Watson teaches that the components which may be “in gas/liquid flow communication” include a vacuum pump member, the trap and desiccator cartridge, a delivery tube, and an occlusive wound dressing. *Id.* at 2:49-52 (“vacuum pump member or pump head”), 2:35-36 (“trap comprises a desiccator cartridge”), 6:16-20 (“delivery tube 32” and “wound site covered by an occlusive dressing”). Watson explains that “[i]n particular, the desiccator cartridge 14 is removable from the device 10 and separately disposable.” *Id.* at 7:21-23. In a particular embodiment, Watson teaches that the “desiccator cartridge and vacuum pump head are combined as a single integrated unit,” such that both can be easily removed and disposed of together. Figure 4 of Watson depicts this integrated desiccator cartridge-vacuum pump head unit:



*Id.* at Fig. 4 (annotated).

161. While not explicitly disclosed in Watson, a POSITA would have seen the advantage of having the entire airflow path contained within the disclosed integrated disposable. This eliminates potential user errors in attaching tubes or fittings which can leak or become dislodged and cause the system to not work properly.

162. A POSITA would have had knowledge of other prior art teaching similar disposable and detachable components, like those of Watson. For example, U.S. Patent No. 3,841,331 invented by Joseph R. Wilder, et al. (“Wilder”) was filed on November 17, 1972 and issued on October 15, 1974, thirty years before the Critical Date of the ’554 Patent. Ex. 1029. Wilder teaches a disposable system that draws fluids from a wound using suction applied by a motor-driven pump. *Id.* at Abstract, 1:44-49. Wilder teaches the “evacuator assembly, which includes the pump, is separable from the driver and no fluid derived from the site being evacuated reaches or makes contact with the driver,” thus, “there is no need to resterilize the driver after use.” *Id.* at 1:64-67. Additionally, Wilder discloses that the entire assembly is easily attachable and detachable from the syringe, and disposable after use. *Id.* at 2:1-4, 2:19-26. Wilder specifically teaches:

In the course of operation, the collector bottle fills with body fluid, and the syringe, because it draws air from the bottle, becomes contaminated. However, contaminants contained in the syringe are isolated from the

driver. When the bottle is filled, the entire assembly may be discarded, after first detaching the syringe from the driver fittings.

*Id.* at 3:59-65.

163. As another example, U.S. Patent No. 6,695,823 invented by Cesar Z. Lina, et al. (“Lina”) was filed on April 7, 2000, and issued on February 24, 2004, over a year before the Critical Date of the ’554 Patent. Ex. 1018. Lina teaches an NPWT system with “a disposable wound fluids canister and a porous pad”. *Id.* at Abstract. Lina explains that the purpose of the disposability of the components is to “protect the wound closure apparatus from contamination.” *Id.* at 2:46-49. “After the cannister is filled, it is removed from the chamber, disposed of, and replaced with another canister to continue therapy.” *Id.* at 3:19-21.

164. Like Lina, Dolliver teaches that the components of the system which come into contact with the wound exudate “form a disposable set.” Ex. 1005 at [0033]. Dolliver explains:

The drain catheter 102, variable-volume rotor 302, and tubing 122 may form a disposable set in which fluids are collected and processed. The disposable set may also include various storage containers for storing, without limitation, anticoagulant or one of the separate components, and appropriate valving to direct the fluid in the desired manner.

*Id.* A non-disposable controller “interfaces with the disposable set.” *Id.* at [0034].

165. As another example, U.S. Patent No. 6,764,462 invented by James R. Risk, Jr., et al. (“Risk”) was filed on May 31, 2002 and issued on July 20, 2004, also

over a year before the Critical Date of the '554 Patent. Ex. 1017. Risk teaches that “fluid and exudate from the wound 300 are drawn from bandage 14 through evacuating tube 20 and into a waste canister 26 where it is collected. It is contemplated that the canister 26 can be discarded when filled and replaced with a new canister.” *Id.* at 4:39-43. Risk also describes the waste canister as a “disposable unit.” *Id.* at 7:9. The waste canister of Risk is easily attached and detached from the vacuum system as it “snaps into’ side portion 38 of housing 4.” *Id.* at 7:8-10. Additionally, “[e]ach canister 26, 27 includes a grip portion 40 for convenient removal and replacement. Canisters 26, 27 are illustratively secured into each cavity by a friction fit.” *Id.* at 5:1-4. This is depicted in Risk Figure 7:

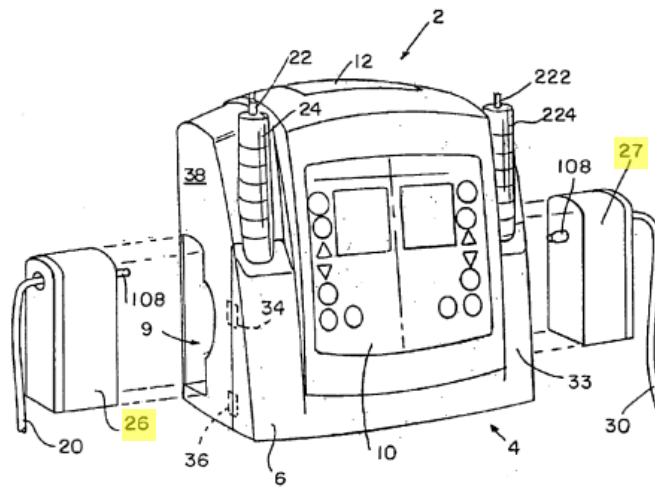


*FIG 7*

*Id.* at Fig. 7 (highlighting added to indicate waste canisters 26 and 27).

166. Lastly, Hunt itself teaches that its canister 100 from containing exudate 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.” Ex. 1003 at 1:67 – 2:3. Thus, a POSITA reading the teachings of Hunt would have expected success in similarly attaching other disposable components that can be easily removed using the same latch or release mechanism. Hunt already describes using these design choices and the combination with a similar reference, like Watson, would have been obvious to a POSITA.

167. For at least these reasons, as of July 24, 2005, a POSITA would have been well-aware of the use disposable components of an NPWT system that can be readily attached and detached from the system. Thus, implementing Hunt’s NPWT system with the disposable and detachable components of Watson would have simply been combining known prior art elements according to methods known to a POSITA prior to the priority date of the ’554 Patent. Moreover, a POSITA would have understood that this combination would yield the predictable result reflected in the above-cited references—i.e., preventing contamination from wound fluids within the vacuum system and between patients.

**ii. Watson expressly suggests improving the NPWT system of Hunt.**

168. A POSITA also would have been motivated to combine Hunt with Watson given Watson's disclosures of its improvements over Hunt. Watson refers to Hunt's apparatus, explaining that both inventions are similar in that they are portable and unobtrusive. Ex. 1004 at 1:60 – 2:10. Watson, however, explains that “the Hunt apparatus utilizes a liquid reservoir containing the fluids drained from a wound site” which “are subject to slouching, which may adversely affect the function of the Hunt apparatus if the fluid prematurely enters an inappropriate pathway (the outlet end of the canister).” *Id.* at 1:64 – 2:2. A POSITA reading Watson would have recognized that utilizing the disposable components and design of Watson may improve the functionality of Hunt's system. Additionally, a POSITA would have known that by using the disposable components of Watson in the similar system of Hunt would avoid contaminants from entering the non-disposable parts of the system (i.e., “if the fluid prematurely enters an inappropriate pathway” in the Hunt system).

169. It is my opinion that (1) the prior art discussed immediately above explain the well-known techniques and motivation for using disposable and easily detachable components to limit the vacuum system's exposure to contaminants; (2) Watson explicitly teaches that its invention attempts to improve the design and

functionality of Hunt's taught system; (3) Hunt specifically suggests incorporating easily attachable and detachable components (canister 100); and (4) Watson and the other prior art references teach that these disposable components are useful in NPWT systems.

170. Accordingly, it is my opinion that a POSITA would have been motivated to implement the disposable and detachable components of Watson with the NPWT system of Hunt.

**iii. It would have been obvious to try combining the disposable components of Watson with the non-disposable components of Hunt.**

171. It is also my opinion that it would have been obvious to try the use of Watson's disposable enclosure, tubing, waste container, and pump with the non-disposable electric motor of Hunt.

172. A POSITA would have recognized that the parts of the NPWT system which are exposed or are potentially exposed to wound exudate are subject to biological contamination from the patient. A POSITA would have also understood that there are a limited number of predictable options to remove that contamination: disposing and replacing those exposed components with new components, removing and cleaning those components, or cleaning those components in place.

173. Watson and Wilder make obvious the benefits of ensuring that any component that can be contaminated being easily attachable and detachable from the vacuum system's housing such that they could be removed and disposed of or cleaned. Additionally, given that disposable components were well-known in the art as one of a limited number of ways to remove exudate contamination from an NPWT system, it would have been obvious for a POSITA to try implementing the disposable enclosure, tubing, waste container, and pump of Watson in conjunction with Hunt's NPWT system.

174. Thus, a POSITA looking at the components of the NPWT system of Hunt would have found it obvious to try using disposable components for the elements that contact wound exudate—like those disclosed in Watson—to avoid contamination within the system, while ensuring those parts can be replaced and the system reused for further wound therapy treatment. Especially considering Watson's specific teachings of the setbacks in Hunt's invention and Hunt's specific teachings of a readily detachable waste container, a POSITA would have had good reason to try combining the two inventions.

175. Furthermore, I believe it would have been obvious for a POSITA to try different design choices and materials (choosing disposable and replaceable elements versus choosing reusable elements that would require cleaning after each

use) in a system like Hunt's. A POSITA would have known to make specific design choices based on the goals of the specific system and planned uses.

176. As I explain below, a POSITA also would have had a reasonable expectation of success in trying the disposable and detachable components of Watson with Hunt's NPWT system.

**iv. A POSITA would have expected to succeed in implementing Watson's disposable and detachable components with Hunt's NPWT system.**

177. It is my opinion that a POSITA would have expected success in implementing the disposable components—enclosure, tubing, waste container, and pump—as taught in Watson with the NPWT system of Hunt. Adding these components to Hunt's system would not have altered the function of the system. Moreover, this implementation could be easily accomplished by manufacturing these components of Hunt's system with disposable materials (to the extent Hunt's system is not already using disposable materials) as taught by Watson. And Hunt already teaches the “latch or release mechanism” to easily attach or detach the canister from the housing. Ex. 1003 at 1:67 – 2:3. A POSITA would have known that this same mechanism could be used to attach the pump to the motor as well, making it easily attachable and detachable along with the canister so it could be removed and replaced.

178. For all of these reasons, I conclude that a POSITA would have been motivated to combine Hunt and Watson, and would have expected success in doing so.

### **3. Claim 14**

179. Based on my review and for the reasons that follow, it is my opinion that claim 14 is rendered obvious over Hunt in view of Watson.

#### **i. Limitation 14[pre]: The vacuum system of claim 12,**

180. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 14, it is my opinion that Hunt teaches limitation 14[pre]. As I explain above in Ground 1, Hunt teaches the vacuum system of claim 12. The analysis and my discussion of claim 12 is hereby incorporated by reference.

181. Accordingly, it is my opinion that Hunt teaches limitation 14[pre].

#### **ii. Limitation 14[a]: wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit,**

182. In my opinion, Hunt discloses the vacuum source of claim 12 and Watson discloses a disposable pump unit detachably attachable to a non-disposable drive unit.

183. Watson discloses a “vacuum pump member or pump head” that is connected to a motor shaft which drives the pump. Ex. 1004 at 2:49-53; 3:57-65.

The vacuum pump member or head corresponds to the claimed “pump unit”. Watson teaches that the vacuum pump member is “readily separable” from the motor shaft which drives the pump. *Id.* at 3:57-65. For example, the vacuum pump member may be “mechanically coupled” or “magnetically coupled” to the motor (i.e., the drive unit). *Id.* The connection between the pump member 22 and motor (or “electric motive 36”) is schematically depicted in Figure 1 below:

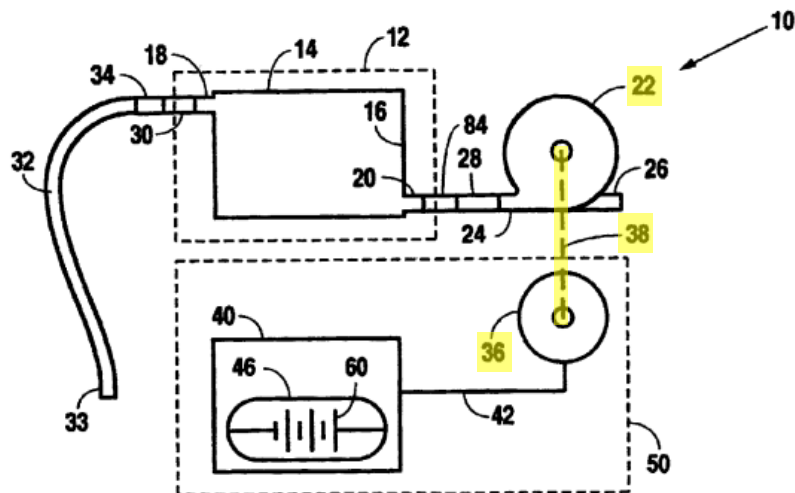


Fig. 1

*Id.* at Fig. 1 (annotated to identify pump head 22, electric motive 36, and the connection 38 between them). A POSITA would have understood that mechanically or magnetically coupling the pump member (i.e., pump unit) to the electric motive (i.e., drive unit) so that it is readily separable would render the pump unit detachably attachable based on a plain and ordinary meaning of those terms.

184. Watson further discloses that “the housing may contain the electric motive means and the electrical control circuit, while the other components are simply attached to the housing, e.g., an integrated pump head/trap combination assembly.” *Id.* at 4:26-29, Fig. 1, Fig. 4. A POSITA would have understood that the pump unit, then is detachably attached to the drive unit within the housing.

185. A POSITA would have further understood, based on the teachings of Watson, that the pump unit is disposable while the drive unit is non-disposable. Watson teaches that “the trap and all other components of the desiccator device that contact the aspirated biological materials are removable from the device and are replaceable.” *Id.* at 2:28-32. Additionally, “[t]he trap comprises a desiccator cartridge enclosing an interior space or chamber.” *Id.* at 2:35-36. “The desiccator cartridge is removable from the vacuum desiccator and separately disposable. A fresh desiccator cartridge is installed in the desiccator to replace the removed cartridge.” *Id.* at 3:18-21.

186. In an embodiment, Watson discloses that “the vacuum pump member and the desiccator cartridge are integrated together as a unit.” *Id.* at 3:64-65. Especially where the pump member is “readily separable” from the motor, Watson explains that this particular embodiment is “particularly useful.” *Id.* at 3:59-65. In this embodiment, a POSITA would have recognized that the pump unit—integrated

with the desiccator cartridge—can be disposed of with the desiccator cartridge and replaced. *Id.* at 3:18-21, 4:17-30. Moreover, Watson teaches:

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.* at 7:16-32. Watson explicitly states that the “vacuum pump member or pump head is connected in gas flow communication with the interior chamber of the trap” and, as such, is one of these replaceable and disposable components. *Id.* at 2:49-52. A POSITA would have understood that pump unit of Watson can be disposable.

187. On the other hand, Watson teaches away from the drive unit (i.e., electric motive) being a disposable element in the system. As explained above, the electric motive which drives the pump sits within the housing, separable from the parts of the vacuum system that come into contact with wound fluids. *Id.* at 4:17-29, Fig. 1. A POSITA reading Watson would have understood, then, that the electric motive (i.e., drive unit) is non-disposable under the plain and ordinary meaning of that term in that it would not need to be replaced and disposed of like the detachable components which come into contact with wound fluid.

188. Accordingly, it is my opinion that Hunt in view of Watson renders obvious limitation 14[a].

**iii. Limitation 14[b]: 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**

189. In my opinion, Hunt teaches limitation 14[b]. As explained regarding claim 12 above, Hunt teaches an “enclosure” in the form of porous wound dressing 102 that is “pressed onto the wound.” *Id.* at 5:19-21. A POSITA would have understood that this porous wound dressing 102 necessarily comes into contact with biological contamination from the patient at the wound site and would be disposed of after use. Additionally, the enclosure comprises a multi-layer “surgical drape” with a polyurethane film layer 701 that is “adhered to the patient’s skin around the wound site.” *Id.* at 5:27-38. Like the porous wound dressing, a POSITA would have recognized that this surgical drape is also disposable as it comes in contact with the patient and would necessarily be thrown away to avoid contamination after use.

190. Also as explained regarding claim 12 above, Hunt teaches a “waste container” (i.e., canister 100). As explained regarding claim 13 above, canister 100 contains exudate removed from a patient’s wound during treatment. Hunt also discloses that canister 100 is replaceable. *Id.* at 4:12-15 (“a message on the LCD and/or buzzer that the canister requires replacement”). A POSITA would have

understood that the canister is disposable under the plain and ordinary meaning of that word as it can be replaced by a new canister when full and/or when treatment with a patient is finished.

191. To the extent, however, Hunt does not explicitly this limitation, in my opinion it is rendered obvious by the combination of Hunt and Watson. Watson teaches that “all of the components in gas/liquid flow communication are replaceable” and further teaches disposing these “contaminated components.” *Id.* at 7:16-18, 4:19-22. Watson specifically teaches that “[t]he desiccator cartridge is removable from the vacuum desiccator and separately disposable.” *Id.* at 3:18-21. Watson also teaches a “delivery tube 32” and “occlusive dressing” to cover the wound. *Id.* at 6:16-20. Because this tube and dressing would necessarily come into contact with wound fluid, a POSITA reading Watson would have known that the tube and dressing are disposable. *Id.* at 4:17-22. In the combined system of Hunt and Watson, a POSITA would have understood that the venting arrangement of Hunt (as explained regarding claim 12 of Ground 1 above) would be utilized in conjunction with the disposable tubing, enclosure, canister, and pump of Watson. Thus, the liquid or aerosolized exudate that enters the tube in the combined system of Hunt and Watson only comes into contact with the disposable elements, including the tube, enclosure, waste container, and (potentially) the pump unit.

192. Accordingly, in my opinion Hunt alone and/or Hunt in view of Watson render obvious limitation 14[b].

**iv. Limitation 14[c]: and said drained liquids may be disposed of together with said disposable elements.**

193. In my opinion, Hunt teaches limitation 14[c]. Hunt specifically teaches that its waste container (canister 100), which is filled with drained liquids from the wound, can be “readily removed and replaced” and is, therefore, disposable. Ex. 1003 at 1:67 – 2:3. Hunt does not teach that canister 100 is to be removed, emptied, cleaned, and reinstalled. As such, a POSITA would have understood that the canister could be disposed of with the wound exudate and replaced with a new canister once it is full as explained in Hunt.

194. To the extent Hunt is not deemed to explicitly disclose this limitation, however, it is taught by Watson. Watson explicitly discloses a disposable waste container (i.e., desiccator cartridge of Watson) that may be thrown away with any liquids drained from the wound contained therein. For example, Watson teaches that the desiccator cartridge retains fluid drawn from a wound. Ex. 1004 at 2:35-48. “When the amount of moisture retained [in the desiccator cartridge] approaches saturation . . . the desiccator cartridge 14 may [] be removed and disposed of”. *Id.* at 7:1-5. Thus, a POSITA would have understood that the drained liquids from the wound, housed within the desiccator cartridge, are disposed of along with the

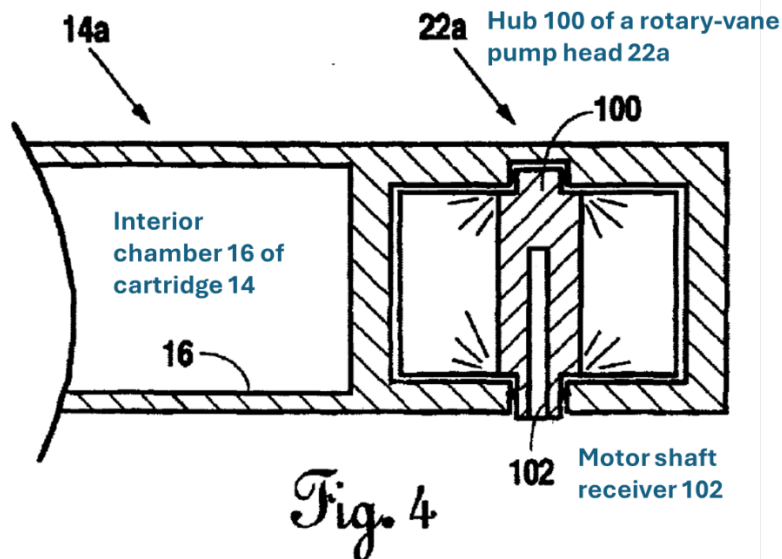
cartridge and any other disposable elements (such as the integrated desiccator cartridge and pump unit). *Id.* at 7:29-31, Fig. 4.

195. Accordingly, it is my opinion that Hunt alone and/or Hunt in view of Watson renders obvious limitation 14[c].

196. For the reasons stated above, it is my opinion that Hunt alone and/or Hunt in view of Watson teaches and renders obvious each of the limitations of claim 14 of the '554 Patent.

**4. Claim 15: 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.**

197. Hunt in view of Watson renders obvious claim 15. As explained above, Hunt in view of Watson teaches and renders obvious claim 14. Also, as explained above regarding limitation 14[a], Watson discloses a pump unit (vacuum pump member) that is detachably attached to a drive unit (motor shaft or electric motive). Ex. 1004 at 2:49-53; 3:57-65. Watson teaches that the vacuum pump member is “readily separable” from the motor shaft which drives the pump. *Id.* at 3:57-65. For example, the vacuum pump member may be “mechanically coupled” or “magnetically coupled” to the motor (i.e., the drive unit). *Id.* By way of example, Watson teaches a cartridge and vacuum pump head as an integral, disposable unit as shown in Fig 4:



*Id.* at Fig. 4 (annotated). The pump head has a receiver in its shaft that easily mechanically couples to the motor by sliding the two together. A POSITA would have understood that mechanically or magnetically coupling the pump member (i.e., pump unit) to the electric motive (i.e., drive unit) so that it is readily separable would mean that a person could attach or detach the pump and drive unit using simple hand manipulations under the plain and ordinary meaning of that term.

198. A POSITA reading the disclosures of Watson would have understood that Watson does not disclose, describe, or teach the use of tools or complicated manufacturing processes to attach the pump to the electric motive. Additionally, Watson discloses that the pump is “simply attached to the housing.” *Id.* at 4:26-29, Fig. 1, Fig. 4. A POSITA would have understood that the pump unit could be attached and detached to the drive unit using simple hand manipulations.

199. Accordingly, it is my opinion that Hunt in view of Watson renders obvious claim 15.

**C. Ground 3: Analysis of Claims 12, 13, 16, 17, 26, and 27 Based on Hunt in view of Dolliver**

200. In my opinion, claims 12-17, 26, and 27 are invalid because they are obvious over the teachings of Hunt in view of Dolliver, as detailed below.

**1. Overview of the Combination of Hunt and Dolliver**

201. As explained in Ground 1, Hunt teaches a vacuum system for applying negative pressure to a wound that comprises: an enclosure, venting arrangement with flow restrictor, tube, vacuum source, and waste container. Hunt does not explicitly teach the use of a venting arrangement in the form of a porous body, as recited in dependent claims 17 and 23.

202. Dolliver teaches a vacuum-assisted wound drainage system that applies varying pressure to a wound to draw fluid from the wound, comprising a tube with a venting arrangement and flow restrictor in the tube that controls the flow of ambient air entering said tube without entering the enclosure. Dolliver teaches a “vent valve, positioned between the drain catheter and the suction means.” Ex. 1005 at [0007]. The vent valve in Dolliver opens to the atmosphere to allow ambient air into the tube “thereby decreasing the amount of suction applied at the drain catheter 102.” *Id.* at [0029].

203. Dolliver also teaches a filter included in the vent valve “for preventing introduction of outside contaminants into the conduit system 122 which may adversely affect the wound.” *Id.* This filter is porous and a POSITA would have recognized it to be a porous body.

204. The vacuum system of Dolliver, including the vent valve 119 located between the wound and vacuum source is shown below:

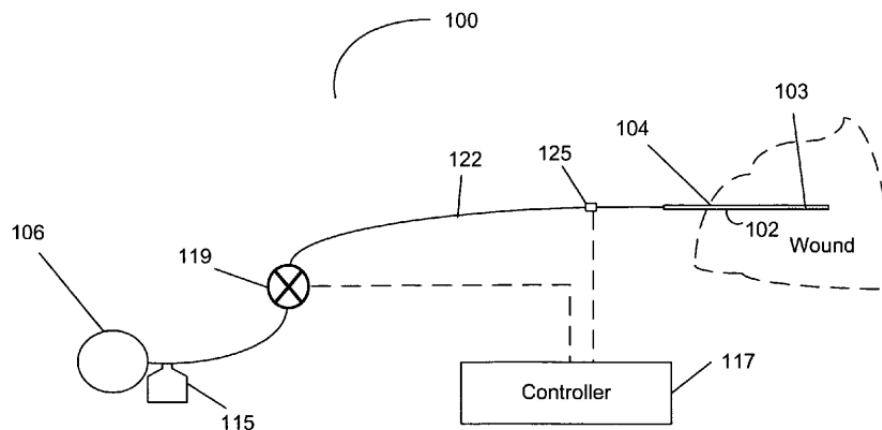


Fig. 1

*Id.* at Fig. 1.

205. As I set forth below, a POSITA would have been motivated to combine Hunt’s NPWT system with the vent valve of Dolliver, containing a filter, that is located within the suction tube.

**2. Motivation to Combine and Expectation of Success (Hunt in view of Dolliver)**

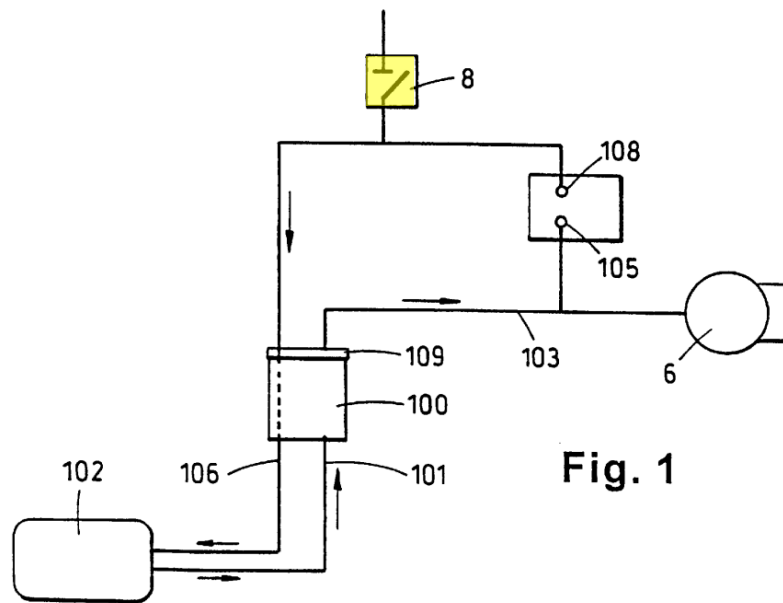
206. I understand Hunt and Dolliver are considered to be analogous art as they are within the same field of endeavor—vacuum-assisted wound drainage systems. In particular, Hunt and Dolliver both teach systems that use a valve to control the level of negative pressure (vacuum) being applied to the wound. Moreover, both Hunt and Dolliver specifically teach that the valve is connected to tubing to admit ambient air into the system. In my opinion, a POSITA would have been motivated to combine the teachings of Hunt and Dolliver, as it relates to the vent valve located within the suction tube, for several reasons.

**i. Modifying the system of Hunt to include a vent valve in the suction tube based on the teachings of Dolliver would have been using well-established prior art elements according to known methods to yield predictable results.**

207. Prior to July 24, 2005, it was well-known and well-understood that a valve could be used to admit ambient air into NPWT systems, thereby controlling the level of negative pressure applied at the wound. Ex. 1003, Ex. 1005, Ex. 1017, Ex. 1018. Both Hunt and Dolliver utilize valves to control the amount of pressure applied at the wound site by allowing ambient air to enter the tube.

208. Hunt teaches a pressure relief valve 8 connected to the pressure sensing tube 106 that admits ambient air into the vacuum system. Ex. 1003 at 3:63-65. Hunt

explains that the pressure relief valve 8 “enables the pressure at the wound site to be brought to atmospheric pressure rapidly” and “will open for a specified period, allow the pressure to equalize at the wound site and then close to restore the suction.” *Id.* at 4:17-24. The pressure relief valve in Hunt is shown in Figure 1 below:



*Id.* at Fig. 1 (highlighting added).

209. Like Hunt, Dolliver teaches a valve in the tubing. In Dolliver, vent valve 119 is located in the suction tube, located between the wound and vacuum source. Regarding the “vent valve,” Dolliver teaches:

The valve means 119 may include, without limitation, a vent valve 119 that may be positioned within the conduit 122. The vent valve selectively opens (fully or partially) to allow conduit 122 to vent to the atmosphere, thereby decreasing the amount of suction applied at the drain catheter 102.

Ex. 1005 at [0029]. The vent valve 119 of Dolliver is shown in Figure 1:

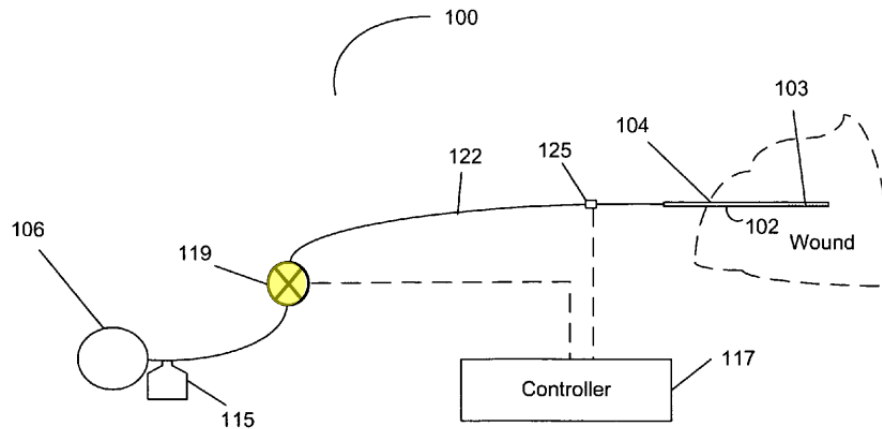


Fig. 1

*Id.* at Fig. 1 (highlighting added).

210. Additionally, POSITAs would have knowledge of other prior art NPWT devices that utilize valves in different locations to admit ambient air into the system. For example, Lina discloses a “bleed valve” that “communicates with the atmosphere to release pressure developed within line 62 by vacuum pump 84.” Ex. 1018 at 12:56-58. Lina further explains that “Bleed valve 86 is sufficiently small to ensure that it generally does not affect the vacuum pressure levels achieved by vacuum pump 84 as it evacuates air from canister 19, except to prevent overpressurization . . . .” *Id.* at 12:59-63. Bleed valve 86 in Lina is located on the pump housing, as depicted below:

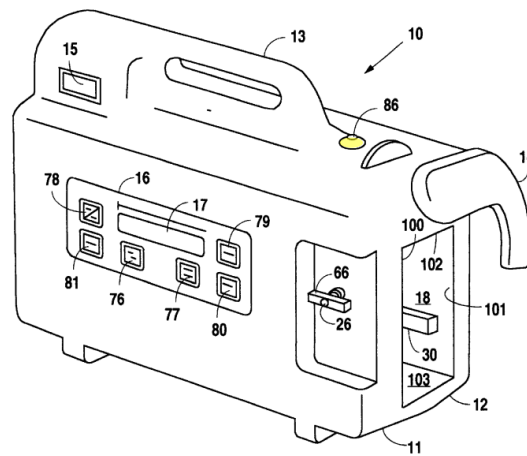
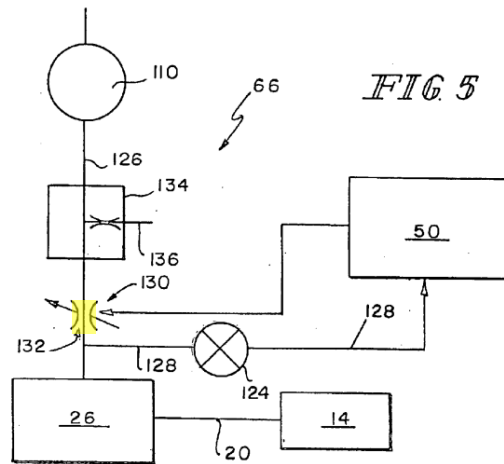


Fig. 1

*Id.* at Fig. 1 (highlighting added).

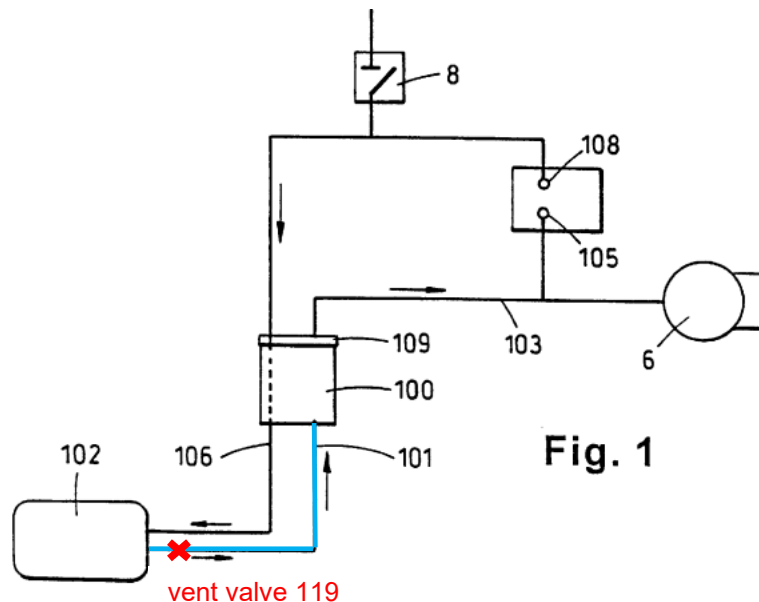
211. Similarly, U.S. Patent No. 6,764,462, entitled “Wound Treatment Apparatus,” to James R. Risk, Jr., et al., filed May 31, 2002 and issued July 20, 2004 (“Risk”) teaches a proportional valve within the conduit between the waste canister and vacuum pump. The proportional valve 130 in Risk includes a flow orifice 132 that “selectively dilates or constricts, thereby controlling the negative pressure level through sub-system 66.” Ex. 1017 at 7:43-47. The proportional valve 130 in Risk is depicted in Figure 1 below:



*Id.* at Fig. 1 (highlighting added). In addition to the valve in line 126, Risk also teaches including port 136, located within the pump housing, which “opens so that pump 110 can draw more air to maintain a sufficient flow through pump 110, to prevent it from becoming damaged.” *Id.* at 8:2-5. Like the vent valve in Dolliver, port 136 in Risk includes an air filter 137 that “filter[s] particulates from the air prior to reaching pump 110.” *Id.* at 8:5-7.

212. Thus, prior to July 24, 2005, POSITAs were well-aware of the use of valves in NPWT systems to admit ambient air into the vacuum system in different locations. In fact, as demonstrated by Risk, it was common to include more than one orifice/valve open to the atmosphere to control the level of negative pressure within the system. As such, modifying Hunt’s NPWT system with pressure relief valve 8 on the pressure sensing tube to also include vent valve 119 of Dolliver would have simply been combining prior art elements according to methods known for years.

An exemplary depiction of the combined Hunt-Dolliver system is depicted in Hunt Figure 1 below, including my annotations:



Ex. 1003 at Fig. 1 (annotated in blue to identify tube 101 with vent valve 119 added in red). The location of the vent valve in Figure 1 above is exemplary and could be located elsewhere along tube 101. A POSITA would have known to place vent valve 119 on tube 101 in an optimal location that would bring ambient air into the system while helping to remove blockages from wound exudate. Alternatively, a POSITA would have recognized that pressure relief valve 8, within the combined Hunt-Dolliver system, could be eliminated so there is no extra hardware required in this configuration. In this configuration, pressure relief valve 8 (on line 106) would be replaced with vent valve 119 (on line 101).

213. Moreover, a POSITA would have understood that this combination would yield the predictable result reflected in the above-cited references—i.e., further controlling the amount of negative pressure applied at the wound site to achieve the desired level of suction. Additionally, as explained in Dolliver, another purpose of including the vent valve within the suction tube is to help prevent occlusion of the suction tube, unclogging exudate that is removed from the wound to improve the functionality of the system and promote the healing process. Ex. 1005 at 1:33-42, 1:50-56. Accordingly, it is my opinion that a POSITA would have been motivated to modify the NPWT system of Hunt to include the vent valve of Dolliver in the suction tube, near the wound dressing where wound exudate is removed, based on well-established prior art elements and known methods to yield predictable results.

**ii. It would have been obvious to try combining the vent valve of Dolliver with the suction tube of Hunt.**

214. It is also my opinion that it would have been obvious to try adding the vent valve of Dolliver to the suction tube, between the wound and waste canister, in the NPWT system of Hunt.

215. A POSITA would have understood that there are a limited number of predictable ways to (a) control the level of negative pressure within the vacuum system, and (b) prevent occlusion within the suction tube when removing exudate

from a wound. As demonstrated by the prior art, a POSITA would have understood to use an opening in the tube—via a valve or orifice of some kind—to allow ambient air into the system to do this.

216. Given that valves and orifices were well known in the art in NPWT systems, it would have been obvious for a POSITA to try including a valve in the suction tube of Hunt in conjunction with Hunt's pressure relief valve in the pressure sensing tube. As Risk discloses, prior to 2005, it was well-understood it may be advantageous to admit ambient air into an NPWT system in multiple locations to control the level of pressure within the system and at the wound site. Moreover, as explained in Dolliver, a concern with NPWT systems is the build-up of exudate within the suction tube that may prevent the wound exudate from fully draining and/or harm the vacuum system. A POSITA would have thus found it obvious to try adding the vent valve of Dolliver within the suction tube of Hunt to break-up any exudate and help promote the flow of exudate to the canister.

217. Furthermore, it would have been obvious for a POSITA to try using more than one valve or tube orifice (such as those used in the NPWT system of Risk) in the NPWT system of Hunt. A POSITA would decide whether the addition of a valve on the suction tube, in conjunction with the valve on the pressure sensing tube,

would help to more reliably achieve the desired amount of ambient air in the system, while also helping to more easily break-up any exudate within the suction tube.

218. As I explain below, a POSITA also would have had a reasonable expectation of success in trying the vent valve of Dolliver in Risk's NPWT system and suction tube.

**iii. Adding a valve within the suction tube to the NPWT system of Hunt with a valve in the pressure sensing tube is a simple combination of known elements in the prior art.**

219. For the same reasons as discussed above, at least as early as July 24, 2005, a POSITA would have recognized that adding the vent valve of Dolliver to the suction tube 101 of Hunt would simply be an addition of a known element. As taught in Risk, it was known in the prior art to utilize two different orifices within the same system to control the level of negative pressure within the system by allowing ambient air to enter the tubing. Both Hunt and Dolliver teach a valve that selectively opens to the atmosphere. In my opinion, POSITAs would have found it obvious to add the vent valve of Dolliver within the suction tube of Hunt to provide further control of the negative pressure levels and prevent occlusion of the suction tube based on known elements within the prior art before the filing of the '554 Patent.

**iv. A POSITA would have expected to succeed in combining Hunt's NPWT system with Dolliver's vent valve.**

220. It is my opinion that a POSITA would have expected success in modifying Hunt's NPWT system to include a vent valve connected to the suction tube as taught in Dolliver. Adding Dolliver's vent valve to the suction tube 101 of Hunt's NPWT system could conveniently be accomplished by the same methods utilized in adding the pressure relief valve 8 to Hunt's pressure sensing tube.

221. Hunt's NPWT system is already configured to include a valve that exposes the system to ambient air, and the valve is selectively controlled by the controller. Ex. 1003 at 4:17-33. Claim 3 of Hunt specifically recites "a controller adapted to operate said relief valve such that suction at the wound may be intermittently applied and relieved." *Id.* at claim 3. Similarly, Dolliver teaches that a controller "controls the suction device 106, as opposed to, or in addition to a valve means, to periodically increase and decrease the application of suction . . . ." Ex. 1005 at [0031]. Therefore, a POSITA would have had a reasonable expectation of success in combining the vent valve of Dolliver with the NPWT system of Hunt which already includes a controller configured to operate a valve means.

222. For all of these reasons, I conclude that a POSITA would have motivated to combine Hunt and Dolliver and would have had a reasonable expectation of success in doing so.

### 3. Claim 12

223. Based on my review and for the reasons that follow, it is my opinion that claim 12 is obvious based on the teachings of Hunt and Dolliver.

#### i. **Limitation 12[pre]: A vacuum system for applying negative pressure to a wound, the vacuum system comprising:**

224. I understand that a preamble generally does not state a claim limitation. However, as explained in Ground 1, to the extent the preamble limits claim 12, it is my opinion that Hunt teaches a vacuum system for applying negative pressure to a wound. The analysis and my discussion of claim limitation 12[pre] in Ground 1 is hereby incorporated by reference.

225. Accordingly, it is my opinion that Hunt teaches limitation 12[pre].

#### ii. **Limitation 12[a]: an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume;**

226. As explained in regarding limitation 12[a] in Ground 1, it is my opinion that Hunt teaches an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume. The analysis and my discussion of claim limitation 12[a] in Ground 1 is hereby incorporated by reference.

**iii. Limitation 12[b]: a tube;**

227. As explained in regarding limitation 12[b] in Ground 1, it is my opinion that Hunt teaches a tube. The analysis and my discussion of claim limitation 12[b] in Ground 1 is hereby incorporated by reference.

**iv. Limitation 12[c]: a venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement,**

228. As explained regarding limitation 12[c] in Ground 1, it is my opinion that Hunt teaches this limitation. To the extent that the Board does not find Hunt to explicitly teach the flow restrictor, in my opinion, Hunt in view of Dolliver renders obvious limitation 12[c]. Additionally, in my opinion, a POSITA would have been motivated to combine the NPWT system of Hunt with the vent valve taught by Dolliver, as I explain above in Part VIII.C.2. Dolliver teaches a “vent valve” within the suction conduit “positioned between the drain catheter and the suction means.” Ex. 1005 at 2:1-3. A POSITA would have found it obvious to modify tube 101<sup>2</sup> of Hunt to include the vent valve of Dolliver. *See* Part VIII.C.2, above.

229. A POSITA would have understood that, in the combination of Hunt and Dolliver, tube 101 of Hunt necessarily contains an open hole where it meets vent

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<sup>2</sup> Tube 101 of Hunt is operatively connected to tube 103 in the canister and, therefore, applies suction to the wound dressing. Ex. 1003 at 3:60-66, Fig. 1.

valve 119 of Dolliver that allows ambient air to enter the tube. Additionally, a POSITA would have understood that the opening in vent valve 119 and the tube constitute a “venting arrangement” as that term is used in the ’554 Patent. For example, the opening in the valve is an orifice that allows ambient air to enter the tube and flow into the vacuum system. I understand that any construction of “venting arrangement” includes an orifice, therefore, it is my opinion that the combination of Hunt and Dolliver discloses a venting arrangement.

230. Dolliver further teaches that vent valve 119 “may include a filter, such as but not limited to a bacterial filter.” Ex. 1005 at 4:61-63. A POSITA would have understood that the filter disclosed in Dolliver is a porous material that necessarily restricts the flow of ambient air entering the tube through the open end at the vent valve, thereby providing a controlled flow of ambient air through the venting arrangement. Thus, a POSITA would have considered this filter to be a flow restrictor based on the plain and ordinary meaning of that term as it is used in the ’554 Patent.

231. Accordingly, in my opinion, Hunt in view of Dolliver renders obvious limitation 12[c].

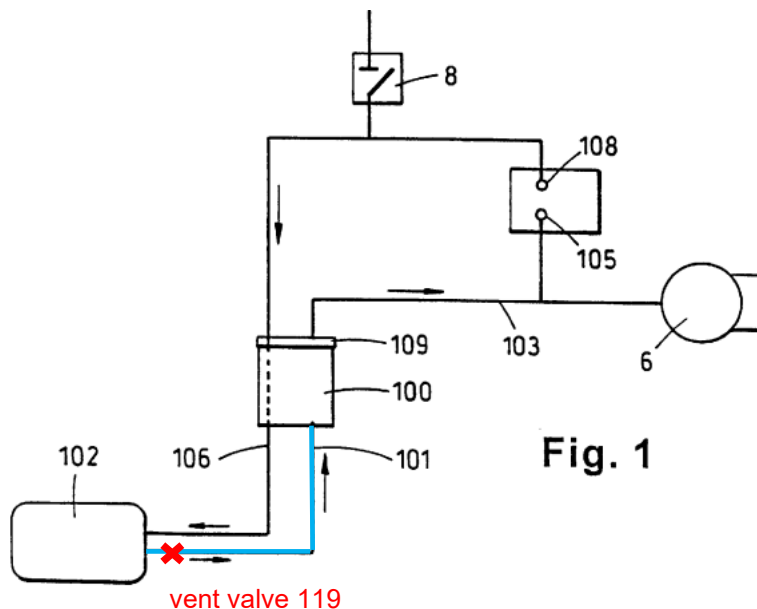
- v. **Limitation 12[d]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be created in said volume,**

232. As explained regarding limitation 12[d] in Ground 1, it is my opinion that Hunt teaches an enclosure having an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be created in the volume confined by the enclosure. The analysis and my discussion of claim limitation 12[d] in Ground 1 is hereby incorporated by reference.

- vi. **Limitation 12[e]: said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure; and**

233. As explained regarding limitation 12[e] in Ground 1, it is my opinion that Hunt teaches this limitation. To the extent that the Board does not find Hunt to explicitly teach air not entering the enclosure, in my opinion, Hunt in view of Dolliver renders obvious limitation 12[e]. Additionally, in my opinion, a POSITA would have been motivated to combine the NPWT system of Hunt with the vent valve taught by Dolliver, as I explain above in Part VIII.C.2. As I explained with regard to limitation 12[c] above, Hunt in combination with Dolliver discloses a “venting arrangement”. Specifically, Dolliver teaches a “valve means, such as a vent valve, positioned between the drain catheter and the suction means. The valve means

may be disposed in, without limitation, a conduit in fluid communication with the suction means and the drain catheter.” Ex. 1005 at 2:1-5. Like Dolliver, Hunt includes a “conduit in fluid communication with the suction means”—tube 101—that applies suction to the wound. The combination of Hunt’s tube 101 with Dolliver’s vent valve 119 is shown in Hunt Figure 1 below and constitutes a venting arrangement:



Ex. 1003 at Fig. 1 (annotated in blue to identify tube 101 with vent valve 119 added in red). As shown above, vent valve 119 is located outside the enclosure (i.e., wound dressing 102 and surgical drape).

234. A POSITA looking at the combined system of Hunt and Dolliver would have understood the orifice within vent valve 119 allows ambient air to enter tube 101—an orifice corresponding to the claimed “venting arrangement”. A POSITA

would also have understood that vent valve 119 admits ambient air into the tube. As shown in annotated Figure 1 above, ambient air that enters tube 101 through its opening at vent valve 119.

235. Looking at the combined system of Hunt and Dolliver, as depicted above, a POSITA would have understood that ambient air enters tube 101 via vent valve 119. The arrows within Figure 1 above indicate the direction of airflow, indicating ambient air entering tube 101 through vent valve 119 would flow towards the vacuum source. Thus, ambient does not enter the enclosure covering the wound 102.

236. Accordingly, it is my opinion that Hunt in view of Dolliver renders obvious limitation 12[e].

**vii. Limitation 12[f]: a waste container in fluid communication with said vacuum source.**

237. As explained in regarding limitation 12[f] in Ground 1, it is my opinion that Hunt teaches a waste container in fluid communication with the vacuum source. The analysis and my discussion of claim limitation 12[f] in Ground 1 is hereby incorporated by reference.

238. For the reasons stated above, it is my opinion that Hunt in view of Dolliver teaches and/or renders obvious all the limitations of claim 12 of the '554 Patent.

**4. Claim 13**

239. As explained regarding limitation 13 in Ground 1, it is my opinion that Hunt teaches this limitation. To the extent that the Board does not find Hunt to explicitly teach each limitation of claim 13, in my opinion and for the reasons that follow, it is my opinion that claim 13 is obvious over Hunt in view of Dolliver.

**i. Limitation 13[pre]: The vacuum system of claim 12,**

240. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 13, it is my opinion that Hunt in view of Dolliver renders obvious limitation 13[pre]. As I explain above, in my opinion Hunt in view of Dolliver renders obvious the vacuum system of claim 12. The analysis and my discussion of claim 12 is hereby incorporated by reference.

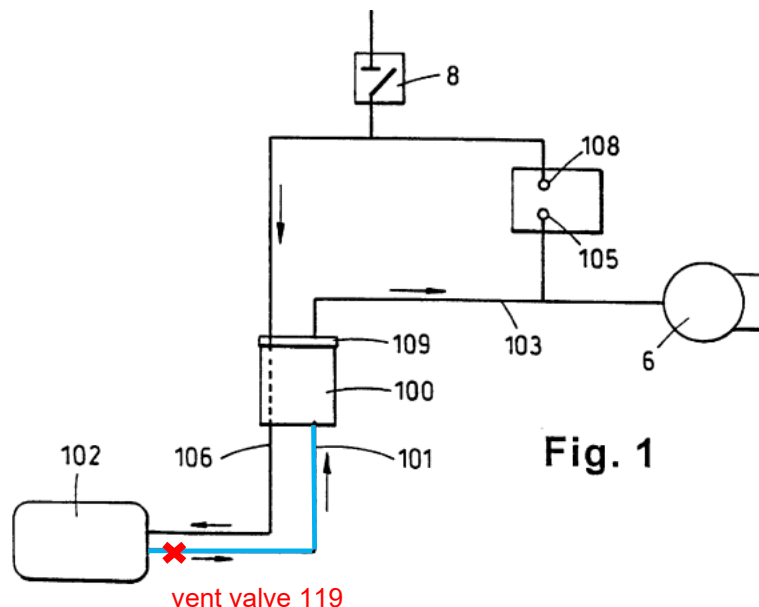
241. Accordingly, it is my opinion that Hunt in view of Dolliver renders obvious limitation 13[pre].

**ii. Limitation 13[a]: wherein said vacuum system further operates to drain the wound from fluids exuded therefrom,**

242. As explained in regarding limitation 13[a] in Ground 1, it is my opinion that Hunt teaches a vacuum system that operates to drain the wound from exuded fluids. The analysis and my discussion of claim limitation 13[a] in Ground 1 is hereby incorporated by reference.

**iii. Limitation 13[b]: wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure,**

243. As explained in regarding limitation 13[b] in Ground 1, it is my opinion that Hunt teaches this limitation. To the extent that the Board does not find Hunt to explicitly teach each limitation of claim 13[b], based on my review and for the reasons that follow, in my opinion, Hunt in view of Dolliver renders obvious limitation 13[b]. As I explained regarding limitation 12[e], in the combined system of Hunt and Dolliver, the venting arrangement (vent valve 119 and tube 101) allows ambient air to enter the tube (tube 101) and flows towards the vacuum source (pump 6). The combined system of Hunt and Dolliver is depicted below:



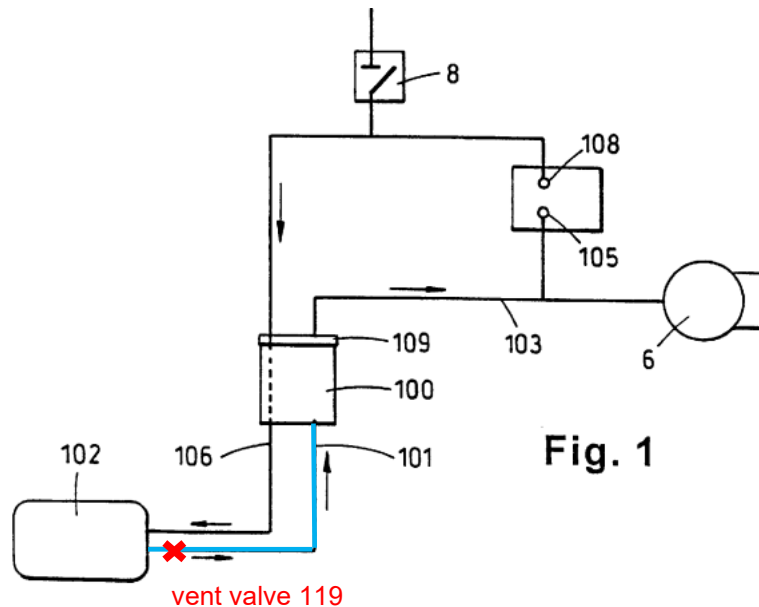
Ex. 1003 at Fig. 1 (annotated in blue to identify tube 101 with vent valve 119 added in red).

244. Also, as explained regarding limitation 13[b] in Ground 1 above, Hunt teaches canister 100 that collects exudate removed from the wound and carried in suction tube 101. A POSITA would have understood that when suction was applied by pump 6 (i.e., negative pressure is applied), vent valve 119 admits ambient air into the system which flows together with exudate removed from the wound towards the canister and pump 6.

245. Accordingly, in my opinion, Hunt in view of Dolliver renders obvious limitation 13[b].

**iv. Limitation 13[c]: and facilitates draining of the exuded fluids to said waste container.**

246. As explained in regarding limitation 13[c] in Ground 1, it is my opinion that Hunt teaches this limitation. To the extent that the Board does not find Hunt to explicitly teach each limitation of claim 13[c], based on my review and for the reasons that follow, in my opinion, Hunt in view of Dolliver renders obvious limitation 13[c]. As I explained immediately above, the vent valve of Dolliver admits ambient air into suction tube 101 and flows towards canister 100, along with any exudate removed from the wound under the application of negative pressure. The combined system of Hunt and Dolliver is depicted below:



Ex. 1003 at Fig. 1 (annotated in blue to identify tube 101 with vent valve 119 added in red).

247. A POSITA would have understood that the venting arrangement (i.e., vent valve 119 and tube 101) facilitates draining of the exuded fluids from the wound to canister 100. Specifically, a POSITA would have known that the introduction of ambient air into the system would help control the level of negative pressure applied at the wound site and would have further known that ambient air admitted into the tube could help unclog any exudate that becomes trapped. For example, prior art references prior to the time of invention, such as Lina, disclosed that valves could be used “to facilitate un-clogging . . . in the event of a blockage.” Ex. 1018 at 13:5-7.

248. Accordingly, in my opinion Hunt in view of Dolliver renders obvious limitation 13[c].

249. For the reasons stated above, it is my opinion that Hunt in view of Dolliver teaches and renders obvious claim 13.

**5. Claim 16: The vacuum system according to claim 12, wherein said venting arrangement comprises one or more bleeding holes.**

250. As explained in regarding claim 16 in Ground 1, it is my opinion that Hunt teaches all the limitations in claim 16. To the extent that the Board does not find Hunt to explicitly teach each limitation of claim 16, in my opinion, Hunt in view of Dolliver renders obvious claim 16. As explained above, Hunt in view of Dolliver renders obvious the vacuum system of claim 12. In my opinion, Dolliver also teaches the additional limitations in claim 16 because the vent valve 119 has a bleeding hole.

251. As I explained with regard to claim 12 above, Dolliver teaches a “venting arrangement” that admits ambient air into the tube 101 via vent valve 119 and flows towards canister 100. A POSITA would have recognized that the vent valve necessarily has a bleeding hole where it opens to admit ambient air into tube 101. Thus, based on the plain and ordinary meaning of the term “bleeding hole,” a POSITA would have recognized that the venting arrangement in Hunt comprises a bleeding hole.

252. Accordingly, in my opinion Hunt in view of Dolliver renders obvious claim 16.

**6. Claim 17: The vacuum system according to claim 12, wherein said venting arrangement is provided in the form of a porous body.**

253. As explained in regarding claim 12 in Ground 1, it is my opinion that Hunt alone teaches all the limitations in claim 17. To the extent that the Board does not find Hunt to explicitly teach claim 17, in my opinion, Hunt in view of Dolliver renders obvious claim 17. As I explained regarding limitation 12[c] above, Dolliver teaches a venting arrangement (vent valve 119 and tube 101) that comprises a filter.

254. Specifically, Dolliver teaches that vent valve 119 “may include a filter, such as but not limited to a bacterial filter.” Ex. 1005 at [0029]. A POSITA would have understood that the filter disclosed in Dolliver is a porous material constituting a porous body.

255. Accordingly, in my opinion Hunt in view of Dolliver renders obvious claim 17.

**7. Claim 26: The vacuum system according to claim 12, wherein the venting arrangement is a tube orifice.**

256. As explained in regarding claim 26 in Ground 1, it is my opinion that Hunt teaches all the limitations in claim 26. To the extent that the Board does not find Hunt to explicitly teach each limitation of claim 26, in my opinion, Hunt in view

of Dolliver renders obvious claim 26. As explained above, Hunt in view of Dolliver renders obvious the vacuum system of claim 12. In my opinion, the combination of Hunt and Dolliver also teaches the additional limitations in claim 26 because the venting arrangement comprising vent valve 119 and tube 101 is a tube orifice.

257. As I explained with regard to claim 12 above, Hunt teaches a “venting arrangement” that admits ambient air into tube 101 via the vent valve 119 which flows through tube 101 towards canister 100. A POSITA would have recognized that vent valve 119 has an opening (i.e., an orifice) that allows the ambient air to flow into the lumen of tube 101. A POSITA would have understood that the opening in vent valve 119 constitutes an orifice under the plain and ordinary meaning of that term. Since vent valve 119 has an opening between the atmosphere and the lumen of tube 101, a POSITA would have understood that the orifice within vent valve 119 is a tube orifice.

258. Accordingly, in my opinion Hunt in view of Dolliver renders obvious claim 26.

**8. Claim 27: The vacuum system according to claim 26, said orifice having a smaller opening than a cross-section of the tube.**

259. In my opinion, Hunt in view of Dolliver renders obvious claim 27. As explained immediately above, Hunt in view of Dolliver renders obvious the vacuum

system of claim 26 and discloses a venting arrangement that is a tube orifice. Additionally, as explained above, the opening within vent valve 119 that is used to admit ambient air into tube 101 is a tube orifice. A POSITA would have understood that this valve opening (i.e., tube orifice) in certain positions between being fully opened and fully closed would necessarily be smaller than the cross-section of the multi-partitioned tube.

260. Accordingly, in my opinion Hunt in view of Dolliver renders obvious claim 27.

**D. Ground 4: Analysis of Claims 14 and 15 Based on Hunt in view of Dolliver and Watson**

261. In my opinion, claims 14 and 15 of the '554 Patent are invalid because they are obvious over the teachings of Hunt in view of Dolliver and in further view of Watson, as detailed below. As explained in Ground 3, Hunt in view of Dolliver renders obvious independent claim 12, on which claims 14 and 15 depend. However, neither Hunt nor Dolliver explicitly teach the disposable and detachable components of the vacuum system as recited in claims 14 and 15, but Watson teaches those limitations.

**1. Overview of the Combination of Hunt, Dolliver, and Watson**

262. As explained in Ground 2, prior to July 24, 2005, POSITAs were well-aware that certain components of NPWT systems could be disposable and detachable from the other components in the system. I hereby incorporate my discussion of the prior art background regarding disposable and detachable components from Parts VIII.B.1-2 by reference.

263. As I explain in more detail in Parts VIII.D.3-4 below, the combined system of Hunt and Dolliver and the disposable and detachable components of Watson teaches and/or renders obvious claims 14 and 15 of the '554 Patent.

**2. Motivation to Combine and Expectation of Success (Hunt in view of Watson)**

264. The rationale and motivation to combine Hunt's NPWT system with Watson's disposable and detachable components is explained in Part VIII.B.2 of Ground 2 above. I hereby incorporate Part VIII.B.2 by reference.

265. A POSITA would have been motivated to implement the combined Hunt-Dolliver NPWT system with the disposable components of Watson for the same reasons as discussed in Ground 2. As explained in Ground 2, both Hunt and Dolliver teach the use of removable, detachable, and disposable elements, like those disclosed in Watson. A POSITA would have been motivated to implement the Hunt-

Dolliver NPWT system with the disposable components of Watson. A POSITA would have found it an obvious choice to use the disposable and detachable components of Watson to avoid the introduction of biological material between patients based on what is known in the art alone, or at the very least, based on the teachings of Watson.

266. For all of these reasons, I conclude that a POSITA would have been motivated to combine Hunt and Watson, and would have expected success in doing so.

### **3. Claim 14**

267. Based on my review and for the reasons that follow, it is my opinion that claim 14 is rendered obvious over Hunt in view of Dolliver and Watson.

#### **i. Limitation 14[pre]: The vacuum system of claim 12,**

268. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 14, it is my opinion that Hunt in view of Dolliver renders obvious limitation 14[pre]. As I explain above in Ground 3, Hunt in view of Dolliver renders obvious the vacuum system of claim 12. The analysis and my discussion of claim 12 in Ground 3 is hereby incorporated by reference.

269. Accordingly, it is my opinion that Hunt in view of Dolliver teaches limitation 14[pre].

**ii. Limitation 14[a]: wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit,**

270. In my opinion, Hunt in view of Dolliver renders obvious limitation 14[a] as explained in Ground 3 above. Also, as I discussed in Ground 2, Watson teaches limitation 14[a]. The analysis and my discussion of limitation 14[a] from Grounds 2 and 3 is hereby incorporated by reference.

271. As I discussed in Part VIII.D.2, a POSITA would have been motivated to combine the NPWT system of Hunt and Dolliver with the disposable and detachable components of Watson.

272. Accordingly, it is my opinion that Hunt in view of Dolliver and Watson renders obvious limitation 14[a].

**iii. Limitation 14[b]: 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**

273. In my opinion, Hunt in view of Dolliver renders obvious limitation 14[b] as explained in Ground 3 above. Hunt specifically teaches that its waste container (canister 100) can be “readily removed and replaced” and is, therefore, disposable. Ex. 1003 at 1:67 – 2:3. Dolliver also teaches a “disposable set”

comprising the tubing and parts that contact ambient air admitted through vent valve 119. Ex. 1005 at [0033]. Hunt and Dolliver also disclose that ambient air entering the tube only contacts the disposable elements of Hunt, as explained above in Ground 3 regarding limitation 14[b]. To the extent, however, Hunt and Dolliver do not explicitly this limitation, in my opinion it is rendered obvious by the combination of Hunt in view of Dolliver and Watson.

274. As I discussed in Ground 2, Watson teaches limitation 14[b]. The analysis and my discussion of limitation 14[b] from Ground 2 is hereby incorporated by reference.

275. As I discussed in Part VIII.D.2, a POSITA would have been motivated to combine the NPWT system of Hunt and Dolliver with the disposable and detachable components of Watson.

276. Accordingly, it is my opinion that Hunt in view of Dolliver and Watson renders obvious limitation 14[b].

**iv. Limitation 14[c]: and said drained liquids may be disposed of together with said disposable elements.**

277. In my opinion, Hunt teaches limitation 14[c] as explained in Ground 2 above. Hunt specifically teaches that its waste container (canister 100), which is filled with drained liquids from the wound, can be “readily removed and replaced”

and is, therefore, disposable. Ex. 1003 at 1:67 – 2:3. To the extent Hunt is not deemed to explicitly disclose this limitation, however, it is taught by Watson.

278. As I discussed in Ground 2, Watson also teaches limitation 14[c]. The analysis and my discussion of limitation 14[c] from Ground 2 is hereby incorporated by reference.

279. As I discussed in Part VIII.D.2, a POSITA would have been motivated to combine the NPWT system of Hunt and Dolliver with the disposable and detachable components of Watson.

280. Accordingly, it is my opinion that Hunt in view of Dolliver and Watson renders obvious limitation 14[c].

281. For the reasons stated above, it is my opinion that Hunt in view of Dolliver and Watson teaches and renders obvious each of the limitations of claim 14 of the '554 Patent.

**4. Claim 15: 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.**

282. As I discussed in Ground 2, Hunt in view of Watson discloses claim 15. The analysis and my discussion of claim 15 from Ground 2 is hereby incorporated by reference.

283. As I discussed in Part VIII.D.2, a POSITA would have been motivated to combine the NPWT system of Hunt and Dolliver with the disposable and detachable components of Watson.

284. Accordingly, it is my opinion that Hunt in view of Dolliver and Watson renders obvious claim 15.

**IX. NO SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS**

285. I am informed by counsel that evidence of secondary considerations of non-obviousness are considered when determining whether a patent is invalid as obvious. I understand that secondary considerations include: (1) an invention's commercial success; (2) a long-felt, but unmet, need; (3) failure of others; (4) professional skepticism; (5) industry praise; (6) copying; (7) unexpected results; and (8) any other relevant consideration. I also understand from counsel that it is Patent Owner's burden to demonstrate the existence of secondary considerations.

286. I understand from counsel that the Patent Owner in the related district court litigations has not affirmatively identified any evidence with respect to secondary considerations of non-obviousness. To the extent that the Patent Owner subsequently identifies any other evidence of non-obviousness, I reserve the right to consider and revise any of my opinions if necessary.

**X. CONCLUSION**

287. For at least the preceding reasons, in my opinion, claims 12-17, 26, and 27 of the '554 Patent are anticipated by and/or would have been obvious to a person of ordinary skill in the art at the time of invention based on the prior art references that I have cited and analyzed above.

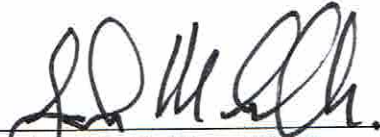
288. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in this proceeding. If required, I will appear for cross-examination at the appropriate time. I reserve the right to offer opinions relevant to the invalidity of the '554 Patent claims at issue and/or offer testimony in support of this declaration.

289. I hereby declare that all statements made herein of my own knowledge are true and that all statements are made on information and belief and believed to be true. Furthermore, these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Petition for *Inter Partes* Review of  
U.S. Patent No. 8,506,554 B2  
Exhibit 1002

Dated: June 17, 2024

Respectfully submitted,

  
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John M. Collins, Ph.D.