

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDELA LLC and MEDELA AG,
Petitioners

v.

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

Case No. IPR2024-01076

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

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

Title: WOUND CLOSURE AND DRAINAGE SYSTEM

DECLARATION OF JOHN M. COLLINS, PH.D.

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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. 8,858,534 (the “’534 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.

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. 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 '534 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:

Exhibit No.	Description of Document
1001	U.S. Patent No. 8,858,534 B2 to Carmeli Adahan (Application filed June 14, 2013, issued October 14, 2014)
1003	U.S. Patent No. 6,764,462 to James R. Risk, et al. (Application filed May 31, 2002, issued July 20, 2004)

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1004	U.S. Patent No. 7,790,945 to Richard L. Watson, Jr. (Application filed April 5, 2004, issued September 7, 2010)
1005	U.S. Patent No. 6,695,823 to Cesar Z. Lina, et al. (Application filed April 7, 2000, issued February 24, 2004)
1006	U.S. Patent No. 6,142,982 to Kenneth William Hunt, et al. (Application filed May 13, 1998, issued November 7, 2000)
1007	U.S. Patent Application Publication No. US 2005/0192548 to Phillip B. Dolliver, et al. (Application filed February 26, 2004, published September 1, 2005)
1008	'534 Patent Claim Listing
1009	Complaint, <i>M.E.A.C. Engineering Ltd. v. Medela, LLC, et al.</i> , Case No. 1:23-cv-14045 (N.D. Ill.)
1010	U.S. Patent No. 8,506,554 B2 to Carmeli Adahan (Application filed July 24, 2005, issued August 13, 2013)
1011	File History of U.S. Patent No. 8,858,534
1012	File History of U.S. Patent No. 8,506,554
1013	Northern District of Illinois Time-to-Trial Statistics, Lex Machina, available at https://law.lexmachina.com/court/ilnd/cases?pending-from=2009-01-01&filters=true&view=analytics&tab=timing&cols=475 (last accessed June 14, 2024)
1014	Medela Answer and Counterclaims, <i>M.E.A.C. Engineering Ltd. v. Medela LLC, et al.</i> , Case No. 1:23-cv-14045 (N.D. Ill.)
1015	Christine Miller, "The History of Negative Pressure Wound Therapy (NPWT): From 'Lip Service' to the Modern Vacuum System," J. Am. Coll. Clin. Wound Spec. 4: 61-62 (2014)

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Exhibit No.	Description of Document
1016	U.S. Patent No. 1,889,425 to George L. Sorenson (Application filed March 2, 1931, issued November 29, 1932)
1017	U.S. Patent No. 3,026,874 to R.C. Stevens (Application filed November 6, 1959, issued March 27, 1962)
1018	U.S. Patent No. 4,569,674 to Earl G. Phillips, et al. (Application filed August 3, 1982, issued February 11, 1986)
1019	Michael J. Morykwas, Louis C. Argenta, Eric I. Shelton-Brown, Wyman McGuirt, “Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Animal Studies and Basic Foundation,” <i>Annals of Plastic Surgery</i> , Vol. 38, No. 6 (June 1997)
1020	U.S. Patent No. 7,678,102 to Keith Patrick Heaton (PCT Application filed November 8, 2008, issued March 16, 2010)
1021	U.S. Patent No. 6,071,267 to David S. Zamierowski (Application filed February 6, 1998, issued June 6, 2000)
1022	U.S. Patent No. 5,735,833 to Daniel H. Olson (Application filed December 11, 1996, issued April 7, 1998)
1023	U.S. Patent Publication No. 2003/0125649 to Laura Janet McIntosh, et al. (Application filed October 29, 2002, published July 3, 2003)
1024	U.S. Patent No. 7,708,724 to Richard Scott Weston (Application filed April 4, 2005, issued May 4, 2010)
1025	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)
1026	U.S. Patent No. 6,241,739 to Stephen H. Waldron (Application filed November 12, 1999, issued June 5, 2001)

Exhibit No.	Description of Document
1027	U.S. Patent No. 6,045,516 to James Phelan (Application filed December 18, 1998, issued April 4, 2000)
1028	U.S. Patent No. 7,955,318 to Joseph P. Schultz, et al. (Provisional Application filed July 16, 2004, Application filed July 11, 2005, issued June 7, 2011)
1029	M.H. Worth, et al., “The Effectiveness of Bacterial Filtration in Vented Wound Drains,” N.Y.U. School of Medicine (Jan. 29, 1979)
1030	U.S. Patent No. 5,549,584 to James R. Gross (Application filed February 14, 1994, issued August 27, 1996)
1031	U.S. Patent No. 6,135,116 to Richard C. Vogel et al. (Application filed July 30, 1997, issued October 24, 2000)
1032	U.S. Patent No. 4,795,448 to Gary R. Stacey et al. (Application filed December 30, 1987, issued January 3, 1989)

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 '534 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 '534 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:

- 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;
- 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;
- combining prior art elements according to known methods to yield predictable results;
- applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
- 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);

- simple substitution of one known element for another to obtain predictable results; or
- 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. 1015 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. Ex. 1015 at 2; Ex. 1023 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. 1016. By 1960, doctors were using vacuum-assisted drainage devices to remove exudate. Ex. 1017. 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. 1018 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. 1019. 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. Ex. 1019.

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 '534 patent, have acknowledged that these devices were well-known in the art by the late 1990s and early 2000s. Exs. 1003-1006, 1020, 1021. 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. 1020 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, 1005-1007.

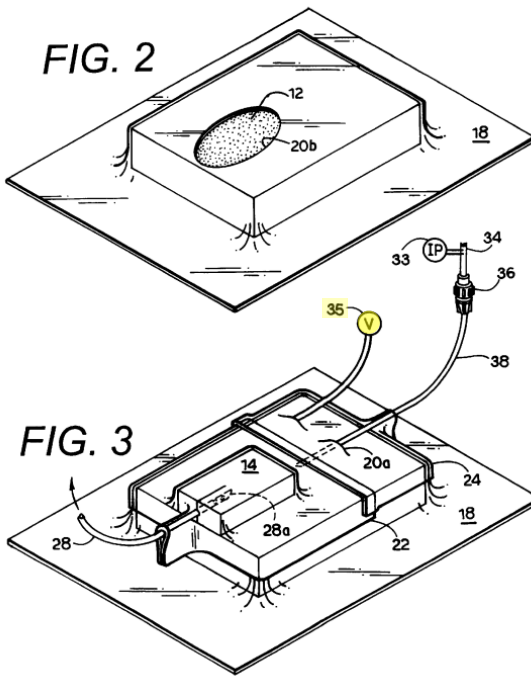
B. Introduction of Ambient Air is Required in Negative Pressure Wound Therapy Devices

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 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.

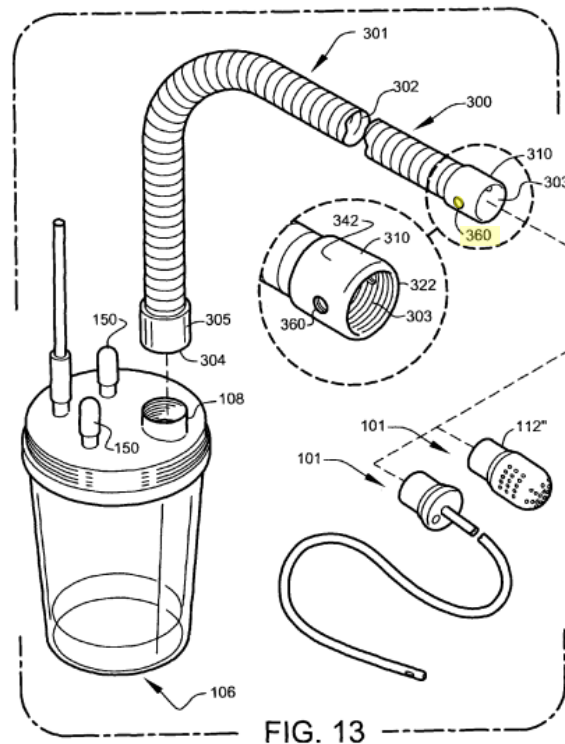
46. While NPWT systems have an opening through which ambient air can enter, systems developed in the late 1990s and early 2000s included these openings in different locations within the system. Some NPWT inventors chose to put a vent directly on the wound cover. Ex. 1003, 1021-1024. This exposes the wound to ambient air to release pressure as needed (Ex. 1023 at [0040]) and allows the wound to breathe (Ex. 1024 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. 1021 at Fig. 3 (highlighting added to show vent – “v” 35). *See also* Ex. 1021 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. 1003, 1017, 1025. 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. Exs. 1026-1028. 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. 1028 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.:

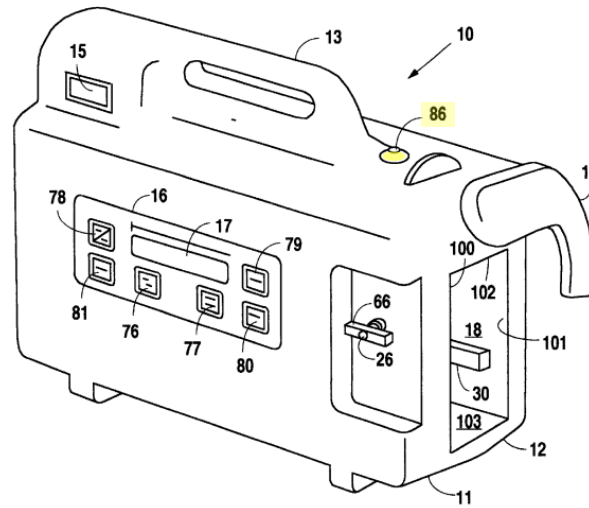


Fig. 1

Ex. 1005 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.

C. Motor Control for Negative Pressure Pumps

50. Modern NPWT devices utilize an electric motor driven pump and control system to produce and control the negative pressure applied to a wound. For example, the prior art cited in this petition disclose the following motors:

- Risk: a 12VDC brushless motor. Ex. 1003 at 8:15-17.
- Lina: a 12VDC motor. Ex. 1005 at 13:34-39.
- Hunt: a DC motor. Ex. 1006 at 1:61-63.
- Dolliver: an electric motor. Ex 1007 at 5:23-25.

51. Motors convert input electrical power (proportional to voltage times current) into a pump's mechanical shaft power (proportional to speed times torque) which generates fluid dynamic power (proportional to flow rate times pressure), with each step having conversion efficiencies as a function of the operating conditions.

52. Using different electric motor types and their associated control method is a simple design choice for a POSITA. As shown above, DC motors are very common for NPWT pumps which are often portable and powered by batteries. The relationship between a DC motor's constant speed with the torque generated, voltage

applied, as well as motor configuration is well known and given by the following equation¹:

$$\omega = \frac{1}{k} \left(V - \frac{T * R}{k} \right)$$

Where:

ω = rotational speed

V = supply voltage

T = motor torque

Motor factors:

k = motor constant

R = motor resistance

53. So, for example, speed increases with voltage, but at any given voltage the speed decreases with increased torque. In addition, it is known that the current that flows through a DC motor is directly related to the motor's torque. So, a POSITA would know that the applied voltage, motor speed and motor torque (or current) are all related for a given configuration. These equations therefore can be used to determine the fluid dynamic power (a function of pressure and flow rate) generated from the mechanical power (a function of shaft speed and torque) that is generated by the input electrical power (a function of voltage and current).

¹ See: The relationship between voltage and dc motor output speed accessed on 4/21/2024 at: <https://www.motioncontroltips.com/faq-whats-relationship-voltage-dc-motor-output-speed/>

54. Different pumps convert the mechanical shaft power to fluid dynamic power with different efficiencies, but each can correlate the pressure with volumetric flow rate at any pump speed. As such, a POSITA would know how to control a DC motor driven pump's pressure in a given design and operating condition by controlling any two of the variables of motor speed, voltage, or torque (or current).

IV. THE '534 PATENT

55. I understand that the '534 Patent issued on October 14, 2014 from an application that was filed on June 14, 2013. Ex. 1001. I further understand that the '534 Patent claims priority to U.S. Application No. 11/989,297 ("the '297 application"), filed as PCT Application, PCT No. IL2005/000784, which was filed on July 24, 2005. Ex. 1001. The '297 application issued as U.S. Patent No. 8,506,554 ("the '554 Patent"). Ex. 1010. I also understand that Petitioners are challenging the validity of claims 1-22 of the '534 Patent in the Petition for *Inter Partes* Review to which this declaration will be attached. Those claims are reproduced in Exhibit 1008. In rendering my opinions, I have considered all claims of the '534 Patent, the '534 Patent specification, the '534 Patent prosecution history, and the '554 Patent prosecution history.

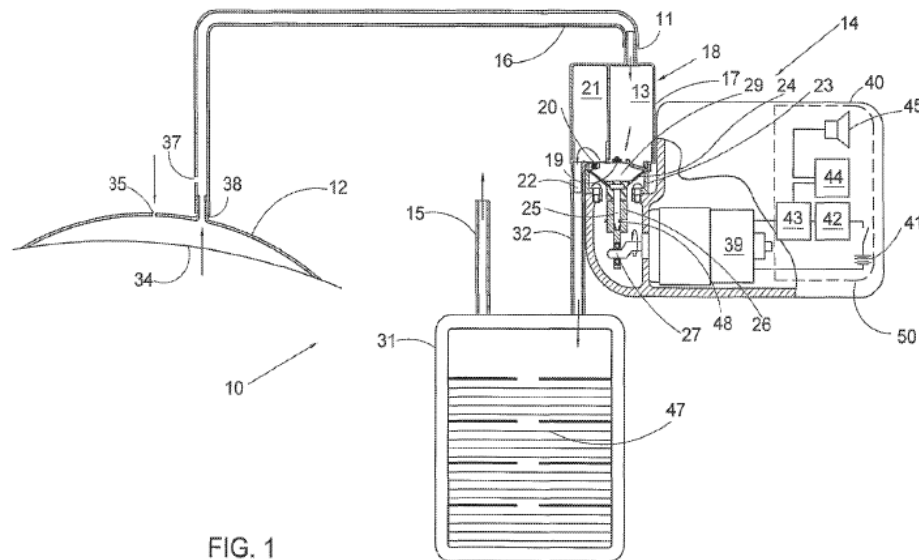
A. Overview of the '534 Patent

56. The '534 Patent relates to a vacuum system that utilizes negative pressure to drain liquids from a wound ("NPWT system"). Ex. 1001, Abstract. The '534 Patent describes the invention as a vacuum system 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.

Ex. 1001, Abstract.

57. Figure 1 of the '534 Patent depicts the exemplary NPWT system, showing the relevant components:



58. NPWT systems were well-known as of the priority date of the '534 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.”² Ex. 1001 at 1:14-16. The '534 Patent specification further identifies “deficiencies” of the prior art systems, including:

- wound exudate may contaminate the pump or “require costly and complex methods of isolating the pump” from the use of negative pressure pump suction (Ex. 1001 at 1:41-45);

² The '534 Patent shares a common specification with its priority application, now the '554 patent. All citations herein are to the '534 patent unless otherwise indicated.

- the use of a “rigid canister” which is “bulky and inconvenient” for patients who carry their containers with them (Ex. 1001 at 1:46-49);
- airtight sealing of the wound “requires a pressure relief or bleed valve to produce the pressure cycling desirable to obtain accelerated wound closure” (Ex. 1001 at 1:50-55);
- 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” (Ex. 1001 at 1:56-60); and
- monitoring negative pressure “requires the use of a vacuum transducer, gage or relief valve . . . connected to the suction tube, which is subject to contamination” (Ex. 1001 at 1:61-67).

59. Thus, the ’534 Patent purports to improve on prior art NPWT systems “by providing a wound drainage enclosure and vacuum system, which are [sic] impervious to contamination and easy to use.” The specification and claims focus on three main features.

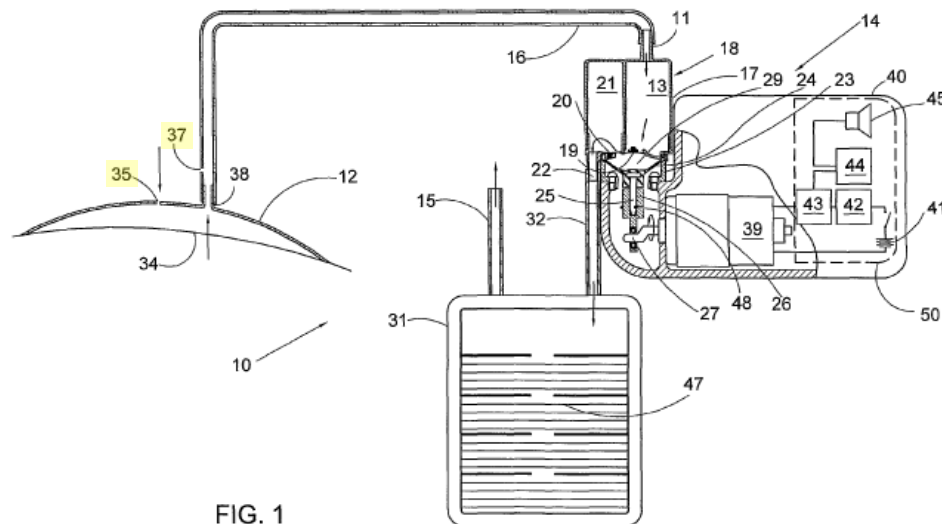
60. **Venting Arrangement with Flow Restrictor:** The independent claims of the ’534 Patent require a “venting arrangement” that includes a “flow restrictor” to maintain a controlled flow of ambient air into the system towards the vacuum

source. Ex. 1001, claims 1, 11, 19. The claimed venting arrangement may comprise bleeding holes, a porous body, or a tube orifice. Ex. 1001, claims 10, 18, 22. 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”. Ex. 1001 at 2:19-21; *see also* Ex. 1001 at 3:9 (“The enclosure may have bleeding holes as described above.”). The ’534 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.” Ex. 1001 at 2:22-24, 4:43-46. The specification also explains that “flow restrictors may be used to provide controlled flow of ambient air into the enclosure or into the outlet.” Ex. 1001 at 4:41-42.

61. 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.” Ex. 1001 at 2:25-27. This allows ambient air to flow from the bleeding hole into the tube and “flow together with the exuded liquids when negative pressure is present” and prevents coagulation of exudate in the tube. Ex. 1001 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 and “render[s] enclosure . . . vented.” Ex. 1001 at 4:29-30.

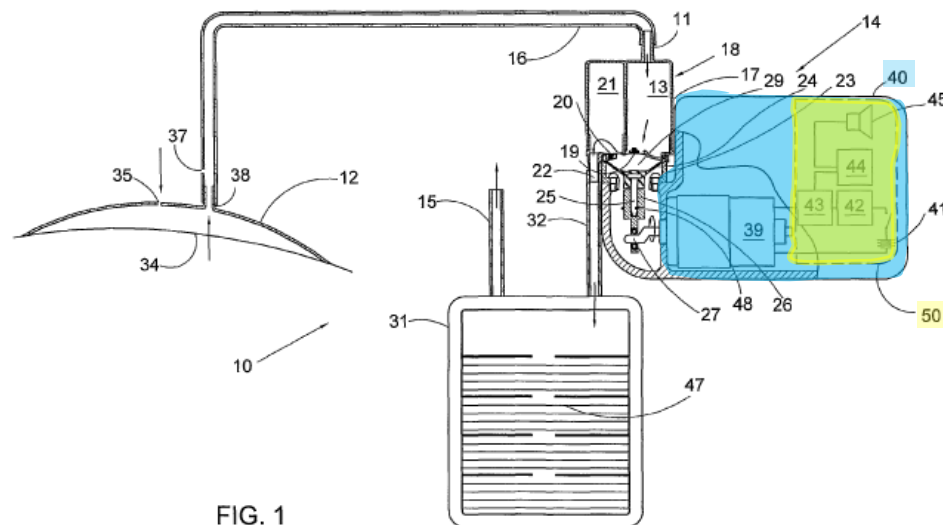
62. The '534 Patent specification describes a bleeding orifice on the enclosure itself as well as a tube orifice that is upstream and adjacent to the enclosure. These orifices are depicted in Figure 1 as bleeding orifice 35 on the enclosure and tube orifice 37 adjacent to the enclosure:



Ex. 1001 at Fig. 1 (highlighting added). The '534 Patent claims also recite a flow restrictor provided on the enclosure or the tube. Ex. 1001 at claim 2.

63. **Control Block and Sensor to Monitor Negative Pressure:** A second feature contained within the '534 Patent that purports to overcome deficiencies in the prior art is the control block that sets, maintains, and monitors the amount of negative pressure within the enclosure. Ex. 1001 at 3:23-33. The control block sits

within the drive unit of the vacuum system. Ex. 1001 at 5:37-50; Fig. 1. The drive unit 40 (highlighted in blue) and control block 50 (highlighted in green) are depicted in Figure 1 below:



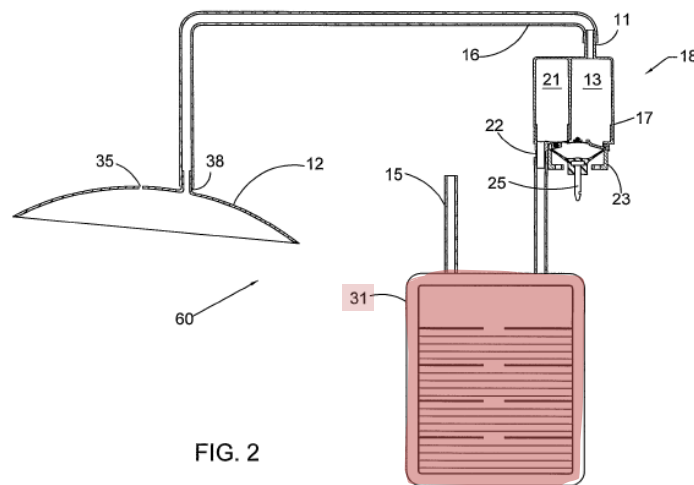
Ex. 1001 at Fig. 1 (highlighting added).

64. The '534 Patent explains that the control block includes a sensor “for sensing working parameters of the drive unit and means for detecting the level of negative pressure in the confined volume from these working parameters, in order to maintain said predetermined level.” Ex. 1001 at 3:28-31. The '534 Patent purports to overcome deficiencies in the prior art by providing a sensor that can indirectly monitor the level of negative pressure at the wound without contacting the exudate. Ex. 1001 at 3:45-53; claims 3, 12. “For example, if the motor 39 is a direct electric motor, a sensor may sense the electric current driving the motor” and the control

block “compares the desired set negative pressure level obtained by pump 18, and the actual monitored negative pressure level as obtained indirectly from the motor voltage and current monitoring and control 43.” Ex. 1001 at 5:51-53, 5:64 – 6:1. Thus, expensive sensors do not need to be disposed of because they are not contaminated. Ex. 1001 at 45-53; 5:37-50.

65. The control block also controls the pump itself, including turning the motor on and off and cycle control. Ex. 1001 at 5:37-42. Specifically, the '534 Patent specification and claims disclose controlling the electric current, voltage, and output torque. Ex. 1001 at 5:37-63; claims 7-8, 15-17, 20-21.

66. **Waste Container for Wound Exudate:** A third feature that the '534 Patent purports overcomes the deficiencies in prior art NPWT systems is a waste collection bag that can be disposed of after use. Ex. 1001 at 3:18-22. Additionally, unlike existing “rigid” waste canisters that were “bulky and an inconvenient burden for ambulatory patients” (Ex. 1001 at 1:46-49), the '534 Patent’s waste container is “made of thin plastic sheet” and “adapted to be carried by an ambulatory patient.” Ex. 1001 at 5:33-36, 2:50-61. The '534 Patent also explains the waste container “may contain a porous media adapted to soak up the drained liquids and may be in the form of a collapsible or foldable bag.” Ex. 1001 at 3:13-15. Figure 2 depicts the waste bag 31 as disclosed in the '534 Patent:



Ex. 1001 at Fig. 2 (highlighting added).

67. The other parts of the disclosed NPWT system in the '534 Patent are not claimed to be improvements of prior art systems. This includes the wound enclosure, tube, and vacuum source.

B. '534 Patent Prosecution History

68. I understand that the '534 Patent issued from U.S. Patent Application No. 13/917,865 (the "'865 Application") which is a continuation of the '297 application, now the '554 Patent. I also understand that for purposes of evaluating the validity of the '534 Patent, July 24, 2005 is treated as the applicable priority date of the '534 Patent (the "Critical Date"). For purposes of this declaration, I have been asked to assume a priority date of July 24, 2005, but I make no opinion as to the propriety of that priority date regarding the '534 Patent.

69. Based on the file history, I understand the '865 Application was filed on June 14, 2013. The Examiner issued a Non-Final Rejection of the '865 Application on March 11, 2014. Ex. 1011 at 143-48. The Examiner rejected all claims of the '865 Application on the ground of non-statutory double patenting over claims 1, 6, 8, 9, 20, and 24 of the '554 Patent in view of U.S. Patent Pub. No. 2001/0029956 to Argenta et al. *Id.* at 146. The Examiner explained that the only difference between the independent claims of the '865 Application and the '554 Patent is the presence of a controller and/or controlling the vacuum system, which is taught by Argenta. *Id.* at 146. The Examiner also found all the limitations in the '865 Application's dependent claims to be within the '554 Patent claims. *Id.* at 147.

70. I understand that on June 2, 2014, the applicant submitted a terminal disclaimer with respect to the '554 Patent to overcome the Examiner's non-final rejection. *Id.* at 123-35. The terminal disclaimer was approved by the Examiner. *Id.* at 127. On June 18, 2014, the Examiner issued a Notice of Allowance of claims 1-22 of the '865 Application. *Id.* at 28-34. The '534 Patent issued on October 14, 2014. *Id.* at 18.

C. The Challenged Claims

71. This Declaration addresses claims 1-22 (the "Challenged Claims"). There are three independent claims within the Challenged Claims. Independent

claims 1 and 11 recite a vacuum system for applying negative pressure to a wound. Independent claim 19 recites a method for applying negative pressure to a wound by providing a vacuum system with functionality similar to that recited in the limitations of claims 1 and 11. So, I will treat claim 1 as a representative claim. It recites:

1. A vacuum system for applying negative pressure to a wound, the vacuum system comprising: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller:

the enclosure being attachable to a periphery of the wound so as to define a confined volume;

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

the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said vacuum system upstream of the vacuum source;

the controller configured for controlling operation of the vacuum source while providing venting of the vacuum system via said venting arrangement to provide a desired level of said negative pressure in said confined volume.

72. I address each of the claims further in my detailed analysis in Part VIII below.

V. LEVEL OF ORDINARY SKILL IN THE ART

73. In determining the characteristics of a person of ordinary skill in the art of the field of the '534 Patent at the time of the claimed invention (a "POSITA")³, 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 also considered the level of education necessary to understand the '534 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.

74. Based on the above, I have concluded that a POSITA in the field of art of the '534 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

³ I considered the level of ordinary skill in the art as of July 24, 2005, the assumed critical date of the '534 Patent, as explained more fully above in Part IV.B.

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 '534 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 '534 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 '534 Patent. My opinions herein would not change if a slightly different definition of a POSITA is adopted.

VI. CLAIM CONSTRUCTION FOR THE '534 PATENT

75. In my analysis of the '534 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 '534 Patent prosecution history to a person of ordinary skill in the art.

76. 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.

77. 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 the Petitioners believe no construction is necessary.

78. I have not yet formed, and do not offer, any opinion on the indefiniteness of any claims of the '534 Patent.

VII. SUMMARY OF THE PRIOR ART

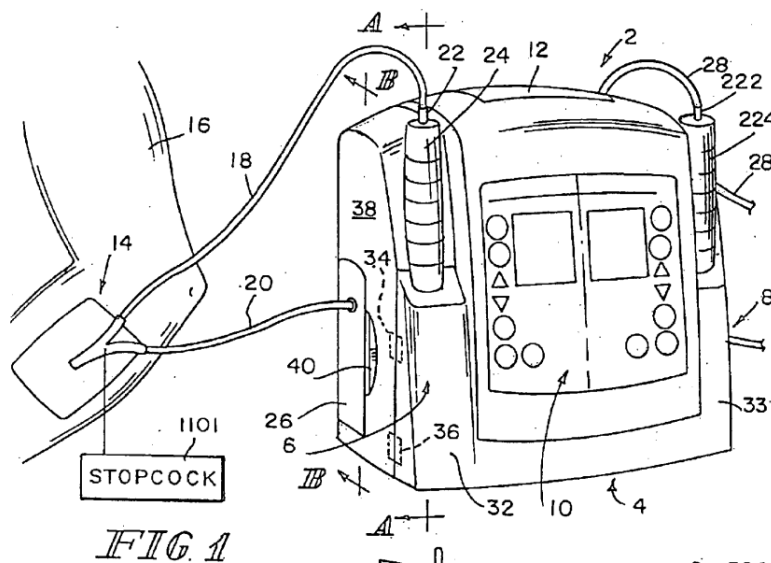
A. Risk (Ex. 1003)

79. U.S. Patent No. 6,764,462 to James R. Risk, Jr. and Robert Petrosenko is an issued patent entitled “Wound Treatment Apparatus” (“Risk”). Ex. 1003. It was filed on May 31, 2002 and issued on July 20, 2004. Risk qualifies as prior art under 35 U.S.C. §§ 102(a), (b), and (e).

80. Risk discloses a NPWT system with a control unit that provides negative pressure wound therapy to a patient. *Id.* at Abstract, 1:7-10, 12:4-17, Figs. 1 and 5. The disclosed system in Risk is a portable unit coupled to a bandage that is attached to a wound on a patient. *Id.* at 4:21-32 (an embodiment describes the wound is located on the patient’s leg). The bandage is coupled to the vacuum system via

evacuating tubes that remove fluid and exudate and deposit the fluid and exudate into a waste canister. *Id.* at 4:30-43. The bandage seals and protects the patient's wound and is vented to the atmosphere. *Id.* at 10:47-48, 11:10-11, 11:10-20, 14:63 – 15:5. The vacuum pump creates negative pressure that is used to remove fluids and exudate from the wound. *Id.* at 8:13-20, 8:58-61.

81. The vacuum system in Risk includes “an electronic control unit that controls apparatus,” “receives user input,” and “provides feedback to user interface.” *Id.* at 5:21-24. Risk also describes various sensors, monitored by the controller, that monitor the pump's operation, level of fluid in the canister, and level of negative pressure being applied by the vacuum pump. *Id.* at 7:39-41, 7:59 – 8:12, 10:23-25. Figure 1 depicts the vacuum housing, which includes the pump and controller, along with the canister and bandage covering the wound:

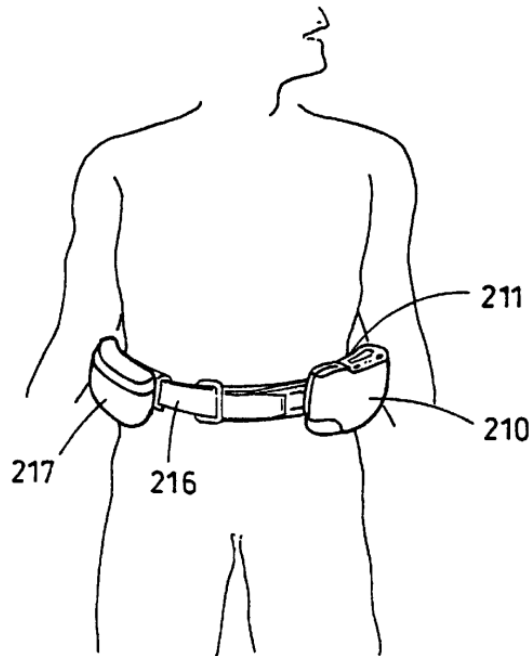


Id. at Fig. 1.

B. Hunt (Ex. 1006)

82. 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. 1006. Hunt was filed on May 13, 1998 and issued on November 7, 2000. It is prior art to the ’534 Patent under 35 U.S.C. §§ 102(a), (b), and (e).

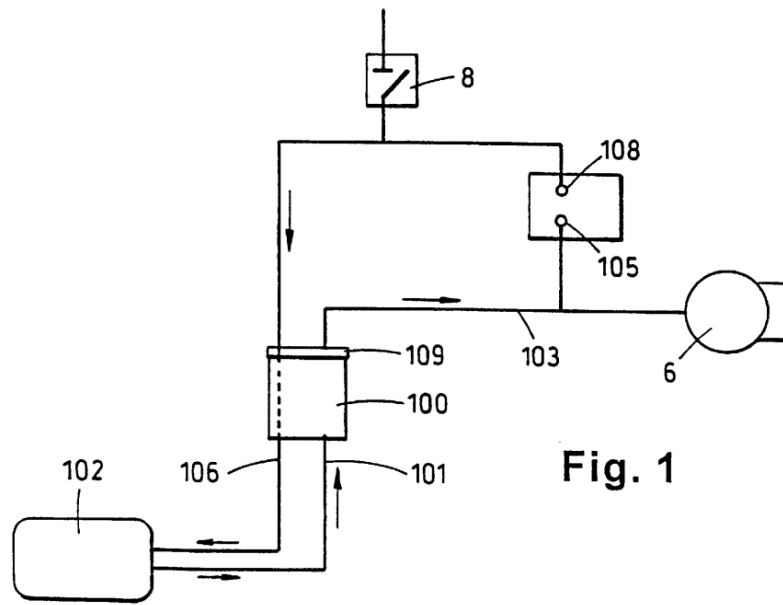
83. Hunt discloses a portable, vacuum-assisted wound treatment system with a suction pump that connects to a wound via a plurality of tubes and a canister to collect fluids drawn from the wound. *Id.* at Abstract. The portability of the patented invention in Hunt is depicted by the apparatus supported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

84. Like Risk, 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):



Id. at Fig. 1.

C. Watson (Ex. 1004)

85. U.S. Patent No. 7,790,945 to Richard L. Watson, Jr. is an issued patent, entitled “Wound Dressing with Absorption and Suction Capabilities” (“Watson”). Ex. 1004. It was filed on April 5, 2004 and issued on September 7, 2010. Watson is prior art to the ’534 Patent under 35 U.S.C. § 102(e).

86. Watson describes a wound dressing and cover with a “suction member adaptable for connection” to a NPWT system. *Id.* at Abstract. The wound dressing and cover are adapted to be connected to a vacuum source, which removes fluid from the wound. *Id.* at 1:18-22. The disclosed wound cover (16) surrounds the entirety of

the wound but is semi-permeable and “allows the wound to breathe.” *Id.* at 1:14-24., 3:20-41, 7:57 – 8:22. Watson further discloses a tube (12), installed beneath the cover, that is connected to a vacuum source. *Id.* at 5:22-29. The wound dressing (10) of Watson is depicted in Figure 2:

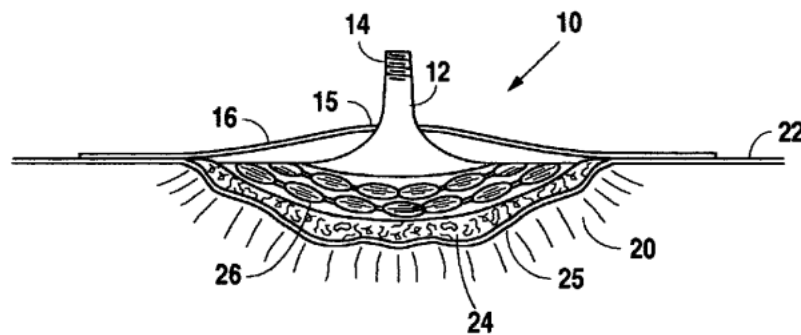


Fig. 2

Id. at Fig. 2.

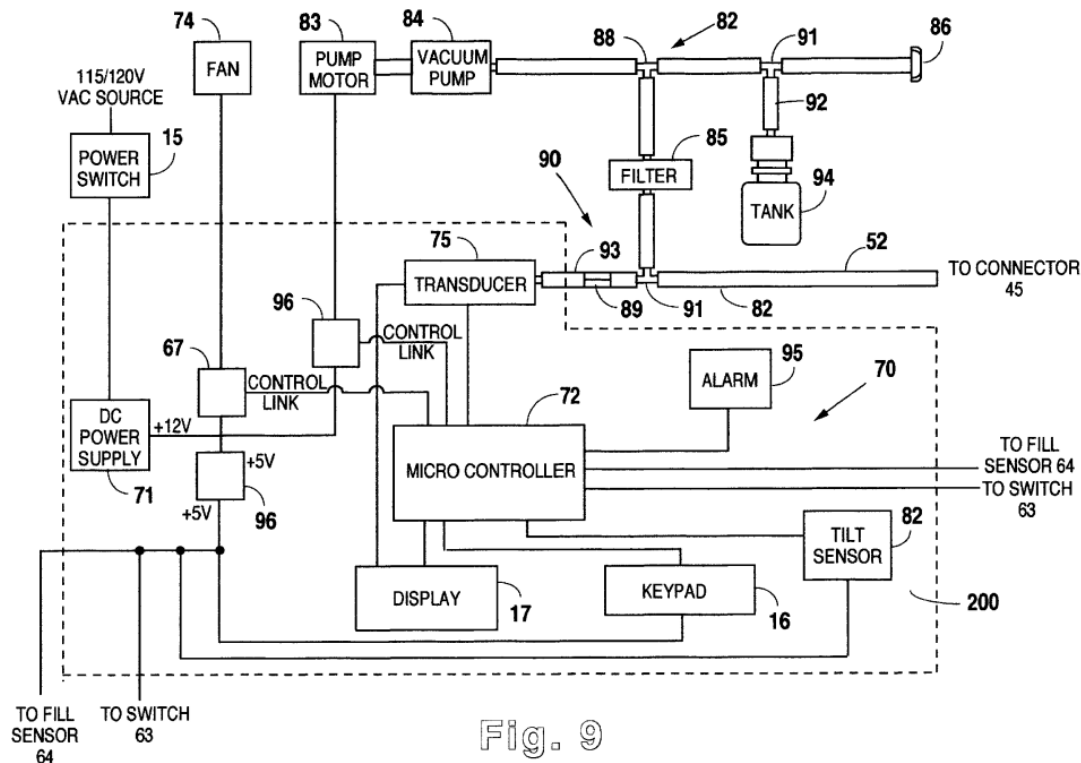
D. Lina (Ex. 1005)

87. U.S. Patent No. 6,695,823 to Cesar Z. Lina, Keith Heaton, and Royce Johnson is an issued patent entitled “Wound Therapy Device” (“Lina”). Ex. 1005. Lina was filed on April 7, 2000 and issued on February 24, 2004. Lina is prior art to the ’534 Patent under 35 U.S.C. §§ 102(a), (b), and (e).

88. Lina describes an NPWT apparatus, including a wound pad, tubing, vacuum pump, and waste canister. *Id.* at Abstract, 12:50-53. Lina also includes a “bleed valve” that “communicates with the atmosphere to release pressure”,

“prevent over-pressurization”. *Id.* at 12:56 – 13:9. Regarding the bleed valve, Lina’s preferred embodiment uses “an orifice of 0.5 mm diameter” and describes “[f]low control orifices” as alternatives. *Id.* at 12:66 – 13:9.

89. Lina also discloses a controller that controls the vacuum pump and, specifically, the voltage regulator that increases or decreases the speed of the pump. *Id.* at 11:19-32, 11:53 – 12:6. Specifically, the controller compares the sensed pressure at the wound with the user-selected negative pressure and adjusts the voltage of the pump motor accordingly. *Id.* at 13:20-50. The various pieces and circuitry of the NPWT system in Lina are depicted in Figure 9:



Id. at Fig. 9.

E. Dolliver (Ex. 1007)

90. U.S. Patent Application Publication No. 2005/0192548 to Phillip B. Dolliver and Alec Bobroff is a published patent application entitled “Wound Drainage Suction Relief” (“Dolliver”). Ex. 1007. Dolliver was filed on February 26, 2004 and published on September 1, 2005. It is prior art to the ’534 Patent under 35 U.S.C. § 102(e).

91. 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.*

92. 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], [0040].

93. Like Risk and 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):

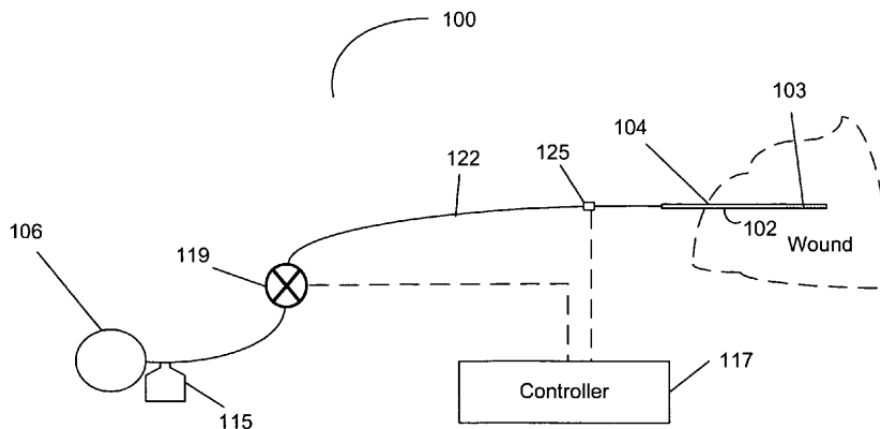


Fig. 1

Id. at Fig. 1.

VIII. APPLICATION OF THE PRIOR ART TO THE CHALLENGED CLAIMS

94. 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 either anticipated or rendered

obvious by the Grounds presented in this declaration. The reasons for my conclusions are explained more fully below.

95. I have reviewed and analyzed the prior art references, including all materials listed in Part I.A.2 above. In my opinion, the claims of the '534 Patent are anticipated and/or rendered obvious based on the following prior art:

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

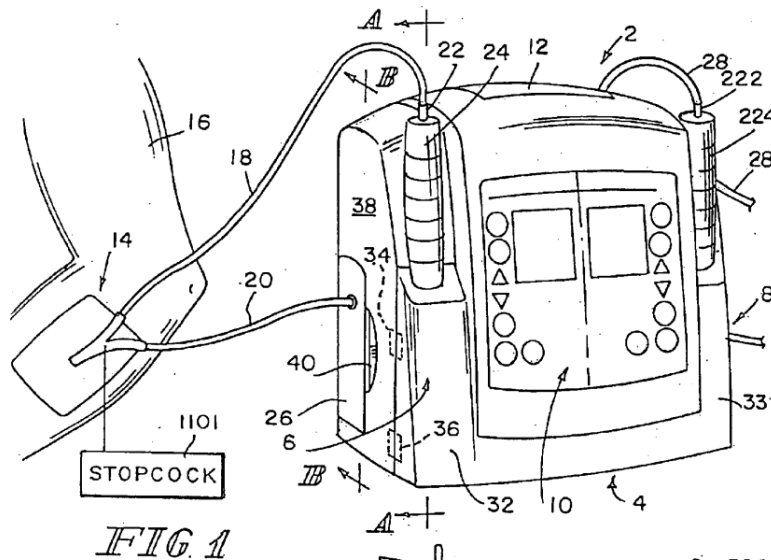
96. I am informed by counsel that each of the references cited in the above grounds qualifies as prior art to the Challenged Claims because each reference was filed and/or published before the Critical Date for the '534 Patent.

A. Ground 1: Analysis of Claims 1-5, 9, 10, 19, and 22 Based on Risk in view of Watson.

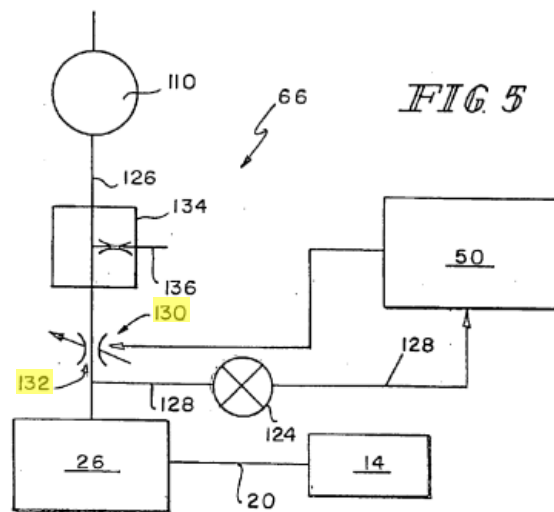
97. In my opinion, claims 1-5, 9, 10, 19, and 22 of the '534 Patent are invalid because they are obvious over the teachings of Risk in view of Watson, as detailed below.

1. Overview of the Combination of Risk and Watson

98. With respect to independent claims 1 and 19, Risk teaches a vacuum system that applies negative pressure to a wound, comprising an enclosure, venting arrangement, tube, vacuum source, and controller. Risk discloses that the bandage covering the wound “has a vent in communication with atmosphere, and air enters interior region 866 through bandage 14” Ex. 1003 at 14:63 – 15:1. While the “vent in communication with atmosphere” is not depicted, Figure 1 of Risk shows the bandage and connection to the vacuum source and canister:



of the NPWT system. For example, Risk teaches a proportional valve (130) that comprises a flow orifice (132) which “selectively dilates or constricts, thereby controlling the negative pressure level through sub-system 66.” *Id.* at 7:43-47. Proportional valve 130 and flow orifice 132 are depicted in Figure 5 (highlighted in yellow):



Id. at Fig 5 (highlighting added). In my opinion, a POSITA would have understood that flow orifice 132 restricts the flow of air through the NPWT system to control the amount of negative pressure that is applied to the wound and present throughout the system.

100. Even though Risk teaches the use of flow orifice 132 that controls the level of negative pressure within the system, a POSITA would have known that the vent at the wound site would also act as another flow restrictor, as explained more

fully below. If the bandage vent had little to no flow restriction, a POSITA would have known that the pressure in the enclosure would remain at or near ambient pressure, rendering the device non-functional. Risk itself teaches the use of a proportional valve with flow orifice to control the amount of negative pressure present within the system in addition to a vacuum regulator 134 to maintain a maximum amount of negative pressure being applied. *Id.* at 7:43-65. In my opinion, a POSITA would have been motivated to incorporate another flow restrictor to provide control over the amount of pressure applied at the wound site.

101. Although Risk teaches the use of a flow restrictor (i.e., flow orifice 132) within the suction line 126, it does not explicitly teach the use of a flow restrictor in conjunction with the venting arrangement at the wound site. As explained above, Risk teaches the use of a bandage vent that allows ambient air to enter the volume underneath the bandage. Risk also teaches that the bandage material may be “semi-occlusive” to allow water vapor to pass through it while still “protect[ing] wound 300 from the outside environment.” *Id.* at 11:14-20. Risk does not explicitly teach, however, the use of the semi-occlusive material in combination with the bandage vent such that the bandage vent comprises a flow restrictor.

102. Prior to 2005, POSITAs were well-aware that flow restrictors could be used in conjunction with a vent on a bandage to further restrict ingress and egress of

airflow and protect the wound from outside contaminants. Watson provides an example of a well-known flow restrictor on a wound bandage through its semi-permeable material that allows air to pass through it but protects the wound from contamination. Ex. 1004 at 1:16-24, 3:24-37. The semi-permeable cover material (16) disclosed in Watson is shown covering the wound in Figure 2:

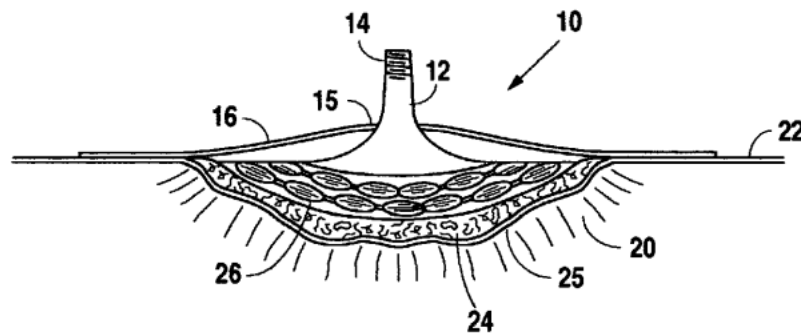


Fig. 2

Id. at Fig. 2.

103. As I set forth below, a POSITA would have been motivated to combine Risk's vent on the wound cover with a semi-permeable material that allows air to pass, while preventing contaminants, like the semi-permeable cover taught in Watson. For the reasons set forth below, a POSITA also would have had a reasonable expectation of success in making this well-understood combination.

104. As I explain in more detail in Part VIII.A.3-11 below, the combination of Risk's NPWT apparatus with the semi-permeable cover of Watson teaches each limitation of claims 1-5, 9, 10, 19, and 22 of the '534 Patent.

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

105. I understand that Risk and Watson are considered to be analogous art since they both relate to NPWT systems. In particular, Risk discloses a wound treatment system that applies suction from a vacuum source to a wound via a tube connected to a vented wound cover. Ex. 1003 at 14:15-18, 14:63 – 15:1. Risk also teaches that the bandage would have a vent. *Id.* at 14:63 – 15:1. As described above, a POSITA would know that the bandage vent needs to be properly configured for the system to accurately control pressure in the bandage/enclosure. Watson teaches a wound dressing with cover made of semi-permeable material that is attachable to a suction tube that connects with a vacuum source and controls the flow of air. Ex. 1004 at 1:14-24. In my opinion, a POSITA would have been motivated to combine the teachings of Risk and Watson for several reasons.

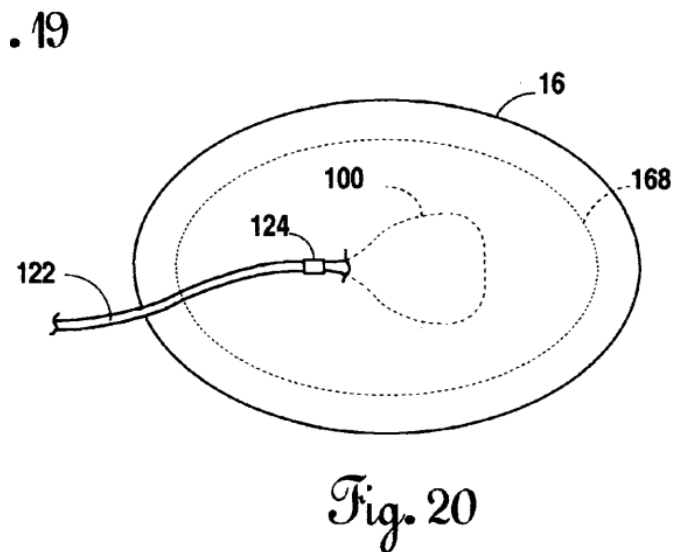
i. Implementing the semi-permeable wound cover based on the teachings of Watson to the bandage vent taught by Risk would have been using well-established prior art elements according to known methods to yield predictable results.

106. Prior to July 24, 2005, it was well-known and well-understood that semi-permeable wound covers could be used in NPWT systems to help restrict the amount of ambient air entering and leaving the wound and to avoid contamination. Wound dressings and coverings that were semi-permeable to air and prevented contaminants from entering a wound, such as the one taught in Watson, were known and commonly used in wound treatment apparatuses at least by 1980. For example, in 1979, literature described the use of a vent on a wound drain to permit ingress of ambient air, but pointed out the problems with airborne bacteria having access to the wound. Ex. 1029 at 405. It was well-understood that some form of semi-permeable material or filter could be used on the wound cover to both allow air to pass over the wound, but limit the risk of bacterial contamination. *Id.* at 406.

107. Watson teaches a semi-permeable cover that accomplishes similar goals as those recognized by Worth in 1980. Specifically, Watson's semi-permeable cover "allows the wound to breathe while protecting the wound from undesirable substances such as bacteria, viruses, or fluids." Ex. 1004 at 1:16-24. Watson also discloses existing semi-permeable materials that could have been used, such as

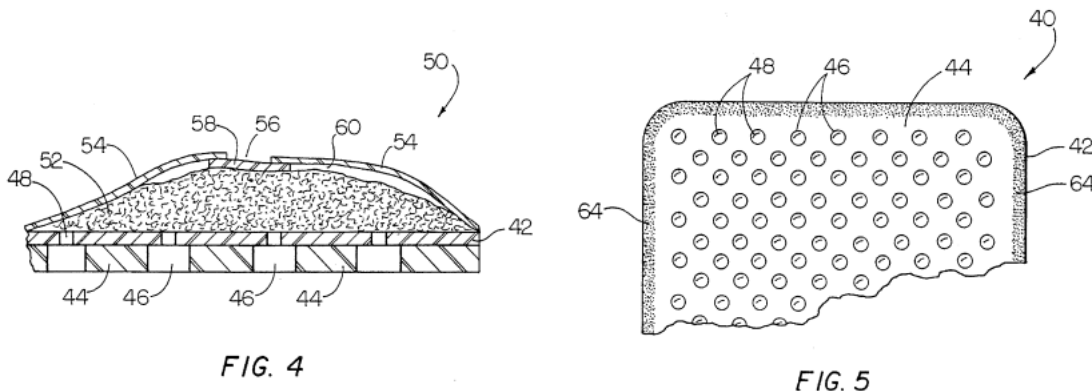
Gore-Tex™, of which a POSITA would also have known. Along with protecting the wound from bacteria and other contaminants, Watson explains that the semi-permeable cover facilitates air circulation which helps in promoting healing of the wound itself (which is the ultimate goal of the NPWT system). *Id.* at 3:24-37, 8:16-19.

108. Watson also explains that its semi-permeable cover is intended to be used in conjunction with an NPWT system, such as the one disclosed in Risk. The wound cover in Watson contains “a suction member adaptable for connection to a source of vacuum pressure.” *Id.* at Abstract. In one embodiment, the suction member 100 is installed beneath the semi-permeable cover, as shown in Figure 20 below:



Id. at Fig. 20. While Watson itself does not show and describe in detail the vacuum source, Watson teaches that its semi-permeable wound cover is intended to be connected to a vacuum source and is used in conjunction with an NPWT system.

109. A POSITA would have had knowledge of other prior art wound covers, like that taught by Watson. For example, U.S. Patent No. 5,549,584, invented by James R. Gross, (“Gross”) was filed on February 14, 1994, over a decade before the ’534 Patent. Gross teaches an NPWT apparatus that utilizes suction to remove exudate from a wound. Ex. 1030 at 1:29-40. Gross’s teachings include a “vented wound dressing” that allows fluid and air to permeate it. *Id.* at 1:41-52. Figures 4 and 5 depict the vented wound dressing of Gross:



Id. at Figs. 4-5.

110. Gross teaches that the wound dressing is only air-permeable in limited portions to protect the wound “from contamination by ambient micro-organisms”. *Id.* at 6:17-23. Specifically, the wound dressing in Gross may compromise a

hydrophobic air permeable filter to prevent bacteria from entering the wound site. *Id.* at 6:64-67. Gross also explains that the outer surface of the wound dressing is air-permeable to promote fluid retention, thereby aiding in the healing process, in the wound. *Id.* at 5:63 – 6:9.

111. Additionally, a POSITA would also have knowledge of other semi-permeable wound covers for use in conjunction with Risk. For example, U.S. Patent No. 7,708,724, invented by Richard Scott Weston, (“Weston”) was filed on April 4, 2005 and claims priority to a provisional application filed on April 5, 2004. Weston teaches an NPWT system that uses a cover 120 to seal the patient’s wound. Ex. 1024 at 9:46-52, 18:41-57. An embodiment in Weston showing the NPWT system connected to the wound cover 120 is shown in Figure 5 below:

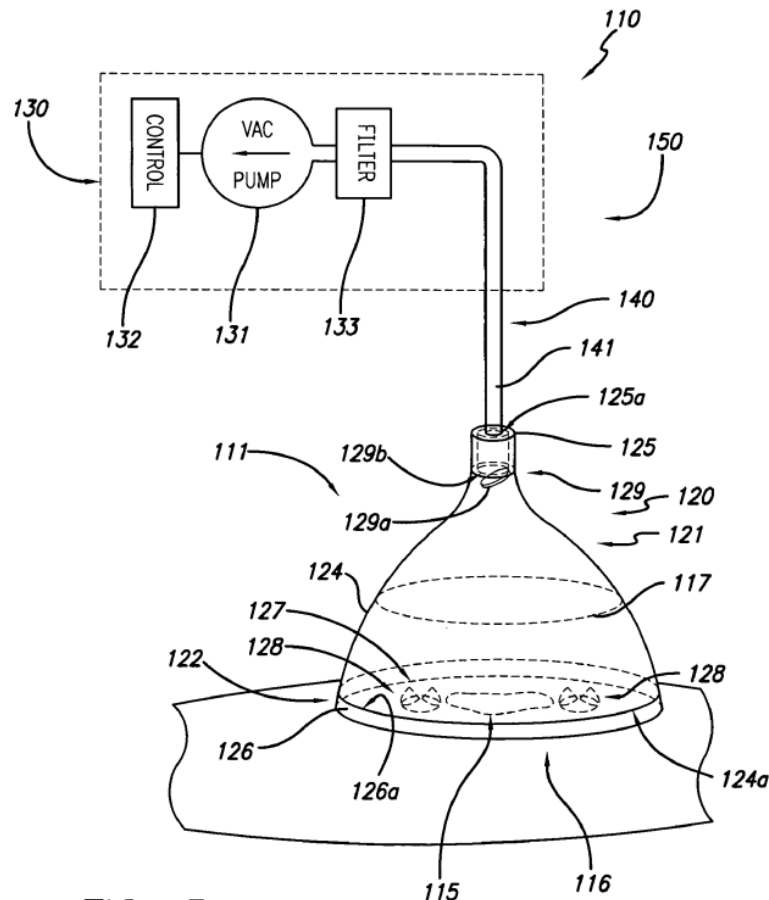


FIG. 5

Id. at Fig. 5. Weston teaches that the cup body member, comprising part of the cover as shown in Figure 5 above, may be made of gas-permeable materials to allow “limited amounts of oxygen” to enter the wound so it can breathe. *Id.* at 9:46-52.

112. Weston teaches that the cover 120 seals the wound, however, it is not necessarily a gas-tight seal and allows for leakage to the atmosphere. *Id.* at 18:41-57. Because Weston teaches an NPWT system, Weston notes that the amount of

leakage must be minimal to maintain the desired level of reduced pressure at the wound site. *Id.*

113. For at least these reasons, as of July 24, 2005, a POSITA would have been well-aware of the use of semi-permeable material in a wound cover as part of an NPWT system. Thus, implementing Risk's NPWT system with a vented cover to incorporate the semi-permeable cover material of Watson as a flow restrictor would have simply been combining known prior art elements according to methods known to a POSITA prior to the priority date of the '534 Patent. Moreover, a POSITA would have understood that this combination would yield the predictable result reflected in the above-cited references—i.e., controlling the amount of ambient air through the cover and allowing the wound to breathe while still protecting it from bacteria or airborne contaminants that would inhibit the wound healing process.

ii. Risk expressly suggests providing a semi-permeable wound cover to protect the wound.

114. A POSITA also would have recognized the benefits of using a semi-permeable material in a vented wound cover based on the teachings in Risk itself.

115. Risk teaches a vacuum bandage 14 that includes cover film 602. Ex. 1003 at 11:10-14. Risk describes the cover film as flexible and able to seal the wound where the negative pressure will be applied. *Id.* at 11:14-20. A side view of bandage 14 with cover film 602 is shown in Figure 9:

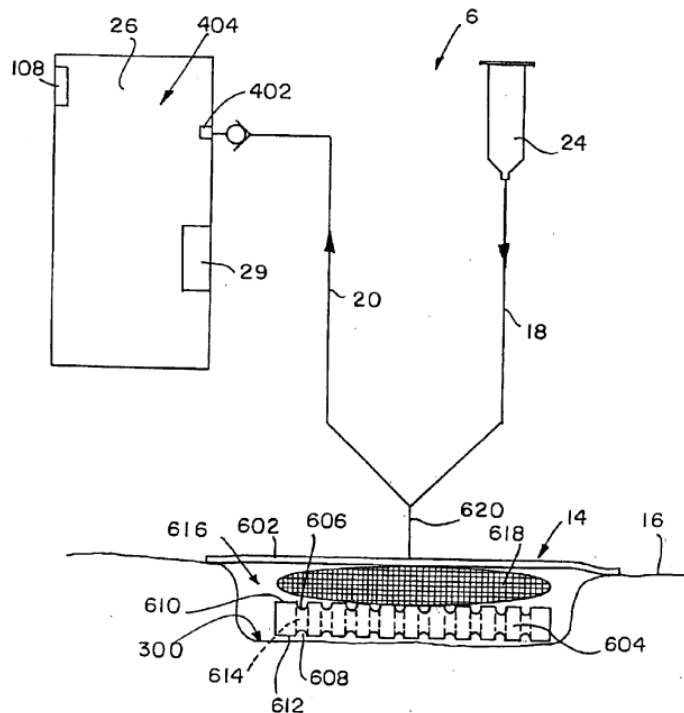


FIG. 9

Id. at Fig. 9. Regarding cover film 602, Risk states:

It is contemplated, however, the film 602 can be made from an occlusive or semi-occlusive material that allows water vapor to permeate there through, but otherwise protects wound 300 from the outside environment.

Id. at 11:16-20. A POSITA reading Risk would have understood that the cover film, which is permeable to water vapor, could also be permeable to ambient air. A POSITA reading Risk would also have understood that Risk's reference to protection of the wound from the outside environment to refer to protecting the

wound against bacteria and outside contaminants, as is suggested in the other prior art references I discuss in Part VIII.A.2.i above.

116. It is my opinion that (1) the prior art discussed in Part VIII.A.2.i above explain the motivation for using a semi-permeable cover material to limit the wound's exposure to bacteria and other contaminants, allow air to pass over the wound so it can breathe, and promote healing of the wound; (2) Risk explicitly suggested the use of a semi-occlusive wound cover to accomplish these purposes; and (3) Risk and the other prior art references teach that these semi-permeable wound covers are useful in NPWT systems.

117. Accordingly, it is my opinion that a POSITA would have been motivated to implement the NPWT system and vented wound cover of Risk with the semi-permeable cover material of Watson to attain the well-understood benefits of protecting the wound from ambient contaminants while still allowing the wound to breathe and heal. Ex. 1003 at 11:14-20; Ex. 1004 at 3:24-37.

iii. It would have been obvious to try combining the semi-permeable material of Watson with the vented wound cover of Risk.

118. It is also my opinion that it would have been obvious to try the use of Watson's semi-permeable cover material for the portion of Risk's wound cover that is vented in its NPWT system.

119. A POSITA would have understood that there are a limited number of predictable options for porosity of the material used to cover a wound with an NPWT system: non-permeable, semi-permeable, or open (completely-permeable).

120. Given that semi-permeable materials were well known in the art as one of a limited number of options to use in covering a wound, it would have been obvious for a POSITA to try implementing a semi-permeable material in conjunction with Risk's vented enclosure. As Risk and the other prior art disclose, prior to 2005, it was well-understood that semi-permeable covers controlled the airflow into a wound, restricted the amount of airborne bacteria and contaminants that could enter a wound, as well as allowed the wound to breathe, and promoted healing of the wound. This is especially the case here where NPWT systems are used to treat a wound and allowing the wound to be exposed to airborne bacteria, without limitation, could serve to inhibit the entire purpose of the system.

121. Thus, a POSITA looking at the vent within the wound cover of Risk would have found it obvious to try a semi-permeable cover material in conjunction with the vent—like that disclosed in Watson—to filter bacteria and other contaminants from the air, while still allowing the wound to breathe and allow ambient air to enter the system. Especially considering Risk's suggestion of a permeable bandage material to protect the wound from the outside environment, a

POSITA would have had good reason to try combining a semi-permeable material with the vented portion of Risk's disclosed cover. This is particularly true because a POSITA would have recognized the benefits of only venting a portion of the cover to be vented and semi-permeable—as discussed in Risk and Watson—to limit the amount of potential contamination and influx of too much ambient air to the wound.

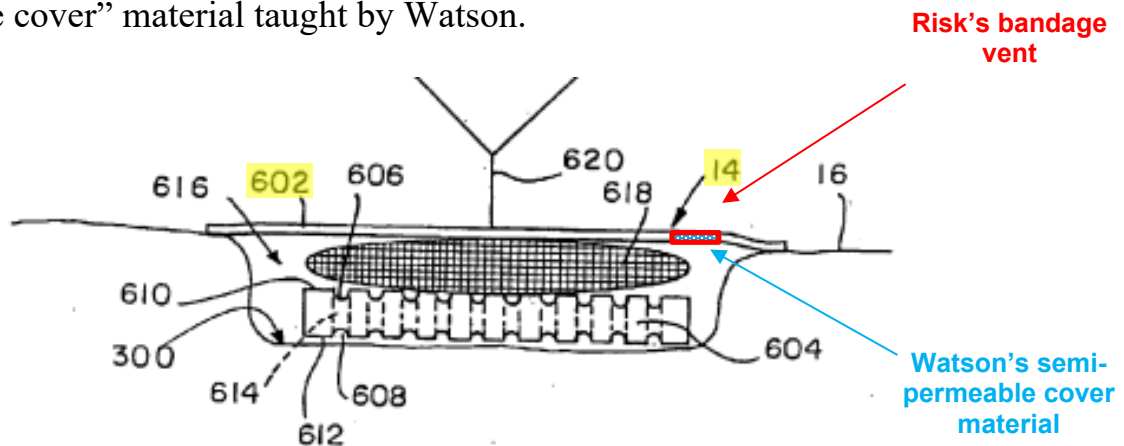
122. Furthermore, I believe it would have been obvious for a POSITA to try different types of known materials with different levels of permeability (such as leaving the vent open versus incorporating a semi-permeable material) in a system like Risk's. A POSITA would decide whether the wound would receive the desired amount of ambient air while limiting the amount of contaminants based on these design decisions.

123. As I explain below, a POSITA also would have had a reasonable expectation of success in trying the semi-permeable cover material of Watson for Risk's NPWT system and vented cover.

iv. A POSITA would have expected to succeed in combining Risk's vented wound cover with Watson's semi-permeable material.

124. It is my opinion that a POSITA would have expected success in modifying Risk's vented cover with a semi-permeable material as taught in Watson within the vented portion. Adding Watson's semi-permeable material to Risk's

vented cover could easily be accomplished by manufacturing the cover with a semi-permeable material (similar to the “semi-occlusive material” discussed in Risk) within the vented portion of the cover. Ex. 1003 at 18. To illustrate the combination of Risk and Watson, I added the “vent in communication with the atmosphere” to cover film 602 of bandage 14—as taught by Risk—and combined it with the “semi-permeable cover” material taught by Watson.



Ex. 1003 at Fig. 9 (bandage portion of figure excerpted and annotated to show modification of Risk with Watson’s semi-permeable cover material).

125. The annotated image above is a side view of the Risk bandage and wound site along with Watson’s semi-permeable cover material. The vent in Risk may be a hole on the top of the cover film 602 and bandage 14. With this combination, Watson’s semi-permeable cover material is embedded in cover film 602 within the vent (or hole) in the cover rendering that portion semi-permeable to ambient air. While a POSITA could also implement other possible configurations

that apply Watson's teaching of a semi-permeable cover material to Risk's NPWT system with vented cover, there would be an expectation of success for each. While the vent on Risk's bandage is not depicted in Risk, the particular location on the bandage does not impact my analysis.

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

3. Claim 1

127. Based on my review and for the reasons that follow, it is my opinion that claim 1 is obvious based on the teachings of Risk and Watson.

128. I have reproduced independent claim 1 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

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

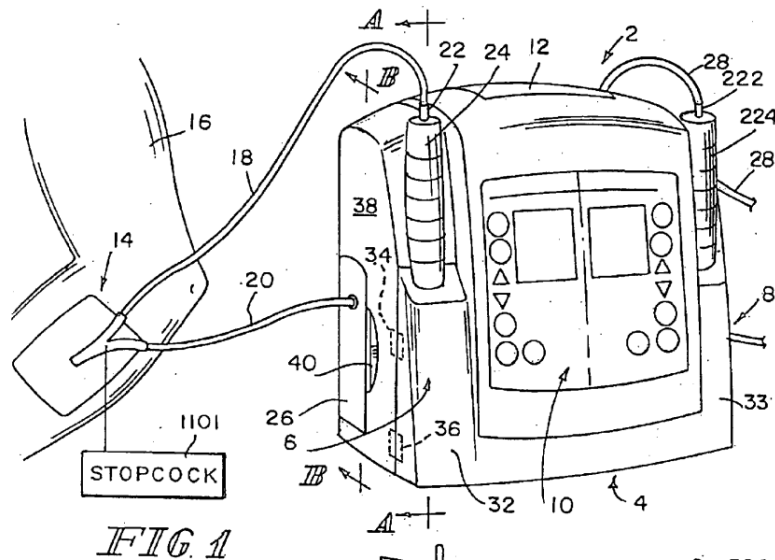
[a] an enclosure, a venting arrangement, a tube, a vacuum source,
and a controller:

[b] the enclosure being attachable to a periphery of the wound so as
to define a confined volume;

- [c] the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume;
- [d] the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said vacuum system upstream of the vacuum source;
- [e] the controller configured for controlling operation of the vacuum source while providing venting of the vacuum system via said venting arrangement to provide a desired level of said negative pressure in said confined volume.

i. Limitation 1[pre]: A vacuum system for applying negative pressure to a wound, the vacuum system comprising:

129. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 1, it is my opinion that Risk teaches a vacuum system for applying negative pressure to a wound. Risk teaches a “wound treatment apparatus [(2)]. . . to provide negative pressure through the vacuum wound bandage to the wound.” Ex. 1003 at 1:44-48. The wound treatment apparatus 2 is shown in Figure 1:



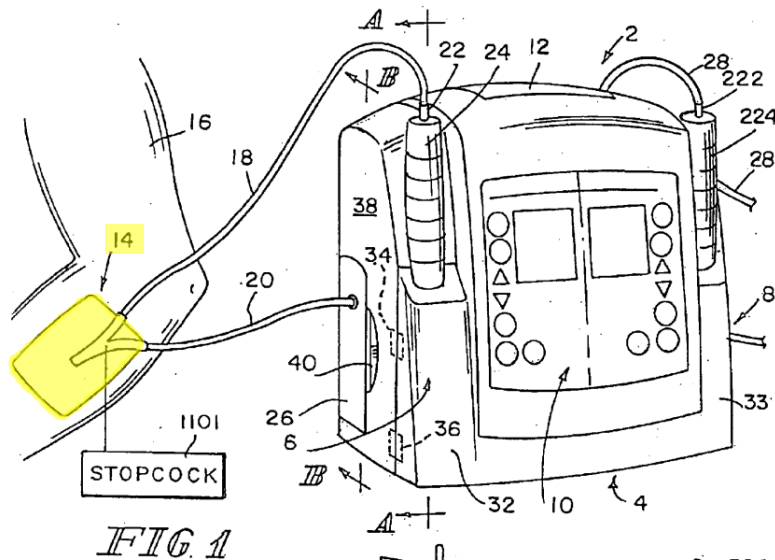
Id. at Fig. 1.

130. Accordingly, in my opinion, Risk teaches limitation 1[pre].

ii. Limitation 1[a]: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller:

131. In my opinion, Risk teaches element 1[a] because Risk teaches a wound treatment apparatus 2 that comprises an enclosure (bandage 14), a venting arrangement on the wound bandage, a tube (evacuating tube/line 20), a “vacuum source” 110, and a “controller” 50.

132. **Enclosure:** As shown in Figure 1, Risk teaches an enclosure that covers the wound being treated.



Id. at Fig. 1 (highlighting added to identify bandage 14). Regarding Figure 1, Risk states: “FIG. 1 also shows wound treatment system 6 coupled to a bandage 14 attached to a patient’s leg 16.” *Id.* at 4:30-32. Additionally, Risk teaches that the bandage 14 is a “vacuum bandage” that has a flexible cover film 602 that seals the wound (*id.* at 11:14-20), as shown in Figure 9:

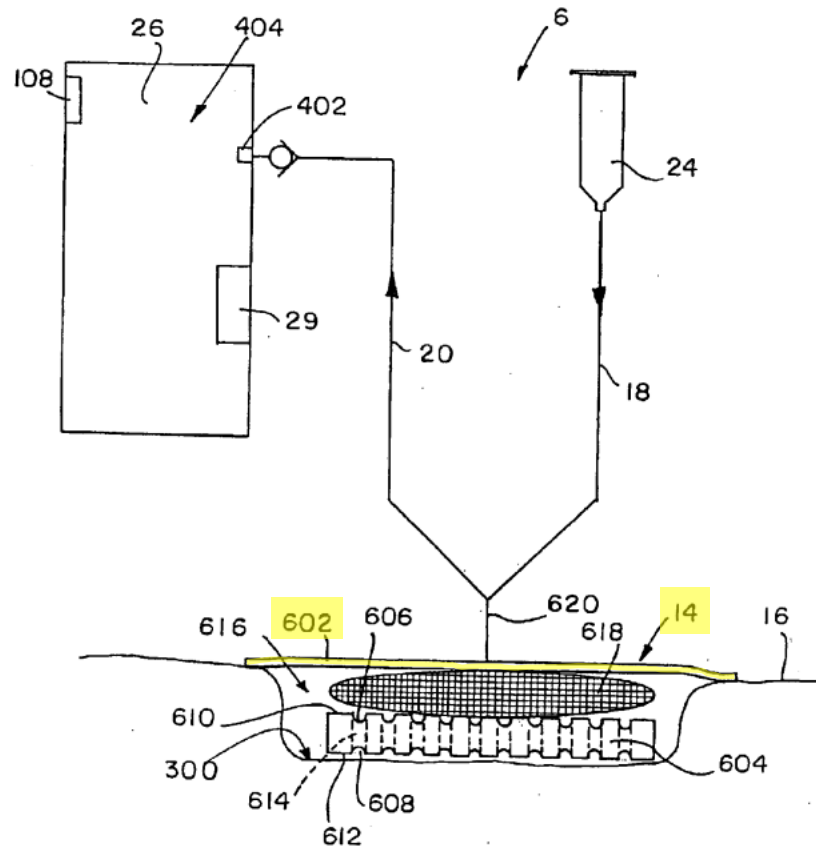


FIG. 9

Id. at Fig. 9 (highlighting added to identify bandage 14 with cover film 602). It is my opinion that the bandage 14, comprising a cover film 602, that seals the wound teaches the claimed “enclosure”.

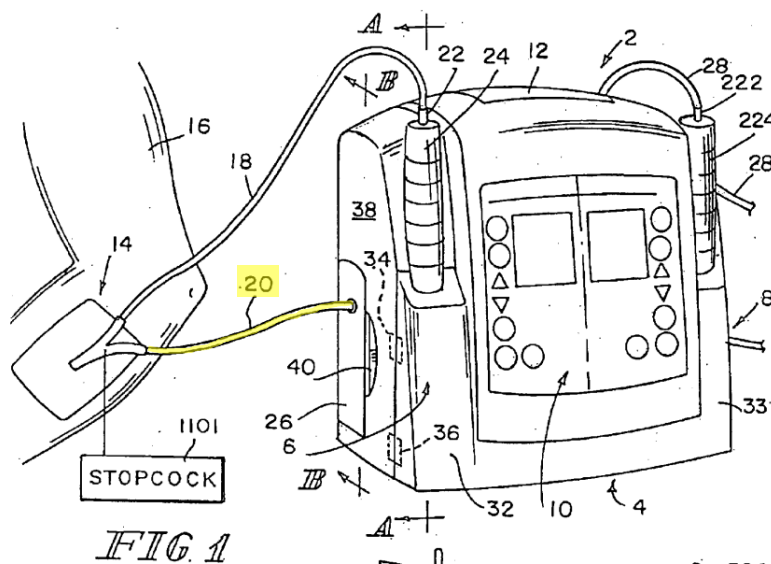
133. **Venting Arrangement:** Risk teaches a “venting arrangement” located on the aforementioned bandage 14. Risk discloses, in an embodiment, that “bandage 14 has a vent in communication with atmosphere, and air enters interior region 866 through bandage 14, line 20, and inlet port 850.” *Id.* at 14:63 – 15:1. Although not

specifically depicted in any of the figures, Risk refers to this as the “bandage vent.”

Id. at 15:1-5.

134. I understand that the '534 Patent teaches a “bleeding orifice” on the enclosure itself or adjacent to the enclosure on the tube. Ex. 1001 at 4:26-29. A POSITA would have understood the disclosed “bandage vent” of Risk to be a “venting arrangement” as that term is used in the '534 Patent. A POSITA would have understood the “bandage vent” taught in Risk is an orifice located on the wound enclosure, just as the recited “venting arrangement.” It is my opinion that Risk’s “bandage vent” is a “venting arrangement.”

135. **Tube:** As shown in Figure 1, Risk teaches a tube through its disclosure of evacuating tube 20 which connects the enclosure to the vacuum source.



Ex. 1003 at Fig. 1 (highlighted to identify evacuating tube 20). Evacuating tube 20 is “coupled to both bandage 14 and system 6.” *Id.* at 4:32-34. Risk teaches that evacuating tube 20—which is also synonymously referred to as evacuating line 20—provides suction to the bandage and removes fluid and exudate from the wound. *Id.* at 4:38-40, 14:1-4. In my opinion, Risk teaches a “tube”.

136. **Vacuum Source:** As shown in Figure 32, Risk discloses a “vacuum source”.

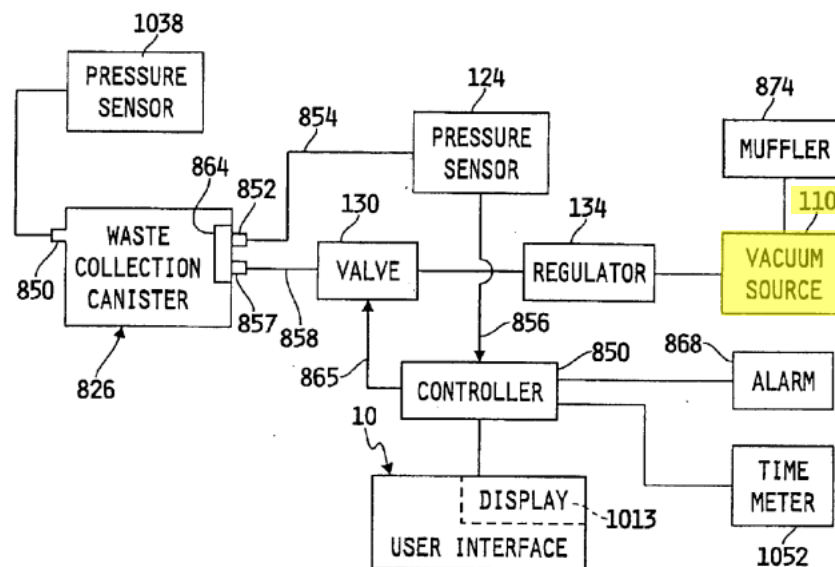


FIG. 32

Id. at Fig. 32 (highlighting added to identify “vacuum source 110”). Risk teaches that “Vacuum pump 110 creates the negative pressure that is present through canister 26” and is ultimately applied to the bandage. *Id.* at 7:31-32, 8:58-61. Risk interchangeably refers to “vacuum pump” and “vacuum source” in the patent. *Id.* at

7:31-32, 8:13-15, 8:58-61, 14:15, 14:19, Figs. 27 and 32. In my opinion, Risk teaches a “vacuum source.”

137. **Controller:** As shown in Figure 32, Risk teaches a “controller”:

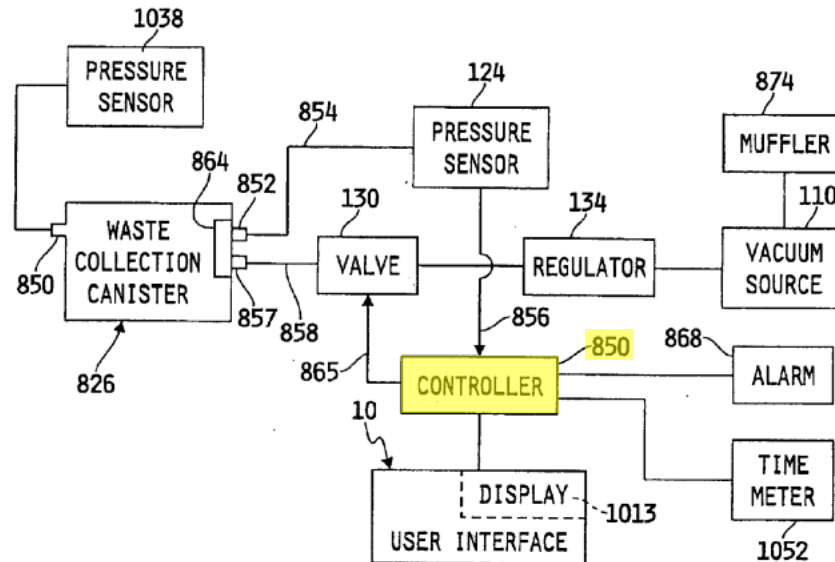


FIG. 32

Id. at Fig. 32 (highlighted to identify controller 850). Specifically, Risk teaches:

A controller 50 is provided in housing 4 and is an electronic control unit that controls apparatus 2. Controller 50 receives user input from and provides feedback to user interface 10 through lines 52, 54, respectively.

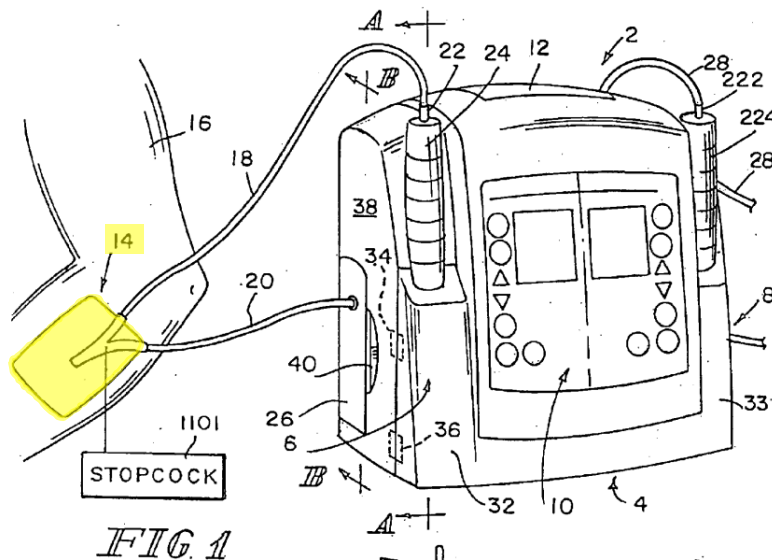
Id. at 5:22-25. Additionally, Risk teaches that the controller controls the various aspects of the NPWT system to ultimately control the level of vacuum pressure being applied to the bandage and wound. *Id.* at 14:35-37. It is my opinion that Risk teaches a “controller”.

138. Accordingly, in my opinion Risk teaches limitation 1[a].

iii. Limitation 1[b]: the enclosure being attachable to a periphery of the wound so as to define a confined volume;

139. In my opinion, Risk teaches limitation 1[b] because Risk teaches an enclosure (bandage 14) that is attachable to a periphery of the wound and defines a confined volume.

140. As explained with respect to limitation 1[a], Risk teaches a wound bandage 14 which corresponds to the claimed “enclosure”. As shown in Figure 1 and taught by Risk, “wound treatment 6 [is] coupled to a bandage 14 attached to a patient’s leg”:



Id. at Fig. 1 (highlighting added to identify bandage 14); *id.* at 4:30-34.

141. As shown in Figure 9 below, bandage 14 is attachable to the periphery of a wound and defines a confined volume therein.

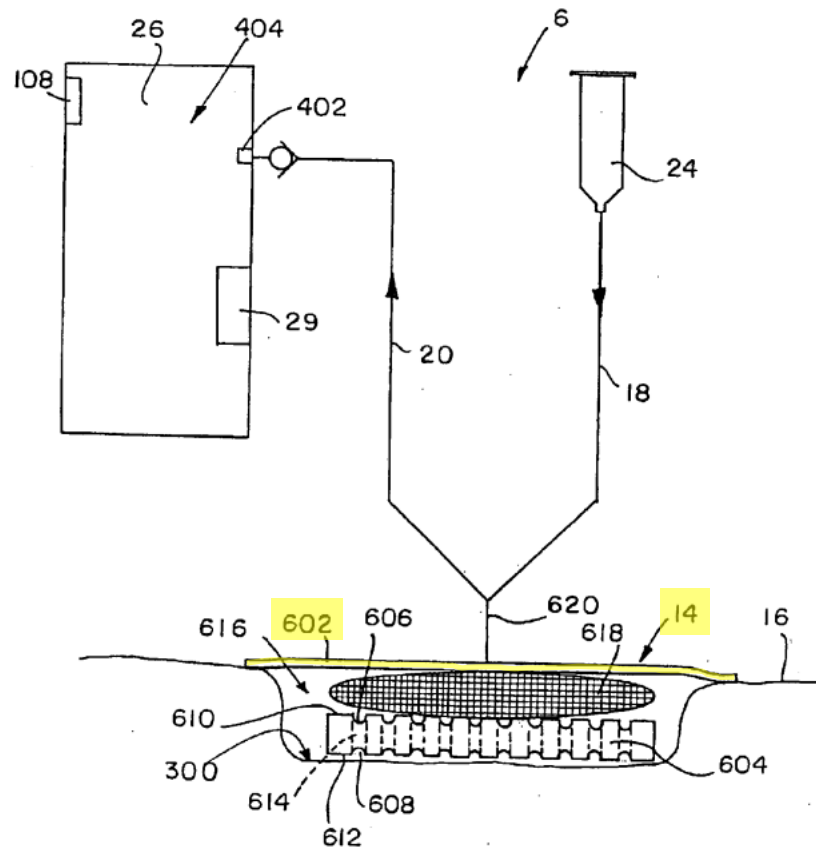


FIG. 9

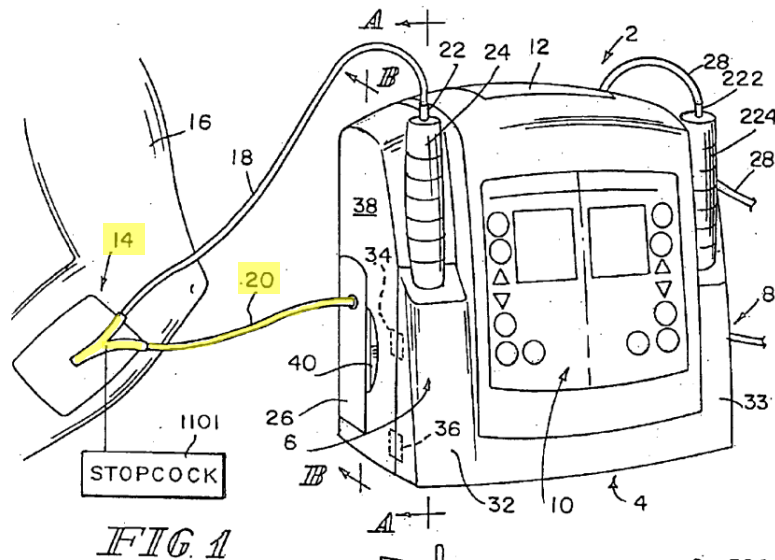
Id. at Fig. 9 (highlighting added to identify bandage 14 with cover film 602). Risk explains: “Bandage 14 comprises a cover film 602, illustratively a flexible cover that seals wound 300 about its outer perimeter.” *Id.* at 11:14-20. Risk also teaches that the bandage “is designed to provide a protective environment around wound”. *Id.* at 10:47-48.

142. Thus, bandage 14 is attachable to a wound and defines a confined volume by forming an operative seal around the perimeter of the wound. It is my opinion that Risk teaches limitation 1[b].

iv. Limitation 1[c]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume;

143. In my opinion, Risk teaches limitation 1[c]. Risk teaches that bandage 14 (corresponding to the claimed “enclosure”) is connected to evacuating tube 20 so that negative pressure can be selectively created at the wound.

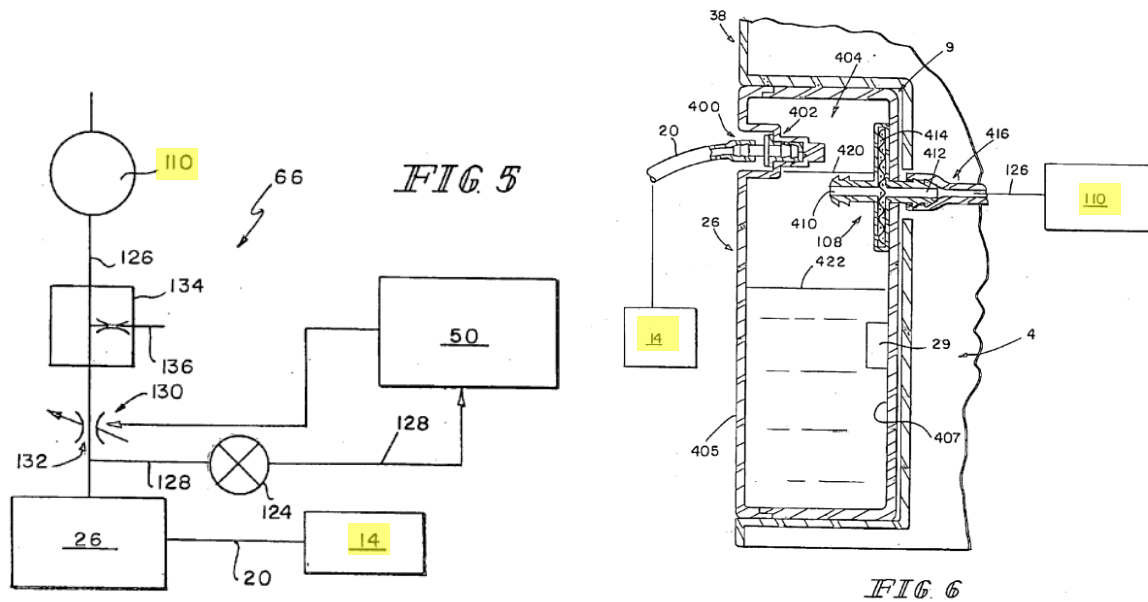
144. Risk teaches the use of two tubes: one to potentially dispense fluid to the wound and one to apply negative pressure and remove exudate from the wound, which is collected in a waste canister. Risk specifically teaches that both tubes, including evacuating tube 20 (which corresponds to the claimed “tube”) are coupled to the bandage and vacuum. Risk states: “Dispensing and evacuating tubes, 18, 20 are coupled to both bandage 14 and system 6.” *Id.* at 4:32-34. A POSITA would understand that evacuating line 20 being “coupled” to bandage 14 necessarily requires a connectable outlet. Additionally, the connection between the bandage 14 (the claimed “enclosure”) and the vacuum source via evacuating tube 20 is shown in Figure 1:



Id. at Fig. 1 (highlighted to identify evacuating tube 20 that connects the bandage 14 to the vacuum system). Risk also teaches this connection: “Vacuum evacuating subsystem 66 cooperates with bandage 314, similar to bandage 14, to draw the fluid and exudate from the surface of wound 300, and collect same into waste canister”.

Id. at 10:47-57.

145. As shown in Figure 1, the evacuating tube is connected to a waste canister, where exudate is deposited, which is in turn connected to the vacuum source 110. This is depicted in Figures 5 and 6 below:



Id. at Figs. 5 and 6 (highlighting added). As noted above and shown in Figures 5 and 6, Risk teaches that bandage 14 is connected canister 26 via tube 20 and canister 26 is connected to vacuum source 110 via connector 416. Specifically, Risk states “Connector 416 is in communication with line 126 and ultimately with pump 110.” *Id.* at 9:66 – 10:11. In my opinion, a POSITA would have understood that vacuum source 110 is operatively connected to bandage 14 because vacuum source 110 applies suction through canister 26 and tube 20 to the volume underneath bandage 14 to remove exudate from the wound which is deposited into canister 26.

146. Limitation 1[c] does not recite a direct connection between the enclosure and vacuum source. As such, a POSITA would have understood that the invention of Risk teaches an operative or fluidic connection between the bandage

and vacuum source via tube 20. Moreover, Risk teaches that this connection provides the application of negative pressure to the wound volume underneath bandage 14. *Id.* at 1:44-48 (“provid[ing] negative pressure through the vacuum wound bandage to the wound”).

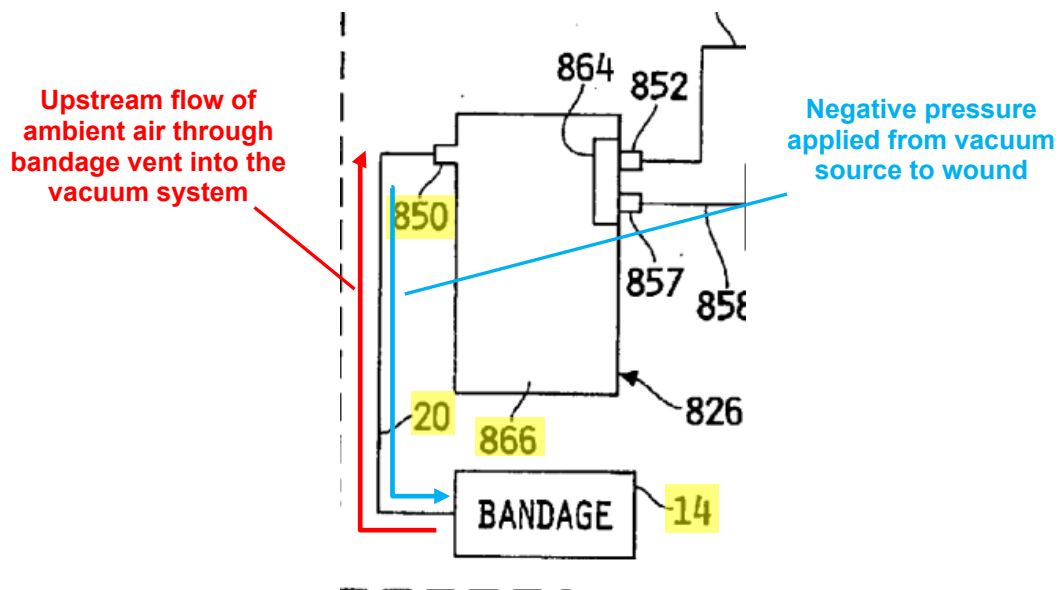
147. Risk also teaches that negative pressure may be “selectively” created at the wound. For example, Risk teaches that a caregiver using the disclosed NPWT system “can set the level of negative pressure” and “choose between continuous, intermittent (profile), and no negative pressure modes.” *Id.* at 12:8-17.

148. It is my opinion that Risk teaches limitation 1[c].

- v. **Limitation 1[d]: the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said vacuum system upstream of the vacuum source;**

149. In my opinion, the combination of Risk and Watson teaches limitation 1[d].

150. As previously discussed regarding limitation 1[a], Risk teaches a “venting arrangement” (bandage vent). Risk teaches that its bandage vent is “in communication with atmosphere, and air enters interior region 866 through bandage 14, line 20, and inlet port 850.” *Id.* at 14:63 – 15:1. This air flow is depicted in Figure 27 below, which I have excerpted and annotated below to identify the airflow:



Id. at Fig. 27 (excerpted and annotated). The entire vacuum system including the vacuum source 110, as depicted in Figure 27 from which the above image is excerpted, is shown below:

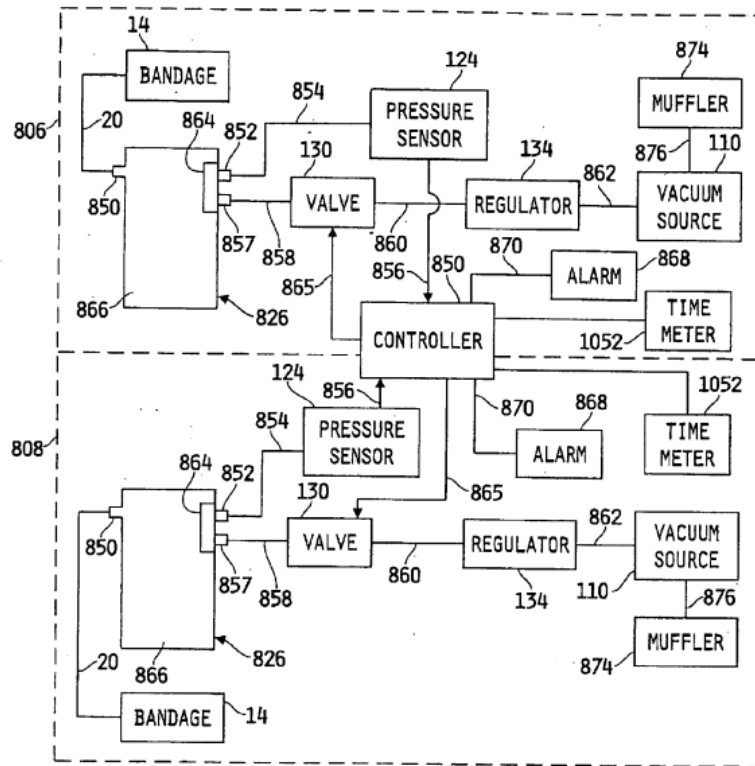


FIG. 27

Id. at Fig. 27. A POSITA would have understood that ambient air entering the bandage through the bandage vent and flowing through tube 20 into the vacuum source is necessarily upstream of the vacuum source.

151. Thus, in my opinion, Risk teaches a “venting arrangement” that allows for ambient air to enter into the vacuum system upstream of the vacuum source. Additionally, in my opinion, a POSITA would have been highly motivated to combine the bandage vent of Risk with the semi-permeable material as taught by Watson, as I explain above in Part VIII.A.2.

152. Watson teaches “a semi-permeable” cover material that “allows the wound to breathe while protecting the wound from undesirable substances such as bacteria, viruses, or fluids.” *Id.* at 1:16-24. The semi-permeable cover “allows air to pass through it” while preventing the influx of certain bacteria and other airborne contaminants. *Id.* at 3:24-37. The semi-permeable cover necessarily restricts the flow of air through it, thereby controlling the flow of ambient air that enters into the wound area.

153. In my opinion, Watson’s semi-permeable cover material is a “flow restrictor” in the context of the ’534 Patent under any potential, plausible construction of that term. The ’534 Patent specification recites: “flow restrictors may be used to provide for controlled flow of ambient air into the enclosure or into the outlet. For instance, 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.” Ex. 1001 at 4:41-45. In my opinion, the semi-permeable material on a wound cover is akin to open cell foam that restricts and controls the flow of ambient air into the wound and, ultimately, the vacuum system. Regardless of how the term “flow restrictor” is ultimately interpreted, however, Watson’s semi-permeable cover material constitutes a “flow restrictor.”

154. As I discussed in Part VIII.A.2 above, a POSITA would have been motivated to combine Watson's semi-permeable cover material with the vented portion of Risk's bandage 14 to restrict and control the flow of ambient air into the wound, and ultimately into the vacuum system, to promote healing and protect the wound from airborne bacteria and contaminants.

155. Therefore, in my opinion, Risk in view of Watson teaches and renders obvious limitation 1[d].

vi. Limitation 1[e]: the controller configured for controlling operation of the vacuum source while providing venting of the vacuum system via said venting arrangement to provide a desired level of said negative pressure in said confined volume.

156. In my opinion, Risk teaches limitation 1[e]. As previously explained, Risk teaches a "controller" and "venting arrangement". Risk teaches that "controller 50 is provided in housing 4 and is an electronic control unit that controls apparatus 2." Ex. 1003 at 5:22-25. The controller is depicted in Figure 32 below:

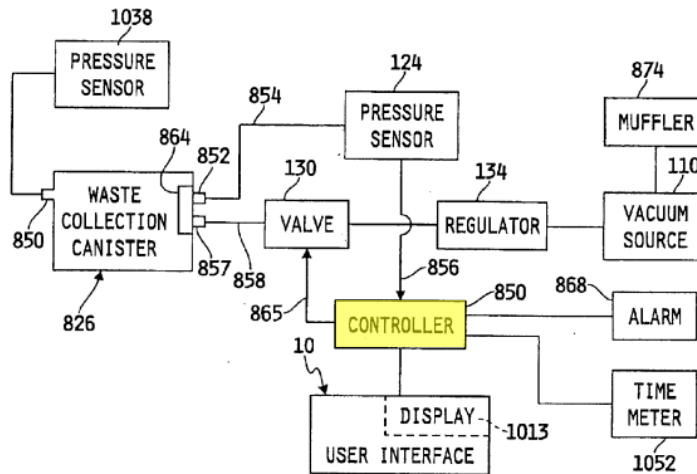


FIG. 32

Id. at Fig. 32 (highlighting added to identify controller). Risk further teaches that “Controller 50 also monitors the status of all various sensors, and provides input for the valves and motors”. *Id.* at 5:28-30. The vacuum pump 110 that applies negative pressure to the wound contains one such motor—specifically, Risk teaches “vacuum pump 110 is mounted on the end of a single 12VDC brushless motor 138 to drive the pump”. *Id.* at 8:13-20. Thus, Risk teaches that the controller is configured to control operation of the vacuum source.

157. As explained in limitation 1[d] above, Risk also teaches that the bandage vent provides venting of the vacuum system to control the negative pressure within the wound volume. To the extent it is not explicitly stated in Risk that the controller controls the operation of the vacuum source while the system is vented, it

would have been obvious to a POSITA that the vent is constantly venting the system, while the pump is on and off. For example, the bandage vent disclosed in Risk is always open to the atmosphere thereby allowing ambient air to enter the enclosure at all times. Thus, a POSITA would have understood the NPWT system disclosed in Risk to include venting to the atmosphere at all times during operation of the system.

158. Accordingly, it is my opinion that Risk teaches limitation 1[e].

159. For the reasons discussed above, therefore, it is my opinion that the combination of Risk and Watson teaches and renders obvious all the limitations of claim 1 of the '534 Patent.

4. Claim 2: The vacuum system according to claim 1, wherein said flow restrictor is provided in any one of the enclosure or the tube.

160. In my opinion, the combination of Risk and Watson teaches and renders obvious claim 2. As explained above, the combination of Risk and Watson teaches the vacuum system of claim 1. In my opinion, the combination of Risk and Watson also teaches the additional limitation in claim 2 because, as explained above, Risk teaches a bandage vent located on the enclosure and Watson teaches a semi-permeable material for the enclosure that restricts flow of ambient air into the enclosure. Thus, Watson teaches a flow restrictor which is provided in the enclosure.

161. As I explained regarding limitation 1[d], it is my opinion that Watson teaches a flow restrictor through its disclosure of a semi-permeable cover material that restricts the flow of air into the wound. As I also explained in Part VIII.A.2, a POSITA would be highly motivated to combine the semi-permeable material of Watson with the vented portion of bandage 14 as taught by Risk.

162. Accordingly, it is my opinion that Risk in view of Watson teaches and renders obvious claim 2.

5. Claim 3: The vacuum system according to claim 1, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.

163. It is my opinion that the combination of Risk and Watson teaches and renders obvious claim 3. For the reasons stated above, the combination of Risk and Watson teaches the vacuum system of claim 1. In my opinion, Risk also teaches the additional limitations in claim 3 because Risk teaches a sensor for *enabling* determination of the level of negative pressure in the confined volume at the wound.

164. As shown in Figure 32, Risk teaches a “pressure sensor”:

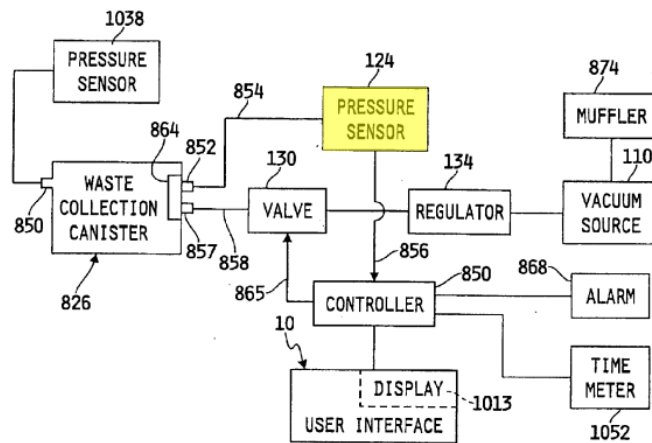


FIG. 32

Ex. 1003 at Fig. 32 (highlighting added). Specifically, Risk teaches the pressure sensor 124 is a “vacuum pressure transducer 124” that “measures the negative pressure that is present through canister 26.” *Id.* at 7:33-39. Risk also teaches that the vacuum pump 110 creates the negative pressure that is present through the canister 26 and underneath bandage 14 at the wound. *Id.* at 1:44-48, 7:30-31, 14:15-18.

165. The vacuum pressure transducer 124 conveys the sensed pressure within the canister to the controller, which “monitors the negative pressure by comparing the measured value from the transducer 124 with the caregiver-defined value entered into controller 50 through user interface 10.” *Id.* at 7:35-42. Risk teaches that if the controller determines the amount of negative pressure sensed by pressure transducer 124 is more or less than the caregiver-defined level, it dilates or

constricts the proportional valve orifice 132 between fully open and fully closed to increase or decrease the amount of pressure. *Id.* at 7:43-53. A POSITA would have understood that the measured level of negative pressure within canister 26 enables the controller to determine whether the level of negative pressure at the wound is more, less, or equivalent to the desired amount of negative pressure. Thus, pressure transducer 124 enables the determination of a level of negative pressure in said confined volume.

166. Accordingly, it is my opinion that the combination of Risk and Watson teaches and renders obvious claim 3.

6. Claim 4: The vacuum system according to claim 1, further comprising a waste container in fluid communication with said vacuum source.

167. In my opinion, the combination of Risk and Watson teaches and renders obvious claim 4. For the reasons stated above, the combination of Risk and Watson teaches the vacuum system of claim 1. In my opinion, Risk also teaches the additional limitations in claim 4 because Risk teaches a waste canister 26 that collects exudate removed from the wound and is connected to the vacuum source 110. Risk teaches “fluid and exudate from wound 300 are drawn from bandage 14 through evacuating tube 20 and into a waste canister 26 where it is collected.” Ex. 1003 at 4:38-40.

168. As shown in Figure 6 below, waste canister 26 is in fluid communication with vacuum source 110 via line 126:

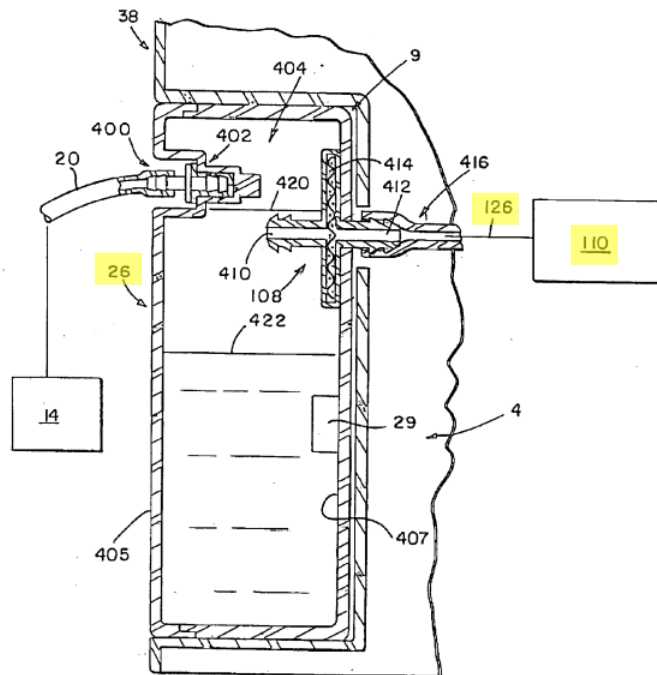


FIG. 6

Id. at Fig. 6 (highlighting added). Regarding the specific connection between waste canister 26 and vacuum source 110 (as shown in Figure 6 above), Risk discloses:

Filter 108 in canister 26 is shown having an inlet 410 provided in space 404 and an outlet 412 coupled to connector 416 with a barrier of hydrophobic material 414 provided there between. . . . Outlet 412 of filter 108 is in communication with connector 416. . . . Connector 416 is in communication with line 126 and ultimately with pump 110.

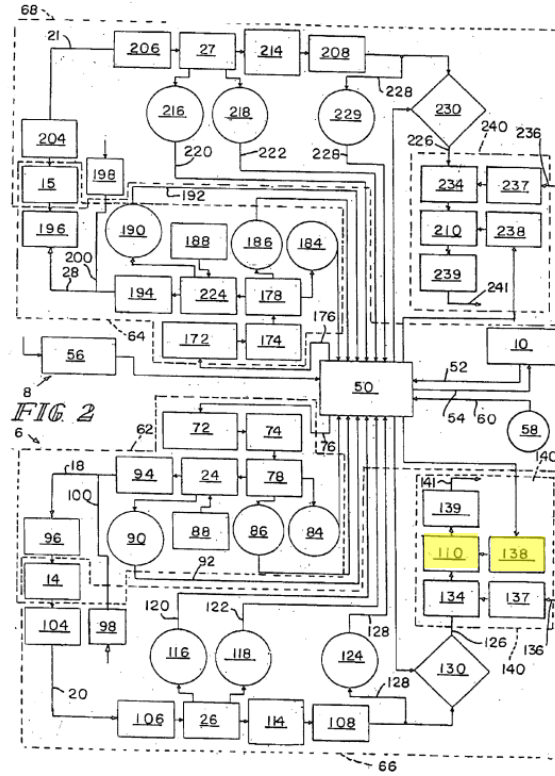
Id. at 9:66 – 10:11. Thus, Risk teaches that waste canister 26 is in fluid communication with vacuum source 110.

169. Accordingly, it is my opinion that Risk in view of Watson teaches and renders obvious claim 4.

7. Claim 5: The vacuum system according to claim 1, wherein said vacuum source comprises a vacuum pump driven by a motor.

170. In my opinion, the combination of Risk and Watson teaches and renders obvious claim 5. For the reasons stated above, the combination of Risk and Watson teaches the vacuum system of claim 1. In my opinion, Risk also teaches the additional limitations in claim 5 because Risk teaches vacuum pump 110 is driven by a motor.

171. As I explained with respect to claim 1, Risk teaches “vacuum source 110” which is a vacuum pump. Risk teaches that “Vacuum pump 110 is, illustratively, a diaphragm-type compressor that flows about two liters per minute at 250-mmHg (4.83-PSIG) vacuum. Illustratively, **vacuum pump 110 is mounted on the end of a single 12VDC brushless motor 138 to drive the pump.**” *Id.* at 8:13-17 (emphasis added). Vacuum pump 110 and motor 138 are depicted in the block diagram of Risk’s NPWT system as shown in Figure 2:



Id. at Fig. 2 (highlighting added).

172. Accordingly, it is my opinion that the combination of Risk and Watson teaches and renders obvious claim 5.

8. Claim 9: The vacuum system according to claim 1, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating.

173. In my opinion, the combination of Risk and Watson teaches and renders obvious claim 9. For the reasons stated above, the combination of Risk and Watson teaches the vacuum system of claim 1. In my opinion, Risk also teaches the additional limitations in claim 9.

174. As I explained with respect to claim 1, Risk teaches a vent on bandage 14 covering the wound, which allows ambient air to enter the volume under the bandage. *Id.* at 14:63 – 15:1. A POSITA would have understood that the bandage vent taught by Risk would allow ambient air to enter the volume beneath the bandage both when the vacuum pump is turned on and operating, and when it is turned off. A POSITA would have understood that the bandage vent is open to the atmosphere and, as such, when the pump is turned off and negative pressure is no longer being applied to the wound ambient air still enters the enclosure. A POSITA would have recognized that when the only fluid exchange through the bandage 14 is ambient air entering through the bandage vent, ambient pressure would be restored in the confined volume under bandage 14. In addition, Risk teaches that the pressure under the bandage is atmospheric when valve 130 is fully closed, blocking the communication between vacuum source 110 and the bandage. This is effectively the same as not operating the vacuum system. *Id.* at 18:51-55.

175. Accordingly, it is my opinion that the combination of Risk and Watson teaches and renders obvious claim 9.

9. Claim 10: The vacuum system according to claim 1, wherein said venting arrangement comprises at least one of: one or more bleeding holes, a porous body, an orifice.

176. In my opinion, the combination of Risk and Watson teaches and renders obvious claim 10. For the reasons stated above, the combination of Risk and Watson teaches the vacuum system of claim 1. In my opinion, Risk also teaches the additional limitations in claim 10 because the bandage vent in Risk comprises an orifice.

177. As I explained regarding claim 1, Risk teaches a vent on bandage 14 that is open to the atmosphere. A POSITA would have understood the disclosed “vent” to be an orifice, or hole, that allows ambient air into the wound.

178. I note that claim 10, by virtue of its dependence on claim 1, requires that the venting arrangement comprises a flow restrictor and also comprises a bleeding hole, porous body or an orifice. It isn’t clear to me whether the bleeding hole or porous body recited in claim 10 is also intended to be a flow restrictor or some other structure. As I explained regarding claim 1, however, the combination of Risk and Watson teaches the venting arrangement of Risk comprises the semi-permeable cover material of Watson as a flow restrictor. A POSITA would have understood the semi-permeable cover material as taught by Watson to be a “porous body” in connection with the bandage vent taught by Risk.

179. Accordingly, it is my opinion that the combination of Risk and Watson teaches and renders obvious claim 10.

10. Claim 19

180. Based on my review and for the reasons that follow, it is my opinion that claim 19 is obvious based on the teachings of Risk and Watson.

181. I have reproduced independent claim 19 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

19[pre] A method for applying negative pressure to a wound, comprising:

[a] providing a vacuum system comprising at least: an enclosure, a venting arrangement, a tube, and a vacuum source:

[b] the enclosure being attachable to a periphery of the wound so as to define a confined volume;

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

[d] the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a

controlled flow of ambient air into said vacuum system upstream
of the vacuum source;

[e] controlling operation of the vacuum source while the vacuum
system is being vented via the venting arrangement to thereby
provide a desired level of said negative pressure in said confined
volume.

**i. Limitation 19[pre]: A method for applying negative
pressure to a wound, comprising:**

182. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 19, it is my opinion that Risk teaches a method for applying negative pressure to a wound. As I explained in limitation 1[pre] above, Risk teaches a negative wound pressure treatment apparatus. Additionally, Risk teaches a method of operating that device. For example, Risk teaches how a caregiver can operate the NPWT device:

Illustratively, the caregiver may activate system 6, by means previously described, to draw exudate from wound 300 through channels 606, 608 and apertures 614 of bandage member 604, packing 618 and film 602, through splitter tube 620 connected to evacuating tube 20, and deposit in canister 26. The negative pressure applied to wound 300 created by pump 110 can be applied for a period of time as determined by the caregiver.

Ex. 1003 at 11:36-43. By fully describing the manner by which the taught NPWT device functions and is operated, Risk teaches a method for applying negative pressure to the wound.

183. Accordingly, it is my opinion that Risk teaches limitation 19[pre].

ii. Limitation 19[a]: (a) providing a vacuum system comprising at least: an enclosure, a venting arrangement, a tube, and a vacuum source:

184. Limitation 19[a] is substantively identical to limitations 1[pre] and 1[a].

The analysis and my discussion of limitations 1[pre] and 1[a] is hereby incorporated by reference.

185. Accordingly, it is my opinion that Risk teaches limitation 19[a].

iii. Limitation 19[b]: the enclosure being attachable to a periphery of the wound so as to define a confined volume;

186. Limitation 19[b] is identical to limitation 1[b]. The analysis and my discussion of limitation 1[b] is hereby incorporated by reference.

187. Accordingly, it is my opinion that Risk teaches limitation 19[b].

iv. Limitation 19[c]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume;

188. Limitation 19[c] is identical to limitation 1[c]. The analysis and my discussion of limitation 1[c] is hereby incorporated by reference.

189. Accordingly, it is my opinion that Risk teaches limitation 19[c].

- v. **Limitation 19[d]: the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said system upstream of the vacuum source;**

190. Limitation 19[d] is substantively identical to limitation 1[d]. The analysis and my discussion of limitation 1[b] is hereby incorporated by reference.

191. Accordingly, it is my opinion that Risk in view of Watson teaches and renders obvious limitation 19[d].

- vi. **Limitation 19[e]: (b) controlling operation of the vacuum source while the vacuum system is being vented via the venting arrangement to thereby provide a desired level of said negative pressure in said confined volume.**

192. Limitation 19[e] is substantively identical to limitation 1[e]. The analysis and my discussion of limitation 1[e] is hereby incorporated by reference.

193. Accordingly, it is my opinion that Risk teaches limitation 19[e].

194. Thus, it is my opinion that the combination of Risk and Watson teaches and renders obvious independent claim 19.

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

195. In my opinion, the combination of Risk and Watson teaches and renders obvious claim 22. For the reasons stated above, the combination of Risk and Watson

teaches the method of claim 19. In my opinion, Risk also teaches the additional limitations in claim 22. Claim 22 is substantively identical to claim 10. The analysis and my discussion of claim 10 is hereby incorporated by reference.

196. Accordingly, it is my opinion that the combination of Risk and Watson teaches and renders obvious claim 22.

B. Ground 2: Analysis of Claims 6-8, 20, and 21 Based on Risk in view of Watson and Lina

197. In my opinion, claims 6-8, 20, and 21 of the '534 Patent are invalid because they are obvious over the teachings of Risk in view of Watson in further view of Lina, as detailed below.

1. Overview of the Combination of Risk, Watson, and Lina

198. As explained in Ground 1, the combination of Risk and Watson teach and render obvious the limitations of independent claims 1 and 19, as well as certain dependent claims. Also, as explained in Ground 1, Risk teaches a controller 50 that operates the pump in connection with various sensors to provide a desired amount of negative pressure at the wound. Risk, however, does not teach that the controller controls the operation of the pump motor, including the current or voltage of the motor, to provide a desired level of negative pressure at the wound. Instead, when the controller in Risk determines the amount of negative pressure needs to be adjusted, it controls flow orifice 132, which is part of proportional valve 130, which

“selectively dilates or constricts, thereby controlling the negative pressure level through sub-system 66.” Ex. 1003 at 7:43-51.

199. Prior to July 24, 2005, POSITAs were well aware that an NPWT controller could be configured to control the pump vacuum level via the motor speed, instead of controlling a valve and flow orifice, to increase or decrease the amount of negative pressure being applied. Lina provides an example of this well-known practice. As explained in Lina, which teaches a NPWT device similar to that of Risk, “Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83.” Ex. 1005 at 13:20-21.

200. As I set forth below, a POSITA would have been motivated to combine Risk’s NPWT system with a controller that directly controls the voltage, and hence the speed, of the pump motor to selectively apply a desired negative pressure, such as the microcontroller disclosed in Lina. Additionally, as explained below, a POSITA would have found it obvious to modify the controller of Risk to control the pump speed based on the teachings of Lina.

2. Motivation to Combine and Expectation of Success (Risk in view of Watson and Lina)

201. I understand Risk, Watson, and Lina are considered to be analogous art as they are all within the same field of endeavor—NPWT systems. In particular, Risk and Lina both teach NPWT systems that use a controller to operate the system

and further teach the use of electric motors for the vacuum pump. In my opinion, a POSITA would have been motivated to combine the teachings of Risk and Lina, as it relates to the controller and vacuum pump motor, for several reasons. While I do not discuss Watson as part of the motivation to combine, in my opinion the inclusion of Watson in this proposed combination would not alter the motivations discussed below.

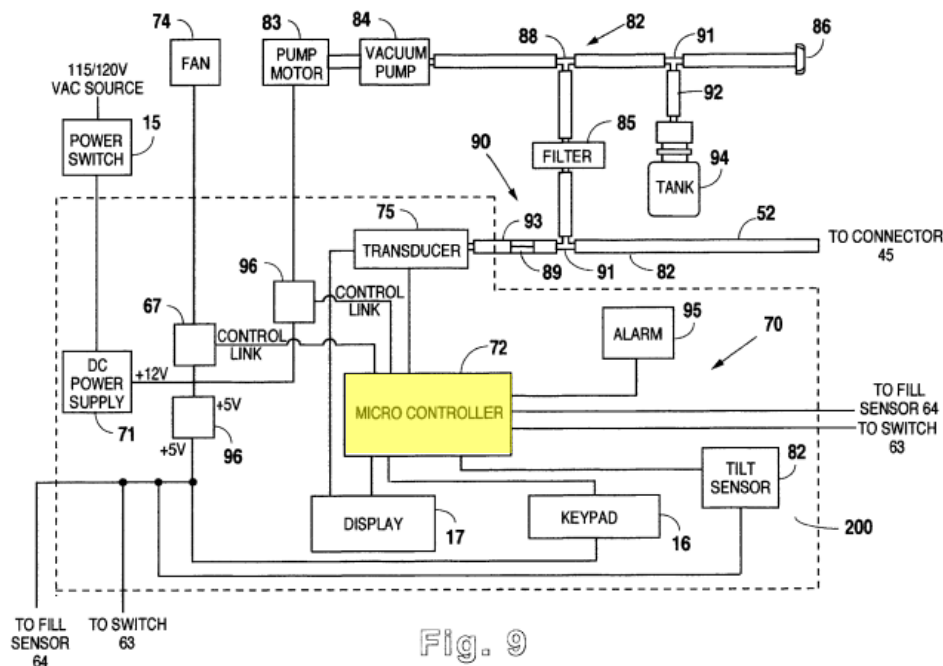
i. Modifying the controller of Risk to control the pump's motor based on the teachings of Lina would have been using well-established prior art elements according to known methods to yield predictable results.

202. Prior to July 24, 2005, it was well known and well understood that a controller could be used to control the voltage, and hence the speed, of a pump motor in NPWT systems. Controllers, such as the one taught in Lina, were used in conjunction with NPWT systems at least by the 1990s. Lina, which was filed in 2000, teaches a NPWT system, similar to the one taught by Risk, which includes a microcontroller that controls the vacuum pump's motor to variably adjust the negative pressure being applied to the wound. Ex. 1005 at 13:35-43. Specifically, Lina teaches:

Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83. . . . After receiving the wound pressure signal from transducer 75, microcontroller 72 compares the wound pressure with the user selected pressure. If the wound pressure is higher than the user

selected vacuum pump pressure, microcontroller 72 reduces pump motor speed to decrease vacuum pump pressure and thus the pressure at the wound.

Id. at 13:20-31. Moreover, Lina explains that “[m]icrocontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83.” *Id.* at 13:35-36. The microcontroller of Lina is shown in Figure 9:



Id. at Fig. 9 (highlighting added).

203. A POSITA also would have knowledge of many other NPWT systems with controllers that operate the speed of the vacuum pump's motor to control the amount of negative pressure provided to the wound. For example, Hunt, filed in 1998, teaches a microprocessor that controls the increase or decrease of the pump

speed to control the negative pressure applied. Ex. 1006 at 2:15-21. Specifically, Hunt teaches:

The pressure detecting means can be linked to a microprocessor programmed to maintain such pressure within a predetermined range irrespective of the movement of the patient. This can be done by, for example, signaling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced.

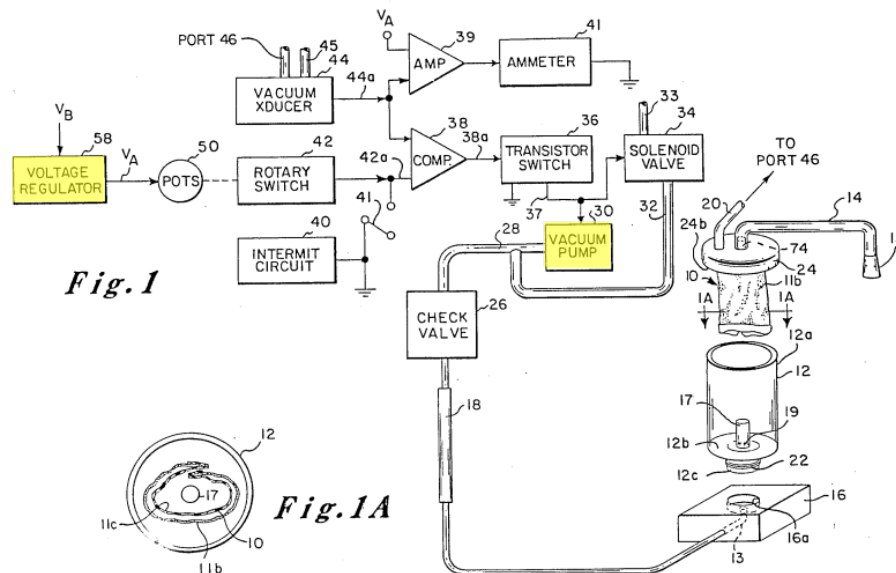
Id.

204. Additionally, POSITAs would have knowledge of other prior art controllers that control pump speed, such as U.S. Patent No. 6,135,116, invented by Richard C. Vogel et al., (“Vogel”) and U.S. Patent No. 4,795,448, invented by Gary R. Stacey et al., (“Stacey”). Exs. 1031-1032.

205. Vogel, filed in 1997, teaches a vacuum-assisted wound closure system that utilizes a “control system[] to achieve desired therapy.” Ex. 1031 at 2:54-56. Vogel teaches a “micro-controller unit 203” with “a vacuum pump speed control circuit 225” and “a vacuum pump control circuit 226.” *Id.* at 6:3-6. After monitoring feedback from the control circuits, the microcontroller in Vogel adjusts the speed of the vacuum pump to increase or decrease the amount of suction being delivered at the wound site. *Id.* at 7:53-56.

206. Similarly, Stacey teaches an electronic regulator that controls the vacuum pump by “periodically energizing and de-energizing” it. Ex. 1032 at 2:15-

22. Specifically, the electronic regulator is a “voltage regulator” that controls the amount of voltage supplied to the vacuum pump’s motor to increase or decrease the amount of negative pressure being applied. The voltage regulator and relevant circuitry is depicted in Figure 1 below:



Id. at Fig. 1 (highlighting added). Stacey describes how the system compares the intended voltage to the current voltage and adjusts the speed of the pump motor (“motor windings of vacuum pump”) accordingly. *Id.* at 3:65 – 4:30, 6:46 – 8:19.

207. For at least these reasons, as of July 24, 2005, POSITAs were well aware of NPWT controllers that controlled the vacuum pump motor (including the voltage of that motor). As such, modifying Risk’s NPWT system and controller to incorporate the functionality of Lina’s controller would have simply been combining prior art elements according to methods known for years. Moreover, a POSITA

would have understood that this combination would yield the predictable result reflected in the above-cited references—i.e., adjusting the amount of negative pressure applied at the wound site to achieve the desired level of suction.

ii. It would have been obvious to try combining the controller of Lina with the NPWT system of Risk.

208. It is also my opinion that it would have been obvious to try the use of Lina's controller within the NPWT system of Risk.

209. A POSITA would have understood there are a limited number of predictable ways to control the amount of negative pressure being applied in an NPWT system: for example, (1) adjusting the amount of air being allowed into the system to counteract the level of negative pressure while keeping the pump's motor speed constant, or (2) adjusting the vacuum pump speed itself to increase or decrease the amount of negative pressure while keeping the geometry of the vent to ambient air entering the system constant.

210. Given at least these two options known to a POSITA, it would have been obvious for a POSITA to try implementing the controller that varies the motor speed of Lina for the controller that varies the valve of Risk. I also believe it would have been obvious for a POSITA to try different types of known controller functionalities in a system like Risk's. A POSITA would decide which type of

controller best fit the needs of the NPWT system and could most effectively maintain the desired pressure at the wound site.

211. A POSITA would have known that you can control the rotational speed of a brushless DC motor by changing the applied voltage. As described above, A POSITA would understand the relationship between applied electrical power (a product of current and voltage) with motor shaft power (a product of rotational speed and torque) and with fluid dynamic power (a product of flow rate and pressure).

212. A POSITA would have also known that you can control the torque applied by a brushless motor by changing the applied amperage.

213. As I explain below, a POSITA would have also had a reasonable expectation of success in trying the controller that operates motor speed for Risk's NPWT system.

iii. Using a controller that operates the valve instead of or in addition to a controller that operates the speed of the pump motor is a simple substitution of known elements in the prior art.

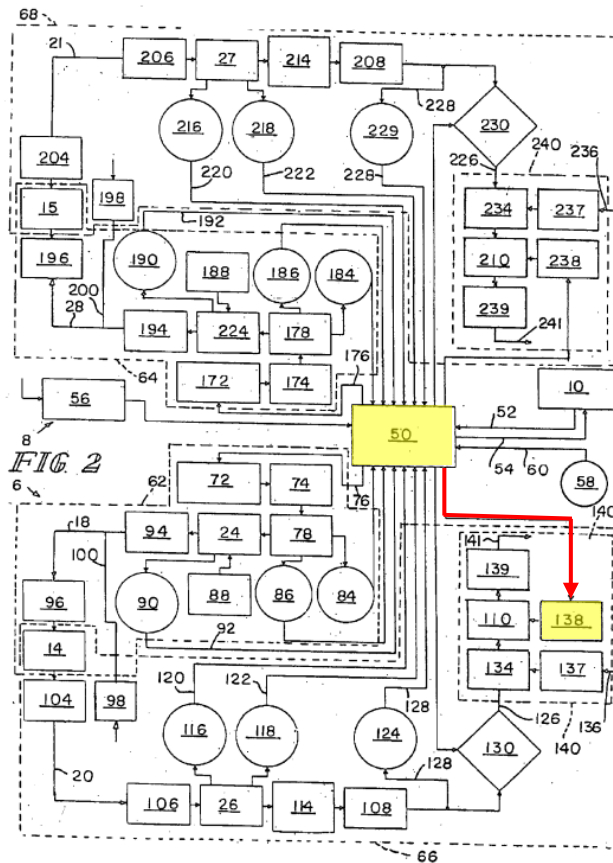
214. For the same reasons as discussed above, at least as early as July 24, 2005, a POSITA would have recognized that using the motor-speed controller of Lina instead of or in addition to the controller of Risk amounted to nothing other than a simple substitution of known elements. Both controller configurations have

been known and used for years, and POSITAs have used both controllers in NPWT systems before the filing of the '534 Patent.

215. In fact, the arrangement contemplated by Lina is a much simpler solution, eliminating the need for the proportional valve. In a situation where the system designer was trying to save overall cost without sacrificing function, they would have looked to Lina to replace the arrangement of components in Risk.

iv. A POSITA would have expected to succeed in combining Risk's NPWT system with Lina's controller.

216. It is my opinion that a POSITA would have expected success in modifying Risk's NPWT system in a way to include a controller that controls the speed of the vacuum pump motor as taught in Lina. Using Lina's control scheme in Risk's NPWT system could routinely be accomplished by substituting the controller disclosed in Risk that controls the valve in response to an undesirable negative pressure to, instead, communicate with the pump speed to adjust the pressure. Risk teaches that "vacuum pump 110 is mounted on the end of a single 12VDC brushless motor 138 to drive the pump". Ex. 1003 at 8:13-20. And, as is shown in Figure 2, the controller of Risk is already operably connected to motor 138 to power the pump:



Id. at Fig. 2 (annotations added to indicate the connection between controller 50 and pump motor 138). Thus, Risk's controller is already designed to operate pump motor 138 and, modifying it to control the pump speed in response to a detected pressure that does not match the desired negative pressure level, instead of controlling valve 130, would be an easy modification to a POSITA.

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

3. Claim 6

218. Based on my review and for the reasons that follow, it is my opinion that claim 6 is obvious based on the teachings of Risk and Watson in further view of Lina.

219. I have reproduced dependent claim 6 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

6[pre] The vacuum system according to claim 5:

[a] wherein said motor is an electric motor:

[b] and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.

i. Limitation 6[pre]: The vacuum system according to claim 5,

220. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 6, it is my opinion that Risk and Watson teach and render obvious limitation 6[pre]. As I explain above, in my opinion the combination of Risk and Watson teach and render obvious the vacuum system of claim 5. The analysis and my discussion of claim 5 is hereby incorporated by reference.

221. Accordingly, it is my opinion that Risk and Watson teach and render obvious limitation 6[pre].

ii. Limitation 6[a]: wherein said motor is an electric motor,

222. In my opinion, Risk teaches limitation 6[a] because Risk teaches an electric motor to power vacuum pump 110.

223. Risk teaches that the NPWT system, including “controller 50 and all the attendant systems in housing 4” are driven by a power supply and can be plugged into a conventional wall socket. *Id.* at 5:34-39. Risk further discloses that “vacuum pump 110 is mounted on the end of a single 12VDC brushless motor 138 to drive the pump.” *Id.* at 8:13-14. Specifically, Risk describes this pump motor as “**electric motor 138**”. *Id.* at 8:29-30 (emphasis added).

224. Accordingly, it is my opinion that Risk teaches limitation 6[a].

iii. Limitation 6[b]: and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.

225. In my opinion, the combination of Risk and Lina teach and render obvious limitation 6[b] because the combination includes a controller that controls the speed of the electric motor to attain a desired level of negative pressure at the wound site (i.e., in the confined volume underneath the enclosure).

226. As explained in Ground 1, Risk discloses a controller 50 which controls operation of the vacuum system. To adjust the amount of negative pressure being applied to the wound, however, Risk teaches that the controller selectively opens and closes a valve with flow orifice. *Id.* at 7:30-42. In my opinion, as I discuss in Part VIII.B.2, a POSITA would have been motivated to modify Risk to allow the controller to directly control the speed of the disclosed electric motor within the vacuum pump to adjust the amount of negative pressure being applied to the wound as taught in Lina.

227. Lina teaches the use of a “microcontroller” that receives a user’s preference of negative pressure and then “activates pump motor 83 which, in turn, drives vacuum pump 84 to begin removal of air from canister 19.” Ex. 1005 at 12:41-49. Specifically, Lina explains:

Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83. . . . After receiving the wound pressure signal from transducer 75, microcontroller 72 compares the wound pressure with the user selected pressure. If the wound pressure is higher than the user selected vacuum pump pressure, microcontroller 72 reduces pump motor speed to decrease vacuum pump pressure and thus the pressure at the wound.

Id. at 13:20-31.

228. As I discussed in Part VIII.B.2, a POSITA would have been motivated to combine the NPWT system of Risk with the controller of Lina to control the pump

motor speed, instead of controlling the opening of a valve, thereby providing a desired level of negative pressure in said confined volume.

229. Therefore, in my opinion, Risk in view of Lina teaches and renders obvious limitation 6[b].

230. Accordingly, it is my opinion that the combination of Risk, Watson, and Lina teach and render obvious claim 6.

4. Claim 7: The vacuum system according to claim 6, wherein said controller controls the electric current or the voltage of said motor to control said level of said negative pressure in said confined volume.

231. It is my opinion that the combination of Risk and Watson in further view of Lina render claim 7 obvious. For the reasons stated above, the combination of Risk, Watson, and Lina teach and render obvious the vacuum system of claim 6. In my opinion, Lina also teaches the additional limitations in claim 7 because Lina explicitly teaches that the controller can control the voltage of the pump motor to adjust the amount of negative pressure applied at the wound site.

232. Lina teaches that the microcontroller controls the amount of voltage that is received by the vacuum pump's motor. For example, Lina teaches:

Microcontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83. That is, microcontroller 72 receives the 12 VDC signal from DC power supply 71 and outputs a voltage between 0 and 12 VDC to pump motor 83 to control its speed in accordance wit [sic] the user selected vacuum pump pressure value.

Accordingly, microcontroller 72 employs feedback to ensure that the wound experiences the user selected vacuum pump pressure.

Ex. 1005 at 13:35-43 (emphasis added). Lina also explains the microcontroller controls the provision of the 12VDC power supply to the pump motor. *Id.* at 11:19-32. A POSITA would have understood that by altering the amount of voltage received by the pump motor, the controller is controlling the amount of negative pressure being applied to the wound (i.e., to the confined volume under the enclosure).

233. As I discussed in Part VIII.B.2, a POSITA would have been motivated to combine the NPWT system of Risk with the controller of Lina to control the pump motor speed instead of controlling the opening of a valve.

234. For the reasons stated above, in my opinion, Risk in view of Watson and in further view of Lina teaches and renders obvious claim 7.

5. Claim 8: The vacuum system according to claim 6, wherein said controller controls the torque of said motor to control said level of said negative pressure in said confined volume.

235. It is my opinion that the combination of Risk and Watson in further view of Lina render claim 8 obvious. For the reasons stated above, the combination of Risk, Watson, and Lina teach and render obvious the vacuum system of claim 6. In my opinion, the combination of Risk, Watson, and Lina also renders claim 8 obvious.

236. As explained above, the torque of a DC electric motor is directly proportional to the current. As such, to control the torque of the motor, the controller would control the amperage applied to the motor.

237. Lina explicitly teaches a controller that controls the voltage of the pump's motor to control the level of negative pressure within the confined volume. A POSITA would have found it obvious to continuously adjust the voltage applied to the motor to result in the desired current and thereby control the torque of the motor to control the level of negative pressure. A POSITA would have known that the speed of a pump motor can be control in a limited number of ways and found it obvious to control the voltage so that the current applied to the motor controls the torque of the pump disclosed in Risk and/or Lina.

238. For the reasons stated above, in my opinion, Risk in view of Watson and in further view of Lina renders obvious claim 8.

6. Claim 20

239. Based on my review and for the reasons that follow, it is my opinion that claim 20 is obvious based on the teachings of Risk and Watson in further view of Lina.

240. I have reproduced dependent claim 20 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

20[pre] The method according to claim 19:

[a] wherein the vacuum source comprises a vacuum pump driven by
an electric motor:

[b] and wherein step (b) comprises controlling operation of said
motor to thereby provide a desired level of said negative pressure
in said confined volume.

**i. Limitation 20[pre]: The method according to claim
19,**

241. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 20, it is my opinion that Risk and Watson teach and render obvious limitation 20[pre]. Limitation 20[pre] merely refers to the method of claim 19. For the reasons stated above in Ground 1, the combination of Risk and Watson teach and render obvious claim 19.

242. Accordingly, it is my opinion that Risk and Watson teach and render obvious limitation 20[pre].

ii. Limitation 20[a]: wherein the vacuum source comprises a vacuum pump driven by an electric motor,

243. Limitation 20[a] is substantively identical to claim 5 and limitation 6[a].

The analysis and my discussion of claim 5 and limitation 6[a] is hereby incorporated by reference.

244. Accordingly, it is my opinion that Risk teaches limitation 20[a].

iii. Limitation 20[b]: and wherein step (b) comprises controlling operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.

245. Limitation 20[b] is substantively identical to limitation 6[b]. The analysis and my discussion of limitation 6[b] is hereby incorporated by reference.

246. Accordingly, it is my opinion that the combination of Risk and Lina teaches and renders obvious limitation 20[b].

247. For the stated reasons, it is my opinion that Risk in view of Watson and in further view of Lina teach and render obvious claim 20.

7. Claim 21: The method according to claim 20, wherein step (b) comprises controlling at least one of the electric current, or the voltage, or the torque of said motor to control said level of said negative pressure in said confined volume.

248. In my opinion, the combination of Risk in view of Watson and in further view of Lina teach and render obvious claim 21. For the reasons stated above,

Risk in view of Watson and Lina teach and render obvious the method of claim 20.

In my opinion, Lina teaches the additional limitations of claim 21.

249. Claim 21 is substantively identical to claim 7, but adds that instead of controlling current or voltage, the controller could control the torque of the motor. I am informed that because the claim recites “at least one of” current, voltage *or* torque, that the prior art only needs to teach one of the three recited options. Because, as explained with regard to claim 7, Lina teaches that the controller controls the voltage of the vacuum pump motor to control the amount of negative pressure created in the volume under the enclosure, Lina teaches claim 21. The analysis and my discussion of claim 7 is hereby incorporated by reference.

250. Additionally, in my opinion a POSITA would have found it obvious to control the torque of the motor, as I explained with regard to claim 8. The analysis and my discussion of claim 8 is hereby incorporated by reference.

251. Accordingly, it is my opinion that Risk in view of Watson and in further view of Lina teaches and renders obvious claim 21.

C. Ground 3: Analysis of Claims 1-6, 9-15, 17-20, and 22 Based on Hunt

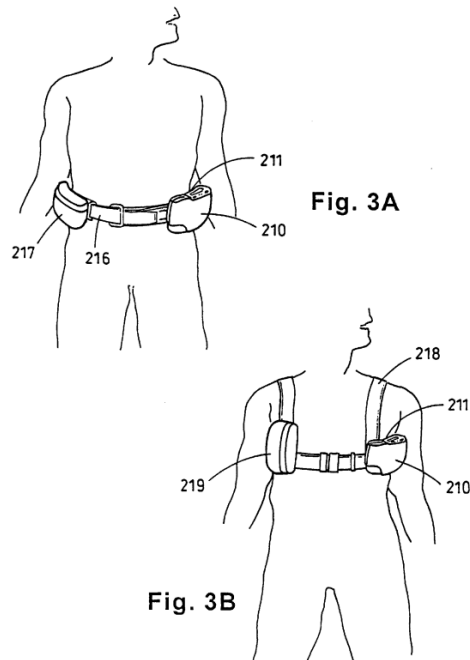
252. Regarding Ground 3, in my opinion, claims 1-6, 9-15, 17-20, 22 of the '534 Patent are invalid because they are anticipated by Hunt, as detailed below.

1. Claim 1

253. Based on my review and for the reasons that follow, it is my opinion that claim 1 is anticipated by the teachings of Hunt.

i. Limitation 1[pre]: A vacuum system for applying negative pressure to a wound, the vacuum system comprising:

254. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 1, it is my opinion that Hunt teaches a vacuum system for applying negative pressure to a wound. Hunt discloses a “portable therapeutic apparatus for stimulating the healing of superficial wounds in a person.” Ex. 1006 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.

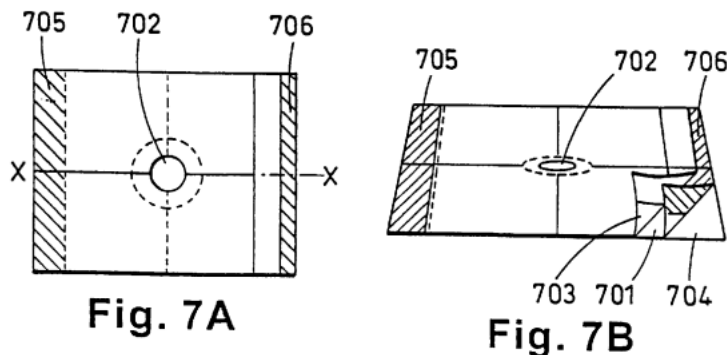
255. Accordingly, it is my opinion that Hunt teaches limitation 1[pre].

ii. Limitation 1[a]: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller:

256. In my opinion, Hunt teaches limitation 1[a] because Hunt teaches an enclosure (wound dressing with surgical drape), venting arrangement (opening in tube 106), tube (tube 101), vacuum source (suction pump 6), and a controller (microprocessor 4).

257. **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:

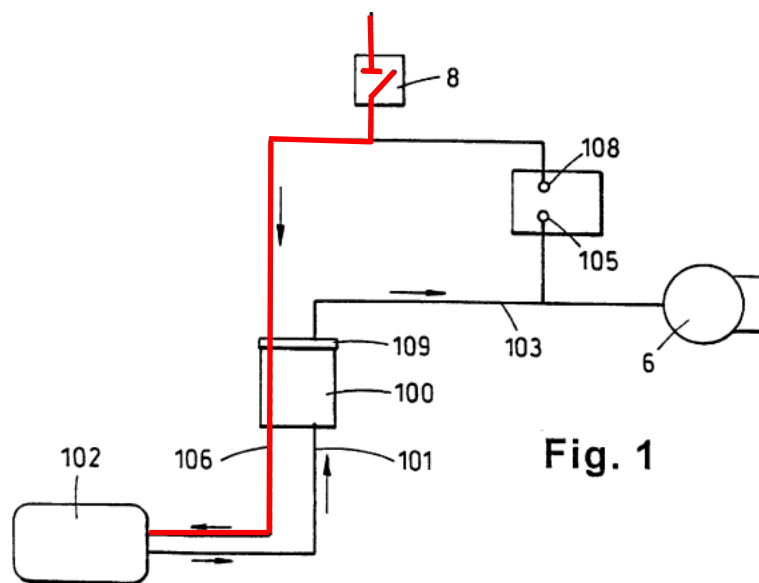


Id. at Figs. 7A-7B.

258. 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.

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

260. **Venting Arrangement:** In my opinion, Hunt teaches a “venting arrangement.” 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 the 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:



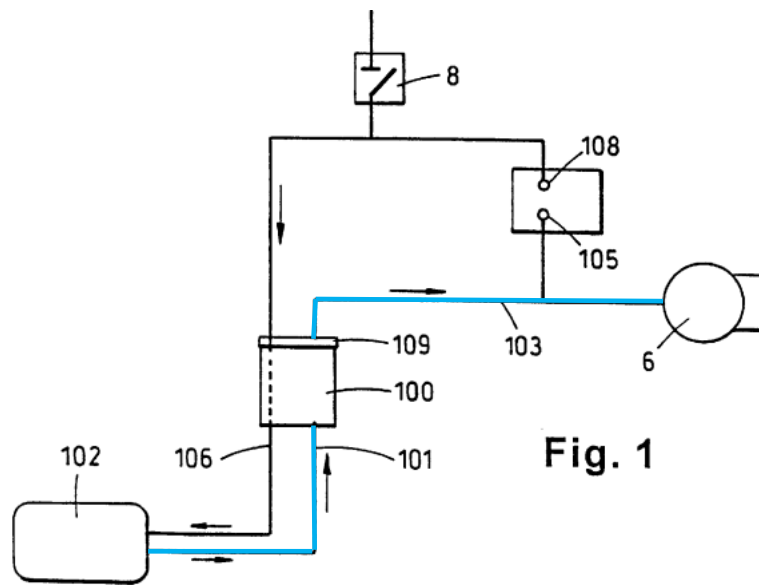
Id. at Fig. 1 (tube 106 and its connection to pressure relief valve 8 annotated in red).

261. 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 ’534 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.

262. 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 in connector spout 602, allowing ambient air to enter tube 106 via the opening in pressure relief valve 8 and flow into the vacuum.

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

264. **Tube:** It is my opinion that Hunt teaches a “tube.” As noted immediately above, Hunt describes multiple tubes that run to and from the wound dressing in the disclosed NPWT system. 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:



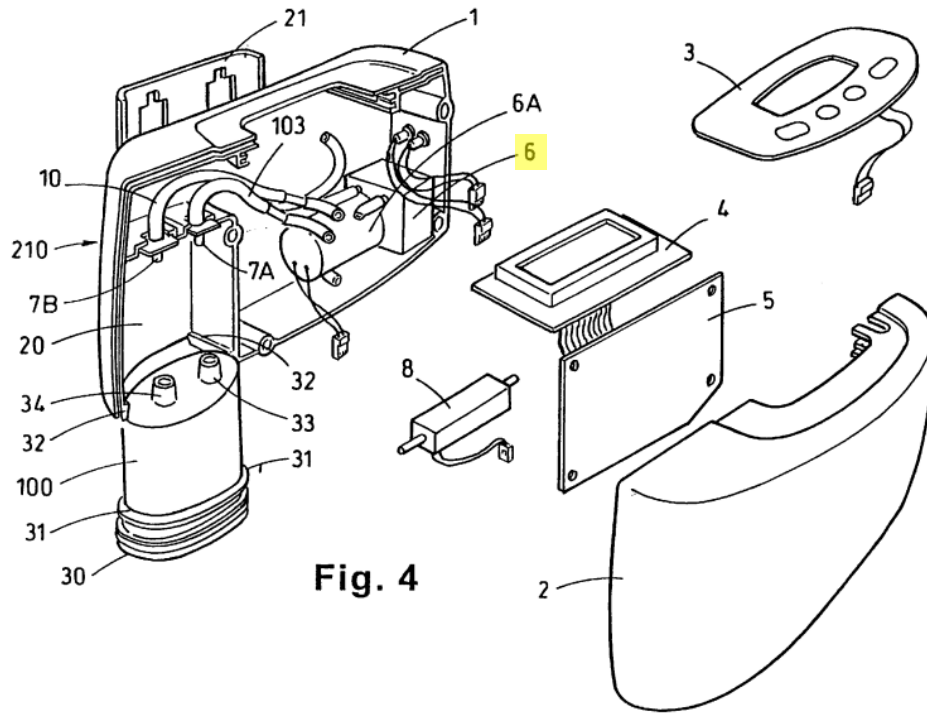
Id. at Fig. 1 (annotated in blue to identify the tubes 101 and 103). Hunt teaches that the suction pump 6 is connected by a silicon rubber tube 103 to the canister 100. *Id.* at 3:31-34. Hunt also teaches that canister 100 is connected via tube 101 to porous dressing 102 at the wound site. Therefore, 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.

265. Additionally, Hunt teaches that “it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister.” *Id.* 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 be connected to apply suction to the wound dressing.

266. Accordingly, it is my opinion that Hunt teaches a “tube”.

267. **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.

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

269. **Controller:** It is my opinion that Hunt discloses a “controller.” Hunt teaches a microprocessor which is “programmed to maintain such [negative] pressure within a predetermined range.” *Id.* at 2:15-18. The microprocessor 4 is included within the system housing, as depicted in Figure 4 below:

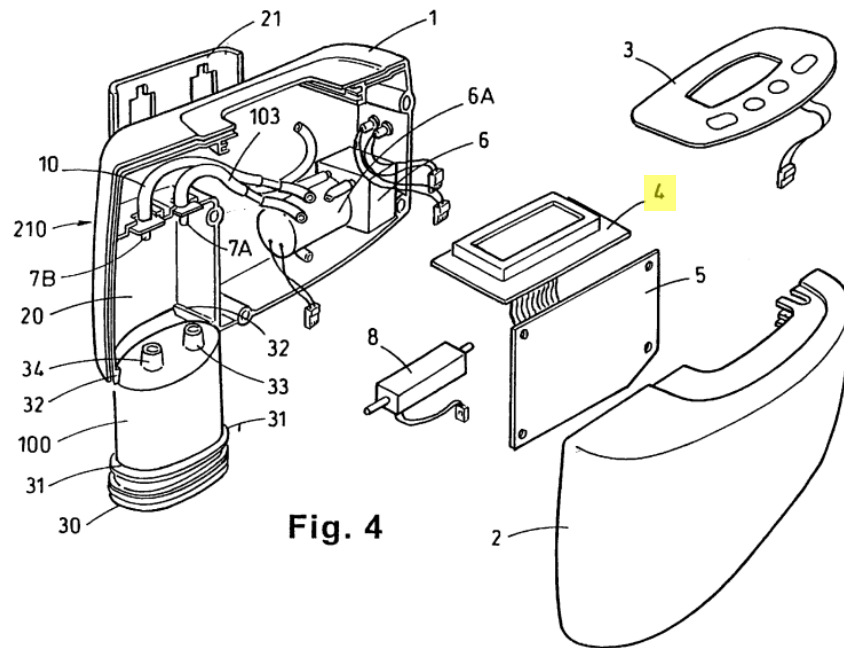


Fig. 4

Id. at Fig. 4 (highlighting added to identify microprocessor 4).

270. Accordingly, in my opinion Hunt teaches a “controller”.

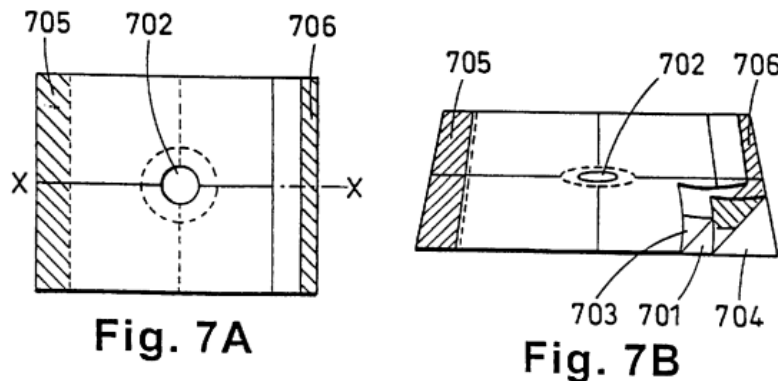
271. For the reasons stated above, in my opinion Hunt teaches limitation 1[a].

iii. Limitation 1[b]: the enclosure being attachable to a periphery of the wound so as to define a confined volume;

272. In my opinion, Hunt teaches limitation 1[b] because Hunt discloses an enclosure (wound dressing with surgical drape) that attaches to the periphery of the wound and defines a confined volume therein.

273. Hunt teaches a porous dressing that “is cut to correspond with the extent of the wound and pressed onto the wound” *Id.* at 5:19-21. This porous wound

dressings 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:



Id. at Figs. 7A-7B.

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

275. Accordingly, in my opinion, Hunt teaches limitation 1[b].

iv. Limitation 1[c]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume;

276. In my opinion, Hunt teaches limitation 1[c] 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.

277. 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:

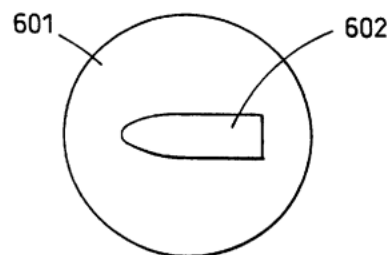


Fig. 6A

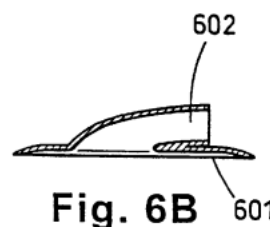


Fig. 6B

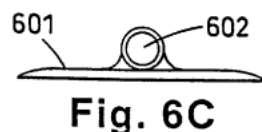


Fig. 6C

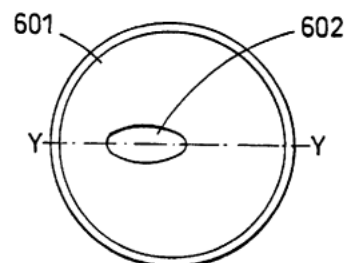


Fig. 6D



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.

278. 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.

279. 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 with regard to limitation 1[a] 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:

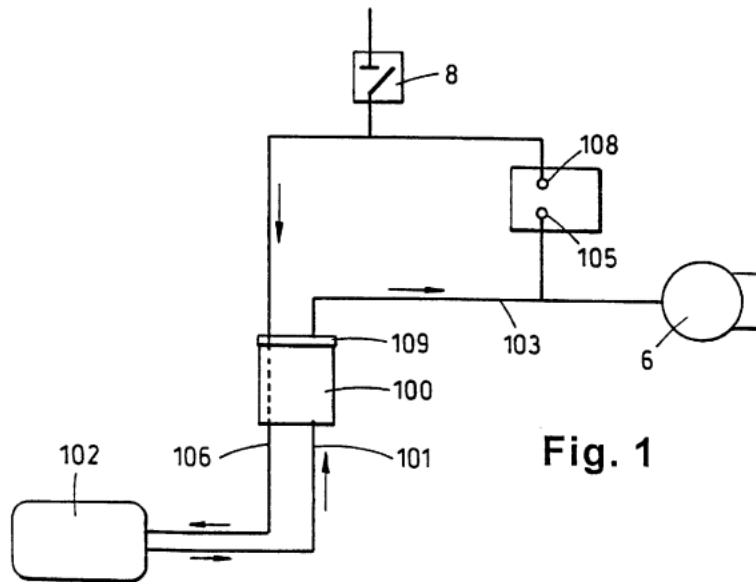


Fig. 1

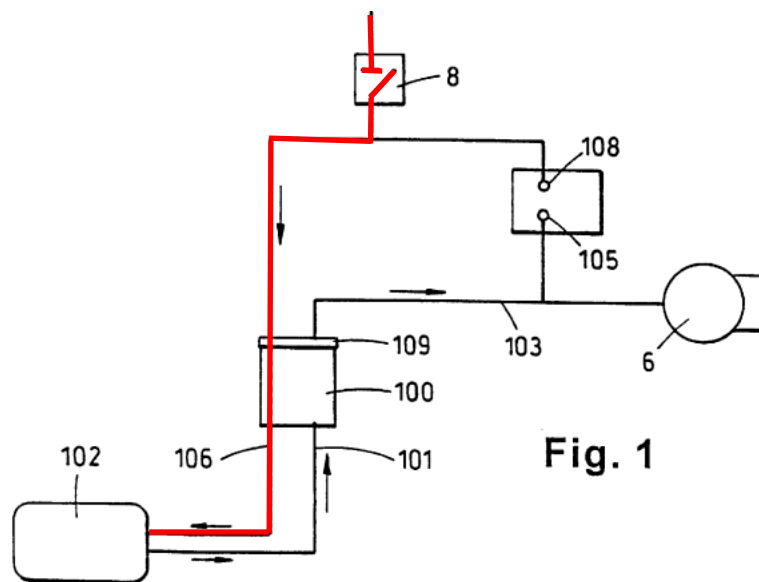
Id. at Fig. 1.

280. Accordingly, it is my opinion that Hunt teaches limitation 1[c].

- v. **Limitation 1[d]: the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said vacuum system upstream of the vacuum source;**

281. In my opinion, Hunt teaches limitation 1[d] because as described above, Hunt discloses a pressure relief valve 8 and tube 106 which constitute a “venting arrangement”. Additionally, the pressure relief valve 8 constitutes a “flow restrictor,” under the plain and ordinary meaning of that term, which allows and restricts the flow of ambient air through the tube, providing a controlled flow of ambient air into the vacuum system upstream of the vacuum source.

282. As I explained with regard to limitation 1[a] above, Hunt discloses a “venting arrangement”. Specifically, Hunt teaches that “tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8” at the other. *Id.* at 3:63-66. A POSITA would have understood that there is an orifice in the relief valve 8 that can be opened or closed. When fully or partially opened, the pressure relief valve 8 allows ambient air to enter tube 106 where it flows into the balance of the vacuum system. The airflow of the ambient air (as shown by the arrows within Figure 1 below) is upstream of the vacuum source, as shown below:

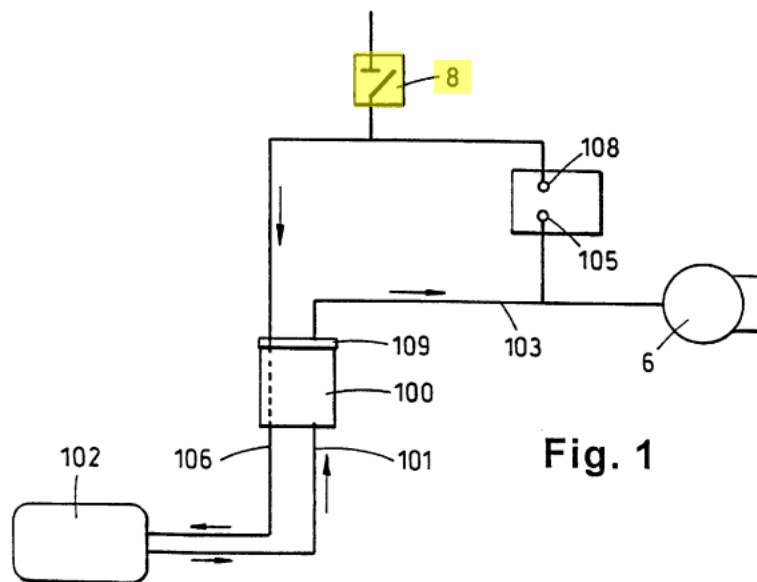


Id. at Fig. 1 (ambient air in tube 106 and valve 108 annotated in red). As shown in Figure 1, the ambient air that enters tube 106 and flows to the wound dressing 102, is then further drawn into the vacuum system via tube 101, upstream of the vacuum source (pump 6).

283. Accordingly, in my opinion Hunt teaches a venting arrangement.

284. In my opinion, Hunt also teaches a “flow restrictor” based on the plain and ordinary meaning that term.

285. Hunt teaches “pressure relief valve 8” that is coupled to tube 106 as shown in Figure 1 below:



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

286. 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 tube 106 into the vacuum system, upstream of the vacuum source. Also, that the valve can 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. An example being the proportional valve disclosed in Risk and discussed above.

287. Accordingly, it is my opinion that Hunt teaches limitation 1[d].

- vi. **Limitation 1[e]: the controller configured for controlling operation of the vacuum source while providing venting of the vacuum system via said venting arrangement to provide a desired level of said negative pressure in said confined volume.**

288. In my opinion, Hunt teaches limitation 1[e] because Hunt discloses a controller (microprocessor 4) that controls the operation of the vacuum source (pump) while the vacuum system is vented by venting arrangement (tube 106 and pressure relief valve 8) to provide a desired level of negative pressure in the confined volume under the enclosure (at the wound site under the dressing and surgical drape).

289. As I explained with regard to limitation 1[a], Hunt teaches a microprocessor which corresponds to the claimed controller. Hunt teaches that the microprocessor is “programmed to maintain such pressure within a predetermined range”. *Id.* at 2:15-18. Additionally, Hunt teaches an LCD screen that can be accessed by a user who uses control buttons 214 “to adjust pressures and treatment intervals.” *Id.* at 3:11-14. Hunt also discloses:

The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a predetermined range irrespective of the movement of the patient. This can be done by, for example, signaling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced.

Id. at 2:14-21. A POSITA would have understood that the microprocessor is, therefore, necessarily controlling operation of the vacuum source and venting arrangement to maintain a desired negative pressure.

290. Additionally, the desired level of negative pressure is that applied within the confined volume of the enclosure at the wound site. Hunt teaches that the negative wound pressure is applied “at the wound site.” *Id.* at 3:60-61.

291. As I explained above, Hunt teaches a venting arrangement which allows ambient air to flow into tube 106 and the vacuum system. Hunt teaches that the vacuum system controls pressure relief valve 8 to admit ambient air into the system via tube 106 and pressure relief valve 8 (the venting arrangement). *Id.* at 4:17-33.

Hunt explains that when the vacuum system is programmed to apply intermittent suction at the wound, relief valve 8 “will open for a specified period, allow the pressure to equalize at the wound site and then close to restore the suction.” *Id.* at 4:20-24. A POSITA would have understood that the controller taught by Hunt is, therefore, controlling the intermittent operation of the vacuum pump while also providing venting of the vacuum system tube 106 and pressure relief valve 8.

292. A POSITA would understand that because Hunt teaches that the pressure is “allowed to equalize at the wound site” while the relief valve is open and before the relief valve is closed to restore the suction, that the equalized pressure need not be atmospheric. A POSITA would know that running the pump while the relief valve is open allows the system to reach any desired equalized pressure between atmospheric and the maximum allowed by the pump. This can be achieved by varying the speed of the pump and/or “pulse modulating” the pump or the valve opening and closing. Hunt explicitly teaches pulse modulating the pump on/off as one way to control the vacuum level. *Id.* at 4:27-29.

293. Accordingly, in my opinion Hunt teaches limitation 1[d].

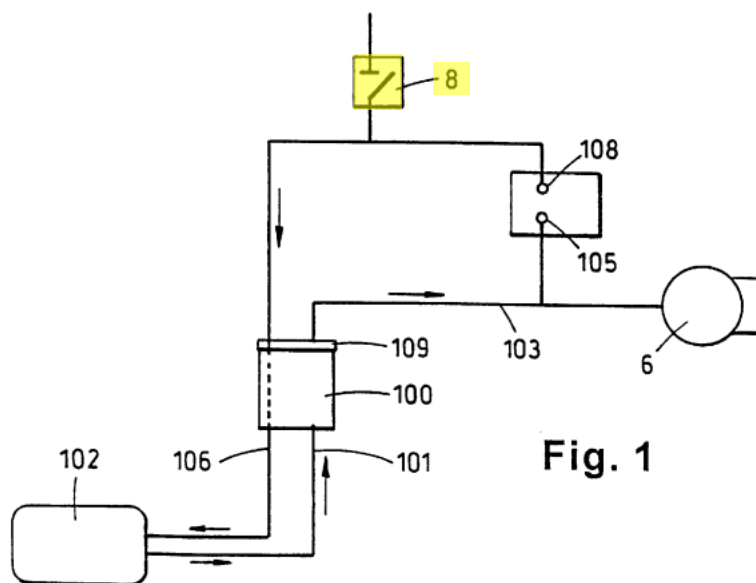
294. For the reasons stated above, it is my opinion that Hunt teaches all the limitations of claim 1 of the '534 Patent.

2. Claim 2: The vacuum system according to claim 1, wherein said flow restrictor is provided in any one of the enclosure or the tube.

295. In my opinion, Hunt teaches claim 2. As explained above, Hunt teaches the vacuum system of claim 1. In my opinion, Hunt also teaches the additional limitations in claim 2 because Hunt teaches a pressure relief valve 8 which sits within tube 106.

296. As I explained regarding claim 1 above, Hunt teaches a “flow restrictor” in the form of a pressure relief valve 8 and a “tube” (i.e., tube 101) that applies negative pressure to the wound site.

297. As shown in Figure 1 below, pressure relief valve 8 is located in tube 106:



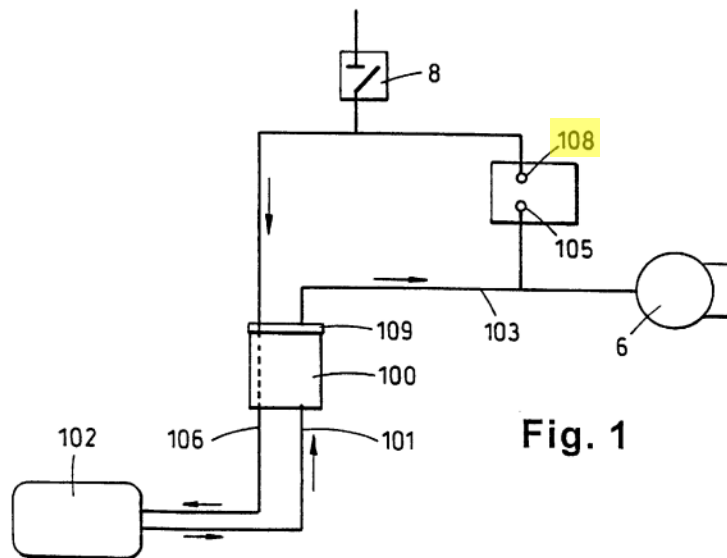
Id. at Fig. 1 (highlighting added to identify pressure relief valve 8). A POSITA would have considered pressure relief valve 8 to be in the tube because there must be an opening in the tube where it meets the valve such that ambient air can flow into tube 106. Hunt further teaches that “it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister.” *Id.* at 4:34-39; 3:63-66 (“A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tube 106 and 101 can be combined in a multi-partitioned tube . . .”). As I explained with regarding to claim 1 above, Hunt teaches the claimed “tube” which is tube 101 that applies negative pressure to the wound. A POSITA would have understood the teachings of Hunt in combining tubes 106 and 101 to mean the pressure valve 8 would be located in the “single” “multi-partitioned tube” that also applies the negative pressure to the wound.

298. Accordingly, in my opinion Hunt teaches claim 2.

3. Claim 3: The vacuum system according to claim 1, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.

299. In my opinion, Hunt teaches claim 3. As explained above, Hunt teaches the vacuum system of claim 1. In my opinion, Hunt also teaches the additional limitations in claim 3 because Hunt teaches a sensor (pressure transducer) that monitors and reports the pressure at the wound site.

300. Hunt teaches a pressure transducer 108 that is connected to tube 106 which is able to “measure[] or monitor[]” the amount of negative pressure at the wound site. *Id.* at 3:66 – 4:1. Pressure transducer 108 is shown in Figure 1 (below) which senses the amount of negative pressure at the wound through tube 106. When the relief valve 8 is closed, there is no air flow through tube 106, so the pressure at the transducer would be the same as that at the wound site (as the hydrostatic head of an air column is insignificant). The sensor, therefore, enables the determination of a level of negative pressure.



Id. at Fig. 1 (highlighting added to identify pressure transducer 108).

301. Hunt further teaches that its NPWT invention “overcomes” the problem of having difficulty determining the negative pressure level at the wound site by “providing an additional conduit [tube 106] connecting the wound site or an area

close thereto to a pressure-detecting means.” *Id.* at 2:4-15. Additionally, Hunt explains that if there is a leak in the wound dressing, the leak may be detected by the disclosed transducer. *Id.* at 5:4-7.

302. Accordingly, in my opinion Hunt teaches claim 3.

4. Claim 4: The vacuum system according to claim 1, further comprising a waste container in fluid communication with said vacuum source.

303. In my opinion, Hunt teaches claim 4. As explained above, Hunt teaches the vacuum system of claim 1. In my opinion, Hunt also teaches the additional limitations in claim 4 because Hunt discloses a “canister for containing fluids drawn from the wound by said pump.” *Id.* at 1:49-50.

304. 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.

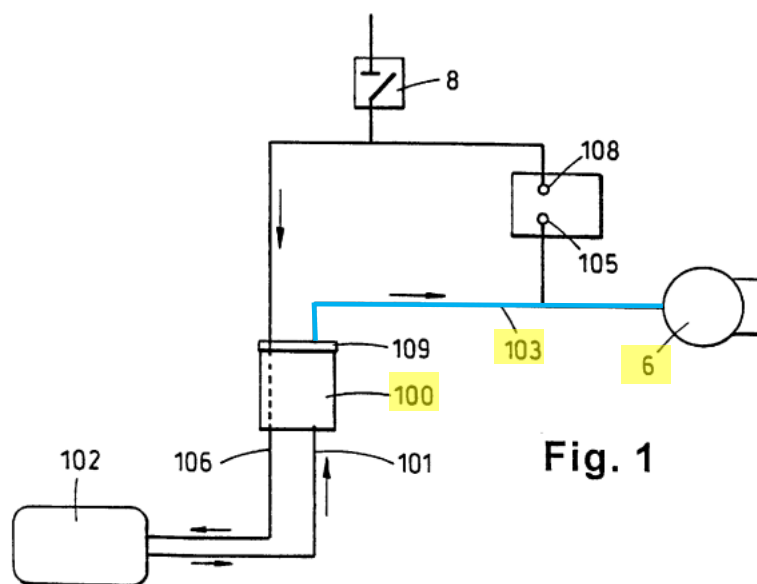


Fig. 1

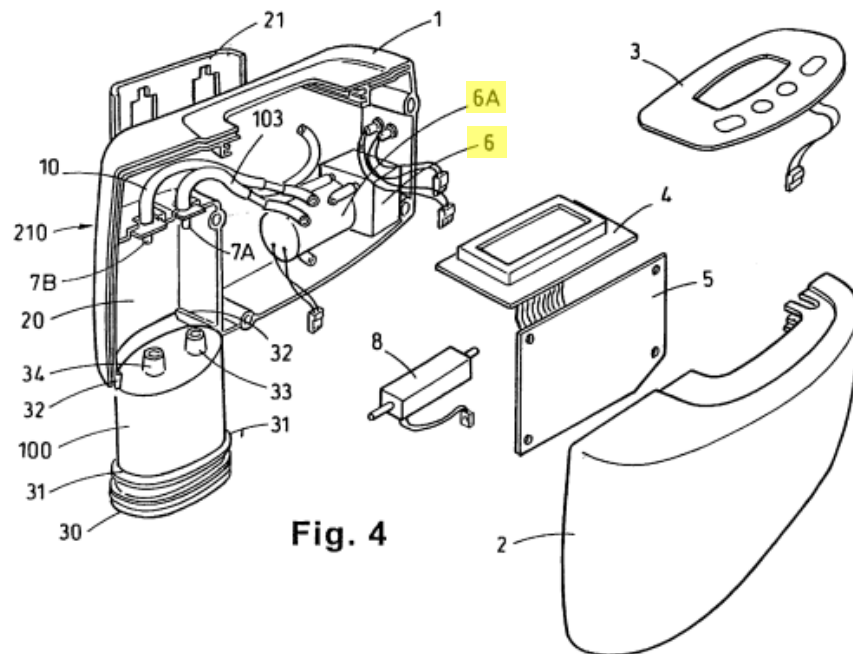
Id. at Fig. 1 (highlighted to identify the canister 100 and tube 103 (annotated in blue) connecting it to the vacuum pump 6). Hunt specifically teaches “the pump is connected by a silicon rubber tube 103 to a canister spigot 7A in a compartment 20 for the canister 100.” *Id.* at 3:33-35. Additionally,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

305. Accordingly, in my opinion Hunt teaches claim 4.

5. Claim 5: The vacuum system according to claim 1, wherein said vacuum source comprises a vacuum pump driven by a motor.

306. In my opinion, Hunt teaches claim 5. As explained above, Hunt teaches the vacuum system of claim 1. In my opinion, Hunt also teaches the additional limitations in claim 5 because Hunt teaches that pump 6 is driven by a motor.

307. Specifically, Hunt teaches “suction pump is conveniently driven by an electric motor”. *Id.* at 1:61-62. The motor 6A is shown in Figure 4 below connected to the pump 6:



Id. at Fig. 4 (highlighted to identify vacuum pump 6 and pump motor 6A). As is shown in Figure 4 above, “suction pump 6 with associated electric motor 6A” is located within the vacuum system housing. *Id.* at 3:32-33.

308. Accordingly, it is my opinion that Hunt teaches claim 5.

6. Claim 6

309. Based on my review and for the reasons that follow, it is my opinion that claim 6 is anticipated by Hunt.

i. Limitation 6[pre]: The vacuum system according to claim 5,

310. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 6, it is my opinion that Hunt teaches

limitation 6

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[pre]
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. As I explain above, in my opinion Hunt teaches the vacuum system of claim 5. The analysis and my discussion of claim 5 is hereby incorporated by reference.

311. Accordingly, it is my opinion that Hunt teaches limitation 6

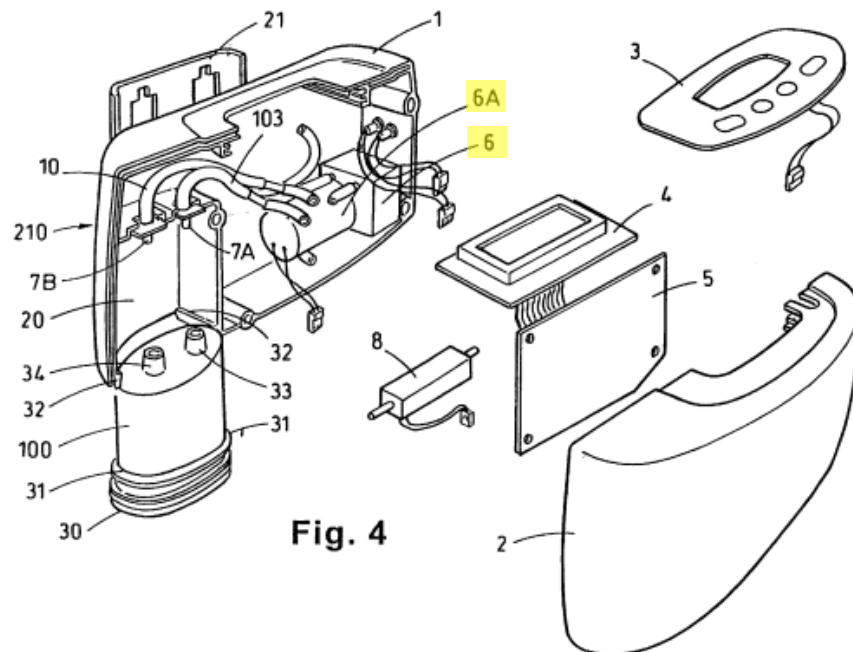
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[pre]
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.

ii. Limitation 6[a]: wherein said motor is an electric motor, and

312. In my opinion, Hunt teaches limitation 6[a] because Hunt teaches an electric motor to power pump 6.

313. Hunt teaches that “suction pump is conveniently driven by an electric motor.” *Id.* at 1:61-62, 8:29-30. The electric motor 6A is shown next to suction pump 6 within the system’s housing, as shown in Figure 4 below:



Id. at Fig. 4 (highlighted to identify vacuum pump 6 and pump motor 6A).

314. Accordingly, it is my opinion that Hunt teaches limitation 6[a].

iii. Limitation 6[b]: said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.

315. In my opinion, Hunt teaches limitation 6[b] because the microprocessor in Hunt is configured to increase or decrease the pump's speed when it detects the amount of negative pressure is outside of the predetermined, desired range.

316. As I explained with regard to claim 1, Hunt teaches a microprocessor, which corresponds to the claimed "controller." Hunt also teaches that the microprocessor controls the operation of the pump, which comprises an electric motor (as discussed for limitation 6[a] above). Specifically, Hunt discloses:

The pressure detecting means can be linked to a **microprocessor programmed to maintain such pressure within a predetermined range** irrespective of the movement of the patient. **This can be done by, for example, signaling the pump to increase its speed** where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced.

Id. at 2:15-21 (emphasis added). A POSITA would have understood that by "signaling the pump to increase its speed," the microprocessor of Hunt is controlling the operation of the pump's motor which powers the pump.

317. Therefore, in my opinion, Hunt teaches limitation 6[b].

318. Accordingly, it is my opinion that Hunt teaches claim 6.

7. **Claim 9: The vacuum system according to claim 1, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating.**

319. In my opinion, Hunt teaches claim 9. As explained above, Hunt teaches the vacuum system of claim 1. In my opinion, Hunt also teaches the additional limitations in claim 9 because Hunt teaches that venting arrangement can restore ambient pressure at the wound site when the pump is turned off.

320. As previously explained regarding claim 1, Hunt teaches a pressure relief valve 8 that can be opened to allow ambient air into the system. Hunt teaches **“pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly.”** *Id.* at 4:17-28 (emphasis added). Hunt further explains that during intermittent treatment, pressure relief valve 8 will open for specified time periods to “allow pressure to be equalized” but is then closed when suction is being reapplied. *Id.* Moreover, Hunt teaches: **“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.* (emphasis added).

321. A POSITA would have understood that relief valve 8, which admits ambient air into the system through tube 106 (together, the “venting arrangement”),

restores ambient pressure in the confined volume beneath the wound dressing when the vacuum pump is not applying suction.

322. Accordingly, it is my opinion that Hunt teaches claim 9.

8. Claim 10: The vacuum system according to claim 1, wherein said venting arrangement comprises at least one of: one or more bleeding holes, a porous body, an orifice.

323. In my opinion, Hunt teaches claim 10. As explained above, Hunt teaches the vacuum system of claim 1. In my opinion, Hunt also teaches the additional limitations in claim 10 because the relief valve 8 has an orifice.

324. As I explained with regard to claim 1 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 the relief valve has an orifice and that the opening constitutes a bleeding hole.

325. Accordingly, in my opinion Hunt teaches claim 10.

9. Claim 11

326. Based on my review and for the reasons that follow, it is my opinion that claim 11 is anticipated by Hunt.

327. I have reproduced independent claim 11 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

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

[a] an enclosure, a venting arrangement, a tube, a vacuum source,
and a controller:

[b] the enclosure being attachable to a periphery of the wound so as
to define a confined volume;

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

[d] said venting arrangement located outside said enclosure and
comprising a flow restrictor to restrict flow through said venting
arrangement and to thereby provide a controlled flow of ambient
air into said tube,

[e] said controlled flow of ambient air entering said tube via said
venting arrangement without entering said enclosure;

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

i. Limitation 11[pre]: A vacuum system for applying negative pressure to a wound, the vacuum system comprising:

328. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 11, it is my opinion that Hunt teaches a vacuum system for applying negative pressure to a wound.

329. Limitation 11[pre] is identical to limitation 1[pre]. The analysis and my discussion of limitation 1[pre] is hereby incorporated by reference.

330. Accordingly, it is my opinion that Hunt teaches limitation 11[pre].

ii. Limitation 11[a]: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller:

331. Limitation 11[a] is identical to limitation 1[a]. The analysis and my discussion of limitation 1[a] is hereby incorporated by reference.

332. Accordingly, it is my opinion that Hunt teaches limitation 11[a].

iii. Limitation 11[b]: the enclosure being attachable to a periphery of the wound so as to define a confined volume;

333. Limitation 11[b] is identical to limitation 1[b]. The analysis and my discussion of limitation 1[b] is hereby incorporated by reference.

334. Accordingly, it is my opinion that Hunt teaches limitation 11[b].

- iv. **Limitation 11[c]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume,**

335. Limitation 11[c] is identical to limitation 1[c]. The analysis and my discussion of limitation 1[c] is hereby incorporated by reference.

336. Accordingly, it is my opinion that Hunt teaches limitation 11[c].

- v. **Limitation 11[d]: said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said tube,**

337. In my opinion, Hunt teaches limitation 11[d]. As explained above regarding claim 1, Hunt teaches a venting arrangement (tube 106 and pressure relief valve 8) comprising a flow restrictor (pressure relief valve 8). The venting arrangement and flow restrictor of Hunt restrict the flow of ambient air through the venting arrangement to provide a controlled flow of ambient air into the tube.

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

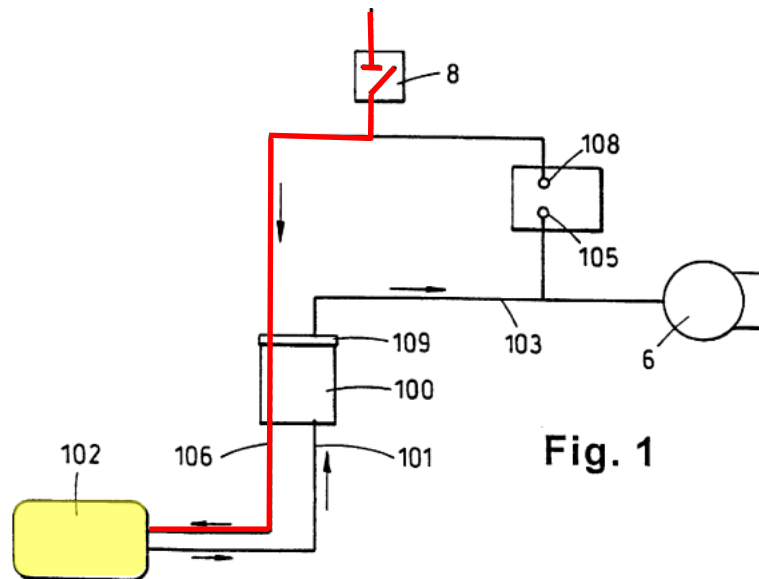


Fig. 1

Id. at Fig. 1 (tube 106 and valve 108 annotated in red with wound dressing 102 annotated in yellow). As indicated above, the venting arrangement and flow restrictor allow 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.

339. 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:

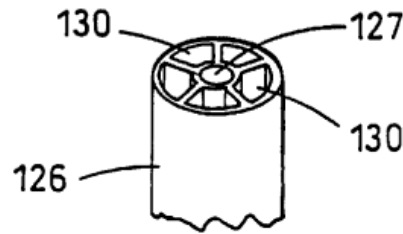


Fig. 5F

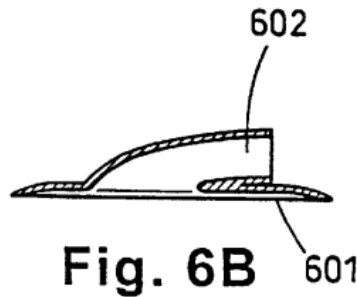
Id. at Fig. 5F. In this embodiment, a POSITA would have understood that the venting arrangement and flow restrictor (pressure relief valve 8 and tube 106) necessarily provides a controlled flow of ambient air into the multi-partitioned tube.

340. Accordingly, it is my opinion that Hunt teaches limitation 11[d].

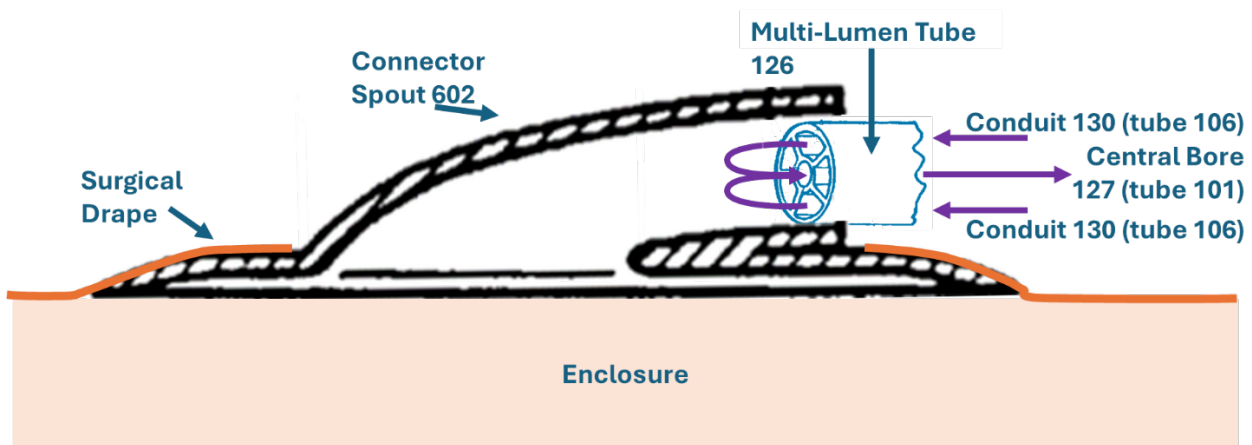
vi. Limitation 11[e]: said controlled flow of ambient air entering said tube via said venting arrangement without entering said enclosure,

341. In my opinion, Hunt teaches limitation 11[e]. As explained immediately above, Hunt teaches that the venting arrangement provides a controlled flow of air into the tube via pressure relief valve 8 and tube 106.

342. As I 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 a hole 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.

343. Accordingly, it is my opinion that Hunt teaches limitation 11[e].

- vii. Limitation 11[f]: the controller configured for controlling operation of the vacuum source while said tube is being vented via said venting arrangement to provide a desired level of said negative pressure in said confined volume.**

344. Limitation 11[f] is substantively identical to limitation 1[e]. The analysis and my discussion of limitation 1[e] is hereby incorporated by reference. Additionally, as explained immediately above, Hunt teaches that the venting arrangement vents the tube by providing ambient air into the tube through pressure relief valve 8.

345. Accordingly, it is my opinion that Hunt teaches limitation 11[f] and therefore teaches all the limitations of claim 11 of the '534 Patent.

10. Claim 12: The vacuum system according to claim 11, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.

346. In my opinion, Hunt teaches claim 12. As explained above, Hunt teaches the vacuum system according to claim 11. Claim 12 is substantively identical to claim 3. The analysis and my discussion of claim 3 is hereby incorporated by reference.

347. Accordingly, it is my opinion that Hunt teaches limitation 12.

11. Claim 13: The vacuum system according to claim 11, further comprising a waste container in fluid communication with said vacuum source.

348. In my opinion, Hunt teaches claim 13. As explained above, Hunt teaches the vacuum system according to claim 11. Claim 13 is substantively identical to claim 4. The analysis and my discussion of claim 4 is hereby incorporated by reference.

349. Accordingly, it is my opinion that Hunt teaches limitation 13.

12. Claim 14: The vacuum system according to claim 11, wherein said vacuum source comprises a vacuum pump driven by a motor.

350. In my opinion, Hunt teaches claim 14. As explained above, Hunt teaches the vacuum system according to claim 11. Claim 14 is substantively identical

to claim 5. The analysis and my discussion of claim 5 is hereby incorporated by reference.

351. Accordingly, it is my opinion that Hunt teaches limitation 14.

13. Claim 15: The vacuum system according to claim 14, wherein said motor is an electric motor, and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.

352. In my opinion, Hunt teaches claim 15. As explained above, Hunt teaches the vacuum system according to claim 14. Claim 15 is substantively identical to claim 6. The analysis and my discussion of claim 6 is hereby incorporated by reference.

353. Accordingly, it is my opinion that Hunt teaches limitation 14.

14. Claim 17: The vacuum system according to claim 11, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating.

354. In my opinion, Hunt teaches claim 17. As explained above, Hunt teaches the vacuum system according to claim 11. Claim 17 is substantively identical to claim 9. The analysis and my discussion of claim 9 is hereby incorporated by reference.

355. Accordingly, it is my opinion that Hunt teaches limitation 17.

15. Claim 18: The vacuum system according to claim 11, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice.

356. In my opinion, Hunt teaches claim 18. As explained above, Hunt teaches the vacuum system according to claim 11. Claim 18 is substantively identical to claim 10. The analysis and my discussion of claim 10 is hereby incorporated by reference.

357. Accordingly, it is my opinion that Hunt teaches limitation 18.

16. Claim 19

358. Based on my review and for the reasons that follow, it is my opinion that claim 19 is anticipated by Hunt.

i. Limitation 19[pre]: A method for applying negative pressure to a wound, comprising:

359. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 19, it is my opinion that Hunt teaches a method for applying negative pressure to a wound. As I explained in limitation 1[pre] above, Hunt teaches a negative wound pressure treatment apparatus. Hunt further teaches “[t]he method of operation of the apparatus can be appreciated from the schematic layout in FIG. 1” *Id.* at 3:57-58. Figure 1 is reproduced below:

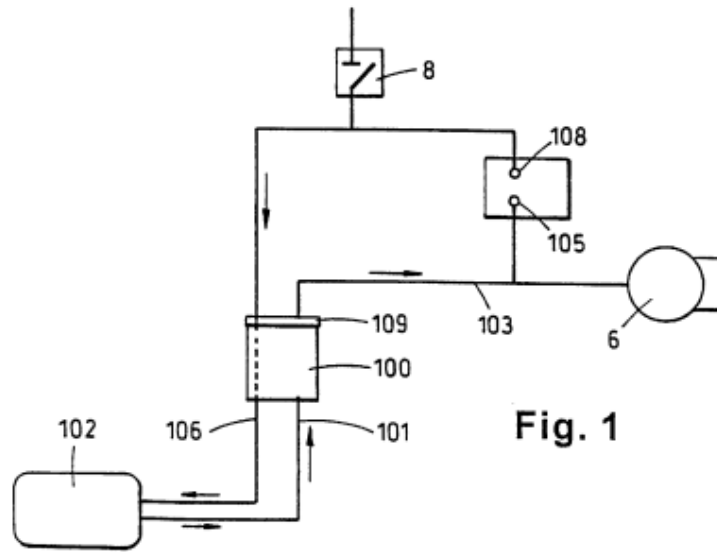


Fig. 1

Id. at Fig. 1.

360. Accordingly, it is my opinion that Hunt teaches limitation 19[pre].

ii. Limitation 19[a]: providing a vacuum system comprising at least: an enclosure, a venting arrangement, a tube, and a vacuum source:

361. Limitation 19[a] is substantively identical to limitations 1[pre] and 1[a].

The analysis and my discussion of limitations 1[pre] and 1[a] is hereby incorporated by reference.

362. Accordingly, it is my opinion that Hunt teaches limitation 19[a].

iii. Limitation 19[b]: the enclosure being attachable to a periphery of the wound so as to define a confined volume;

363. Limitation 19[b] is identical to limitation 1[b]. The analysis and my discussion of limitation 1[b] is hereby incorporated by reference.

364. Accordingly, it is my opinion that Hunt teaches limitation 19[b].

- iv. **Limitation 19[c]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume;**

365. Limitation 19[c] is identical to limitation 1[c]. The analysis and my discussion of limitation 1[c] is hereby incorporated by reference.

366. Accordingly, it is my opinion that Hunt teaches limitation 19[c].

- v. **Limitation 19[d]: the venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said system upstream of the vacuum source;**

367. Limitation 19[d] is substantively identical to limitation 1[d]. The analysis and my discussion of limitation 1[b] is hereby incorporated by reference.

368. Accordingly, it is my opinion that Hunt teaches limitation 19[d].

- vi. **Limitation 19[e]: (b) controlling operation of the vacuum source while the vacuum system is being vented via the venting arrangement to thereby provide a desired level of said negative pressure in said confined volume.**

369. Limitation 19[e] is substantively identical to limitation 1[e]. The analysis and my discussion of limitation 1[e] is hereby incorporated by reference.

370. Accordingly, it is my opinion that Hunt teaches limitation 19[e].

371. Thus, it is my opinion that Hunt teaches the limitations of independent claim 19.

17. Claim 20

372. Based on my review and for the reasons that follow, it is my opinion that claim 20 is anticipated by Hunt.

i. Limitation 20[pre]: The method according to claim 19,

373. I understand that a preamble generally does not state a claim limitation. However, to the extent the preamble limits claim 20, it is my opinion that Hunt teaches limitation 20[pre]. Limitation 20[pre] merely refers to the method of claim 19. For the reasons stated above, Hunt teaches claim 19.

374. Accordingly, it is my opinion that Hunt teaches limitation 20[pre].

ii. Limitation 20[a]: wherein the vacuum source comprises a vacuum pump driven by an electric motor, and

375. Limitation 20[a] is substantively identical to claim 5 and limitations 6[pre] and 6[a]. The analysis and my discussion of claims 5, limitation 6[pre], and limitation 6[a] is hereby incorporated by reference.

376. Accordingly, it is my opinion that Hunt teaches limitation 20[a].

iii. Limitation 20[b]: wherein step (b) comprises controlling operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.

377. Limitation 20[b] is substantively identical to limitation 6[b]. The analysis and my discussion of limitation 6[b] is hereby incorporated by reference.

378. Accordingly, it is my opinion that Hunt teaches limitation 20[b].

379. For the stated reasons, it is my opinion that Hunt teaches claim 20.

18. Claim 22: The method according to claim 19, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice.

380. In my opinion, Hunt teaches claim 22. For the reasons stated above, Hunt teaches the method of claim 19. In my opinion, Hunt also teaches the additional limitations in claim 22. Claim 22 is substantively identical to claim 10. The analysis and my discussion of claim 10 is hereby incorporated by reference.

381. Accordingly, it is my opinion that Hunt teaches claim 22.

D. Ground 4: Analysis of Claims 7, 8, 16, and 21 Based on Hunt in view of Lina

382. In my opinion, claims 7, 8, 16, and 21 of the '534 Patent are invalid because they are obvious over the teachings of Hunt in view of Lina, as detailed below.

1. Overview of the Combination of Hunt and Lina

383. As explained in Ground 3, Hunt anticipates the limitations of independent claims 1 and 19, as well as certain dependent claims. Also, as explained in Ground 3, Hunt teaches a microprocessor that operates the pump and various sensors to provide a desired amount of negative pressure at the wound. Hunt also teaches that its microprocessor controls the speed of the vacuum pump. *Id.* at 2:15-21. Hunt, however, does not explicitly disclose that the way in which the microprocessor controls the speed of the pump is by controlling the voltage applied to the pump motor.

384. Prior to July 24, 2005, as described above, POSITAs were well-aware that there were many types of electric motors and commercially available ways to control the motor speed, including for NPWT pumps with DC motors. Controllers could be configured to control the amount of voltage applied to the pump motor to increase or decrease the amount of negative pressure being applied. Lina provides an example of this well-known practice. Lina specifically teaches that the microcontroller “controls pump motor 83 by varying the amount of voltage received by pump motor 83.” Ex. 1005 at 13:35-36.

385. As I set forth below, a POSITA would have been motivated to implement Hunt’s NPWT system with a microcontroller that directly controls the

voltage of the pump motor to selectively apply a desired negative pressure, such as the microcontroller disclosed in Lina. Additionally, as explained below, a POSITA would have found it an obvious choice for the microprocessor of Hunt to control the voltage applied to the pump motor based on what is known in the art alone, or at the very least, based on the teachings of Lina.

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

386. I understand Hunt and Lina are considered to be analogous art as they are all within the same field of endeavor—NPWT systems. In particular, Hunt and Lina both teach NPWT systems that use a controller to operate the system and further teach the use of DC electric motors for the vacuum pump. Moreover, both Hunt and Lina specifically teach that the controller (microprocessor or microcontroller) control the speed of the vacuum pump. In my opinion, a POSITA would have been motivated to combine the teachings of Hunt and Lina, as it relates to the controller and voltage received by the vacuum pump motor, for several reasons.

i. Choosing that the controller of Hunt would control the pump's motor based on the teachings of Lina would have been using well-established prior art elements according to known methods to yield predictable results.

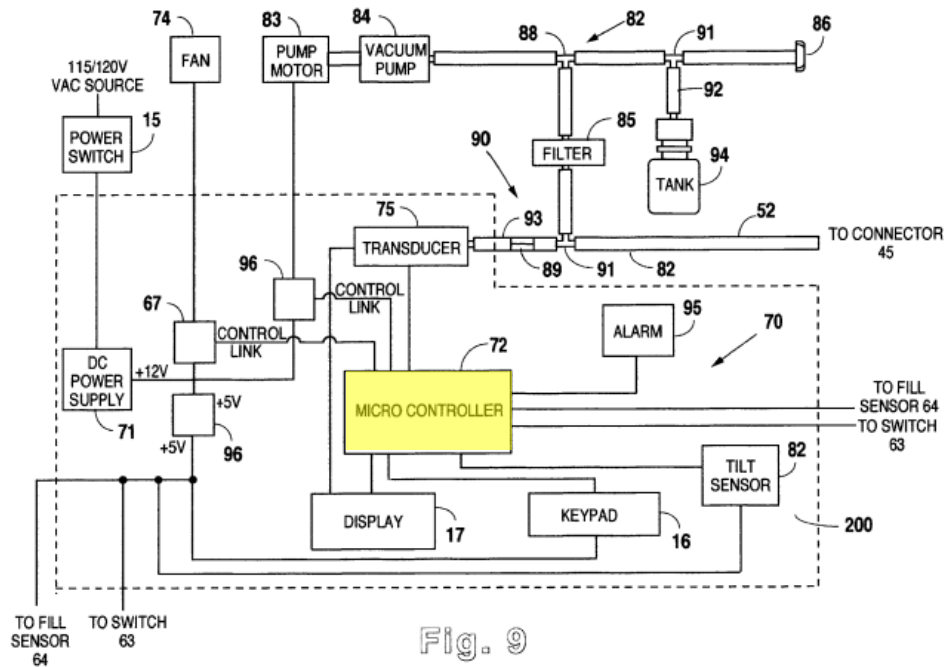
387. Prior to July 24, 2005, it was well-known and well-understood that a controller could be used to control voltage of a pump motor in NPWT systems to

control the motor speed and resulting pressure level. Hunt left the choice of control method open as the options were well understood by a POSITA. Controllers, such as the one taught in Lina, were used in conjunction with NPWT systems at least by the 1990s. Lina, which was filed in 2000, teaches a NPWT system, similar to the one taught by Hunt, which includes a microcontroller that controls the vacuum pump's motor to variably adjust the negative pressure being applied to the wound.

Id. at 13:35-43. Specifically, Lina teaches:

Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83. . . . After receiving the wound pressure signal from transducer 75, microcontroller 72 compares the wound pressure with the user selected pressure. If the wound pressure is higher than the user selected vacuum pump pressure, microcontroller 72 reduces pump motor speed to decrease vacuum pump pressure and thus the pressure at the wound.

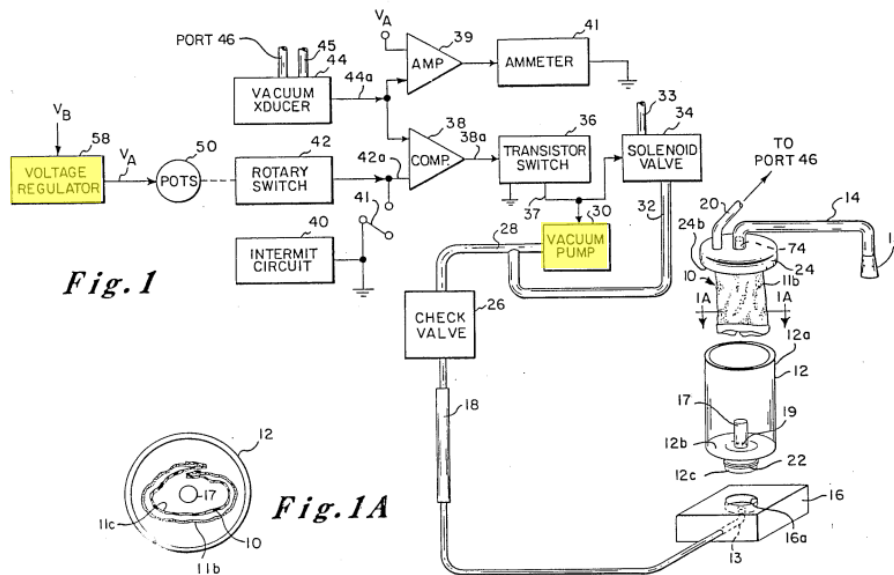
Id. at 13:20-31. Moreover, Lina explains that “[m]icrocontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83.” *Id.* at 13:35-36. The microcontroller of Lina is shown in Figure 9:



Id. at Fig. 9 (highlighting added).

388. Additionally, POSITAs would have knowledge of other prior art controllers such as Stacey, that teaches controlling the amount of voltage applied to a vacuum pump motor, as I explained in Part VIII.B.2.i above. Ex. 1032.

389. Stacey teaches a “voltage regulator” that controls the amount of voltage supplied to the vacuum pump’s motor to increase or decrease the amount of negative pressure being applied. The voltage regulator and relevant circuitry is depicted in Figure 1 below:



Id. at Fig. 1 (highlighting added). Stacey describes how the system compares the intended voltage to the current voltage and adjusts the speed of the pump motor (“motor windings of vacuum pump”) accordingly. *Id.* at 3:65 – 4:30, 6:46 – 8:19.

390. For at least these reasons, as of July 24, 2005, POSITAs were well-aware of NPWT controllers that controlled the vacuum pump motor (including, specifically, the voltage of that motor). As such, modifying Hunt’s NPWT system and controller to incorporate the functionality of Lina’s controller would have simply been combining prior art elements according to methods known for years. Moreover, a POSITA would have understood that this combination would yield the predictable result reflected in the above-cited references—i.e., adjusting the amount of negative pressure applied at the wound site to achieve the desired level of suction.

ii. It would have been obvious to try combining the controller of Lina with the NPWT system of Hunt.

391. It is also my opinion that it would have been obvious to try the use of Lina's controller within the NPWT system of Hunt.

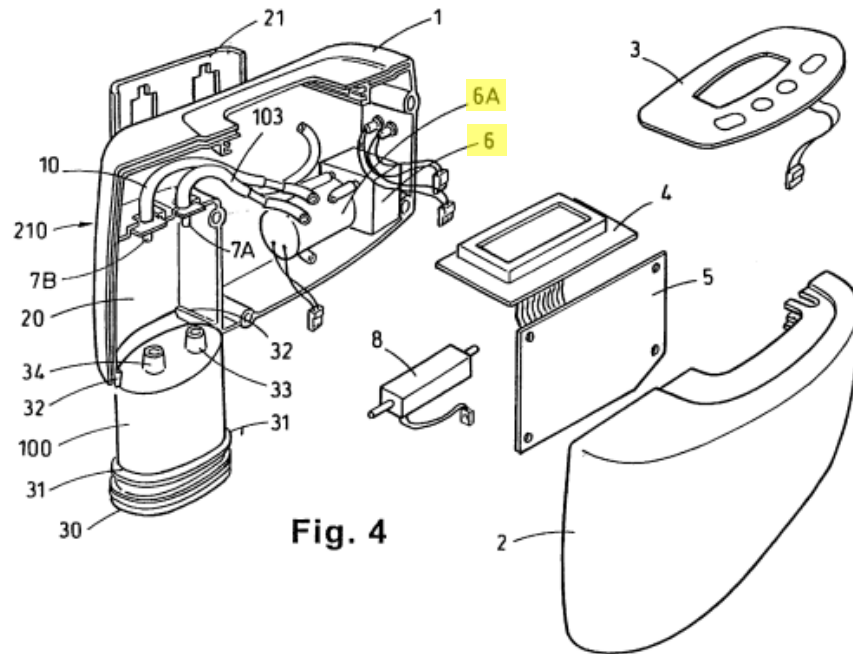
392. Like Lina, Hunt teaches that its microprocessor controls the speed of the vacuum pump to adjust the amount of negative pressure applied at the wound site without specifying which of the available methods to use. Ex. 1006 at 2:15-21. A POSITA would have understood there are a limited number of predictable ways to control the speed of a pump, including (1) adjusting the electric current applied to the pump motor; (2) adjusting the voltage applied to the pump motor; and (3) adjusting the frequency and duration of voltage or current (e.g., pulse with modulation) applied to the pump motor.

393. Given the three options known to a POSITA, it would have been obvious for a POSITA to try controlling the voltage applied to the vacuum pump motor, as taught by Lina. I also believe it would have been obvious for a POSITA to try controlling the speed of the pump motor in Hunt in different ways. A POSITA would have decided which method of controlling the speed of the pump motor was easiest to control and implement with Hunt's disclosed microprocessor.

394. As I explain below, a POSITA would have also had a reasonable expectation of success in trying the controller that operates motor speed for Hunt's NPWT system.

iii. A POSITA would have expected to succeed in combining Hunt's NPWT system with Lina's controller.

395. It is my opinion that a POSITA would have expected success in implementing Hunt's NPWT system to include a controller that controls the voltage received by the vacuum pump motor as taught in Lina. Adding Lina's controller to Hunt's NPWT system could routinely be accomplished by utilizing the microprocessor disclosed in Hunt that controls the speed of the motor with the microcontroller disclosed in Lina that specifically controls the voltage applied to the pump motor. Hunt teaches that the "suction pump is conveniently driven by an electric motor." Ex. 1006 at 1:61-62. As is shown in Figure 4 below, motor 6A sits next to and drives pump 6:



Id. at Fig. 4 (highlighted to identify vacuum pump 6 and pump motor 6A). Additionally, Hunt specifically teaches that its microprocessor signals the pump to increase or decrease its speed. *Id.* at 2:15-21. Thus, Hunt's microprocessor is already designed to operate pump motor 6A and, configuring it to control the amount of voltage applied to the pump in response to a detected pressure that does not match the desired negative pressure level would be an easy and obvious modification to a POSITA.

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

3. Claim 7: The vacuum system according to claim 6, wherein said controller controls the electric current or the voltage of said motor to control said level of said negative pressure in said confined volume.

397. It is my opinion that Hunt and Lina render claim 7 obvious. For the reasons stated in Ground 3 above, Hunt teaches and render obvious the vacuum system of claim 6. In my opinion, Lina teaches the additional limitations in claim 7 because Lina explicitly teaches that the controller can control the voltage of the pump motor to adjust the amount of negative pressure applied at the wound site.

398. As I discussed in Ground 2, Lina teaches claim 7. The analysis and my discussion of claim 7 from Ground 2 is hereby incorporated by reference.

399. As I discussed in Part VIII.D.2, a POSITA would have been motivated to combine the NPWT system of Hunt with the controller of Lina to control the voltage of the pump motor.

400. For the reasons stated above, in my opinion, Hunt in view of Lina teaches and renders obvious claim 7.

4. Claim 8: The vacuum system according to claim 6, wherein said controller controls the torque of said motor to control said level of said negative pressure in said confined volume.

401. It is my opinion that the combination of Hunt in view of Lina renders claim 8 obvious. For the reasons stated above, the combination of Hunt and Lina

teach and render obvious the vacuum system of claim 6. In my opinion, the combination of Hunt and Lina also renders claim 8 obvious.

402. As explained above, Lina explicitly teaches a controller that controls the voltage of the pump's motor to control the level of negative pressure within the confined volume. A POSITA would have found it obvious to control the torque of the motor to control the level of negative pressure. As explained above, Hunt and Lina both teach NPWT systems that use a controller to operate the system and further teach the use of DC electric motors for the vacuum pump. A POSITA would have known that DC current is directly related to torque and found it obvious to control the torque applied to the motor of the pump disclosed in Hunt and/or Lina, instead of the voltage being applied as is explicitly taught by Lina.

403. For the reasons stated above, in my opinion, Hunt in view of Lina renders obvious claim 8.

5. Claim 16: The vacuum system according to claim 15, wherein said controller controls at least one of the electric current of said motor, or the voltage of said motor, or the torque of said motor to control said level of said negative pressure in said confined volume.

404. In my opinion, the combination of Hunt and Lina teach and render obvious claim 16. For the reasons stated above in Ground 3, Hunt teaches the method of claim 15. In my opinion, Lina teaches the additional limitations of claim 5.

405. Claim 16 is substantively identical to claims 7 and 8. The analysis and my discussion of claims 7 and 8 immediately above is hereby incorporated by reference.

406. As I discussed in Part VIII.D.2, a POSITA would have been motivated to combine the NPWT system of Hunt with the controller of Lina.

407. Accordingly, it is my opinion that Hunt in view of Lina teaches and renders obvious claim 16.

6. Claim 21: The method according to claim 20, wherein step (b) comprises controlling at least one of the electric current, or the voltage, or the torque of said motor to control said level of said negative pressure in said confined volume.

408. In my opinion, the combination of Hunt and Lina teach and render obvious claim 21. For the reasons stated above in Ground 3, Hunt teaches the method of claim 20. In my opinion, Lina teaches the additional limitations of claim 21.

409. As I discussed in Ground 2, Lina teaches claim 21. The analysis and my discussion of claim 21 from Ground 2 is hereby incorporated by reference.

410. As I discussed in Part VIII.D.2, a POSITA would have been motivated to combine the NPWT system of Hunt with the controller of Lina to control the voltage of the pump motor.

411. Accordingly, it is my opinion that Hunt in view of Lina teaches and renders obvious claim 21.

E. Ground 5: Analysis of Claims 11-18 Based on Hunt and Lina in further view of Dolliver

412. In my opinion, claims 11-18 of the '534 Patent are invalid because they are obvious over the teachings of Hunt and Lina in further view of Dolliver, as detailed below.

1. Overview of the Combination of Hunt, Lina, and Dolliver

413. As explained in Ground 3 and 4, Hunt teaches a vacuum system for applying negative pressure to a wound that comprises: an enclosure, venting arrangement with flow restrictor, tube, vacuum source, controller, sensor, waste container, and electric motor. As explained in Ground 4, Hunt in view of Lina teaches controlling the electric motor by applying voltage to modify the speed of the pump motor.

414. Independent claim 11 recites a “venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said tube, said controlled flow of ambient air entering said tube via said venting arrangement without entering said enclosure.” While it is my opinion that Hunt teaches this claim, as explained in Ground 3 above, to the extent it is determined that Hunt does not explicitly disclose the ambient air flowing from tube 106 into tube 101 without entering the enclosure, this limitation is taught by Dolliver.

415. 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. 1007 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.” *Id.* at [0029].

416. 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.*

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

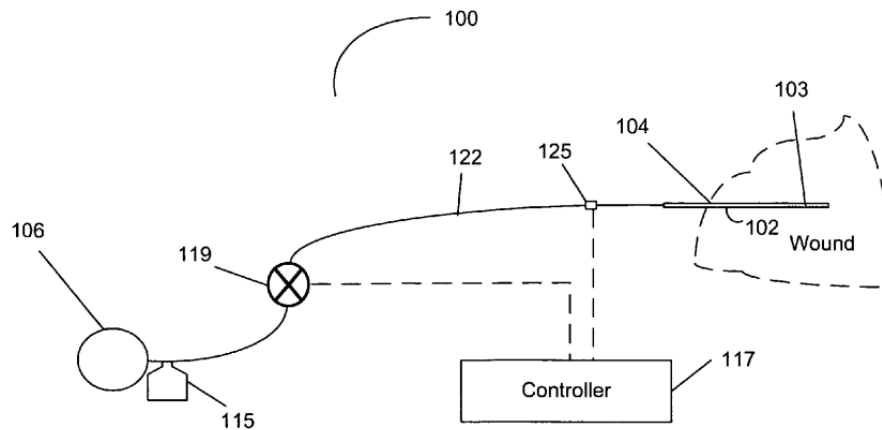


Fig. 1

Id. at Fig. 1.

418. 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)

419. 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 pressure 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 a simple design choice of where the vent valve is 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.**

420. Prior to July 24, 2005, it was well-known and well-understood that a valve could be used admit ambient air into NPWT systems, thereby controlling the level of negative pressure applied at the wound. Exs. 1003, 1005-1007. Both Hunt and Dolliver utilize valves to control the amount of pressure applied at the wound site, while allowing ambient air to enter the tube.

421. Hunt teaches a pressure relief valve 8 connected to the pressure sensing tube 106 that admits ambient air into the vacuum system. Ex. 1006 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:

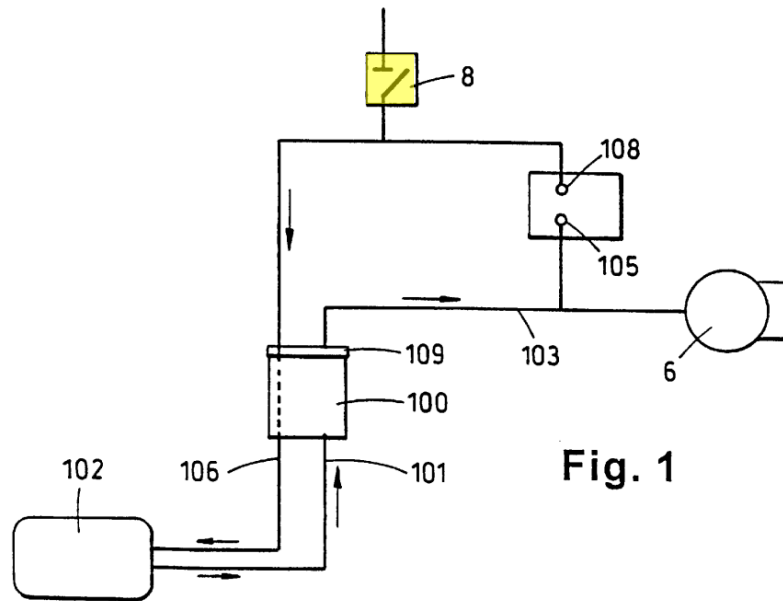


Fig. 1

Id. at Fig. 1 (highlighting added).

422. 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. Ex. 1007 at Fig. 1, [0029]. 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.

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

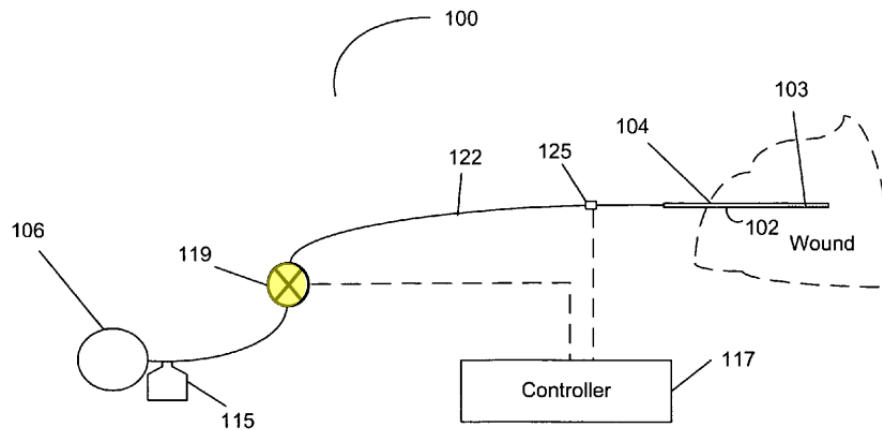


Fig. 1

Id. at Fig. 1 (highlighting added).

423. 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. 1005 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:

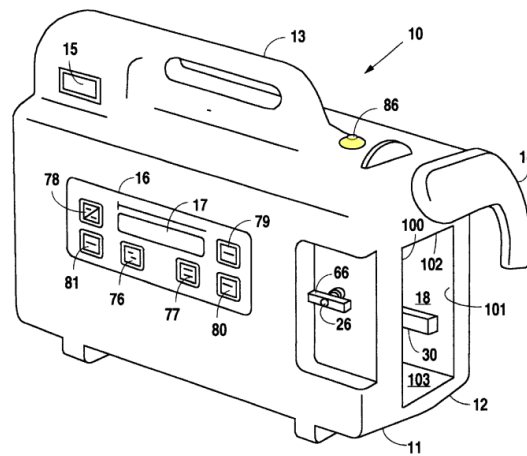
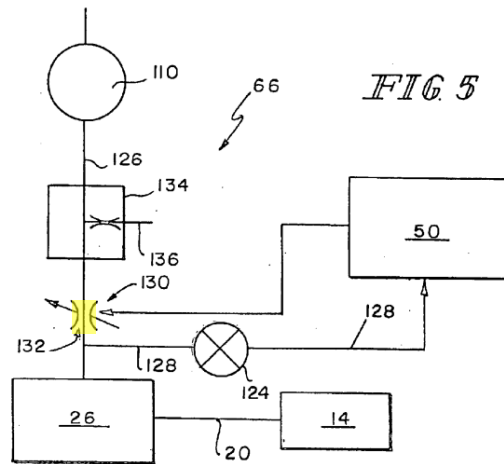


Fig. 1

Id. at Fig. 1 (highlighting added).

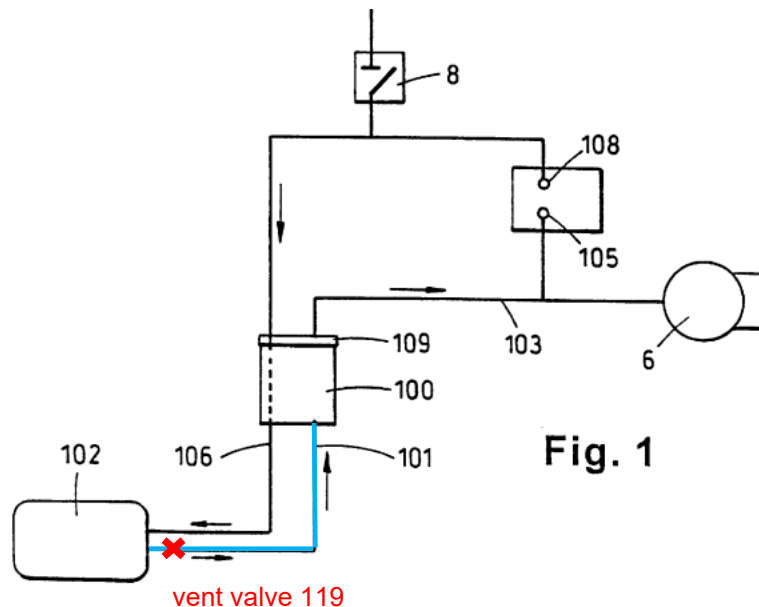
424. Similarly, Risk teaches a proportional valve within the conduit between the waste canister and vacuum pump. The proportional valve 130 in Risk includes a flow orifice 132 that “selectively dilates or constricts, thereby controlling the negative pressure level through sub-system 66.” Ex. 1003 at 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.

425. 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. 1006 at Fig. 1 (annotated in blue to identify tube 101 with vent valve 119 added in red). The location of the vent valve 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 removing 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).

426. 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. 1007 at [0005], [0006]. 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 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.

427. 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.

428. 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.

429. 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.

430. 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.

431. 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.

432. 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 in the prior art before the filing of the '534 Patent.

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

433. 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.

434. 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. 1006 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 cl. 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. 1007 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.

435. 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 11

436. Based on my review and for the reasons that follow, it is my opinion that claim 11 is obvious based on the teachings of Hunt and Dolliver.

437. I have reproduced independent claim 11 below and divided up the limitations using bracketed notations to facilitate identification of the limitations in my analysis below.

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

- [a] an enclosure, a venting arrangement, a tube, a vacuum source,
and a controller;
- [b] the enclosure being attachable to a periphery of the wound so as
to define a confined volume;
- [c] the enclosure having an enclosure outlet connectable to said
vacuum source via said tube so that negative pressure can be
selectively created in said volume;
- [d] said venting arrangement located outside said enclosure and
comprising a flow restrictor to restrict flow through said venting
arrangement and to thereby provide a controlled flow of air into
said tube,
- [e] said controlled flow of ambient air entering said tube via said
venting arrangement without entering said enclosure;

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

i. Limitation 11[pre]: A vacuum system for applying negative pressure to a wound, the vacuum system comprising:

438. I understand that a preamble generally does not state a claim limitation. However, as explained in Ground 3, to the extent the preamble limits claim 11, 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 1[pre] in Ground 3 is hereby incorporated by reference.

439. Accordingly, it is my opinion that Hunt teaches limitation 11[pre].

ii. Limitation 11[a]: an enclosure, a venting arrangement, a tube, a vacuum source, and a controller:

440. As explained in Ground 3, it is my opinion that Hunt teaches an enclosure, a venting arrangement, a tube, a vacuum source, and a controller. The analysis and my discussion of claim limitation 1[a] in Ground 3 is hereby incorporated by reference.

441. 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.E.2. Dolliver teaches a “vent valve” within the suction conduit “positioned between the drain catheter and the suction means.” Ex. 1007 at [0007]. A POSITA would have found it obvious to modify tube 101⁴ of Hunt to include the vent valve of Dolliver. *See* Part VIII.E.1-2, above.

442. 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 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 constitutes a “venting arrangement” as that term is used in the ’534 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.

443. Accordingly, it is my opinion that the combination of Hunt and Dolliver teaches and renders obvious limitation 11[a].

⁴ Tube 101 of Hunt is operatively connected to tube 103 in the canister and, therefore, applies suction to the wound dressing. Ex. 1006 at 3:60-66, Fig. 1.

iii. Limitation 11[b]: the enclosure being attachable to a periphery of the wound so as to define a confined volume;

444. As explained in Ground 3, it is my opinion that Hunt teaches an enclosure being attachable to the periphery of the wound so as to define a confined volume. The analysis and my discussion of claim limitation 1[b] in Ground 3 is hereby incorporated by reference.

445. Accordingly, it is my opinion that Hunt teaches limitation 11[b].

iv. Limitation 11[c]: the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be selectively created in said volume,

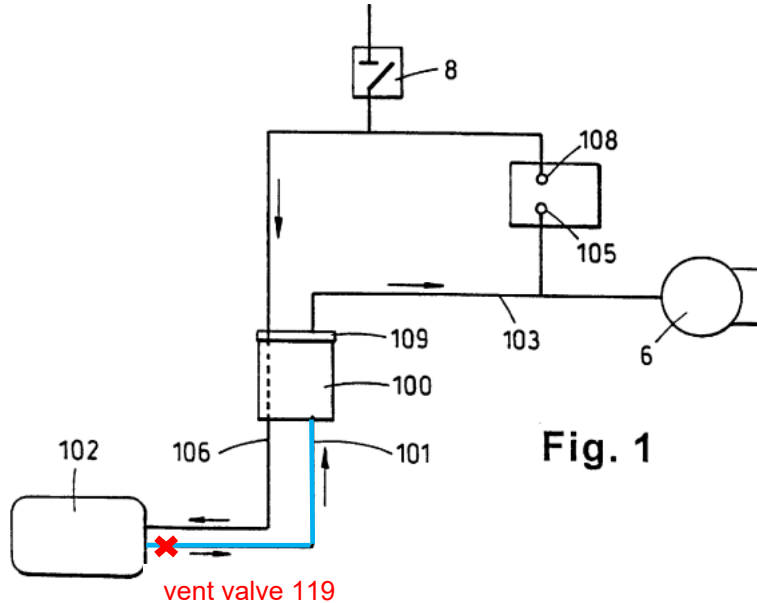
446. As explained in Ground 3, it is my opinion that Hunt teaches an enclosure having an enclosure outlet connectable to the vacuum source via the tube so that negative pressure can be selectively created in said volume. The analysis and my discussion of claim limitation 1[c] in Ground 3 is hereby incorporated by reference.

447. Accordingly, it is my opinion that Hunt teaches limitation 11[c].

- v. **Limitation 11[d]: said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement and to thereby provide a controlled flow of ambient air into said tube,**

448. In my opinion, Hunt in view of Dolliver teaches limitation 11[d] because Hunt combined with Dolliver teaches a “venting arrangement” (the vent valve 119 of Dolliver that connects with the tube) that comprises a flow restrictor (filter in the vent valve of Dolliver), which is located outside the enclosure and restricts the flow of ambient air through the tube and provides a controlled flow of ambient air into the tube.

449. As I explained with regard to limitation 11[a] 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. 1007 at [0007]. 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. 1006 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.

450. Dolliver further teaches that vent valve 119 “may include a filter, such as but not limited to a bacterial filter.” Ex. 1007 at [0029]. 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 into the tube.

451. 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 the tube—an orifice corresponding to the claimed “venting arrangement”. A POSITA would also have understood that vent valve 119 admits ambient air into the tube, through the filter (i.e., flow restrictor). As shown in annotated Figure 1 above,

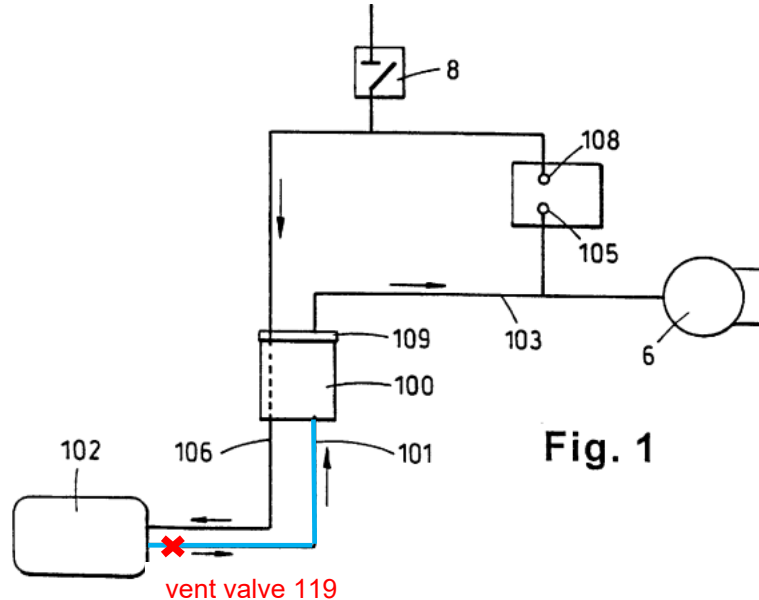
ambient air that enters tube 101 through its opening at vent valve 119 and flows towards the vacuum source (pump 6).

452. Accordingly, in my opinion Hunt in view of Dolliver teaches a venting arrangement and a flow restrictor under any construction of those terms. Thus, it is my opinion that Hunt in view of Dolliver teaches and renders obvious limitation 11[d].

vi. Limitation 11[e]: said controlled flow of ambient air entering said tube via said venting arrangement without entering said enclosure,

453. In my opinion, Hunt in view of Dolliver teaches limitation 11[e]. As explained immediately above, Hunt combined with Dolliver teaches a “venting arrangement” (tube 101 in Hunt and vent valve 119 of Dolliver) which is located outside the enclosure.

454. A combination of Dolliver’s vent valve 119 with Hunt’s NPWT system is depicted in annotated Figure 1 of Hunt below:



Ex. 1006 at Fig. 1 (annotated in blue to identify tube 101 with vent valve 119 added in red). Note that the vent valve 119 is represented schematically and can be located closer to or farther away from wound dressing 102. Looking at the combined system of Hunt and Dolliver, a POSITA would have understood that ambient air enters tube 101 via vent valve 119. That ambient air flows upstream towards the vacuum source (pump 6), without entering the enclosure covering the wound 102.

455. Accordingly, it is my opinion that Hunt in view of Dolliver teaches and renders obvious limitation 11[e].

vii. Limitation 11[f]: the controller configures for controlling operation of the vacuum source while said tube is being vented via said venting arrangement to provide a desired level of said negative pressure in said confined volume.

456. As explained in Ground 3, it is my opinion that Hunt teaches a controller configured for controlling operation of the vacuum source while the tube is being vented via the venting arrangement to provide a desired level of negative pressure in the confined volume. The analysis and my discussion of claim limitation 1[e] in Ground 3 is hereby incorporated by reference.

457. My analysis regarding Hunt’s disclosure is not changed by the addition of the venting arrangement taught by Dolliver. In Ground 3, I explained how Hunt discloses a controller which controls operation of the vacuum source to maintain a desired negative pressure while the system is vented via the pressure relief valve 8. When Hunt is combined with Dolliver, a POSITA would have understood that the controller in Hunt which controls intermittent operation of the vacuum pump is doing so while tube 101 is vented via the venting arrangement—tube 101 and Dolliver’s vent valve 119.

458. For example, Hunt explains that pressure valve 8 “will open for a specified period, allow the pressure to equalize at the wound site and then close to restore the suction.” Ex. 1006 at 4:20-24. Similarly, Dolliver explains that vent valve

119 “selectively opens (fully or partially) to allow [the tube] to vent to the atmosphere, thereby decreasing the amount of suction applied.” Ex. 1007 at [0029], [0007]. A POSITA would have, therefore, recognized that in the combined system of Hunt and Dolliver, the controller of Hunt controls the intermittent application of suction while tube 101 is being vented via the tube and vent valve 119.

459. Accordingly, in my opinion Hunt in view of Dolliver teaches and renders obvious limitation 11[f].

460. For the reasons stated above, it is my opinion that Hunt and Dolliver teach and/or render obvious all the limitations of claim 11 of the '534 Patent.

4. Claim 12: The vacuum system according to claim 11, further comprising a sensor for enabling determination of a level of said negative pressure in said confined volume.

461. In my opinion, Hunt in view of Dolliver teaches and renders obvious claim 12. As explained above, Hunt in view of Dolliver teaches and renders obvious the vacuum system of claim 11. Claim 12 is substantively identical to claim 3. The analysis and my discussion of claim 3, as explained in Ground 3, is hereby incorporated by reference.

462. Accordingly, in my opinion Hunt in view of Dolliver teaches and renders obvious claim 12.

5. Claim 13: The vacuum system according to claim 11, further comprising a waste container in fluid communication with said vacuum source.

463. In my opinion, Hunt in view of Dolliver teaches and renders obvious claim 13. As explained above, Hunt in view of Dolliver teaches and renders obvious the vacuum system of claim 11. Claim 13 is substantively identical to claim 4. The analysis and my discussion of claim 4, as explained in Ground 3, is hereby incorporated by reference.

464. Accordingly, in my opinion Hunt in view of Dolliver teaches claim 13.

6. Claim 14: The vacuum system according to claim 11, wherein said vacuum source comprises a vacuum pump driven by a motor.

465. In my opinion, Hunt in view of Dolliver teaches and renders obvious claim 14. As explained above, Hunt in view of Dolliver teaches and renders obvious the vacuum system of claim 11. Claim 14 is substantively identical to claim 5. The analysis and my discussion of claim 5, as explained in Ground 3, is hereby incorporated by reference.

466. Accordingly, it is my opinion that Hunt in view of Dolliver teaches and renders obvious claim 14.

7. **Claim 15: The vacuum system according to claim 14, wherein said motor is an electric motor, and said controller controls operation of said motor to thereby provide a desired level of said negative pressure in said confined volume.**

467. In my opinion, Hunt in view of Dolliver teaches and renders obvious claim 15. As explained above, Hunt in view of Dolliver teaches and renders obvious the vacuum system of claim 14. Claim 15 is substantively identical to claim 6. The analysis and my discussion of claim 6, as explained in Ground 3, is hereby incorporated by reference.

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

8. **Claim 16: The vacuum system according to claim 15, wherein said controller controls at least one of the electric current of said motor, or the voltage of said motor, or the torque of said motor, to control said level of said negative pressure in said confined volume.**

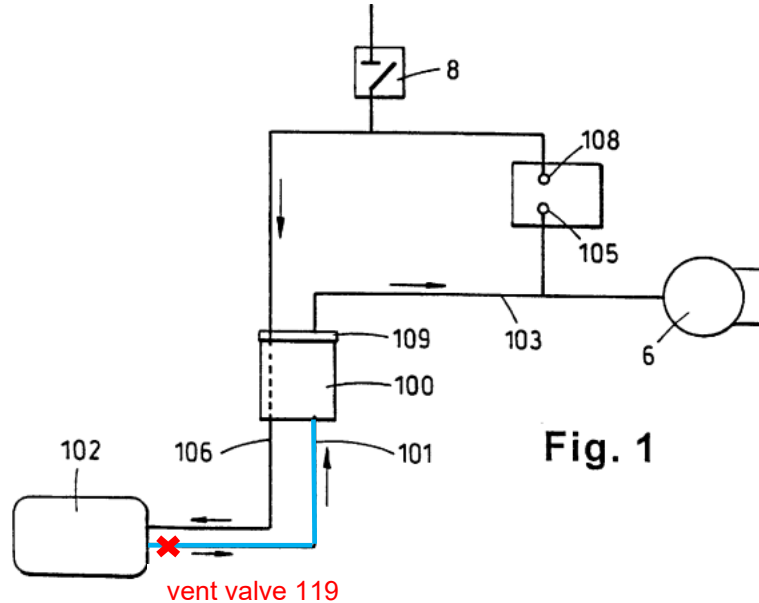
469. In my opinion, Hunt in view of Dolliver and in further view of Lina teach and render obvious claim 16. As explained in Ground 4, Lina teaches claim 16. The analysis and my discussion of claim 16 from Ground 4 is hereby incorporated by reference.

470. Accordingly, it is my opinion that Hunt in view Dolliver and in further view of Lina teaches and renders obvious claim 16.

9. Claim 17: The vacuum system according to claim 11, wherein ambient pressure may be restored in said confined volume via said venting arrangement when said vacuum pump is not operating.

471. In my opinion, Hunt in view of Dolliver teaches and renders obvious claim 17. As explained above, Hunt in view of Dolliver teaches the vacuum system of claim 11. In my opinion, the combination of Hunt and Dolliver also teaches and renders obvious the additional limitations in claim 17 because a POSITA would have understood that ambient pressure is restored at the wound site when the pump is turned off.

472. As previously explained regarding claim 11, Hunt in view of Dolliver teaches a venting arrangement in the form of a hole in tube 101 that meets vent valve 119. A POSITA looking at the disclosures of Dolliver would have understood vent valve 119 is “vent[ed] to the atmosphere” and “decreas[es] the amount of suction applied” to the wound when the pump is turned on. Ex. 1007 at [0029]. The combined system of Hunt and Dolliver is depicted in annotated Figure 1 below:



Ex. 1006 at Fig. 1 (annotated in blue to identify tube 101 with vent valve 119 added in red).

473. A POSITA would have understood that vent valve 119, which admits ambient air into tube 101 via the hole in tube 101 (the “venting arrangement”), restores ambient pressure in the confined volume beneath the wound dressing when the vacuum pump is not applying suction.

474. Accordingly, it is my opinion that Hunt in view of Dolliver teaches and renders obvious claim 17.

10. Claim 18: The vacuum system according to claim 11, wherein said venting arrangement comprises at least one of: one or more bleeding holes; a porous body; an orifice.

475. In my opinion, Hunt in view of Dolliver teaches and renders obvious claim 18. As explained above, Hunt in view of Dolliver teaches and renders obvious

the vacuum system of claim 11. In my opinion, the combination of Hunt and Dolliver also teaches the additional limitations in claim 18 because the venting arrangement includes an orifice within vent valve 119.

476. As I explained with regard to claim 11 above, the hole in suction tube 101 of Hunt where it meets the vent valve 119 of Dolliver constitutes a “venting arrangement”. A POSITA would have recognized that the vent valve (which necessarily includes a hole to allow in ambient air) comprises an orifice. A POSITA would have also understood the hole in vent valve 119 to be a bleeding hole.

477. Accordingly, in my opinion Hunt in view of Dolliver teaches and renders obvious claim 18.

IX. NO SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

478. 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.

479. 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

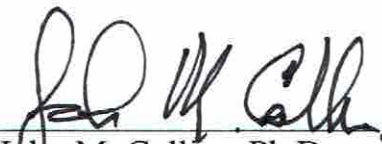
480. For at least the preceding reasons, in my opinion, claims 1-22 of the '534 Patent are anticipated by and/or would have been obvious to a person of ordinary skill in the art at the time of invention based on the prior art references that I have cited and analyzed above.

481. 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 '534 Patent claims at issue and/or offer testimony in support of this declaration.

482. 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.

Dated: June 17, 2024

Respectfully submitted,



John M. Collins, Ph.D.