

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Solventum Corporation,
Petitioners

v.

Wound Healing Technologies, LLC,
Patent Owner

Case No. IPR2025-01042
Patent No. 10,639,404

DECLARATION OF DR. MORTEN O. JENSEN, PH.D., DR.MED.

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I, DR. MORTEN O. JENSEN, PH.D., DR.MED., DECLARE AS FOLLOWS:

1. I am over the age of twenty-one and I am competent to testify as to the matters set forth in this Declaration.

2. I have been retained by counsel to render certain opinions as an expert witness for the above captioned inter partes review (“IPR”) proceeding regarding U.S. Patent Number 10,639,404 (the “’404 Patent”). In connection with my analysis, I have reviewed the ’404 Patent (EX1001) and the additional documents listed in Appendix A to this declaration (“Declaration”). I have been asked to provide my opinions regarding the validity of claims 1-13 (the “Challenged Claims”) of the ’404 Patent.

3. I am being compensated at my standard consulting rate of \$550 per hour for developing my opinions and preparing this declaration, and \$600 per hour for deposition testimony. My compensation is not dependent in any way upon the substance of my testimony, or the outcome of the IPR petition.

I. PERSONAL AND PROFESSIONAL BACKGROUND

4. My qualifications, credentials, and testimony history are stated more fully in my curriculum vitae (Ex. 1003). Here, I provide a summary of my qualifications.

5. My formal education includes a Bachelor of Science degree in Engineering, with honors, from The Engineering College of Aarhus at Aarhus,

Denmark, earned in 1997. I earned a Master of Science degree in Biomedical Engineering from the Georgia Institute of Technology and Emory University School of Medicine (joint program) in 2000. After earning my masters, I pursued and earned two doctoral degrees. I graduated from the University of Aarhus School of Medicine in Denmark in November 2008 with a Ph.D. (doctorate) in medicine. In March 2015, I was granted a Dr.Med. (or dr.med.) in medical science from the University of Aarhus School of Medicine in Denmark. The Dr.Med. degree is a higher-level doctorate degree that is awarded at certain universities in Northern Europe in the field of medicine. Dr.Med. is by law a higher degree than the Ph.D. The Dr.Med. degree is awarded after a candidate's research and publications have proven to make a significant difference in the advancement of medical science. Historically, the Dr.Med. degree has been given only to medical doctors, with rare exceptions. I was the third engineer in Denmark since 1479 to receive this degree.

6. I am currently a professor of biomedical engineering and Arkansas Research Alliance Scholar in the Department of Biomedical Engineering at the University of Arkansas, as well as an adjunct professor of surgery at the University of Arkansas for Medical Sciences. I have been employed with the University of Arkansas since August 2015. The Arkansas Research Alliance is a public-private partnership dedicated to elevating a fundamental belief that “research matters.” This Alliance provides partial financial support for parts of my research in the field of

biomedical engineering and increasing the understanding of the biomechanics and intervention while creating solutions and dedicated devices. I have secured more than \$4.5M in external research funding from the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Defense (DoD), and other funding sources for my research.

7. I hold an Adjunct Professorship at the University Hospital of Aarhus in Denmark where I have taught biomedical engineering to M.D./Ph.D. students and advised on biomechanical projects. I have held that position since July 2009. In 2013-2014, I was an Honorary Clinical Fellow and Senior Lecturer at University College in London, England. Over the past two decades, I have developed and taught numerous courses at both the undergraduate and graduate level, as well as in medical schools, in the field of biomedical engineering, including biomechanics, medical device mechanics, and biomechanical modeling.

8. As set forth in my CV, I have published numerous articles relating to aspects of biomechanics of tissues of the human body. I have also received numerous awards for my research work and teaching, and have served on various committees and boards. This includes review panels such as the NIH RO1 Bioengineering, Technology and Surgical Sciences Study Section panel, Center for Scientific Review (CSR), and the NSF Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Medical Devices programs review panel

member. Thus far, I have published 90 peer reviewed publications (68 journal papers and 22 refereed conference proceedings), 20 magazine articles, 11 books/book chapters, 7 conference keynote addresses, and given more than 170 presentations at conferences and seminars. Some of these publications are with highly relevant collaborators, such as the only Food and Drug Administration (FDA) research facility outside of the Washington DC area, located in Arkansas, near Little Rock. I am also an inventor and/or co-inventor of 9 patent application publications/trade secrets. Additionally, I currently teach the senior design course for the Biomedical Engineering Department at the University of Arkansas.

9. I have also actively participated, and worked alongside surgeons, radiologists, and anesthesiologists in more than 300 large animal experimental surgeries and interventions on 60-80 kg. porcine and ovine models. The pig and sheep are well-known models for the human physiological system in many aspects of medicine. The relevant equipment, tools and systems used on the large animal porcine and ovine model are the same as those used for humans. Hence, the experience of working with these models is extremely relevant to an in-depth understanding of how devices interact with the human biomedical and biomechanical system.

10. Prior to joining the University of Arkansas, I was employed by Vivas LLC as the Chief Technology Officer from 2017 to 2020.

11. From 2009 to 2015, I was an Associate Professor and Director of Research at The Scandinavian School of Cardiovascular Technology.

12. From 2014 to 2015, I was also a member of the Research Faculty in the Department of Biomedical Engineering at Georgia Tech/Emory in Atlanta, Georgia.

13. From 2013 to 2014, I was an Honorary Clinical Fellow and Senior Lecturer at the Department of Mechanical Engineering at the University of the College of London and in the Cardiology Department at The Heart Hospital Specialist Board in London, UK.

14. From 2007 to 2009, I was an Assistant Professor in the Department of Biomedical Engineering at the Engineering College of Aarhus in Aarhus, Denmark.

15. From 2000 to 2005, I worked in industry with a company based in Austin, Texas called National Instruments. Most of my activities with the company were with the consulting services department, where a large part of his work was to consult with manufacturers of medical devices on how to test the devices.

16. From 1992 to 1993, I was in the Communications Unit of the Danish Army Corps of Engineers in Denmark.

17. I am a member of the Biomedical Engineering Society.

18. As part of my work in the field of Biomedical Engineering, I have significant additional experience directly pertaining to the technology at issue in this matter. My twenty-five years of experience in industry and academia has focused on

medical devices. Currently my lab is using vacuum assisted technology in driving fluids with soft tissue. This work has been published and continues to be used for FDA approval of medical devices. I have worked in the past with multiple medical device cases as an expert witness where dynamic vacuum technology was used on the surface of human skin. I have in the past published research in the journal “Skin Research and Technology,” and I also used dynamic pressure and vacuum systems and pumps with soft tissues in my work at Georgia Tech in the late 1990’s. I have taught fluid mechanics principles at the graduate and undergraduate college level for both engineering and medical school students. In addition, I have industry experience and competencies from my six years with National Instruments in medical device development, motion control, and mechanical motor system identification. This work included developing sensor and controls systems using programmable logic or micro-controllers for motors that would drive many things, for example fluid pumps with controls design algorithms such Proportional-Integral-Derivative (PID) and state space controls systems.

19. During my career, I have worked on and evaluated many different medical device types, such as general surgery devices, cardiovascular devices, and orthopedic devices. Hence, because of my background, education, and experience both in industry and academia, I am highly qualified and have a keen ability to review materials and provide opinions relating to the products discussed in this case.

II. SUMMARY OF OPINIONS

20. I have been asked to provide my opinion related to patentability of the Challenged Claims in light of prior-art references that I understand are identified in the Petition for IPR in this matter. For the reasons below, it is my opinion that the Challenged Claims would each have been obvious at the time of alleged invention based on at least the prior art references in the table below. I also note that many of these components and concepts were very well-known to those skilled in this art at that time, and such artisans routinely modified these types of devices/dressings (which I discuss further in this declaration). The below table refers to the references by first name of the inventor or author, which I define further in the sections below. When I use the acronym “POSITA,” I am referring to a person of ordinary skill in the art.

Ground	Claims	Basis of Unpatentability
1	1-7, 11, 13	Obvious over Argenta on its own and/or in view of Hu
2	8-10	Obvious over Argenta in view of Biggie or in view of Biggie and Hu
3	1, 4-7, 12	Obvious over Argenta in view of Lockwood or in view of Lockwood and Hu

III. LEGAL STANDARDS FOR PATENTABILITY

21. I understand that there are several legal principles involved in evaluating the patentability of patent claims. I am not an attorney. However, in considering the subject matter of the '404 Patent and developing my opinions of the Challenged Claims I relied on several legal principles that have been provided to me by counsel. Below is my understanding of those legal principles, which I have applied in my analysis throughout my declaration.

A. Burden of Proof

22. I understand that the patentability of the Challenged Claims is being challenged in an inter partes review proceeding in front of the U.S. Patent and Trademark Office. I understand that Solventum has the burden of proving that the Challenged Claims are unpatentable by a preponderance of the evidence. I understand that a preponderance of the evidence means that a fact or conclusion is more likely than not to be true.

B. Person of Ordinary Skill in the Art

23. I understand that patent claims are interpreted and evaluated from the viewpoint of a POSITA at the time of the alleged invention. I understand that a POSITA is a hypothetical person presumed to be aware of all prior art pertinent to the relevant field and that a POSITA is also a person of ordinary creativity.

24. I understand that several factors may be considered in determining the level of skill in the art, including (A) the education level of the inventor, (B) the education level of active workers in the field, (C) the type of problems encountered in the art, (D) prior art solutions to those problems, (E) the speed with which innovations in the art are made, and (F) sophistication of the technology.

C. Patentability — Anticipation

25. I understand that a patent claim may be unpatentable if it is anticipated by another prior art reference. I understand that a claim is anticipated by a reference if that reference discloses, either expressly or inherently, every single limitation of the claim, arranged as they are arranged in the claim.

D. Patentability — Obviousness

26. I understand that a patent claim may be unpatentable if it would have been obvious in view of a single prior art reference or a combination of several prior art references. I understand that references are prior art to the Challenged Claims if they are patents or printed publications that were publicly available prior to the '404 Patent's "priority date," also known as its "first effective filing date." I also understand that patents and patent publications can in some cases be prior art based on their filing date, even if not published prior to the '404 Patent's priority date. I

have been asked to assume that the references referred to in the table set forth in my Summary of Opinions Section, above, are all prior art to the '404 Patent.

27. I understand that a patent claim would have been obvious if the differences between the subject matter of the claim and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the relevant field and the time the invention was made. I understand this involved consideration of:

- a. The scope and content of the prior art;
- b. The differences between the prior art and the claims at issue;
- c. The knowledge of a POSITA;
- d. Objective indicia of non-obviousness (also called “secondary factors”), such as commercial success, skepticism by others, praise for the claimed invention, unexpected results, copying by others, failure of others, and long-felt but unmet need. I note that I am not aware of any objective indicia of non-obviousness that the patent owner has presented either during prosecution of the '404 Patent, or anywhere else.

28. I understand that for a claim to be considered obvious, a POSITA must have had a reason for modifying a reference, or for combining the teachings of

multiple references together. I understand that several exemplary reasons why a POSITA might have combined two or more references include:

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

29. I understand that for modification of a single reference or a combination of references to render obvious the claimed invention, a POSITA must have been able to arrive at the claimed invention by altering or combining the references and must have had a reasonable expectation of success in doing so.

IV. PERSON OF ORDINARY SKILL IN THE ART

30. The '404 Patent involves technology in the field of wound therapy, more specifically, development of a device or dressing for providing negative pressure wound therapy ("NPT"). I have been asked to provide my opinions as to the state of the art in this field as of 2010, i.e., before the June 3, 2010 filing date of the provisional application referenced on the face of the '404 Patent. EX1001, cover, section (63). In my opinions about the knowledge of a POSITA, the way a POSITA would have understood the '404 Patent or the prior art, or what a POSITA would have been led to do based on the disclosures and teachings of the prior art, I am referring to the early 2010 timeframe, prior to June 3, 2010, unless I specifically state otherwise.

31. In my opinion, a POSITA in early 2010 would have a bachelor's degree in biomedical engineering and either (1) a master's degree in biomedical engineering, or (2) three years of relevant industry experience working with wound dressings as of June 3, 2010.

32. In my opinion, this definition is commensurate with the education level of those in this field who designed dressings and devices to administer NPT. As described throughout my declaration, the problems encountered in the art relate to how one can provide negative pressure in an optimal wound environment, and what materials can be used to do so, while protecting the patient's skin. See, for example, section VI, below.

33. Based on my education and experience as set forth above and, in my curriculum vitae, I believe that I qualified as at least a POSITA in the relevant time frame. At the time of the alleged invention, I had a sufficient level of knowledge, experience, and education to provide an expert opinion in the field of the '404 Patent.

V. THE '404 PATENT

34. I have reviewed the claims, specification, and file history of the '404 Patent and summarize some of the key points below.

A. The Challenged Claims

35. I understand that patents can have both independent and dependent claims, and that a dependent claim includes each limitation of the independent claim from which it depends, and then adds one or more additional limitations. The '404 Patent includes three independent claims and 10 dependent claims.

36. Independent claim 1 is set forth below with individual elements identified by a lower-case letter (e.g., “1[a]”).

1[a] A wound dressing comprising:

1[b] a wound-fluid drain for use in negative pressure wound treatment (“NPT drain”);

1[c] a vacuum/drainage tube comprising a terminus associated with the NPT drain, said NPT drain being configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound;

1[d] fluid-absorbing/transferring layer for distributing negative pressure from the NPT drain, said fluid-absorbing/transferring material being in contact with the NPT drain;

1[e] a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer,

1[f] said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of fluid-absorbing/transferring layer relative to the vapor sealant sheet; and

1[g] a tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet and a portion of the fluid-absorbing/transferring layer, the tube-anchorage component for mechanically maintaining placement of the NPT drain relative to the fluid-absorbing/transferring layer.

37. Claim 2 is another independent claim, similar to claim 1, but with a few notable differences. Claim 2 does not require a configuration to non-simultaneous deliver and withdraw fluids, and does not require that the drain be in contact with the fluid-absorbing/transferring layer (it only requires the vacuum tube be in contact

with that layer). It also does not require a single tube-anchorage component to be in contact with the fluid-absorbing/transferring layer, but it does require a second tube-anchorage component. The individual elements of claim 2 are set forth below:

2[a] A wound dressing comprising:

2[b] a wound-fluid negative pressure treatment (“NPT”) drain;

2[c] a vacuum/drainage tube comprising a terminus associated with the NPT drain;

2[d] fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring material being in contact with the vacuum/drainage tube;

2[e] a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer,

2[f] said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of fluid-absorbing/transferring layer relative to the vapor sealant sheet; and

2[g] a first tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet; and

2[h] a second tube-anchorage component, the first and second tube-anchorage components for mechanically maintaining the NPT drain’s placement relative to the fluid-absorbing/transferring layer.

38. Claim 3 is another independent claim, similar to claim 1, but does not require a drain, a configuration to non-simultaneously deliver and withdraw fluids,

or the tube anchorage components, but instead requires a “*tube-exit sealant component*.” The individual elements of claim 3 are set forth below:

3[a] A wound dressing comprising:

3[b] a vacuum/drainage tube comprising a terminus;

3[c] fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring material being in contact with the vacuum/drainage tube;

3[d] a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer,

3[e] said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of fluid-absorbing/transferring layer relative to the vapor sealant sheet; and

3[f] a tube-exit-sealant component for mechanically maintaining the vacuum/drainage tube’s placement relative to the fluid-absorbing/transferring layer.

39. Claim 4 depends on claim 1 and requires that the fluid-absorbing/transferring layer be comprised of gauze.

40. Claim 5 depends on claim 1 and requires that the fluid-absorbing/transferring layer be comprised of foam.

41. Claim 6 depends on claim 1 and requires that the fluid-absorbing/transferring layer comprises an upper and a lower layer.

42. Claim 7 depends on claim 6 and requires that the NPT drain is enfolded between the lower layer and upper layer.

43. Claim 8 depends on claim 2 and requires that the vacuum/drainage tube comprise a plurality of lumens.

44. Claim 9 depends on claim 8 and requires that at least one lumen is configured to deliver fluid to a wound and at least one lumen is configured to withdraw fluid from the wound.

45. Claim 10 depends on claim 8 and requires that at least one lumen is configured to convey a medical device.

46. Claim 11 depends on claim 3 and requires that the vacuum/drainage tube terminus is associated with an NPT drain.

47. Claim 12 depends on claim 11 and requires that the NPT drain is comprised of a plurality of NPT drains.

48. Claim 13 depends on claim 3 and requires that the vacuum/drainage tube is associated with an external vacuum source.

B. The '404 Patent Specification

49. I cite to specific portions of the '404 Patent's specification throughout my declaration where it bears on my analysis. In addition, in this section I set forth some of the key points from the '404 Patent's specification.

50. First, I note that the '404 Patent includes an extensive section describing conventional prior art NPT dressings. EX1001 at 6:26-10:38, Figures 1-6. These six figures, each labeled "*Prior Art*," depict one type of conventional NPT dressing that includes a drain within wound packing material, here gauze, that is sealed with a flexible draping material.

51. Figure 1 depicts a wound being treated with medication prior to application of the dressing. EX1001 at 7:15-26, Fig. 1.

52. Figure 2 depicts a gauze packing material inserted within the wound bed. EX1001 at 7:27-57.

53. Figure 3 depicts a drain laying on top of a portion of the gauze material, and extra gauze material off to the side of the wound. EX1001 at 7:58-9:4. The drain appears to be, or to be nearly identical to, a traditional Jackson-Pratt drain that was used for removing bodily fluids, and, in some cases, for NPT. EX1016 at p. 61, Fig. 1 (depicting a "*Jackson-Pratt Mini-Snyder hemovac drain*" within a wound); Compare EX1001 Fig. 3 with EX1016 at Fig. 1 (depicting a Jackson-Pratt drain that looks nearly identical to the prior art drain in Fig. 3 of the '404 Patent). EX1004 at ¶20 expressly states that a Jackson-Pratt drain can be used in an NPT device. EX 1019 describes using a Jackson-Pratt drain as an off-the-shelf component that can be used to create an NPT dressing. EX1019 at pp. 235-236.

54. The description of Figure 3 also states that foam, such as V.A.C.® GRNUFOAM™ can be used instead of gauze. EX1001 at 8:1-3. Figure 3 also depicts pieces of tape (number 344) anchoring the vacuum tube to the patient's skin. EX1001 at 8:46-54.

55. Figure 4 depicts the fully packed wound bed, with the gauze material covering the drain, just before the wound is sealed with a drape. EX1001 at 9:5-32.

56. Figure 5 depicts the wound sealed with a contour-conforming draping material that adheres to the patient's skin and effects an airtight seal to permit application of negative pressure. EX1001 at 9:33-65. Figure 5 also depicts a second adhesive material, typically tape, sealing the egress of the tube from the perimeter of the drape. EX1001 at 9:59-65.

57. Figure 6 depicts the conventional NPT dressing with vacuum applied, which creates the negative (subatmospheric) pressure. EX1001 at 9:66-10:38.

58. I agree with this description from the '404 Patent that each of these components was conventional and routinely used in NPT dressings.

59. The specification then describes components of the alleged invention. First, the specification describes the NPT drain as ranging from a structure as simple as *"a section of tube featuring a single hole"* up through a complex drain with multiple parts and functions and uniquely shaped and spaced holes. EX1001 at 11:62-12:3. The drain can be *"a hollow tube-like structure featuring transversely*

perforated walls” (EX1001 at 11:47-51), and may be “*integrally continuous*” with the vacuum tube (EX1001 at 18:61-64).

60. The specification also describes the vacuum/drainage tube as providing a conduit through which low air pressure may be applied (EX1001 at 12:11-16) and may be available as standard tubing materials (EX1001 at 12:23-27). The tube can be single-lumen or multi-lumen, and can be used to deliver fluid to the wound either simultaneously or non-simultaneously while removing fluid from the wound. EX1001 at 12:32-54. The '404 Patent does not appear to describe whether or how the tube must be modified to carry out such functions.

61. The specification also describes a “*vapor sealant sheet*” that overlies the wound and forms an airtight seal. EX1001 at 15:5-24. The vapor sealant sheet can be made “*of materials including a suitable hydrocolloid material or other suitable material that is non-hydrocolloid.*” EX1001 at 15: 17-20. The '404 Patent provides no other description of how one would use a hydrocolloid material as the vapor sealant sheet. Hydrocolloid material is described in more detail below.

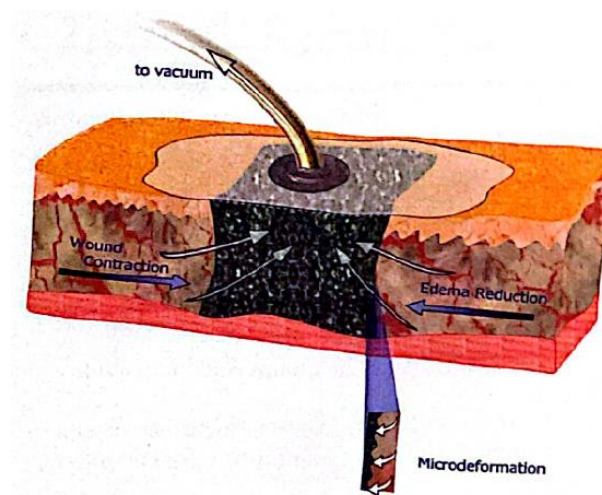
62. The specification describes tube-anchorage and tube-exit sealant components that maintain the drain’s position relative to the fluid-absorbing/transferring layer by immobilizing the tube. Specifically, they maintain the drain’s placement by “*reinforcing the fixation of tube 735 proximal to the tube’s (or tubes’) exit(s) from sheet 757 overlying layer 729.*” EX1001 at 16:7-11.

VI. BACKGROUND OF THE TECHNOLOGY

63. In preparing this Declaration, I reviewed patents and printed publications describing NPT dating back to the 1990's. I also reviewed references describing the state of the art related to wound healing since the 1960's and earlier.

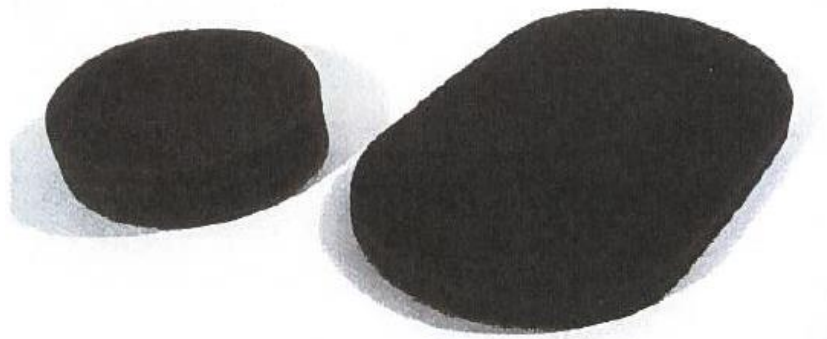
A. NPT Devices

64. Early work that contributed in leading to modern NPT was performed by Dr. Louis Argenta and Dr. Michael Morykwas in the early 1990's. They developed a device containing a vacuum pump with a canister to collect fluid, a tube, a foam, and a semi-occlusive dressing. EX1021 at p. 41. Figure 1 of EX1021, reproduced below, depicts the operation of this type of device. In this figure you can see the black foam filling the wound, the tube that leads to a vacuum source and the semi-occlusive dressing overing the foam and surrounding skin. The collection canister is not depicted, but would be located on the tubing, between the wound and the vacuum source.



EX1021 at p.42, Fig. 1.

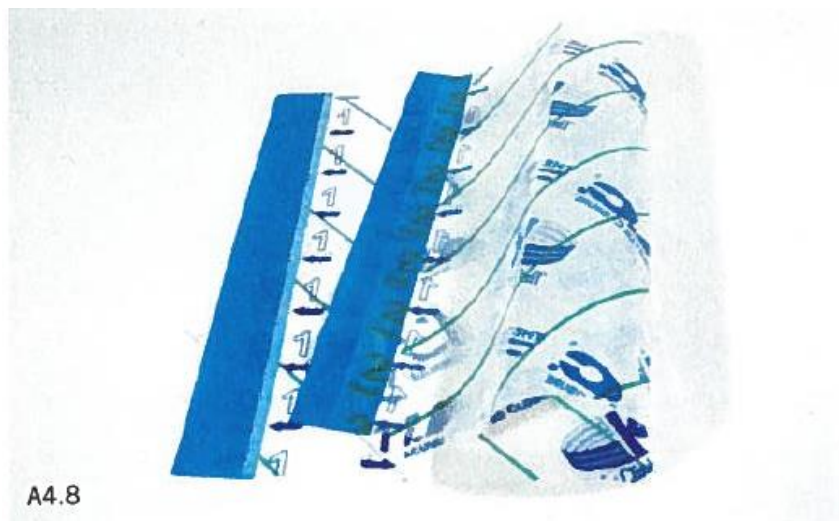
65. EX1025 at pp. 26 and 27, Figures A4.5, A4.8, and A4.9 (reproduced below) depicts several of the components of such a device, including the black foam, an adhesive drape for sealing the wound and the tubing and connector to apply suction.



A4.5

Fig. A4.5 PU foams offering the capability to adapt to wound geometry with minimal effort and without scissors or scalpel, just by removing the outer layers along the perforation lines (examples in the sizes 12.7 x 12.7 x 3.2 cm and 26 x 15 x 1.6 cm).

EX1025 at p. 26, Fig. A4.5.



A4.8

Fig. A4.8 Adhesive drape for sealing the wound (30.5 x 26 cm).

EX1025 at p. 27, Fig. A4.8.



Fig. A4.9 *Trac-pad connector for transmission of suction.*

EX1025 at p. 27, Fig. A4.9.

66. An occlusive dressing is defined as any material that keeps the wounded tissue moist, thereby promoting moist wound healing. EX1030 at p. 175. Semi-occlusive dressings also keep the wound moist, but can allow some level of moisture evaporation from the wound. EX1030 at p. 176. Transparent film dressings (including “adhesive drapes”) such as OpSite (Smith & Nephew) and Tegaderm (3M) are examples of semi-occlusive dressings. EX1030 at p. 176. These film dressings are indicated in a box on the excerpt of the table from EX1030, reproduced below:

Table 1. Types and Characteristics of Occlusive Dressings

Category	Characteristics	Best uses	Advantages	Disadvantages	Product examples
Films	• Polyurethane based • Methods of delivery to wound differ	• Donor sites • Shallow wounds • Abrasions	• Transparent • Retains moisture	• No absorption	• Bioclusive^a • OpSite^b • Tegaderm^c
Foams	• Polyurethane based • Capable of absorbing large volumes of wound fluid • Some have film outer surface to resist water and bacteria • Some are adhesive, some nonadhesive	• Heavily exudating wounds, especially during the early inflammatory phase following debridement and sloughing when drainage is at its peak • Some foams can be used in deep cavity wounds as a packing • Venous leg ulcers	• Comfortable and conformable • Highly absorbent • Does not stick to wound or harm viable tissue • No dressing residue in the wound bed • Nonadhesive foams are useful when surrounding skin is friable (as in the elderly) or painful (as in arterial leg ulcers) • Can absorb under compression stockings and bandages	• Generally requires a secondary dressing • In rare instances, foams may dry the wound if there is too little exudate	• Allevyn^d • PolyMem^e • Sof-Foam^f

EX1030 at p. 178, Table 1 (excerpt, red box added). An image depicting use of such a film dressing in NPT is shown in Fig. A1.11 of EX1025, reproduced below.



Fig. A1.11 Sealing of the wound with an airtight transparent adhesive drape.

EX1025 at p. 7, Fig. A1.11.

67. However, these terms are often not used very precisely in the literature, and “[m]ost of the dressings that are called occlusive today are actually semiocclusive.” EX1030 at pp. 175, 178.

68. The device that Drs. Argenta and Morykwas developed eventually led to the V.A.C.® therapy device, approved by the FDA in 1995 and marketed by a company called Kinetic Concepts (KCI). EX1022 at pp. 376, 379.

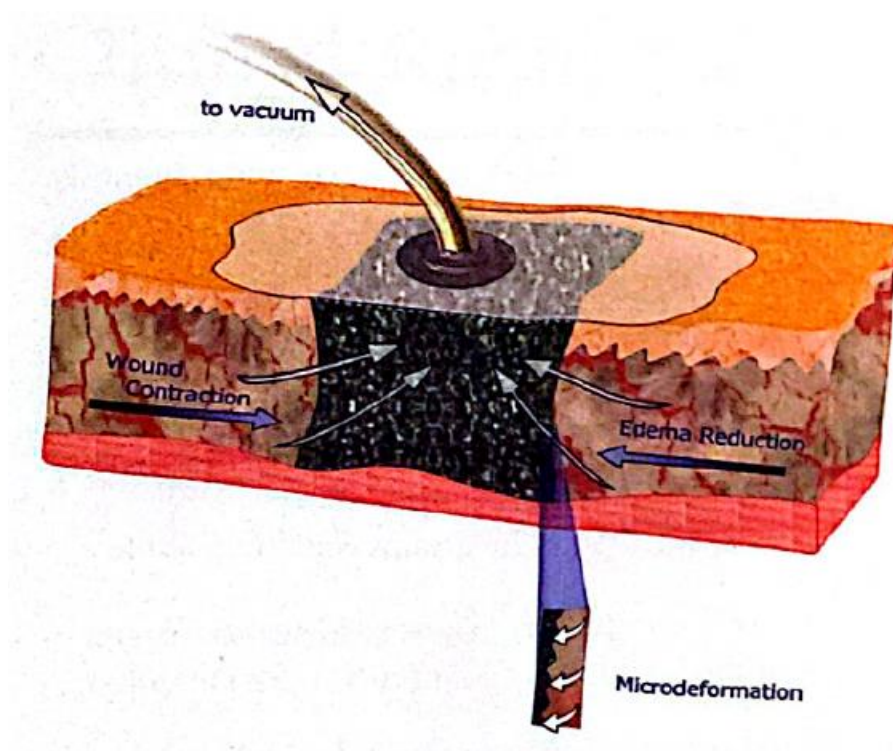
69. Doctors Argenta and Morykwas published two seminal papers in 1997 detailing their work with the V.A.C.® device. One, which names Dr. Morykwas as the first author, focused on “*Animal Studies and Basic Foundation.*” EX1024. The other, which names Dr. Argenta as the first author, focused on “*Clinical Experience.*” EX1023. Doctors Argenta and Morykwas suggested that the V.A.C.® device aided healing by increasing blood flow, withdrawing fluid, and providing mechanical forces to surrounding tissue. EX1022 at p. 376; EX1023 at pp. 572-575; EX1024 at pp. 558-561.

70. Kinetic Concepts remained the leading supplier of NPT devices for the next 15 years after introduction of V.A.C.® therapy because of patent protection for Dr. Argenta and Dr. Morykwas’s pioneering work. EX1022 at p. 376.

71. By 2009, other researchers had extensively used the V.A.C.® system and confirmed Doctors Argenta and Morykwas’s initial findings, describing the four primary mechanisms of action of the V.A.C.® device as (1) contraction of the wound (macrodeformation); (2) stabilization of the wound environment; (3) removal of extracellular fluid; and (4) microdeformation at the foam-wound interface. EX1021

at p. 42. Other literature described similar benefits of NPT in general. EX1005 at ¶2.

See EX1021 at Fig. 1:



72. In their initial work, doctors Argenta and Morykwas used adhesive drapes as the cover in their NPT dressings. EX1024 at p. 553. And many subsequent NPT devices also used self-adhesive film drapes such as OpSite, Ioban, and Tegaderm films (EX1004 at ¶15; EX1009 at ¶86). Other devices used different materials, including hydrocolloids as the cover in an NPT dressing. For example, Hu, which I discuss in further detail below, describes an NPT device with a hydrocolloid cover. EX1005 at ¶59; EX1010 at ¶¶6, 70, 74-75 (a different Hu reference describing the advantages of using a hydrocolloid material as the cover in an NPT dressing). And Biggie describes using a hydrocolloid gel to seal the wound,

and covering that hydrocolloid gel with a standard wound drape. EX1008 at 5:27-44, 7:57-8:18. I describe the properties of hydrocolloids in more detail below, but they can exist in gel, paste, or solid sheet formats.

73. Shortly after the introduction of the V.A.C.® device, doctors began using these NPT wound dressings to irrigate the wound and to instill medication into the wound area, a technique known as “instillation therapy.” EX1017 at p. 192, EX1025 at pp. 33-39. Figure A5.4 from EX1025, reproduced below, depicts an example of an NPT dressing that includes an instillation line to deliver fluid to the wound.



Fig. A5.4 Phlegmon of the left forearm. The instillation tube runs through the superficial foam into the depth of the wound.

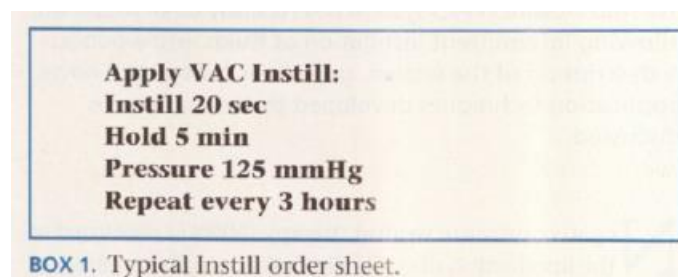
EX1025 at 36, Fig. A5.4.

74. Instillation therapy includes instilling the desired solution into the foam of an NPT dressing, and then after a set time without suction the vacuum is turned

back on and the drug is removed. EX1025 at p. 34. This delay in removing the drug allows time for the drug to take effect. EX1025 at p. 34. Because instillation therapy allows time for the drug to take effect before withdrawing it, the delivery and withdrawal of the fluid does not occur at the same time. In other words, delivery and withdrawal of fluid during instillation therapy is non-simultaneous. EX1025 at p. 34.

75. A different technique known as the “irrigation-suction drainage” technique was described as early as the late 1970’s. EX1025 at p. 35. That technique included simultaneously delivering fluid through an infusion line and withdrawing fluid through a drainage tube, creating an “*irrigation route.*” EX1025 at p. 35 (“*Instillation therapy should not be confused with the irrigation-suction drainage described by Willenegger*”).

76. In 2003 the V.A.C.® Instill was introduced. EX1017 at p. 192. The V.A.C.® Instill is a modified V.A.C.® device that allows clinicians to add solutions to a wound in between cycles of NPT. EX1017 at p. 192. For example, EX1017 at Box 1, reproduced below, depicts a typical Instill order sheet.



EX1017 at p. 192, Box 1. Other prior art references such as Lockwood (EX1009) disclose a simple switch-valve that also allowed one to use the same tube/drain for both instillation/irrigation and for suction. EX1009 at ¶88, Fig. 1.

B. Moist Wound Healing and Different Types of Occlusive Dressings

77. The field of wound healing experienced a major shift in its understanding of optimal wound healing conditions over the second half of the 20th century. Prior to the 1960's, doctors believed that a wound should be kept dry to promote healing. EX1013 at p. 40. But a Nature paper published in 1962 related to wound healing in an animal model (pigs) and subsequent work in humans published the following year, led to the realization that a moist wound environment promoted healing better than a dry wound bed. EX1013 at pp. 40, 52.

78. Over the next few decades medical professionals continued to harness the benefits of a moist wound environment and by early 2010 it was widely accepted that moisture-retentive dressings that maintained a warm, moist wound environment hastened the healing of both acute and chronic wounds. EX1013 at p. 40; EX1030 at pp. 175-177; EX1031 at p. 2S.

79. A moist wound environment operates to improve healing in a number of ways. First, the moist wound environment incorporates the body's own healing enzymes and growth factors that are found in natural wound exudate. Those components can facilitate cell growth and collagen proliferation that helps new

tissue to form, ultimately aiding in wound healing. EX1013 at p. 40; EX1031 at p. 3S. Figure 1 from EX1031, reproduced below, depicts this process and identifies some of the components produced by the body that help a wound to heal when it is in a moist environment under an occlusive dressing, here, a hydrocolloid dressing.

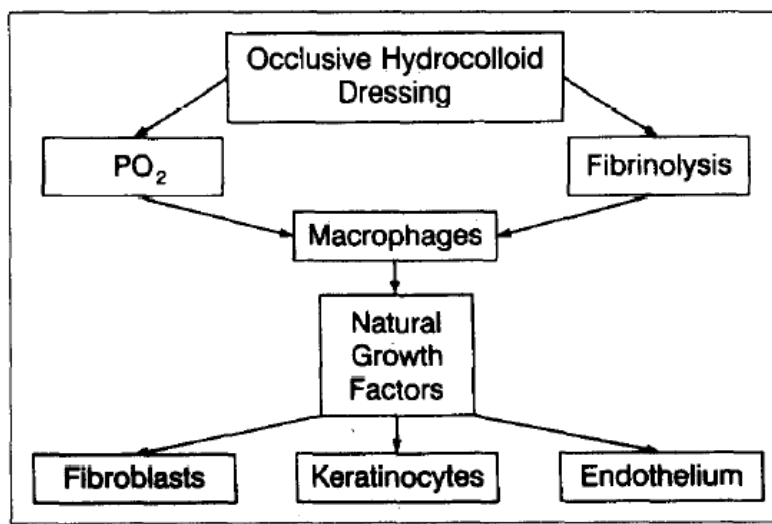


Figure 1. Occlusive dressings help create a permissive environment for growth factor–target cell interaction. PO₂ = partial oxygen tension.

EX1031 at 3S, Fig. 1.

80. It is important, however, to properly balance the moisture level in the wound environment. If a wound is too dry, the environment can lead to wound desiccation, necrosis, and a corresponding poor wound healing rate. EX1013 at p. 40; EX1010 ¶74. If the wound environment is too wet, the surrounding skin can become irritated and macerated, increasing the time needed to heal. EX1013 at p. 40.

81. The understanding that optimal wound healing requires moisture balance in the wound environment led to development of wound dressings designed to optimize moisture levels in the wound. EX1013 at p. 41. Over the second half of the 20th century, medical professionals experimented with various types of dressings and wound covers to try to optimize moisture balance. EX1030 at pp. 175-177.

82. These types of dressings are called occlusive and semi-occlusive dressings. As I explained above, an occlusive dressing is defined as any material that keeps the wounded tissue moist, thereby promoting moist wound healing. EX1030 at p. 175. Semi-occlusive dressings also keep the wound moist but can allow some level of moisture evaporation from the wound. EX1030 at p. 176. These terms are often used interchangeably to refer to dressings that retain moisture and provide a moist wound environment. EX1030 at p. 175 (“*Most of the dressings that are called occlusive today are actually semioclusive.*”). Examples of these types of dressings are films and hydrocolloids, discussed and depicted below when I discuss each of those different types of dressings.

83. By 2010, POSITAs were familiar with many types of wound dressings that could be used to create a moist environment. These different types of dressings are summarized in tables and description provided in EX1013 at pp. 45-50 and EX1030 at pp. 178-179. Those tables are reproduced below.

Table 2.

CONTEMPORARY CLASSES OF WOUND CARE DRESSINGS^{19,19,30,36,41,44,71}

Generic Categories		Care Considerations	
Class	Description/ Mode of Action	Advantages/Disadvantages	Indications/Contraindications
Absorbent	1. Foam	Nonbioresorbable bilaminate opaque dressings with absorbent porous hydrocellular polyurethane center laminated with a semioclusive outer layer	I: Venous ulcers with exudate, deep cavity wounds C: Dry wounds
	2. Hydrofiber	Nonadhesive dressing composed of sodium carboxymethylcellulose gelling agent available in sheets or ropes	I: Moderate to heavy exudate, partial- and full-thickness cavernous wounds with increased bacterial burden C: Dry or nonexuding wounds
	3. Calcium alginate	Nonadherent calcium alginate polysaccharide kelp derivative available in fiber or nonwoven form. Sodium-calcium ion exchange between exudate and dressing promotes formation of sodium alginate gel. High content of mannuronic acid promotes gelling, and high galuronic acid content promotes fiber integrity for packing.	I: Moderately exudative wounds, hemostasis postdebridement C: Diabetic foot ulcers
	4. Hydrogel	Semipermeable (O ₂ , CO ₂ , gases), nonadherent, semitransparent cross-linked hydrophilic polymers	I: Dry, sloughy wounds with mild exudate; partial-thickness wounds C: Ischemic ulcers

Table 2.
CONTEMPORARY CLASSES OF WOUND CARE DRESSINGS, CONTINUED^{18,19,30,39,41,44,71}

Generic Categories		Care Considerations	
Class	Description/ Mode of Action	Advantages/Disadvantages	Indications/Contraindications
Hydrating Dressings	5. Hydrocolloid	Outer polyurethane foam bonded to a middle hydrocolloid CMC/pectin gelling agent and inner adhesive layer	I: Chronic venous ulcers, decubitus ulcers, burns, partial-thickness wounds, diabetic foot ulcers C: Ischemia, infection, vasculitis
	6. Adhesive film	Semipermeable (O ₂ , CO ₂ , gases) 0.2 mm sheet of polyurethane or synthetic polymer coated on one side with adhesive	I: Most commonly used in IV, catheter sites, and partial-thickness wounds C: Clinical infection, highly exudative wounds
	7. Nonadhesive film	Permeable (O ₂ , CO ₂ , gases) 0.2 mm sheet of polyurethane or synthetic polymer bonded to acrylamide, a synthetic monomer	I: Can be used in exuding and infected wounds
	8. Crystalline sodium chloride gauze		I: Highly exudative wounds

Table 2.
CONTEMPORARY CLASSES OF WOUND CARE DRESSINGS, CONTINUED^{16,19,30,39,41,44,71}

Generic Categories		Care Considerations		
Class	Description/ Mode of Action	Advantages/Disadvantages	Indications/Contraindications	
Miscellaneous	9. Hydropolymers	Composed of 4 layers: hydropolymer wound contact layer, nonwoven/ woven acrylate, permeable polyurethane backing, and a border of water-soluble polyurethane backing	A: Two forms; nonwoven acrylate for mild to moderate exudate and woven acrylate for moderate to large exudate. Water-soluble adhesive border makes dressing changes less painful and less traumatic. Hydropolymer wound contact layer conforms to irregular surface of wound.	I: Highly exuding venous leg ulcers
	10. Acrylics	Semipermeable polyurethane membrane coated with acrylic adhesive layer	A: Protective barrier; scab formation is prevented in shallow wounds, allowing for enhanced rate of re-epithelialization.	I: Can be used on wounds that need easy visibility for assessment without dressing removal.

EX1013 at pp. 45-47, Table 2. See also EX1013 at pp. 49-50 for further description of film and hydrocolloid dressings.

84. EX1030, Table 1, reproduced below, also depicts Types and Characteristics of Occlusive Dressings.

Table 1. Types and Characteristics of Occlusive Dressings

Category	Characteristics	Best uses	Advantages	Disadvantages	Product examples
Films	• Polyurethane based • Methods of delivery to wound differ	• Donor sites • Shallow wounds • Abrasions	• Transparent • Retains moisture	• No absorption	• Bioclusive^a • OpSite^b • Tegaderm^c
Foams	• Polyurethane based • Capable of absorbing large volumes of wound fluid • Some have film outer surface to resist water and bacteria • Some are adhesive, some nonadhesive	• Heavily exuding wounds, especially during the early inflammatory phase following debridement and sloughing when drainage is at its peak • Some foams can be used in deep cavity wounds as a packing • Venous leg ulcers	• Comfortable and conformable • Highly absorbent • Does not stick to wound or harm viable tissue • No dressing residue in the wound bed • Nonadhesive foams are useful when surrounding skin is friable (as in the elderly) or painful (as in arterial leg ulcers) • Can absorb under compression stockings and bandages	• Generally requires a secondary dressing • In rare instances, foams may dry the wound if there is too little exudate	• Allevyn^d • PolyMem^e • Sof-Foam^f
Amorphous gels and hydrogels	• Available as sheets and amorphous gels • Can be more than 90% water based • All donate water to desiccated tissue; some absorb also • Soothing effect; are easily applied and removed without discomfort to patient	• Rehydrating eschar and slough for easy removal from wound surface • Creating and maintaining a moist but not wet micro environment over the healing wound	• Simple application and removal • Soothing to the patient • Maintains intimate contact with the wound surface • Creates a moist environment for cell migration	• Amorphous gels always require a secondary dressing • Most hydrogels cannot handle heavily exuding wounds without leakage	• Carrasyn^g • Lamin^h • IntraSite gelⁱ • Nu-Gel^j • SoloSite wound gel^k • Vigilon^l
Hydrocolloids	• Composed of a mixture of adhesive, absorbent, and elastomeric ingredients • Carboxymethylcellulose most common absorptive ingredient • Some contain pectin • All have top film layer for waterproofing • Absorb some wound fluid • Both wet and dry tack • Also available in granules and pastes	• Granulating and epithelializing wounds that are draining low to moderate amounts of exudate • Promoting autolytic debridement	• Waterproof and impermeable to bacteria and environmental contaminants • Conformable for easy application and comfort at the wound site • May be left in place for extended periods • Promotes autolytic debridement	• Moderate to heavy exudation will overwhelm dressing • Impermeable to oxygen; use with caution in wounds with suspected or known anaerobic infection • Some hydrocolloids break down; removal of residue from wound can be time consuming (varies among brands) • May have unpleasant odor upon removal	• Comfeel^m • Cutinova Hydroⁿ • Duoderm^o • RepliCare^p

(Continued)

Table 1. Continued

Category	Characteristics	Best uses	Advantages	Disadvantages	Product examples
Alginates	- Composed of soft nonwoven fibers derived from brown seaweed - Available as wound pads and ropes for packing of deep cavity wounds - Absorb fluid and turn into a gel - Keep wound bed moist	- Wounds with moderate to heavy wound exudate - Granulating and epithelializing wounds where some exudate is present (eg, leg ulcers)	- Especially useful for packing exuding wounds - Rope alginates are easy to apply - Several alginates have good wet strength and can be removed in one piece	- Always require a secondary dressing - Risk of drying wound bed; not recommended for wounds with low-volume exudate - Will not debride hard eschar	- AlgiSite^a - Kaltostat^d - Sorbsan^g
Composites	Island dressing with textile-based absorbent portion	Low to moderately draining wounds	"All-in-one" dressing; no secondary dressing needed - Textile materials are "familiar" to user	- May not "fit" all wound shapes and sizes - May not always maintain a moist wound environment - May "strike through" (when drainage penetrates through backing)	- Airstrip^f - Alldress^h
Specialty dressings	- Designed for a specific purpose, such as absorbency or stimulation - Materials vary	Depends on dressing purpose	Depends on dressing	Depends on dressing	- Aquacel^y - Fibracol^w

^aBiodhesive (Johnson & Johnson, Arlington, TX)
^bOpSite (Smith & Nephew, Inc., Largo, FL)
^cRegaderm (3M Worldwide Operations, St. Paul, MN)
^dAllevyn (Smith & Nephew, Largo, FL)
^ePolyMem (Ferris Manufacturing, Burr Ridge, IL)
^fSoftFoam (Johnson & Johnson, Arlington, TX)
^gCarrasyn (Carrington Laboratories, Irving, TX)
^hAmin (ProCyt, Kirkland, WA)
ⁱIntraSite gel (Smith & Nephew, Largo, FL)
^jNu-Gel (Johnson & Johnson, Arlington, TX)
^kSoloSite wound gel (Smith & Nephew, Largo, FL)
^lVigilon (Bard, Murray Hill, NJ)

^mComfeel (Coloplast Sween, Marietta, GA)
ⁿCutnova Hydro (Beiersdorf-Jobst, Charlotte, NC)
^oDuoDerm (ConvaTec, Princeton, NJ)
^pReplCare (Smith & Nephew, Inc., Largo, FL)
^qAlgiSite (Smith & Nephew, Inc., Largo, FL)
^rKaltostat (ConvaTec, Princeton, NJ)
^sSorbsan (Dow Hickam, Sugarland, TX)
^tAirstrip (Smith & Nephew, Inc., Largo, FL)
^uAlldress (SCA Molnlycke, Eddystone, PA)
^vAquacel (ConvaTec, Princeton, NJ)
^wFibracol (Johnson & Johnson, Arlington, TX)

EX1030 at pp. 178-179, Table 1.

85. Absorbent dressings include certain foam dressings, hydrofiber, and calcium alginate dressings. EX1013 at pp. 45, 47-48. Standard hydrating dressings include hydrocolloids and both adhesive and nonadhesive films. EX1013 at pp. 46, 48-49.

86. Hydrocolloids have been marketed since at least the 1970's and were the first modern moist wound dressing to become widely available. EX1013 at p. 49. They can be formed as gels (EX1008 at 7:4-6, 7:57-8:4; EX1010 at ¶44), pastes (EX1026 at p. 732), or solid sheets (EX1005 at ¶59; EX1010 at ¶¶6, 74-75, EX1026 at p. 732; EX1027) sometimes comprising a hydrocolloid material in between polyurethane film layers (EX1013 at p. 49). They generally contain carboxymethylcellulose and sometimes pectin or other absorbable materials.

EX1013 at p. 49; EX1030 at p. 178. As the hydrocolloid material becomes saturated with wound exudate it forms a gel that includes the beneficial components of the wound exudate and maintains the moist environment that aids in wound healing. EX1013 at p. 49; EX1018 at p. 610; EX1030 at p. 178. There are many examples of hydrocolloid dressings known well before 2010.

87. Granuflex (also known as Duoderm) has been used in wound treatment since the 1960's. EX1026 at p. 730. See EX1026 at Figs. 1 and 2:

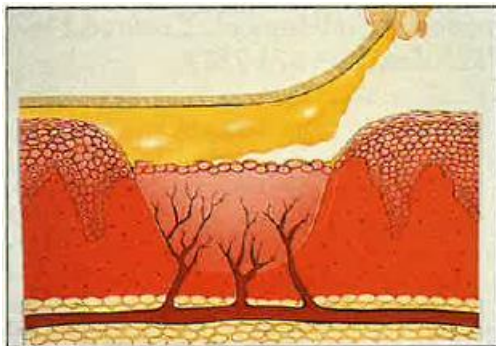


Figure 1. Improved formulation Granuflex has a cross-linked honeycomb matrix that enables the gel to be confined within the structure of the dressing, thereby controlling wound exudate.

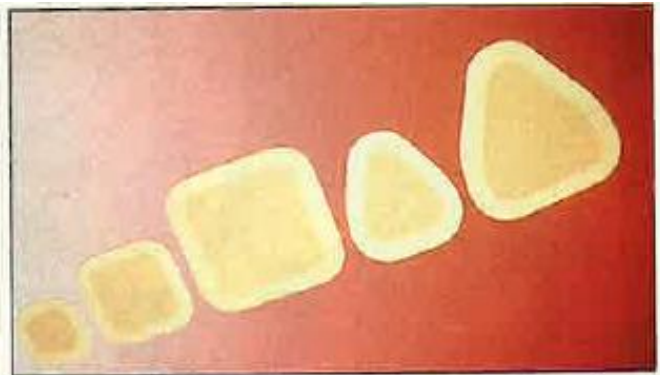


Figure 2. The bordered range comprises two triangular shapes and three square shapes.

88. Hydrocoll (also known as Sureskin) was developed in 1994 and launched in January 1998. EX1027 at p. 1337. See EX1027, Figure 2, reproduced below.

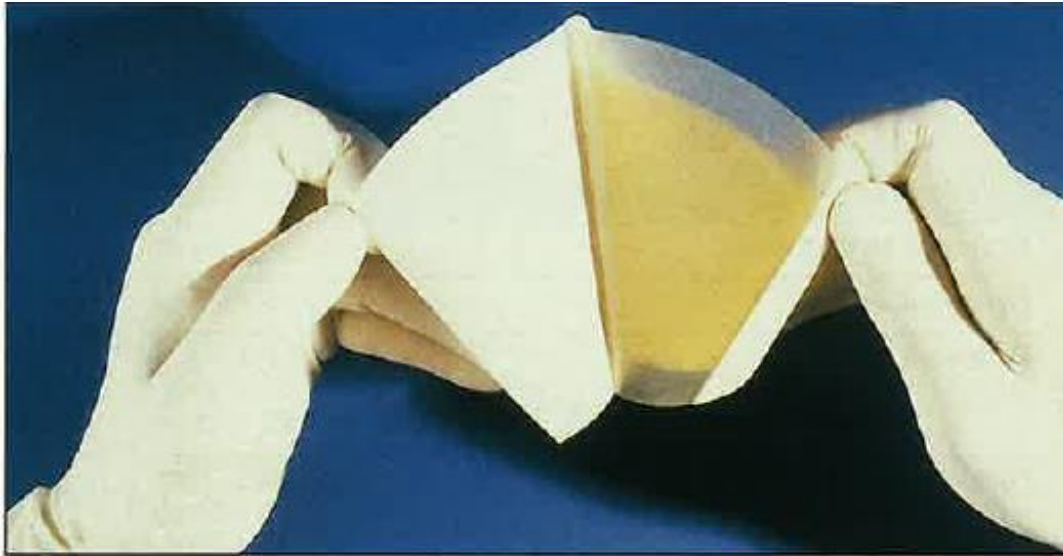


Figure 2. Hydrocoll consists of a film backing and a hydrocolloid containing hydrophilic substances.

You can see the hydrocolloid substance as the darker brown in the center of the dressing.

89. Other hydrocolloid dressings reported as of 2001 are Comfeel, Cutinova Hydro, and RepliCare. EX1030 at p. 178. A review article from 2001 (EX1030) provides a nice summary of some key properties of hydrocolloid dressings and film dressings:

Category	Characteristics	Best uses	Advantages	Disadvantages	Product examples
Films	• Polyurethane based • Methods of delivery to wound differ	• Donor sites • Shallow wounds • Abrasions	• Transparent • Retains moisture	• No absorption	• Bioclusive^a • OpSite^b • Tegaderm^c
Foams	• Polyurethane based • Capable of absorbing large volumes of wound fluid • Some have film outer surface to resist water and bacteria • Some are adhesive, some nonadhesive	• Heavily exuding wounds, especially during the early inflammatory phase following debridement and sloughing when drainage is at its peak • Some foams can be used in deep cavity wounds as a packing • Venous leg ulcers	• Comfortable and conformable • Highly absorbent • Does not stick to wound or harm viable tissue • No dressing residue in the wound bed • Nonadhesive foams are useful when surrounding skin is friable (as in the elderly) or painful (as in arterial leg ulcers) • Can absorb under compression stockings and bandages	• Generally requires a secondary dressing • In rare instances, foams may dry the wound if there is too little exudate	• Allevyn^d • PolyMem^e • Sof-Foam^f
Amorphous gels and hydrogels	• Available as sheets and amorphous gels • Can be more than 90% water based • All donate water to desiccated tissue; some absorb also • Soothing effect; are easily applied and removed without discomfort to patient	• Rehydrating eschar and slough for easy removal from wound surface • Creating and maintaining a moist but not wet micro environment over the healing wound	• Simple application and removal • Soothing to the patient • Maintains intimate contact with the wound surface • Creates a moist environment for cell migration	• Amorphous gels always require a secondary dressing • Most hydrogels cannot handle heavily exuding wounds without leakage	• Carrasyn^g • Lamin^h • IntraSite gelⁱ • Nu-Gel^j • SoloSite wound gel^k • Vigilon^l
Hydrocolloids	• Composed of a mixture of adhesive, absorbent, and elastomeric ingredients • Carboxymethylcellulose most common absorptive ingredient • Some contain pectin • All have top film layer for waterproofing • Absorb some wound fluid • Both wet and dry tack • Also available in granules and pastes	• Granulating and epithelializing wounds that are draining low to moderate amounts of exudate • Promoting autolytic debridement	• Waterproof and impermeable to bacteria and environmental contaminants • Comfortable for easy application and comfort at the wound site • May be left in place for extended periods • Promotes autolytic debridement	• Moderate to heavy exudation will overwhelm dressing • Impermeable to oxygen; use with caution in wounds with suspected or known anaerobic infection • Some hydrocolloids break down; removal of residue from wound can be time consuming (varies among brands) • May have unpleasant odor upon removal	• Comfeel^m • Cutinova Hydroⁿ • Duoderm^o • RepliCare^p

(Continued)

EX1030 at Table 1 (Excerpt, Red box added to highlight hydrocolloid products).

90. Because hydrocolloid dressings absorb exudate and provide a gel containing the natural growth factors and healing components of wound exudate, they can promote healing of not only the primary wound site, but they can also

protect the sensitive periwound skin (the skin immediately surrounding the wound that also plays a role in wound healing). EX1010 at ¶74; EX1013 at p. 49; EX1025 at pp. 352-353, 373; EX1026 at pp. 730, 732; EX1027 at p. 1337.

91. Many studies reported that hydrocolloid dressings were more cost effective and/or superior to other types of dressings. EX1013 at p. 49; EX1018 at p. 612 (summarizing literature comparing hydrocolloids to other types of dressings and concluding that “*there appears to be an obvious advantage associated with the use of the hydrocolloid in most reported studies*”).

92. The other most common hydrating dressings in use by early 2010 were thin, flexible polyurethane films, which were sometimes referred to as “*drapes*” or “*surgical drapes*.” EX1013 at p. 49; EX1030 at p. 178. Examples of film dressings are Tegaderm™ and OpSite™ drapes, which were commonly used as the cover in prior art NPT dressings. EX1004 at ¶15; EX1007 at 4:14-23; EX1030 at p. 178. EX1025 at p. 187, Fig. B13.4d (reproduced below) depicts “*Air-tight sealing with hydrocolloid dressing (Duoderm®) and semipermeable adhesive dressing (Tegaderm®).*”



Fig. B13.4d Air-tight sealing with hydrocolloid dressing (Duoderm®) and semipermeable adhesive dressing (Tegaderm®).

The Tegaderm® film is the clear plastic film covering the tube and other materials in the image above.

93. Unlike hydrocolloid dressings, film dressings have no capacity to absorb wound exudate. Thus, leakage channels can form from the periphery of a film dressing if excess exudate is produced. EX1013 at p. 49. Self-adhesive films can also be difficult to apply if the paper backing is removed from the adhesive side and the thin polyurethane folds and sticks together. EX1013 at p. 49.

VII. SUMMARY OF THE ASSERTED PRIOR ART

A. Argenta (EX1004)

94. Argenta is a U.S. Patent Publication (US2008/0208147) that was published on August 28, 2008. Dr. Louis Argenta is the same individual I discussed above who pioneered the work that led to the V.A.C.® device, however, this patent publication describes a device slightly different from the prior V.A.C.® device.

95. Argenta discloses an apparatus and method for treating wounds with varying negative pressure, compared to atmospheric pressure. EX1004 at ¶1. One embodiment of the device described by Argenta is shown in Figures 1 and 2 reproduced below.

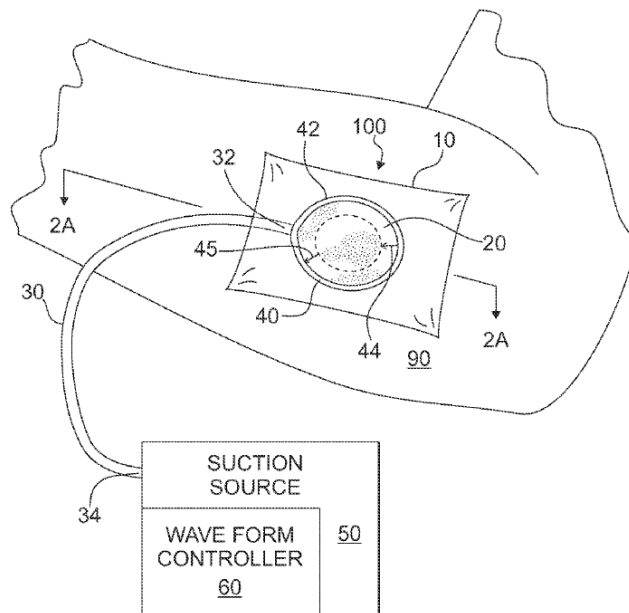


Fig. 1

EX1004 Figure 1.

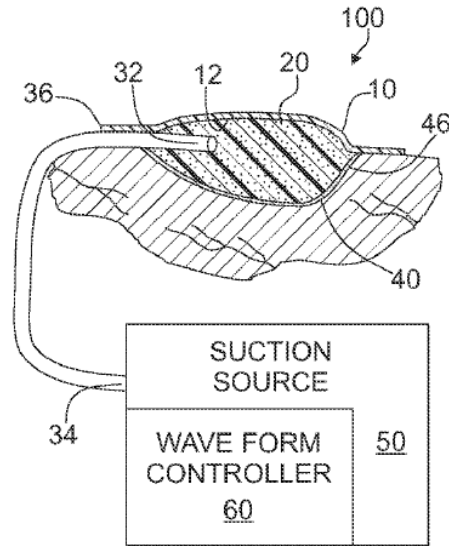


Fig. 2A

EX1004 Figure 2A.

96. Argenta discloses a device with a tube 30 that has a distal end 32. The distal end of the tube may be fenestrated (i.e., have holes applied) or it may be associated with a Jackson-Pratt drain. EX1004 at ¶20. As I describe above, a Jackson-Pratt drain is an elongated hollow piece with multiple holes. See Figure 1 of EX1016 for a picture of a Jackson-Pratt drain.

97. Distal end 32 of the tube can be embedded in a screen 20. Screen 20 can be cut to fit and fill a patient's wound and can be made of a variety of materials including foam and gauze. EX1004 at ¶¶18, 19. Insertion of the tube into screen 20 *“promot[es] even distribution of sub-atmospheric pressure under the cover.”* EX1004 at ¶17.

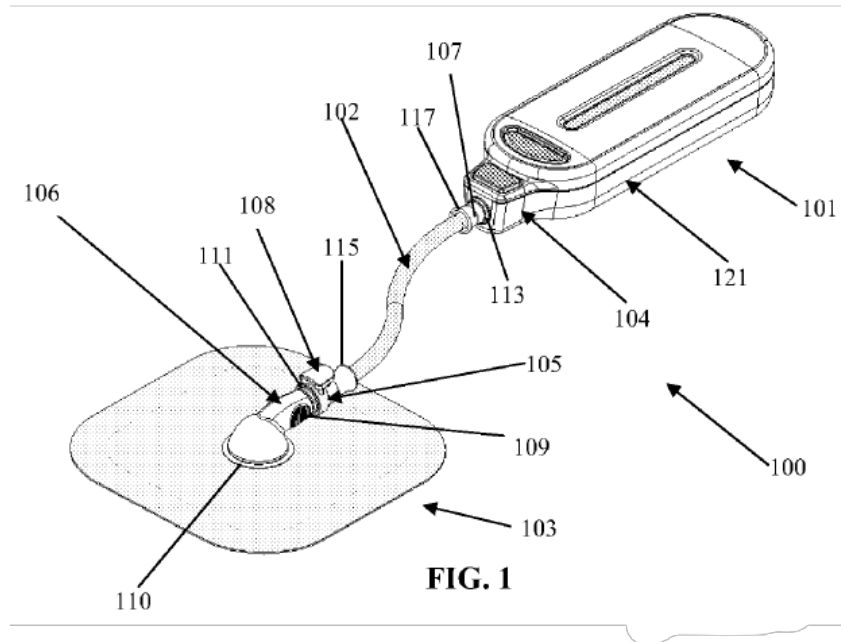
98. Argenta's wound dressing also includes a cover 10 that is placed over top of screen 20 and adheres to the skin around the wound. The cover can also adhere to screen 20 to hold it in place. EX1004 at ¶19 (*"The screen 20 may be held in place by contacting an adhesive coated under surface 12 of the cover 10 to assist in securing screen 20 in a fixed position and to assist in the removal of the screen 20 when the cover 10 is removed."*).

99. To deliver negative pressure, the tube in Argenta's device communicates with the screen 20 through port 36, which can comprise an edge of cover 10 (such as a mesentery) or can be formed as an opening, nipple, or other suitable structure on the surface of cover 10. EX1004 at ¶20. Cover 10 can include an adhesive permitting it to *"attach[] and/or immobilize other components of the apparatus . . . such as suction tube 30."* EX1004 at ¶15. Delivery of sub-atmospheric pressure can then be provided by suction source 50.

B. Hu (EX1005)

100. Hu is a U.S. Patent publication (US2010/0137775) that published on February 18, 2010. Like Argenta, Hu discloses a device that can be used to administer negative pressure, compared to atmospheric pressure, to a wound. Hu uses a sealant layer 103 to cover the wound, a tube 102, and a suction apparatus 101. EX1005 at ¶¶55, 74, Fig. 1. The suction apparatus generates negative pressure that

is transmitted through the tube, through attachment port 106, and under the sealant layer 103. Figure 1 of Hu is depicted below:

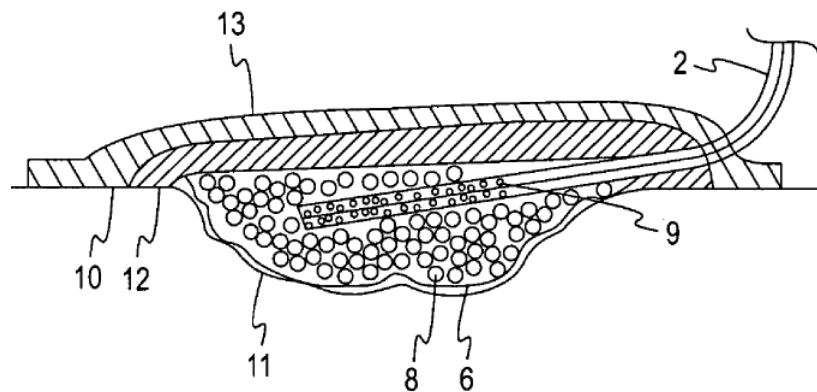


EX1005 at Fig. 1.

101. Hu expressly discloses that the sealant layer (i.e., the square shaped cover with rounded corners (number 103) in Figure 1) that covers the wound may be “*made of a hydrocolloid material.*” EX1005 at ¶59. Hu explains that the cover can be placed over a “*contact layer matrix*” that was placed into the wound, and that contact layer matrix distributes the negative pressure evenly through the wound bed. EX1005 at ¶57.

C. Biggie (EX1008)

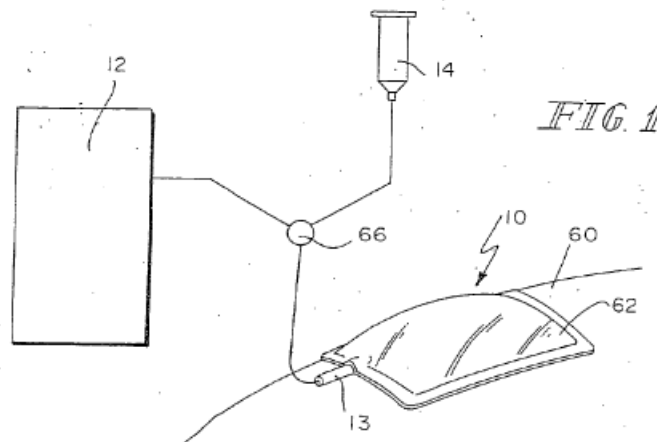
102. Biggie is a U.S. Patent (7,520,872) issued on April 21, 2009. Biggie discloses a slightly different approach to delivering NPT—instead of a gauze or foam filling material, Biggie discloses a pouch filled with beads or other materials that is inserted into the wound bed. EX1008 at 2:14-25. After that pouch is inserted into a wound, it is covered with a flexible gel sealing material (12), for example, a hydrocolloid gel. EX1008 at 6:31-46, 7:1-6, 7:57-8:4. That gel layer is then covered with a protective cover (13). EX1008 at 6:47-53. A multi-lumen tube (2) is inserted into the pouch, with one or more lumens connected to a vacuum source to generate negative pressure, and one or more lumens attached to other sources to, for example, deliver medicament to the wound. EX1008 at 5:8-14, 5:59-6:17. Figure 5, reproduced below, depicts most of these components (the pouch is not numbered, but the bottom layer of the pouch is shown as component 6).



EX1008 at Fig. 5, showing gel sealing layer 12, cover 13, tubing 2, perforations 9, and lower surface 6 of the pouch. EX1008 at 3:52-55, 5:61-6:11, 7:7-19, 8:5-18.

D. Lockwood (EX1009)

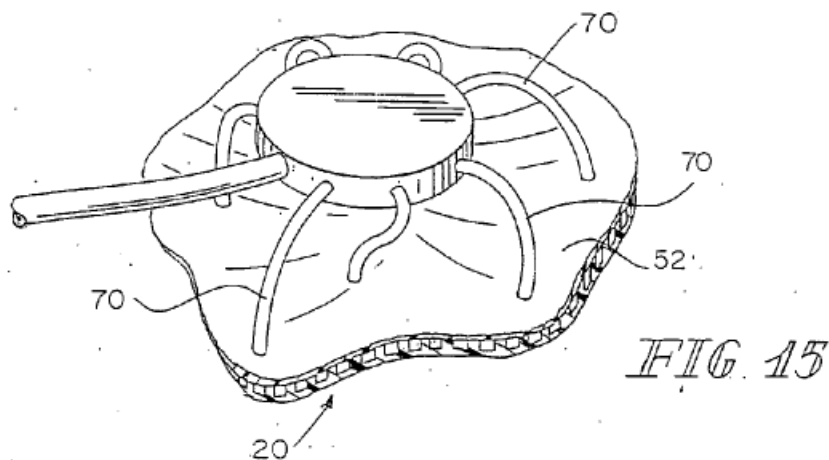
103. Lockwood is a U.S. Patent publication (US2005/0131327) that published on June 16, 2005, that discloses a negative pressure system with two features that were particularly relevant to my analysis. First, in Figure 1, Lockwood discloses a simple switch valve (66) that allows a user to toggle between two different options, see figure reproduced below.



EX1009 at Figure 1, ¶88.

104. One option is to switch on the connection to the vacuum pump and deliver negative pressure compared to atmospheric pressure —i.e., to administer NPT. EX1009 at ¶88. The other option is to switch to a pump that allows irrigation, or deliver fluids to, the wound. EX1009 at ¶88. Because Lockwood depicts a common vacuum tube going under the cover of the NPT dressing, with the switch lying upstream, a POSITA by 2010 could have implemented Lockwood's system in virtually any NPT setup, including those that used a single lumen tube.

105. Second, Lockwood also describes a tube that branches out to a variety of ports effectively providing multiple drains that allow Lockwood's device to better distribute negative pressure throughout the dressing. EX1009 at ¶89, Figure 15.



EX1009 at Figure 15.

VIII. OPINIONS REGARDING PATENTABILITY OF THE CHALLENGED CLAIMS

106. It is my opinion that the Challenged Claims are not patentable for at least the reasons described in Grounds 1, 2, and 3, below.

Ground	Claims	Basis of Unpatentability Obviousness Analysis
1	1-7, 11, 13	Obvious over Argenta on its own and/or in view of Hu
2	8-10	Obvious over Argenta in view of Biggie or Argenta in view of Biggie and Hu
3	1, 4-7, 12	Obvious over Argenta in view of Lockwood or Argenta in view of Lockwood and Hu

A. Ground 1: Claims 1-7, 11, and 13 Would Have Been Obvious over Argenta on its own and/or in view of Hu

1. Claim-by-Claim Analysis

a. Claim 1

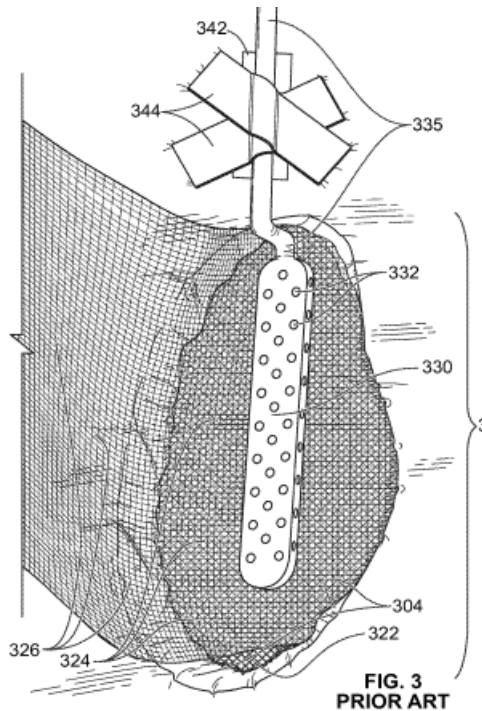
i. 1[a] “*A wound dressing comprising*”

107. The ’404 Patent uses the term “wound dressing” broadly to describe the apparatus used to treat a wound. For example, the patent refers to Figures 1 through 6, which depict the prior art, as depicting a wound “*alone or in association with representative NPT dressings.*” EX1001 at 6:26-28. The ’404 Patent then explains that Figures 7-14 also depict representative dressings. EX1001 at 6:28-30. As detailed fully below, both Argenta and Hu include the same components used for the same purposes as the “wound dressings” described in Figures 1 to 6 and 7 to 14 of the Challenged Patent (EX1001). Accordingly, both Argenta and Hu disclose “wound dressings.”

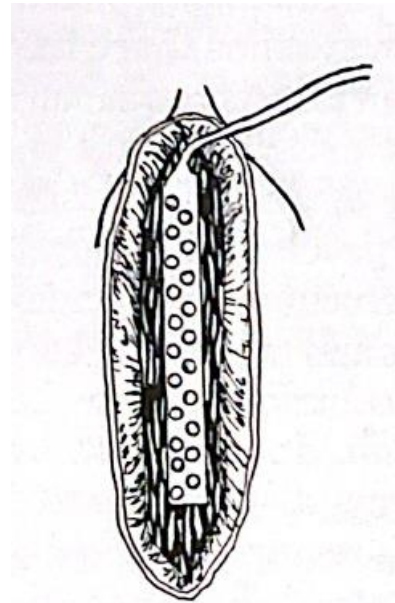
ii. 1[b] “*a wound-fluid drain for use in negative pressure wound treatment (“NPT drain”)*”

108. Argenta discloses the claimed NPT drain. First of all, Argenta expressly states that the vacuum tube can be embedded into the screen 20 underneath the cover, and that the tube “*may comprise a Jackson-Pratt drain.*” EX1004 at ¶20. A Jackson-Pratt drain is a prior art drain long used to drain bodily fluids. EX1016 at Fig. 1. It is also nearly identical to the “*NPT drain*” depicted in the ’404 Patent. The

reproduction of figures below compares EX1001 at Figure 3 with EX1016 at Figure 1:
1:



EX1001 at Figure 3 (Excerpt)



EX1016 at Figure 1 (excerpt)

109. Argenta also discloses that the tube may be fenestrated (i.e., it has holes in it) in the portion that goes under cover 10. EX1004 at ¶20. That is the same portion that is embedded into screen 20. The '404 Patent describes a drain as encompassing even a “*section of tube featuring a single hole,*” (EX1001 at 11:62-64) and explains that it may be integrally continuous with the tube (EX1001 at 18:61-64). Accordingly, Argenta discloses the claimed NPT drain.

- iii. 1[c] “*a vacuum/drainage tube comprising a terminus associated with the NPT drain, said NPT drain being*

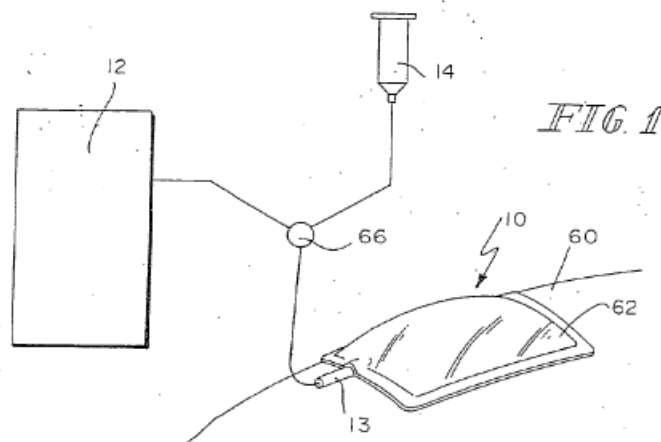
configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound”

110. Argenta discloses a tube (number 30), which is used to provide negative pressure to a wound. EX1004 at ¶20. As discussed extensively in the prior art described above, a tube used in a dressing that is used to deliver negative pressure is a vacuum/drainage tube. Argenta also states that negative pressure is provided by suction source 50 attached to the tube. EX1004 at ¶21. Argenta describes that tube 30 has distal end 32 (which is a “*terminus*” as claimed) that may be disposed under the cover and embedded within screen 20. EX1004 at ¶20. As described in the immediately preceding section, Argenta discloses an NPT drain by virtue of disclosing that the tube comprises a Jackson-Pratt drain, and by disclosing that the section of the tube under the cover can be fenestrated. Accordingly, Argenta discloses a vacuum/drainage tube comprising a terminus associated with an NPT drain.

111. The drain in Argenta is also configured to non-simultaneously withdraw fluid and deliver fluid to the wound. As an initial matter, the tube described and depicted in Argenta has only a single lumen. A single tube with a single lumen physically cannot simultaneously deliver and withdraw fluid—fluid cannot travel in both directions within a single lumen under normal circumstances.

112. Indeed, the prior art techniques that included simultaneously irrigating and withdrawing fluid required the use of multiple tubes. EX1025 at p. 35

(describing the “*irrigation-suction drainage [technique] described by Willenegger*” that uses an inflow via an infusion line and an outflow via a drainage tube). In contrast, prior art techniques that involved the non-simultaneous delivery of fluid and withdrawal of fluid through the same lumen could be controlled by a switch valve that allowed one to toggle between irrigation and suction. Lockwood discloses one such simple mechanism. EX1009 at ¶88 and Figure 1. Figure 1 of Lockwood is reproduced below, showing switch valve 66 that can be used to switch between vacuum and instillation of fluid.



In any event, so long as there is not a valve preventing delivery of fluid, the drain does not need to be configured differently for it to be used to deliver fluid. EX1025 at pp. 33-39.

113. Even if a POSITA did not understand the drain in Argenta to be “*configured to non-simultaneously withdraw fluid from a wound and deliver fluid to*

the wound,” such a configuration would have been obvious to a POSITA by early 2010.

114. By 2010 instillation therapy—the delivery of medication or other fluid in between cycles of NPT was a very common technique. EX1008; EX1009; EX1017; EX1025 at p. 33. EX1025 (published in 2006) is a book focused on vacuum therapy and has an entire chapter on instillation therapy. EX1025 at pp. 33-40. That book reports that “[t]here are currently eight peer-reviewed articles that have been published on the subject of ‘instillation therapy.’” EX1025 at p. 33. Importantly, when medication was delivered during instillation therapy, there was a delay before it was withdrawn. EX1025 at pp. 33-34. This allows time for the medicine to treat the wound before immediately withdrawing it. EX1025 at pp. 33-34. Another reference from 2007 details the VAC Instill device—a modified version of the V.A.C.® device that allows instillation of fluid in between cycles of NPT. EX1017 at p. 192. None of these references indicate that the drain must be somehow modified to allow instillation of fluid.

115. In light of the literature described above reciting the common practice of using an NPT device to deliver fluid and at a different time withdraw fluid, and the absence of any special modification required for a standard drain to both deliver and withdraw fluid, it is my opinion that Argenta discloses a drain configured to do

so, or, at a minimum, it would have been obvious to configure Argenta's system to do so.

iv. 1[d] ***“fluid-absorbing/transferring layer for distributing negative pressure from the NPT drain, said fluid-absorbing/transferring material being in contact with the NPT drain”***

116. Argenta discloses a component, screen 20, that serves as the claimed fluid-absorbing/transferring layer.

117. As explained above, prior art NPT dressings routinely used either foam or gauze to pack a wound, and the vacuum tube/drain was inserted into that foam or gauze to distribute the negative pressure throughout the wound. See, for example, EX1023 at p. 564 (*“Side ports in the tube allow communication of the lumen of the tube to spaces in the reticulated foam, while the open-cell nature of the foam ensures equal distribution of the applied subatmospheric pressure force to every surface of the wound in contact with the foam.”*).

118. Argenta discloses that the tube can be embedded in screen 20 (EX1004 at ¶20), which is made up of foam or gauze (EX1004 at ¶18) and upon application of negative pressure the screen 20 distributes negative pressure from the tube (EX1004 at ¶20). Accordingly, Argenta discloses a *“fluid-absorbing/transferring layer for distributing negative pressure from the NPT drain, said fluid-absorbing/transferring material being in contact with the NPT drain.”*

v. 1[e] *“a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer”*

119. Argenta discloses a vapor sealant sheet that overlies the fluid-absorbing/transferring layer. Specifically, the '404 Patent explains that the claimed vapor sealant sheet lies over top of the other dressing components and seals creates an air-tight seal that is used to allow application of negative pressure. EX1001 at 15:5-28. This is the same function that Argenta's cover 10 provides. EX1004 at ¶¶15-16.

120. Argenta states that its cover can be comprised of a film drape such as an Ioban or OpSite drape (well-known film dressings (see EX1013 at p. 49; EX1030 at p. 179)) or of a more rigid material. EX1004 at ¶15. Argenta does not, however, expressly disclose that its cover 10 can be made of a hydrocolloid material. For the reasons below (and in sections VIII.A.1.a.v and VIII.A.2), I believe that using a hydrocolloid material as the cover in an NPT wound dressing was well within the knowledge of a POSITA and would have been an obvious design choice to incorporate as the cover in Argenta (just as other prior art references did).

121. First, POSITAs developing NPT dressings understood the need to protect the skin around the wound during NPT. Several references recommend using a hydrocolloid dressing for such a purpose (EX1017 at pp. 191-193; EX1025 at pp. 352-353, 373) and there are numerous case studies where medical professionals used

hydrocolloid dressings to protect intact skin when performing NPT (EX1025 at pp. 313-314, 339-341). See section VIII.A.2 for further description. This not only helped the wound to heal, but also provided an appropriate wound dressing over a satellite lesion if a patient developed a satellite lesion near the wound. EX1010 at ¶74.

122. Second, POSITAs developing NPT dressings understood the benefits of using a hydrocolloid material to create a moist wound environment rich in growth factors and beneficial components from wound exudate. EX1013 at pp. 46, 49; EX1031 at p. 3S; EX1026 at p. 730. There have also been numerous reports of better healing when using a hydrocolloid dressing as opposed to a standard polyurethane film dressing. EX1026 at pp. 730-732; EX1031 at p. 3S; EX1018 at p. 612. And, specifically when used in NPT dressings, POSITAs understood that hydrocolloid materials could help to optimize the moisture level. EX1010 at ¶74 (explaining that hydrocolloids optimize the moisture level for the underlying tissue whereas traditional NPT dressings are not optimized).

123. Finally, it was common in this field for a POSITA to combine various components described in the literature to prepare an NPT device for a desired application. EX1019 (describing preparation of an NPT dressing using “*off-the-shelf*” components). I note that the ’404 Patent does not provide any description of how a POSITA would use a hydrocolloid material in the claimed vapor sealant

sheet—it only states that the vapor sealant sheet may be of a suitable hydrocolloid material or another suitable material that is not a hydrocolloid. EX1001 at 15:14-20.

124. Alternatively, even if a POSITA would not formed Argenta's cover from a hydrocolloid material based solely on his or her knowledge at the time (which I truly believe he or she would have), it would have been obvious to combine Argenta with the express teachings of Hu. Hu discloses a similar NPT dressing and expressly discloses that the cover material (called the sealant layer) is made of a hydrocolloid material. EX1005 at ¶59. A POSITA would have been motivated to use the hydrocolloid material disclosed in Hu for the same reasons I set forth in the immediately above paragraphs, as well as the additional reasons in section VIII.A.2, below.

- vi. 1[f] ***“said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of fluid-absorbing/transferring layer relative to the vapor sealant sheet”***

125. Argenta expressly discloses this limitation. First, Argenta discloses that the cover in its NPT dressing may be “*self-adhesive,*” which “*may conveniently permit the cover 10 to be attached to and/or immobilize other components of the apparatus 100 which the cover adhesive contacts, such as suction tube 30 or*

optional screen 20.” EX1004 at ¶15. Argenta also states that “[t]he screen 20 may be held in place by contacting an adhesive coated under surface 12 of the cover 10 to assist in securing the screen 20 in a fixed position and to assist in the removal of the screen 20 when the cover 10 is removed.” EX1004 at ¶19. Screen 20 is located on the wound-facing side and directly below the central portion of cover 10. Ex 1004 at Figure 1 and ¶19. The screen 20 underneath cover 10 is located in the central zone of cover 10 (see, for example, Figure 1 depicting cover 10 centered over the wound with the screen immediately below). Since Argenta discloses that the cover (vapor sealant sheet) has adhesive for immobilizing the screen, Argenta discloses a vapor sealant sheet with adhesive in a central zone.

- vii. 1[g] “a tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet and a portion of the fluid-absorbing/transferring layer, the tube-anchorage component for mechanically maintaining placement of the NPT drain relative to the fluid-absorbing/transferring layer”**

126. Argenta discloses this limitation. Specifically, Argenta discloses that the cover 10 can include port 36, which may be “*an edge of the cover 10 under which the tube 30 passes, such as a mesentery,*” or it can be an opening, or a nipple formed on the cover, or another suitable structure through which the tube passes. EX1004 at ¶20. A POSITA would understand that an opening or a nipple “*disposed at the surface of cover 10*” would necessarily be fixed in a specific place on the cover.

EX1004 at ¶20. Similarly, in light of that description, a POSITA would understand the recited “*other suitable structure*” to be disposed on the surface of Argenta’s cover at a fixed position. Even where the tube passes under the edge of the cover (EX1004 at ¶20) the tube would have to be sealed down to maintain the seal for administration of negative pressure.

127. Indeed, Argenta recognizes the importance of anchoring the tube in place, expressly stating that the cover can “*immobilize other components . . . such as suction tube 30.*” EX1004 at ¶15. A POSITA would have understood that once the tube passes through the relevant structure on Argenta’s cover it is embedded in the screen. This was a particular concern in applications involving skin grafts. EX1025 at p. 150 (“*In order to avoid graft shifting by shear forces and the collection of blood and wound fluid that might lead to graft failure, it is common to secure skin grafts by so-called tie-over bolster dressings. . . . Other options for securing skin grafts include the use of fibrin glue, silicone rubber dressings, and self-adherent films.*”), 153, 255. Accordingly, the fixed position of the structure in conjunction with the embedded tube/drain ensures that the drain is maintained in position relative to the fluid-absorbing/transferring layer.

128. Immobilizing the tube is the same way that the ’404 Patent explains that the tube-anchorage components maintain the drain’s placement—they “*reinforc[e]*

the fixation of tube 735 proximal to the tube's (or tubes') exit(s) from sheet 757 overlying layer 729.” EX1001 at 16:7-11.

129. A POSITA by early 2010 would have understood the importance of immobilizing these components of an NPT dressing, particularly in applications involving skin grafts. EX1025 at p. 150 (“*In order to avoid graft shifting by shear forces and the collection of blood and wound fluid that might lead to graft failure, it is common to secure skin grafts by so-called tie-over bolster dressings. . . . Other options for securing skin grafts include the use of fibrin glue, silicone rubber dressings, and self-adherent films.*”), 153, 255.

130. Argenta’s tube-anchorage components are in contact with both the vapor sealant sheet (cover 10) and the fluid-absorbing/transferring layer (screen 20). Specifically, Argenta discloses that these structures are ***formed on the cover 10*** (EX1004 at ¶20), and that ***cover 10 adheres to screen 20*** via adhesive (EX1004 at ¶19). Because the structure is formed on the cover and the cover touches the screen (especially under negative pressure when all the components are sucked into close proximity to each other), the tube-anchorage component is in contact with both the vapor sealant sheet and the fluid-absorbing/transferring layer. Accordingly, Argenta discloses this limitation.

b. Claim 2

i. 2[a] “*A wound dressing comprising*”

131. This limitation is identical to limitation 1[a] and is disclosed for the same reasons. See section VIII.A.1.a.i, above.

ii. 2[b] “a wound-fluid negative pressure treatment (“NPT”) drain”

132. Argenta discloses an NPT drain for the reasons I explained for limitation 1[b], above. See section VIII.A.1.a.ii, above.

iii. 2[c] “a vacuum/drainage tube comprising a terminus associated with the NPT drain”

133. Argenta discloses this limitation for the same reasons I explained for limitation 1[c], above. See section VIII.A.1.a.iii, above.

iv. 2[d] “fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring layer being in contact with the vacuum/drainage tube;”

134. This limitation differs from claim 1 only in that it requires that the fluid-absorbing/transferring layer distribute negative pressure from the vacuum/drainage tube instead of from the drain, and that the fluid-absorbing/transferring layer be in contact with the tube instead of with the drain. Argenta discloses this limitation for the same reasons I explained for limitation 1[d], above. See section VIII.A.1.a.iv, above. Specifically, Argenta depicts and describes distal end 32 of tube 30 embedded within screen 20. Distal end 32 of tube 30 is associated with the NPT drain, and,

thus, both the tube and drain are embedded within the fluid-absorbing/transferring layer and are used to supply the negative pressure to the fluid-absorbing/transferring layer, which distributes that negative pressure. EX1004 at ¶20.

- v. 2[e] *“a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer”*

135. This limitation is identical to limitation 1[e] and is disclosed for the same reasons. See section VIII.A.1.a.v, above.

- vi. 2[f] *“said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing transferring layer relative to the vapor sealant sheet”*

136. This limitation is identical to limitation 1[f] and is disclosed for the same reasons. See section VIII.A.1.a.vi, above.

- vii. 2[g] *“a first tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet”*

137. This limitation requires a subset of limitation 1[g], specifically a tube-anchorage component that is in contact with a portion of the vapor sealant sheet and is disclosed for the same reasons as limitation 1[g]. See section VIII.A.1.a.vii, above.

- viii. 2[h] *“and a second tube-anchorage component, the first and second tube-anchorage components for mechanically maintaining the NPT drain's placement relative to the fluid-absorbing/transferring layer”*

138. This limitation requires a second tube-anchorage component and requires that both the first and the second tube-anchorage components operate to maintain the NPT drain's placement relative to the fluid-absorbing transferring layer.

139. As noted above, a POSITA by early 2010 would have understood the importance of immobilizing the components of an NPT dressing, particularly in applications involving skin grafts. EX1025 at p. 150 (*“In order to avoid graft shifting by shear forces and the collection of blood and wound fluid that might lead to graft failure, it is common to secure skin grafts by so-called tie-over bolster dressings. . . . Other options for securing skin grafts include the use of fibrin glue, silicone rubber dressings, and self-adherent films.”*), 153, 255. It would have been obvious to a POSITA at the time of the invention to improve the anchoring of the tube—and in turn the anchoring of the associated drain—by adding an additional anchorage component to decrease the chance of movement within the wound bed.

140. Immobilizing the tube is the same way that the '404 Patent explains that the tube-anchorage components maintain the drain's placement—they *“reinforc[e] the fixation of tube 735 proximal to the tube's (or tubes') exit(s) from sheet 757 overlying layer 729.”* EX1001 at 16:7-11.

141. Indeed, use of multiple anchorage components was routine in the prior art. For example, a reference that teaches use of a Jackson-Pratt drain with a vacuum source describes “*crimping*” the film drape around the suction tube to seal the exit and then caulking the exit site with Stomahesive paste *and* adding waterproof tape to seal and anchor the tube. EX1016 at Figures 3 and 4. Another reference describes using an adhesive film layer in an NPT dressing to seal and anchor the tube and then to additionally add an adhesive or tape to further anchor the tube. EX1011 at ¶¶61, 72. Even the ’404 Patent explains that prior art devices used multiple anchorage components, specifically strips of adhesive—most commonly pieces of tape. EX1001 at 9:59-65 and Figure 5. A POSITA would have been motivated to use a second adhesive with Argenta to improve the fixity of the drain just as each of these references teaches.

142. Alternatively, a POSITA would have accomplished this in the Argenta-Hu combination by simply retaining the flexible self-adhesive film cover of Argenta in addition to using the hydrocolloid cover described by Hu. Such a combination would have improved anchorage of the tube and drain as described above. And this is the same configuration used in other prior art references. EX1011 at ¶¶61, 74, 79 (including adhesive film layer 70 as additional anchorage component). Incorporating a similar configuration in the combination of Argenta and Hu would comprise a simple combination of elements from Argenta and Hu (Argenta’s cover and Hu’s

sealant layer) instead of a replacement of Argenta’s cover with Hu’s sealant layer. This combination would retain Argenta’s cover for its stated purpose of “*immobiliz[ing] . . . suction tube 30*” (EX1004 at ¶15) and provided increased fixity of the tube, which a POSITA would have understood to be beneficial for all of the reasons above.

c. Claim 3

i. 3[a] “*A wound dressing comprising*”

143. This limitation is identical to limitation 1[a] and is disclosed for the same reasons. See section VIII.A.1.a.i, above.

ii. 3[b] “*a vacuum/drainage tube comprising a terminus*”

144. This limitation is similar to the limitations in claim 1, but requires only a vacuum/drainage tube, not a tube associated with an NPT drain. Argenta discloses a vacuum/drainage tube comprising a terminus for the same reasons that it discloses limitation 1[c]. See section VIII.A.1.a.iii, above.

- iii. 3[c] *“a fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring layer being in contact with the vacuum/drainage tube”*

145. This limitation is identical to limitation 2[d] and is disclosed for the same reasons. See section VIII.A.1.a.iv, above.

- iv. 3[d] *“a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer”*

146. This limitation is identical to limitation 1[e] and is disclosed for the same reasons. See section VIII.A.1.a.v, above.

- v. 3[e] *“said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing transferring layer relative to the vapor sealant sheet”*

147. This limitation is identical to limitation 1[f] and is disclosed for the same reasons. See section VIII.A.1.a.vi, above.

- vi. 3[f] *“a tube-exit-sealant component for mechanically maintaining the vacuum/drainage tube's placement relative to the fluid-absorbing/transferring layer.”*

148. Argenta discloses this limitation for the same reasons it discloses limitations 1[g] and 2[h]. See sections VIII.A.1.a.vii and VIII.A.1.b.viii, above. Specifically, Argenta discloses that the cover 10 can include port 36, which may be *“an edge of the cover 10 under which the tube 30 passes, such as a mesentery,”* an opening, or a nipple formed on the cover, or another suitable structure through which the tube passes. EX1004 at ¶20. As explained above, each of these components is located in a fixed position on the cover 10 and when the tube passes through these structures and is embedded in the screen, the tube/drain is mechanically maintaining in position. Argenta further explains that the self-adhesive cover can help to *“immobilize other components . . . which the adhesive contacts, such as suction tube 30”* and acts to seal the cover to provide an enclosure for maintaining sub-atmospheric pressure. EX1004 at ¶15. The adhesive is also used to seal the cover to the patient's skin, thus sealing the tube's exit. EX1004 at ¶16.

149. Additionally, in the alternative combination I described above (Section VIII.A.1.b.viii)—where the POSITA retains Argenta's self-adhesive film cover overtop of the added hydrocolloid cover from Hu—Argenta's self-adhesive film cover would also seal the tube's exit and maintain the tube/drain position relative to

the fluid-absorbing/transferring layer. Indeed, that is one of the stated purposes of Argenta's self-adhesive cover. EX1004 at ¶15 (immobilizing suction tube).

150. Immobilizing the tube is the same way that the '404 Patent explains that the tube-anchorage components maintain the drain's placement—they “*reinforc[e] the fixation of tube 735 proximal to the tube's (or tubes') exit(s) from sheet 757 overlying layer 729.*” EX1001 at 16:7-11. Accordingly, Argenta's disclosure of adhesive that seals and immobilizes the tube similarly discloses this limitation.

d. Claim 4: “*The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises gauze.*”

151. Claim 4 depends on independent claim 1. The prior art discloses all of the limitations of claim 1 for the reasons described above. Moreover, the prior art is replete with examples of NPT devices that used gauze as the fluid-absorbing/transferring layer in an NPT dressing, and the '404 Patent even depicts and describes gauze as the material used in a conventional NPT dressing. EX 1001 at 7:44-67, Figures 2 and 3.

152. Argenta expressly discloses that screen 20, which is the fluid-absorbing/transferring layer, can be made of gauze. EX1004 at ¶18 (identifying Aquaphor® Gauze as a non-adherent material that may be used for screen 20). Aquaphor gauze is exactly what it sounds like—gauze impregnated with the healing

ointment aquaphor. Accordingly, Argenta discloses that the fluid-absorbing/transferring layer is comprised of gauze.

e. Claim 5: “*The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises foam.*”

153. Claim 5 depends on independent claim 1. The prior art discloses all of the limitations of claim 1 for the reasons described above. The prior art is also replete with examples of NPT devices that used foam as the fluid-absorbing/transferring layer in an NPT dressing, and the '404 Patent describes one of those exact same foams as the material used in conventional NPT dressings. EX 1001 at 7:44-8:3.

154. Argenta expressly discloses that screen 20, which is the fluid-absorbing/transferring layer, can be made of foam. EX1004 at ¶18 (identifying V.A.C.®GranuFoam® and V.A.C. ® WhiteFoam® as materials that may be used for screen 20). V.A.C.®GranuFoam® and V.A.C. ® WhiteFoam® are types of foam used extensively in prior art dressings and although they are very similar, can sometimes be used for different applications depending on the patient's wound. EX1025 at pp. 23-32 (describing different types of foams used in NPT dressings); EX1029 at p. 2 (identifying differences between types of foam).

f. Claim 6: “*The wound dressing of claim 1 wherein the fluid absorbing/transferring layer comprises an upper layer and a lower layer.*”

155. Claim 6 depends on independent claim 1. The prior art discloses all of the limitations of claim 1 for the reasons described above.

156. Argenta discloses that screen 20 (the fluid-absorbing/transferring layer) comprises both an upper and lower layer. Specifically, Argenta discloses that the distal end of the vacuum tube can be located above or below the screen 20 “*or may be embedded within the screen 20.*” EX1004 at ¶20. When the tube is embedded within the screen, as depicted in Figs. 2A and 2B, the screen is comprised of both upper and lower layers.

157. Moreover, Argenta discloses that the “*screen 20 is desirably cut and shaped to fit into and fill the wound,*” (EX1004 at ¶19) and that “*screen 20 may be provided as a unitary structure or as a composite of separate components assembled upon application to the tissue to be treated*” (EX1004 at ¶18). A POSITA reading Argenta would understand that if the screen is made up of more than one component cut to fit the size of the wound and then assembled on the tissue, those components would be layered on top of one another and would therefore have at least one upper and one lower layer.

158. And, if a POSITA embedded the tube/drain (EX1004 at ¶20) into Argenta’s screen (EX1004 at ¶¶18, 20)—which can either be a unitary structure or a

composite of separate components assembled on the tissue (EX1004 at ¶18)—he or she would have two options to embed the tube into the gauze. He or she could either fold the gauze over top of the drain (if screen is a unitary structure), or use multiple pieces of gauze (if the screen is a composite built on the tissue). Where the piece of gauze was the appropriate size for the wound, one would have preferred folding the gauze to save time and eliminate the steps of cutting and placing a second piece of gauze. Folding a piece of gauze over the drain also decreases the number of pieces of gauze placed in the wound and decreases the chance that one will accidentally be left in the patient’s body. EX1011 at ¶14 (recognizing the risk of accidentally leaving a gauze pad behind after an NPT dressing change). However, if the gauze was not the correct size, it would have to be cut to create a second layer. Either technique would result in the claimed upper and lower layers recited in this claim.

g. Claim 7: “*The wound dressing of claim 6 wherein the NPT drain is enfolded between the lower layer and the upper layer.*”

159. Claim 7 depends on dependent claim 6. The prior art discloses all of the limitations of claim 6 for the reasons described above.

160. Argenta discloses a dressing where the NPT drain is enfolded between the lower layer and the upper layer because Argenta discloses that the screen can be “*a unitary structure*” that can be made of non-adherent materials such as Aquaphor gauze. EX1004 at ¶18. Argenta also discloses that the tube and drain can be

embedded in screen 20. EX1004 at ¶20. For the tube to be embedded in a unitary structure of gauze, a POSITA would have folded the gauze around the drain.

161. And, as I described above for claim 6 (see section VIII.A.1.f, immediately above), a POSITA would have been motivated to use a unitary piece of gauze enfolded around the drain to decrease the number of pieces of gauze in the patient's body and decrease the chance of accidentally leaving gauze behind after an NPT dressing change. EX1011 at ¶14 (explaining the risk of leaving gauze pads in a patient's body after NPT therapy).

h. Claim 11: “*The wound dressing of claim 3 wherein the vacuum/drainage tube terminus is associated with a negative pressure treatment (“NPT”) drain.*”

162. Claim 11 depends on independent claim 3. The prior art discloses all of the limitations of claim 3 for the reasons described above.

163. This limitation further requires an NPT drain. Argenta discloses that the terminus of the vacuum/drainage tube is associated with an NPT drain for the same reasons I set forth for limitation 1[b], above. See section VIII.A.1.a.ii, above.

i. Claim 13: “*The wound dressing of claim 3 wherein the vacuum/drainage tube is further associated with an external vacuum source.*”

164. Claim 13 depends on independent claim 3. The prior art discloses all of the limitations of claim 3 for the reasons described above.

165. Argenta expressly discloses an external vacuum source. Specifically, Argenta discloses that a “*suction source 50*” which can be a “*vacuum pump*” provides the sub-atmospheric pressure to the NPT wound dressing. EX1004 at ¶21. A vacuum pump connected to the wound dressing via a vacuum tube is an external vacuum source.

2. A POSITA would have been motivated to incorporate a hydrocolloid into Argenta and/or to combine Argenta and Hu

166. I described some of the known benefits of a hydrocolloid dressing when discussing the use of a hydrocolloid as the claimed vapor sealant sheet in section VIII.A.1.a.v, above. Below I provide additional reasons why a POSITA would have incorporated a hydrocolloid material as the vapor sealant sheet and explain two ways a POSITA would have been motivated to combine the prior art.

167. Argenta describes an NPT dressing that uses a cover that can be a flexible sheet or surgical drape like the Ioban® or OpSite® drapes. Argenta also discloses that the cover could optionally be a rigid or semi-rigid material. Either way, the cover overlies a foam or gauze screen and provides a sealed space for negative pressure to be applied. EX1004 at ¶15. As was conventional in the prior art by 2010, Argenta’s cover adheres to the periwound skin surrounding the wound and can immobilize the screen and the tube, fixing the dressing and the vacuum tube in place. EX1004 at ¶15.

168. As described above, Hu also discloses an NPT device, but Hu expressly states that the sealant layer (the cover) can be made of a hydrocolloid material. As discussed extensively above, hydrocolloids were well known wound dressings, and it would have been obvious to use them as the cover in an NPT device. Hu confirms that such a modification was obvious to a POSITA at the time.

169. By 2010, POSITAs understood that during NPT, “[p]rotection of the skin at the wound edge and periwound skin is essential.” EX1017 at pp. 191-192. Medical professionals routinely used hydrocolloids to protect the periwound skin and even distant skin during NPT. For example, it was understood that when using the conventional VAC dressing, “[t]he periwound skin should be protected with a skin protectant, barrier film, or hydrocolloid dressing to maintain the air-tight seal, essential for NPWT and to protect the periwound skin from moisture-associated skin damage.” EX1017 at p. 191. The author also recommends “picture framing the wound with hydrocolloid dressing to protect the periwound skin and prevent maceration.” EX1017 at p. 193.

170. Another reference provides practical advice for vacuum therapy that includes protecting skin with a hydrocolloid. For example, when suggesting a tip for bridging two adjacent wounds, the author described an example where “a hydrocolloid dressing was used to protect the skin.” EX1025 at pp. 352-353. This is shown in Figure D4.1, reproduced below:



Fig. D4.1 Place polyurethane (PU) foam on both wounds to the left forearm. Protect the area between the two wounds (here it is covered with a hydrocolloid dressing).

In another piece of advice, the author suggests using a hydrocolloid dressing to allow the epithelium to properly spread from the wound edges. EX1025 at p. 373.

171. In numerous case studies, medical personnel added hydrocolloid sheets to protect the skin near the site of NPT when using existing NPT devices like the V.A.C.® For example, one case study described a patient that presented with a necrotizing infection in his leg who received multiple skin grafts. EX1025 at pp. 313-14. In this case the patient had two wounds in different stages of healing. Clinicians used a standard foam layer as the wound packing material, but used a hydrocolloid to protect the skin between the two wounds prior to affixing the foams with adhesive film drapes. EX1025 at p. 313. Figure C15.3 shows protection of the healthy skin with a hydrocolloid and Figure C15.7 shows the NPT system sealed and working, both figures reproduced below.



Fig. C15.3 Protecting the skin bridge with hydrocolloid drape.

EX1025 at p. 313, Figure C15.3.



Fig. C15.7 Foam soaked, system sealed and working.

EX1025 at p. 314, Figure C15.7.

172. In another case study, *“the skin around the bizarrely shaped ulcer margins was covered with a thin hydrocolloid strip in order to prevent maceration or erosion upon removal of the vacuum dressing foil.”* EX1025 at p. 339. This is depicted in Figure C28.4, reproduced below.



Fig. C28.4 Vacuum therapy after split-thickness skin transplantation with PVA foam. The ulcer margins are protected with hydrocolloid strips beneath the foil dressing.

EX1025 at p. 340, Figure C28.4. The advice to use a hydrocolloid to protect the skin “*applies to any type of vulnerable or irritated periwound skin during vacuum therapy.*” EX1025 at p. 339.

173. In addition to protecting the skin around a wound, hydrocolloid dressings have the added benefit of providing a high-quality wound dressing for any satellite lesions that occur in proximity to the primary wound site. EX1010 at ¶74. Exhibit 1010 is a different patent publication that also names Hu as an inventor, but provides additional information about hydrocolloids used as a cover in an NPT dressing. Importantly, EX1010 explains the benefits of a hydrocolloid material for optimizing moisture level in NPT applications (referred to as “*RPWT*” or “*reduced pressure wound therapy*” in EX1010).

174. In sum, it was very common for doctors to use hydrocolloid dressings in the course of NPT to protect a patient's skin.

175. Another major benefit of hydrocolloid dressings is that they can incorporate the beneficial components of natural wound exudate. Hydrocolloid dressings absorb wound exudate that is rich with growth factors, cells, and enzymes that can remove necrotic tissue, encourage angiogenesis and revascularization (growth of blood vessels), and aid in wound healing. EX1013 at pp. 46, 49; EX1026 at pp. 730-732; EX1031 at pp. 2S-3S. In other words, hydrocolloid dressings optimize the wound environment to provide an ideal moist wound environment. I discussed the benefits of a moist wound environment above in section VI.B, above. These are the benefits that a hydrocolloid cover would impart to an NPT dressing.

176. By 2010 a POSITA would also have understood that a wide range of hydrocolloids with different thicknesses and different moisture vapor transmission rates were available and could be optimized for the particular wound and application as needed. EX1010 at ¶75 (various possible moisture vapor transmission rates), ¶110 (various possible thicknesses); EX1026 (1994 reference describing Granuflex/Duoderm); EX1027 (1998 reference describing Hydrocoll/Sureskin). A POSITA would have selected a hydrocolloid material of appropriate thickness to use in an NPT dressing. Thicker hydrocolloid materials were also known to have fewer problems with self-adherence (i.e., sticking together when the backing is removed

from the adhesive) and leakage channels than thin self-adhesive polyurethane drapes, which is particularly important when they are covering the sensitive periwound skin. EX1013 at pp. 49-50; EX1005 at ¶59.

177. For all of the above reasons, a POSITA would have been motivated to use a hydrocolloid material as the cover in an NPT dressing.

178. A POSITA who wanted to improve the fixity of the tube—i.e., provide extra support for the tube after it exits the cover—would have been motivated to not only include a hydrocolloid as the cover, but also to retain the self-adhesive cover expressly described in Argenta to further “*immobilize*” Argenta’s tube and screen. EX1004 at ¶15. As mentioned above, those skilled in the art understood the importance of preventing movement within the dressing, especially in the case of skin grafts. EX1025 at p. 150 (“*In order to avoid graft shifting by shear forces and the collection of blood and wound fluid that might lead to graft failure, it is common to secure skin grafts by so-called tie-over bolster dressings. . . . Other options for securing skin grafts include the use of fibrin glue, silicone rubber dressings, and self-adherent films.*”), 153, 255. Accordingly one would have been motivated to add an additional level of anchorage for the tube.

179. The prior art is replete with examples of devices using multiple tube sealant and anchorage components. For example, Biggie, EX1008, expressly discloses using a hydrocolloid gel as a sealing layer, and then a standard drape to

add extra support (EX1008 at 6:31-53, 7:45-8:30, Figures 4 and 5)—exactly the combination I identify here. Hoffman (EX1011), another prior art patent publication that discloses an NPT device describes using an atmospheric barrier layer and a second adhesive film layer overtop of the atmospheric barrier layer. The tube can be further sealed with Stomahesive adhesive or waterproof tape. EX1011 at ¶¶61, 72, Figure 2 (components 50, 70, and 102). Finally, the original Chariker paper that describes the use of a Jackson-Pratt drain with a gauze packing material describes crimping the drape to seal the tube (Figure 3) and then sealing with Stomahesive paste and waterproof tape (Figure 4). POSITAs routinely used multiple anchorage components, including a self-adhesive drape overtop of an NPT cover. EX1008 at 6:31-53, 7:45-8:30, Figures 4 and 5; EX1011 at ¶¶61, 72, Figure 2. A POSITA would have been motivated to do the same thing here when combining Argenta and Hu and would have created a combination of those references that retained Argenta’s self-adhesive film.

180. For all of the reasons above, a POSITA would have been motivated to incorporate a hydrocolloid material, such as the sealant layer disclosed in Hu, as the NPT cover in Argenta’s device.

181. A POSITA would have had a reasonable expectation of success in doing so. POSITAs at the time understood that hydrocolloid materials were routinely used to cover wounds to promote healing. And several references showed that

hydrocolloids could be effectively and simply used as the cover of a wound in an NPT dressing. EX1008 at 6:31-53, 7:45-8:30, Figures 4 and 5; EX1005 at ¶59; EX1010 at ¶¶6, 70, 74-75. Moreover, I note that the '404 Patent does not provide any special instructions for using a hydrocolloid material as the vapor sealant sheet. It simply states that the vapor sealant sheet can be a hydrocolloid. EX1001 at 15:17-20. That is not surprising—it was well within the ability of a POSITA to use a hydrocolloid sheet as the vapor sealant sheet in NPT by early 2010.

182. Finally, hydrocolloid materials were one of only a few types of dressings that POSITAs could have selected from to create a moist wound environment. EX1013 at pp. 45-50 describes only three types of hydrating dressings and only eight total (3 of the 10 listed types are variations of polyurethane films). EX1030 at pp. 178-179 provides a table identifying only seven types of occlusive or semi-occlusive dressings, of which two are “*composites*” and “*specialty dressings*.” Based on these disclosures, a hydrocolloid material was one of only a handful of options, and, along with polyurethane films, was the next most likely material a POSITA would have tried.

B. Ground 2: Claims 8-10 Would Have Been Obvious over Argenta in View of Biggie or in View of Biggie and Hu

1. Claim-by-Claim Analysis

a. Claim 8: “*The wound dressing of claim 2 wherein the vacuum/drainage tube comprises a plurality of lumens.*”

183. Claim 8 depends on claim 2 and further requires that the vacuum/drainage tube have a plurality of lumens. The prior art discloses all other limitations of claim 2 for the reasons I described above. See section VIII.A.1.b, above.

184. Biggie (EX1008) discloses a wound dressing with a tube that has multiple lumens. Biggie’s dressing uses a “*pouch*” filled with beads or other filler as the wound packing material. EX1008 at 3:33-63, 4:25-39, 7:20-26. The pouch is placed into the wound bed and a tube with a fenestrated terminus (i.e., a drain) like in Argenta is inserted into the pouch. The tubing used in Biggie’s device “*may be a multi-lumen device which uses one lumen to apply negative pressure to the wound area, and a secondary lumen as a pathway to supply medications and/or antibacterial agents to the pouch.*” EX1008 at 5:8-26, 5:61-6:9. The lumen that provides negative pressure “*withdraw[s] exudates, debris, dead cells, etc.*” EX1008 at 5:30-32.

185. The secondary lumen disclosed in Biggie “*also provides a path for insertion of other devices, such as electrical conductors which are used to provide*

low-level electrical stimulus or heat for treatment of a wound area, or other measurement or treatment devices.” EX1008 at 6:6-11.

186. Accordingly, Biggie discloses a vacuum/drainage tube that comprises a plurality of lumens.

- b. Claim 9: “*The wound dressing of claim 8 wherein the plurality of lumens comprises at least one lumen configured to deliver fluid to a wound and at least one lumen configured to withdraw fluid from the wound.*”**

187. Claim 9 depends on claim 8. The prior art discloses all of the limitations of claim 8 for the reasons described immediately above.

188. Also as explained immediately above, Biggie discloses a multi-lumen tube that includes at least one lumen for delivering fluid (EX1008 at 5:8-26, 5:61-6:9 (describing a secondary lumen as a pathway to supply medications and/or antibacterial agents to the pouch) and at least one lumen for withdrawing fluid from the wound (EX1008 at 5:8-26, 5:61-6:9, 5:30-32 (“*The purpose of the tubing 2 is to provide negative pressure to withdraw exudates, debris, dead cells, etc., through the tubing 2 for disposal.*”))).

- c. Claim 10: “*The wound dressing of claim 8 wherein at least one lumen is configured to convey a medical device.*”**

189. Claim 10 depends on claim 8. The prior art discloses all of the limitations of claim 8 for the reasons described for claim 8, above.

190. Moreover, as I explained in that section, Biggie also expressly states that the secondary lumen “*also provides a path for insertion of other devices, such as electrical conductors which are used to provide low-level electrical stimulus or heat for treatment of a wound area, or other measurement or treatment devices.*” EX1008 at 6:6-11. Accordingly, Biggie describes a device where at least one lumen is configured to convey a medical device.

2. A POSITA would have been motivated to combine Biggie’s multi-lumen tubes with Argenta with Hu

191. As I described in my analysis of Ground 1, a POSITA would have incorporated a hydrocolloid material as the cover in Argenta. See sections VIII.A.1.a.v and VIII.A.2, above. Biggie is directed to the same type of device and adds the simple improvement of using a multi-lumen tube, which adds the freedom to have one lumen dedicated to vacuum and another lumen for administering fluid or medical devices to the wound site.

192. The prior art identified the long-known benefit of a medical practitioner being able to optionally provide medicine or other fluids to the wound site via a multi-lumen tube. EX1025 at pp. 33-39. Biggie explains that the “*multi-tubing 2 allows the delivery of medications without disturbing the wound dressing.*” EX1008 at 8:43-45. Importantly, Biggie also describes the ability to insert a medical device such as a “*measurement or treatment device,*” in a secondary lumen, making the

dressings more versatile. EX1008 at 6:6-9. Although a single lumen tube could be used to withdraw and deliver fluids using a simple switch valve, as disclosed by Lockwood (EX1009 at ¶88, Figure 1), such a configuration would not work well for insertion of medical devices. Moreover, when inserting a device that is used to provide low-level electrical stimulus or heat, a POSITA would have ideally designed a dedicated lumen that was not used to transmit liquid. EX1008 at 6:6-9 (describing devices including electrical conductors that can be inserted through secondary lumen). For all of these reasons, a POSITA would have been motivated to incorporate these features from Biggie into the combination of Argenta and Hu.

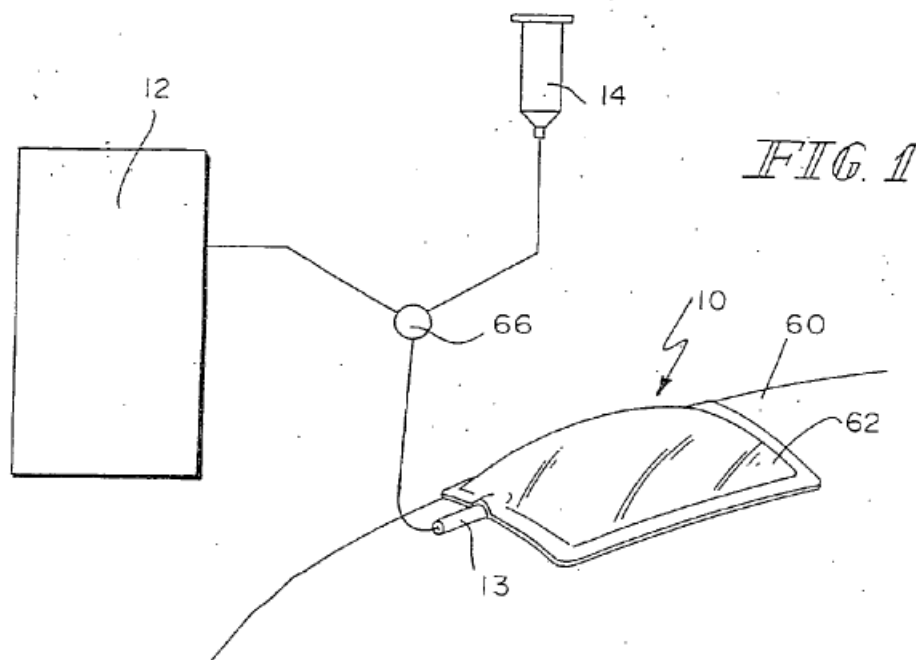
C. Ground 3: Claims 1, 4-7, And 12 Would Have Been Obvious Over Argenta in view of Lockwood or in view of Lockwood and Hu

1. Claim-by-Claim Analysis

a. Claims 1 and 4-7

193. Independent claim 1 requires that the vacuum tube is configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound. In my discussion of Ground 1, I explained my opinion why a POSITA would have understood the tube disclosed by Argenta to be configured to non-simultaneously withdraw and deliver fluid to the wound. And to the extent someone needed to modify the tube in Argenta to do so, it would have been within their level of skill. See Section VIII.A.1.a.iii, above.

194. Nonetheless, to the extent someone disagrees that this simple modification would have been within the POSITA's skill set, a POSITA could have expressly combined the teachings from Lockwood with Argenta and Hu to employ a mechanism for non-simultaneously delivering and withdrawing fluid. Specifically, a POSITA could have incorporated the vacuum and irrigation sources 12 and 14, and the switch valve 66 from Lockwood (see EX1009 Figure 1) with Argenta's dressing.

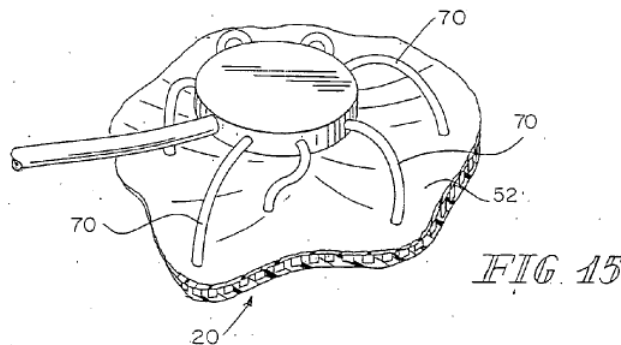


EX1009 at Figure 1 (excerpt). This would have allowed a doctor using the combination of Argenta and Hu to cycle between withdrawing (with the vacuum source) or delivering (with the irrigation source) fluid to the wound. EX1009 at ¶¶28, 88, Figure 1.

b. Claim 12: “The wound dressing of claim 11 wherein the NPT drain comprises a plurality of NPT drains.”

195. Claim 12 depends on claim 11 (which itself depends on claim 3) and further requires that the drain comprises a plurality of drains. The prior art discloses all limitations of claims 3 and 11 for the reasons I discussed above (see sections VIII.A.1.c and VIII.A.1.h, above).

196. In addition to disclosing the switch valve for non-simultaneously withdrawing and delivering fluid, Lockwood also discloses a tube with multiple ports that communicate with the wound dressing member 20. EX1009 at ¶41 and Figure 15.



EX1009 at Figure 15. Lockwood explains that the plurality of ports shown in Figure 15 are coupled to a vacuum/irrigation tube to “*provide an evenly distributed suction force across*” member 20. EX1009 at ¶41.

197. POSITAs at the time would have understood that additional holes in a drain operated to better distribute the negative pressure throughout the packing material. EX1011 at ¶73. Each additional hole provides a point for application of

negative pressure and therefore a POSITA would have understood that additional holes/ports/drains would operate to better distribute the negative pressure throughout the dressing and would have incorporated a plurality of drains based on Lockwood's disclosure.

2. A POSITA would have been motivated to combine Lockwood's configuration with Argenta and Hu

198. I explained in Ground 1 why a POSITA would have been motivated to non-simultaneously withdraw and deliver fluid using the a mechanism from Lockwood. See section VIII.A.1.a.iii, above. To recap—instillation therapy was very well-known by early 2010, and was used to deliver medication for a set amount of time with the vacuum source turned off, allowing the medication to treat the wound. Some time later, the vacuum would be turned back on to withdraw the fluid. EX1025 at pp. 33-39.

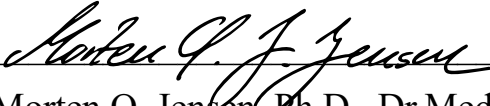
199. Accordingly, to the extent a POSITA needed a specific reference to generate a combination that non-simultaneously withdraws and delivers fluid, then a POSITA would have combined Lockwood with Hu and Argenta. And for the reasons in the immediately preceding section, a POSITA would have also been motivated to incorporate the multi-drain configuration suggested by Lockwood to better distribute negative pressure throughout Argenta's screen. POSITAs at the time understood that additional holes in a tube, and accordingly, additional tubes (which

could of course also have additional holes) operated to better distribute the negative pressure throughout the screen. EX1011 at ¶73.

I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

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

Dated: **June 11th, 2025**



Dr. Morten O. Jensen, Ph.D., Dr.Med.

APPENDIX A

Exhibit No.	Description
1001	U.S. Patent No. 10,639,404 (the “’404 Patent”)
1004	U.S. Publication No. 2008/0208147 (“Argenta”)
1005	U.S. Publication No. 2010/0042021 (“Hu”)
1006	U.S. Patent No. 10,639,404 File History
1007	U.S. Patent No. 6,071,267 (“Zamierowski”)
1008	U.S. Patent No. 7,520,872 (“Biggie”)
1009	U.S. Publication No. 2005/0131327 (“Lockwood”)
1010	U.S. Publication No. 2010/0137775 (“Hu775”)
1011	U.S. Publication 2007/0027414 (“Hoffman”)
1013	Okan D., et al., <i>The Role of Moisture Balance in Wound Healing</i> , Advances in Skin and Wound Care, Vol. 20, No. 1 at 39 (Jan. 2007)
1014	U.S. Publication No. 2009/0234306 (“Vitaris”)
1015	U.S. Publication No. 2004/0073151 (“Weston”)
1016	Chariker, M.E., et al., <i>Effective management of incisional and cutaneous fistulae with closed suction wound drainage</i> , Contemporary Surgery, Vol. 34 at 59 (June 1989)
1017	Jerome, D., <i>Advances in Negative Pressure Wound Therapy The VAC Instill</i> , J. of Wound, Ostomy and Continence Nursing, 34(2) at 191 (March 2007)
1018	Thomas, S., <i>Hydrocolloid Dressings in the Management of Acute Wounds: a review of the literature</i> , Int’l. Wound J., 5(5) at 602 (2008)
1019	Bui, T.D., et al., <i>Negative Pressure Wound Therapy with Off-The-Shelf components</i> , Am. J. of Surgery, 192 at 235 (2006)

Exhibit No.	Description
1021	Orgill D.P., et al., <i>The Mechanism of Action of Vacuum Assisted Closure: More to Learn</i> , Surgery 146(1) at 40 (2009)
1022	Miller-Mikolajczyk C., et al. <i>The Evolution of Commercial Negative Pressure Wound Therapy Systems over the Past Three Decades</i> , Adv. In Wound Care, 13(8) at 375 (2024)
1023	Argenta L.C. & Morykwas, M.J., <i>Vacuum-assisted Closure: A New Method for Wound Control and Treatment: Clinical Experience</i> , Annals Plastic Surgery, 38(6) at 563-576 (1997)
1024	Morykwas, M.J., et. al., <i>Vacuum-assisted Closure: A New Method for Wound Control and Treatment: Animal Studies and Basic Foundation</i> , Annals Plastic Surgery, 38(6) at 553 (1997)
1025	The Theory and Practice of Vacuum Therapy (Christian Willy, ed.) (2006)
1026	Williams, C. <i>Granuflex</i> , Br. J. Nurs., 3(14) at 730 (1994)
1027	Williams, C. <i>Hydrocoll: A 'New Breed' of Hydrocolloid Wound Dressing</i> , Br. J. Nurs., 7(21) at 1337 (1998)
1029	Gabriel, A., et al., <i>A Clinical Review of Infected Wound Treatment with Vacuum Assisted Closure® (V.A.C.®) Therapy: Experience and Case Series</i> , Int'l Wound J., 6 (suppl. 2) at 1 (2009)
1030	Eaglestein, W.H., <i>Moist Wound Healing with Occlusive Dressings: A Clinical Focus</i> , Dermatologic Surgery 27 at 175-181 (2001)
1031	Field, C.K. & Kerstein, M.D., <i>Overview of Wound Healing in a Moist Environment</i> , Am. J. of Surgery, 167(1A(Suppl)) at 1S (Jan. 1994)