IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MÖLNLYCKE HEALTH CARE AB
Petitioner

v.

SMITH & NEPHEW, INC.
Patent Owner.

Case: PGR2018-00035

U.S. Patent No. 9,642,750 B2

PETITION FOR POST-GRANT REVIEW

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I. Introduction

Pursuant to 35 U.S.C. § 321 and 37 C.F.R. § 42.200, Petitioner Mölnlycke Health Care AB ("MHC") petitions for post-grant review of claims 1-24 of U.S. Patent 9,642,750 (Ex. 1001, "the '750 patent"). The '750 Patent is directed to apparatuses, devices, and kits for negative pressure wound therapy ("NPWT").

The '750 Patent is eligible for post-grant review because claims 1-24, which were added after the America Invents Act went into effect, are not supported either by the '750 Patent's disclosure (which was also filed after the AIA went into effect), or the disclosure of any of its parent applications. Consequently, claims 1-24 do not receive the benefit of the filing dates of any of the cited priority applications, and the '750 Patent is eligible for post-grant review.

On the merits, the claims of the '750 Patent—all of which were added after the '750 Patent was filed and years after the claimed priority date—appear to be an effort to draft claims to cover established negative pressure wound treatment systems, and are thus invalid. As might be expected from claims that were added to an application years after the initial filing and after the industry has developed in the interim, all of the claims of the '750 Patent suffer from several fatal flaws that result from the '750 Patent's lack of support for these recently-added claims.

First, claims 18 and 21-24 were copied verbatim from an MHC application for an entirely different approach to a negative pressure wound treatment device.

When transported into the '750 Patent, those claims, as well as dependent claims 19 and 20, find no written description support for several elements. Thus, claims 18-24 are invalid under 35 U.S.C. § 112(a). For the same reason, the '750 Patent is eligible for post grant review.

Second, claims 1-17 were not copied from the MHC Application, but were still added after the '750 Patent was filed, and are still invalid under 35 U.S.C. § 112(a) because there is no written description for several elements of the claims—all of which were added after the '750 Patent was filed. The terms "unobstructed visualization" and "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel" are absent from the specification of the '750 Patent—either literally or in concept—and therefore lack written description support under 35 U.S.C. § 112(a) and are invalid. For this additional reason, the '750 Patent is eligible for post grant review.

Third, claims 1-17 are invalid because they either lack novelty and/or are obvious. Claims 1-17 are invalid under 35 U.S.C. §§ 102 and/or 103 in view of the public sale, offer for sale, and/or public disclosure of the well-known SensaT.R.A.C.® ("SensaTRAC") commercial NPWT product. SensaTRAC discloses each and every element of claims 1-4 and 6-17, and therefore anticipates those claims. Claim 5 would have been obvious over the SensaTRAC device. To

the extent there are differences between the SensaTRAC and claims 1-17, those differences reflect either obvious engineering choices or are disclosed in other prior art NPWT systems, including *Hu* (Ex. 1012, U.S. 2010/0137775), *Vess* (Ex. 1013, U.S. 2009/0227968), and *Hirsch* (Ex. 1014, U.S. Provisional App. No. 61/109,360).

Fourth, Claims 1-17 are invalid as indefinite under 35 U.S.C. § 112(b), because the term "unobstructed" is indefinite.

II. Mandatory Notices (37 C.F.R. § 42.8)

A. Real Parties-In-Interest

The real party in interest for this petition is Petitioner, Mölnlycke Health Care AB. Mölnlycke Health Care AB is a subsidiary of MHC Sweden AB, which is a subsidiary of Mölnlycke Holding AB, which is a subsidiary of Mölnlycke AB, which are all privately held companies and subsidiaries. Mölnlycke AB is owned by Investor AB, a publicly traded company. All of these companies, MHC Sweden AB, Mölnlycke Holding AB, Mölnlycke AB, and Investor AB, are also real parties-in-interest.

B. Related Matters

Pending Applications: U.S. Patent Application No. 15/198,690, filed June 30, 2016; U.S. Patent Application No. 15/256,349, filed September 2, 2016; and U.S. Patent Application No. 15/681,165, filed August 18, 2017, are pending in the U.S. Patent Office and each claims priority to the '750 Patent's filing date.

There are no infringement actions or other related matters.

C. Notice Of Lead And Backup Counsel And Service Information

Pursuant to 37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4) and 42.10(a), MHC appoints MITCHELL A. KATZ (Reg. No. 33,919) as lead counsel and RICHARD W. MILLER (Reg. No. 59,386) as first back-up counsel and E. JONAS JARVHOLM (Reg. No. 69,289) as second back-up counsel. All counsel for MHC can be reached by mail at Ballard Spahr LLP, 999 Peachtree Street, Suite 1000, Atlanta, Georgia, 30309-4471; by phone at (678) 420-9300; by fax at (678) 420-9301; and at the following email for service and all communications:

PGR9642750@ballardspahr.com

MHC consents to electronic service. MHC has executed and is concurrently filing a Power of Attorney appointing the above-named counsel.

III. Grounds For Standing (37 C.F.R. § 42.204(a))

MHC certifies that it has standing to request and is not barred from requesting a post-grant review of the ’750 Patent pursuant to 35 U.S.C. § 321. Neither MHC nor any privy of MHC has filed any civil action challenging the validity of any claim of the ’750 Patent or previously requested a post-grant review or *inter partes* review of the ’750 Patent.

MHC also certifies that it is filing this petition not later than nine months after the date the ’750 Patent was granted, May 9, 2017. 35 U.S.C. § 321(c); 37 C.F.R. § 42.202.

IV. Identification Of Challenged Claims And Specific Statutory Grounds (37 C.F.R. § 42.204(b)(1)-(2))

MHC respectfully requests review and cancellation of claims 1-24 of the '750 Patent on the following grounds:

Ground	Claims	Description
1	18-24	Lack of Written Description under 35 U.S.C. § 112(a)
2	1-17	Lack of Written Description under 35 U.S.C. § 112(a)
3	1-4 and 6-17	Anticipated under 35 U.S.C. § 102 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in 2007
4	1-4 and 6-17	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in 2007
5	5	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in 2007 in view of *Hu*, having an effective filing date of November 25, 2008
6	1-4 and 6-17	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in view of *Vess*
7	5	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in view of *Vess*, in further view of *Hu*
8	1-4 and 6-17	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in view *Hirsch*, made publicly available on April 29, 2010
9	5	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in view *Hirsch*, in further view of *Hu*
10	1-4 and 6-17	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in view of *Vess* and in view of *Hirsch*
11	5	Obvious under 35 U.S.C. § 103 in view of the public sale, offer for sale, and/or public disclosure of SensaTRAC in view of *Vess* and in view of *Hirsch*, in

		further view of *Hu*
12	1-17	Lack of Definiteness under 35 U.S.C. § 112(b)

V. Effective Filing Date Of The Challenged Claims And Eligibility For Post-Grant Review

The post-grant review provisions of the America Invents Act ("AIA") apply to any patent containing one or more claims with an effective filing date after March 15, 2013. *See* AIA §§ 3(n)(1) and 6(f)(2)(A). A claim is only entitled to an effective filing date based on an earlier filed patent application if the earlier application fully supports the claimed invention in compliance with the written description and enablement requirements of 35 U.S.C. § 112(a). *See* 35 U.S.C. §§ 100(i)(1), 119(e), 120; *Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010).

As is the case here, where the priority applications do not adequately support a patent's claims under § 112, the effective filing date of those claims for purposes of post-grant review eligibility is the patent's actual filing date. *See US Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 17, at 13 (P.T.A.B. January 29, 2016) ("[I]f claims 12-16 are shown to lack adequate § 112 support in the '311 application and all of the earlier applications to which priority is claimed, the effective filing date for those claims is the actual filing date of the '311 application."). If even a single claim in a patent lacks section 112 support, every claim in that patent is eligible for post-grant review. 35 U.S.C.

§ 100(i); *Inguran, LLC v. Premium Genetics(UK) Ltd.*, PGR 2015-00017, Paper 8 (P.T.A.B. Dec. 22, 2015).

The application leading to the '750 patent, was filed on February 8, 2016. (Ex. 1002.) The '750 patent is a continuation of and claims priority to a number of earlier filed applications: App. No. 14/267,636, filed on May 1, 2014 (now U.S. Patent No. 9,327,065) (Ex. 1003); App. No. 13/381,885, filed as application No. PCT/US2010/061938 on December 22, 2010 (now U.S. Patent No. 8,801,685) (Ex. 1004); App. No. 61/369,008, filed July 29, 2010 (Ex. 1005); App. No. 61/332,440, filed May 7, 2010 (Ex. 1006); and App. No. 61/289,358, filed December 22, 2009 (Ex. 1007). As described below, neither the '750 Patent nor any application to which it claims priority provides adequate support for claims 1-24.

Regarding claims 18-24, there is no disclosure in the '750 Patent or its priority applications that describe or enable several elements, including: a "connection portion comprising an inspection portion," a "duct wall comprising [an] inspection portion," and "connection portion comprising a partition wall extending at least partially from [the] duct wall." As detailed below, neither the '750 Patent nor any of the cited priority applications "clearly allow[s] persons of skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The failure of the '750 Patent to support these elements (1) renders claims 18-24 invalid under

§112(a) and (2) demonstrates, for purposes of PGR eligibility determination, that the '750 Patent is deemed to be filed on its actual filing date (February 8, 2016).

There is also no disclosure in the '750 Patent or its priority applications that describe or enable several elements of claims 1-17, including: (1) "unobstructed" and (2) "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel." The priority applications' failure to provide adequate § 112(a) support provides an independent basis to conclude that the '750 Patent's "effective filing date" for purposes of PGR eligibility is deemed to be its actual filing date (February 8, 2016). Consequently, the PGR provisions of the AIA apply to the '750 Patent. AIA § 3(n)(1), 125 Stat. at 293; *Inguran,* PGR 2015-00017, Paper 8. The '750 Patent is therefore eligible for post-grant review under AIA §§ 3(n)(1) and 6(f)(2)(A).

VI. Background And Summary Of The '750 Patent

The '750 Patent is titled "Apparatuses and Methods for Negative Pressure Wound Therapy." It was filed on February 8, 2016, and it issued on May 9, 2017. The '750 Patent claims priority to applications filed as early as December 22, 2009. The claims of the '750 Patent are not, however, entitled to the priority dates of any of these earlier applications, because they recite subject matter that is entirely absent from both the '750 Patent, and all of the applications in its priority chain.

A. Summary Of The '750 Patent's Specification

The '750 Patent discloses various embodiments of NPWT apparatuses. (Ex. 1001.) The disclosure in Figures 15A-D and described at 22:1-26:2 is relevant to claims 1-24. Figure 15B, annotated below, is representative and illustrates the disclosure. (Ex. 1010, ¶43.)

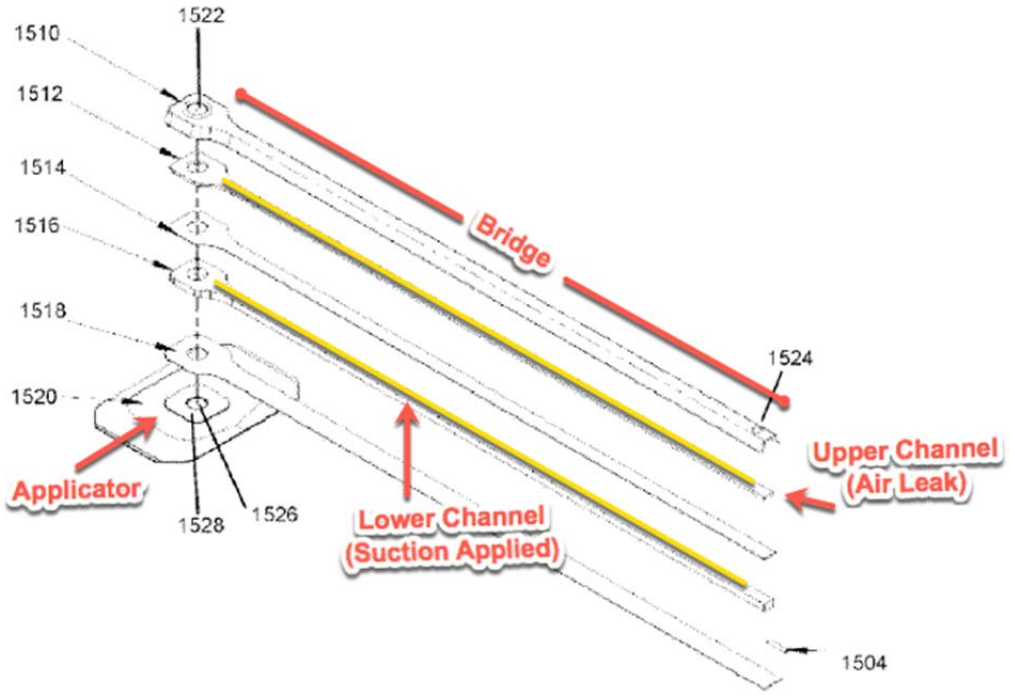


Figure 15B

The '750 Patent discloses a NPWT apparatus having an applicator that is attached to a wound cover at one end and to a bridge at the other end. The bridge is an elongate structure that contains upper and lower channel layers. These two channel layers are constructed from an upper layer, an intermediate layer, and a bottom layer to form two channels in a vertical arrangement. The lower channel is under vacuum and removes the exudate from the wound. The upper channel has an

air leak that draws air in from the atmosphere and moves it over the wound and out through the lower channel. The bridge also contains a viewing window to view the wound when placing the apparatus over the wound during installation and during treatment. (Ex. 1010, ¶44.)

B. Summary Of Prosecution History

The application that issued as the '750 Patent was filed on February 8, 2016. The '750 Patent application is a continuation of App. No. 14/267,636, filed on May 1, 2014 (now U.S. Patent No. 9,327,065); which is a continuation of App. No. 13/381,885, filed as application No. PCT/US2010/061938 on December 22, 2010 (now U.S. Pat. No. 8,801,685); which claims priority to three provisional applications: App. No. 61/369,008, filed July 29, 2010; App. No. 61/332,440, filed May 7, 2010; and App. No. 61/289,358, filed December 22, 2009. (Ex. 1010, ¶45.)

Eight days after filing the '750 Patent, the applicant cancelled all claims and added a new claim set that included two separate groups of claims. The first group, which issued as claims 1-17, was directed to a NPWT apparatus apparently, and without admission that it is actually supported by these figures, attempting to claim the embodiment of Figures 15A-D. (Ex. 1010, ¶46.)

The second group of claims, which issued as claims 18 and 21-24, were copied directly from Petitioner MHC's co-pending patent application no.

14/761,335 (Ex. 1009), filed July 16, 2015 ("the MHC Application") in an attempt to provoke an interference. The claims that issued as claims 19-20, which are directly and indirectly, respectively, dependent upon claim 18, were also added at that time, but were not copied directly from the MHC Application. The applicant provided a statement in the remarks of that amendment directing the Examiner to consider "the possible correspondence between the claims of the present [the '750 Patent] application and the claims of U.S. Patent Application No. 14/761,335 [the MHC application], as Claims 71, and 74-77 of the instant application are substantial copies of Claims 1, 9, and 11-13 of U.S. Patent Application No. 14/761,335 respectively." (Ex. 1002, p.111.) (Ex. 1010, ¶47.)

On March 9, 2017, the Examiner allowed all claims on the first office action. The Examiner's Reasons For Allowance did not address the copied claims. The '750 Patent issued on May 9, 2017. (Ex. 1010, ¶48.)

VII. Claim Construction And Level Of Skill In The Art

Claim construction is implicit in a written description analysis. *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354 (Fed. Cir. 2011). The Board gives each claim term from an unexpired patent "its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *Cuozzo Speed Technologies, LLC v. Lee,* 136 S.Ct. 2131 (2016). Claim terms also are given their ordinary and customary meaning, as would be understood by one of

ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

A. Proposed Claim Constructions

1. "Unobstructed Visualization"

Outside of claim 1, which was added after the '750 Patent was filed, the term "unobstructed visualization" does not appear in the '750 Patent or its file history. (Ex. 1002.) There is no explicit definition or any argument that would assist with the understanding of the term. This term, as discussed below, is indefinite. Nevertheless, for the sake of providing a definition for the written description analysis, a person of ordinary skill in the art would give the term its dictionary meaning. The dictionary definition of "obstruct" is "to block or close up by an obstacle" or "to cut off from sight." (Ex. 1015) Unobstructed, thus, means "unblocked." Therefore, if the term is not determined to be indefinite, a person of ordinary skill in the art would understand "unobstructed visualization" to mean an unblocked view of the wound site. (Ex. 1010, ¶23.)

2. "Duct Wall"

Outside of Claim 18, which was added after the '750 Patent was filed, the terms "duct" and "duct wall" do not appear in the '750 Patent or its file history. (Ex. **1002.)** There is no explicit definition or any argument that would assist with the understanding of these terms. Accordingly, a person of ordinary skill in the art would give the term "duct" its dictionary meaning, which is "a pipe, tube, or

channel that conveys a substance." (**Ex. 1016.) A "duct wall" is the wall of a duct.** (Ex. 1010, ¶24.)

3. "Partition Wall"

Outside of Claim 18, which was added after the '750 Patent was filed, the term "partition wall" does not appear in the '750 Patent or its file historyThere is no explicit definition or any argument that would assist with the understanding of the term. Accordingly, a person of ordinary skill in the art would give the term its dictionary meaning, which is "something that divides; *especially*: an interior dividing wall." (Ex. 1017**.) A "partition wall" here is an interior dividing wall.** (Ex. 1010, ¶25.)

B. Level Of Skill In The Art

The claims of the '750 Patent are directed to: 1) an apparatus to provide suction to a wound site; 2) a suction device for a negative pressure wound therapy system; and 3) a kit for a negative pressure wound therapy system. Because these claims are directed to providing suction or negative pressure to a wound, they relate to the field of negative pressure wound therapy. A person of ordinary skill in the art (POSITA) would typically have a Masters or a Ph.D. in engineering, e.g. biomedical or mechanical engineering, and at least 3 to 5 years of experience in the field of wound care. (Ex. 1010, ¶20.)

VIII. Grounds Of Unpatentability

A. Ground 1 – Claims 18-24 Are Invalid Because The Written Description Of The '750 Patent Does Not Satisfy 35 U.S.C. § 112

1. Written Description Legal Standard

Section 112(a) requires that a patent's written description "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad*, 598 F.3d at 1351. Section 112(a) "limits patent protection to those who actually perform the difficult work of 'invention'—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public." *Id.* at 1353.

The written description requirement is "especially meaningful when a patentee is claiming entitlement to an earlier filing date." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002). Requiring applicants to clearly articulate and disclose *what* they have invented, and limiting subsequent claims to the scope of that disclosure, are critical safeguards in preventing the retroactive claiming of others' inventions. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("The written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office."). This requirement is particularly important for patents issuing from continuation applications, such as the '750 Patent. *See Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366,

1379 (Fed. Cir. 2009) ("The written description doctrine prohibits new matter from entering into claim amendments, particularly during the continuation process.").

Where, as here, claims 18 and 21-24 have been copied from another application, the '750 Patent's specification must provide the written description support. *Agilent,* 567 F.3d at 1380-1383 (finding a copied claim must receive written description support from the application it was copied into). Thus, to satisfy § 112(a), the '750 Patent's written description must demonstrate to those skilled in the art that the inventor had actual "possession" of the claimed subject matter as of the filing date sought. *Ariad*, 598 F.3d at 1351; *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

It is insufficient to show that the written description would render the claimed invention obvious. *Ariad*, 598 F.3d at 1352. It is also insufficient to point to disjointed language in the written description that separately covers each limitation. The test is not about "the presence or absence of literal support in the specification for the claim language," *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983), but whether the specification conveys possession of the "complete and final invention with all of its claimed limitations." *Ariad*, 593 F.3d at 1353; *see also Enzo*, 323 F.3d at 968 ("Even [where the claim language appears verbatim in the specification], the language of the specification, to the extent possible, must

describe the claimed invention so that one skilled in the art can recognize what is claimed.").

Even if only one element of the claim lacks support, the claim is invalid for lacking written description. The written description requirement is satisfied only where the applicant "describe[es] the invention, with all its claimed limitations." *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998).

2. **Claim 18 Does Not Satisfy 35 U.S.C. § 112**

Claim 18 of the '750 Patent reads as follows (with paragraphing added):

> 18. A suction device for a negative pressure wound therapy system, said suction device comprising
>
> (18.1) an attachment portion adapted to be attached to a wound cover member,
>
> (18.2) said suction device comprising
>
> (18.2.1) a fluid inlet being at least partially circumscribed by said attachment portion, said suction device also comprising
>
> (18.2.2) a fluid outlet, said suction device further comprising
>
> (18.2.3) a connection portion adapted to, at least during one operation condition of said suction device, provide a fluid communication between said fluid inlet and said fluid outlet,
>
> (18.3) said connection portion comprising
>
> (18.3.1) an inspection portion that is transparent to thereby facilitate the positioning of said suction device

> relative to said wound cover member, wherein said connection portion comprises
>
> (18.3.2) a duct wall at least partially defining a connection duct from said inlet to said outlet,
>
> (18.3.3) said duct wall comprising said inspection portion, said connection portion comprising
>
> (18.3.4) a partition wall extending at least partially from said duct wall.

(Ex. 1010, ¶51.)

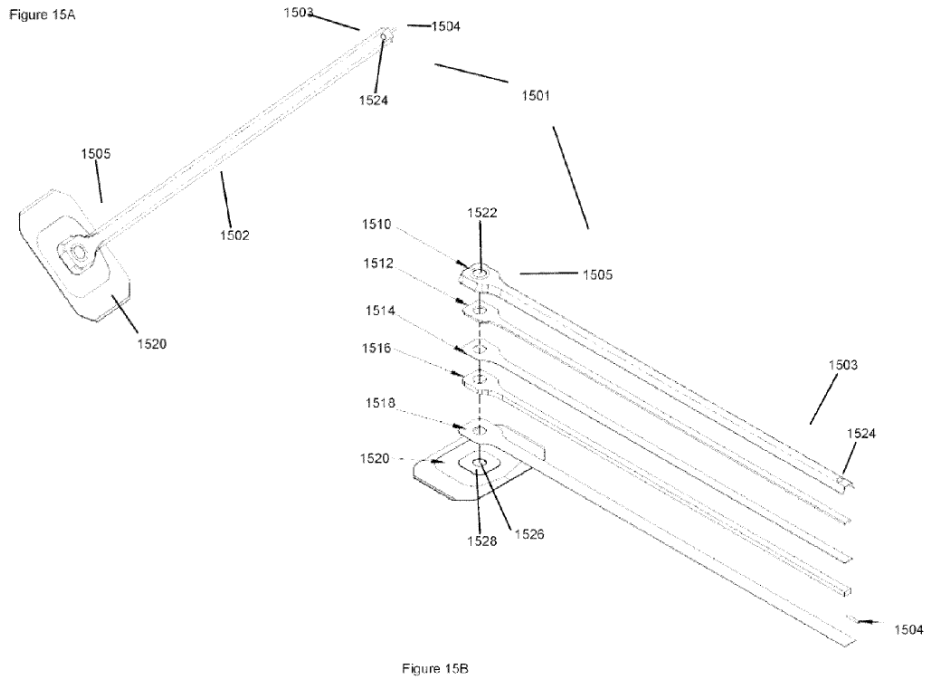
Claims 18 and 21-24 of the ’750 Patent were copied verbatim from claims 1, 9, and 11-13 of the MHC application from the MHC claim amendment of November 9, 2015, during the prosecution of the ’750 Patent on February 16, 2016, but after the filing date of the ’750 Patent of February 8, 2016. As a result, many of the limitations in claims 18-24 are not in the specification of the ’750 Patent (or any of its priority applications). Moreover, considering the claims as a whole, claims 18-24 do not have the necessary written description support to satisfy 35 U.S.C. § 112. (Ex. 1010, ¶52.)

A person of ordinary skill in the art reading the specification and the claims would not conclude that the inventors were in possession of the device claimed in claim 18, or claims 19-24, which depend therefrom and incorporate the unsupported elements of claim 18. As demonstrated below, walking through the claim elements demonstrates that most of the claim elements lack literal support. In addition, even interpreting the disclosure and the figures in the light most favorable

to the Patent Owner, Smith & Nephew, the specification of the '750 Patent has no disclosure that supports at least three limitations: a "connection portion comprising an inspection portion," a "duct wall comprising [an] inspection portion," and the "connection portion comprising a partition wall extending at least partially from [the] duct wall." (Ex. 1010, ¶53.)

3. Claims 18-24 Must Find Written Description Support In Figures 15A-D And The Accompanying Text

Claim 18 recites "[a] suction device for a negative pressure wound therapy system." Figures 15A-D of the '750 Patent describe a suction device (1501) for a NPWT system is shown in various views. (Ex. 1010, ¶54.)



Figures 15A & B

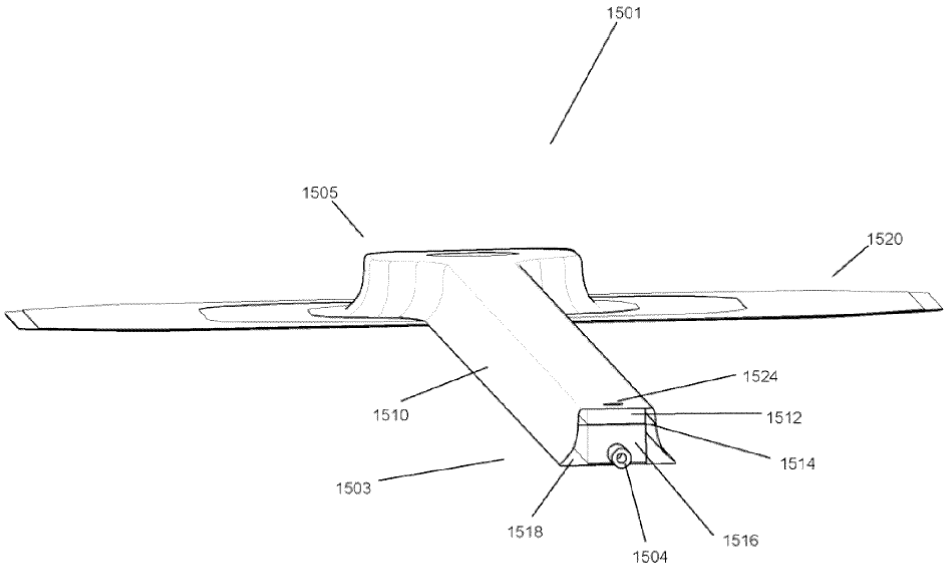


Figure 15C

Figure 15C

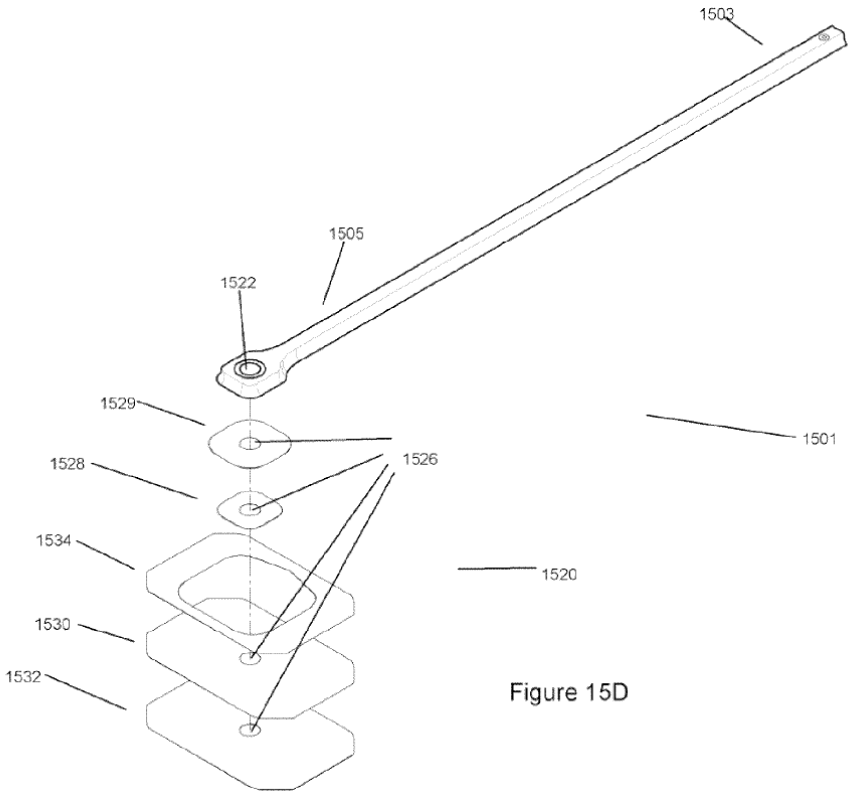


Figure 15D

Figure 15D

Without admitting there is any support, which there is not, it becomes clear that Figures 15A-D and the accompanying text are the only disclosure in the '750 Patent that could potentially relate to claims 18-24 (as well as claims 1-17). Claims 18-24 all require an "inspection portion" that allows the user of the NPWT device to see the wound. The only possible disclosure in the '750 Patent that could possibly relate to an "inspection portion" is the "viewing window" (1522), the apertures underneath the viewing window, and the corresponding text at 22:1-26:2.[1] (Ex. 1001, 22:1-26:2.) Figure 15B (reproduced below) illustrates the disclosure of the "viewing window." (Ex. 1001, FIG. 15B.) Consequently, when analyzing claims 18-24 for written description support, that support must be found in Figures 15A-D and the corresponding text at 22:1-26:1. (Ex. 1001, FIG. 15A-D, 22:1-26:1.) (Ex. 1010, ¶55-56.)

[1] Notably, the Applicants chose Figure 15A as the representative figure for inclusion on the face of the patent. ('750 Patent at cover page.)

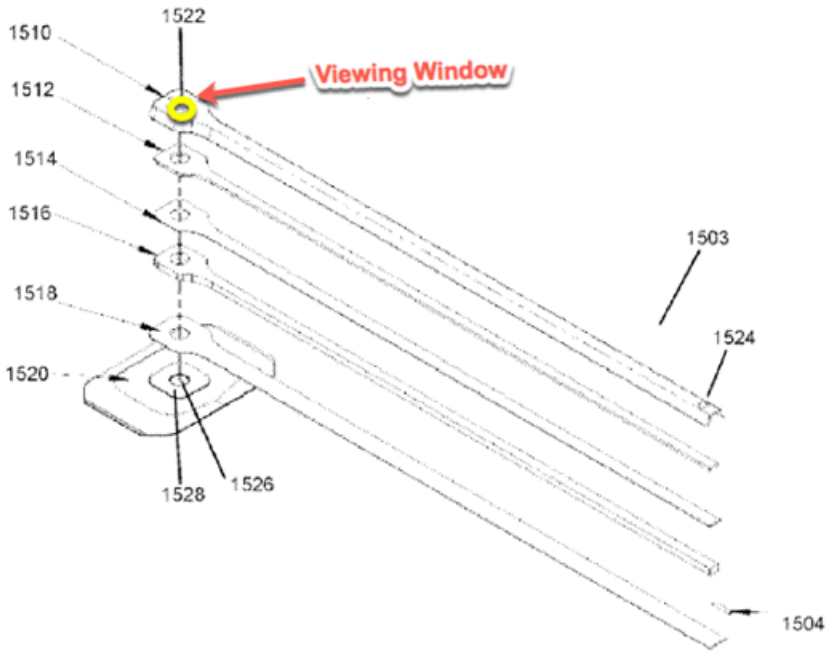


Figure 15B

4.	**(18.1) The "attachment portion adapted to be attached to a wound cover member"**

The '750 Patent does not recite an "attachment portion" nor identify any structure in Figures 15A-D as an "attachment portion." (Ex. 1010, ¶57.)

A person of ordinary skill in the art searching the '750 Patent for any disclosure that could plausibly relate to an "attachment portion," would identify the "applicator" 1520 in Figures 15A-D as the only such disclosure. (Ex. 1001, 24:35-64.) The "applicator" is "designed for placement over a wound site" and includes various polyurethane and adhesive layers. (Ex. 1001, 24:36-55, Fig. 15D (reproduced below).) (Ex. 1010, ¶58.)

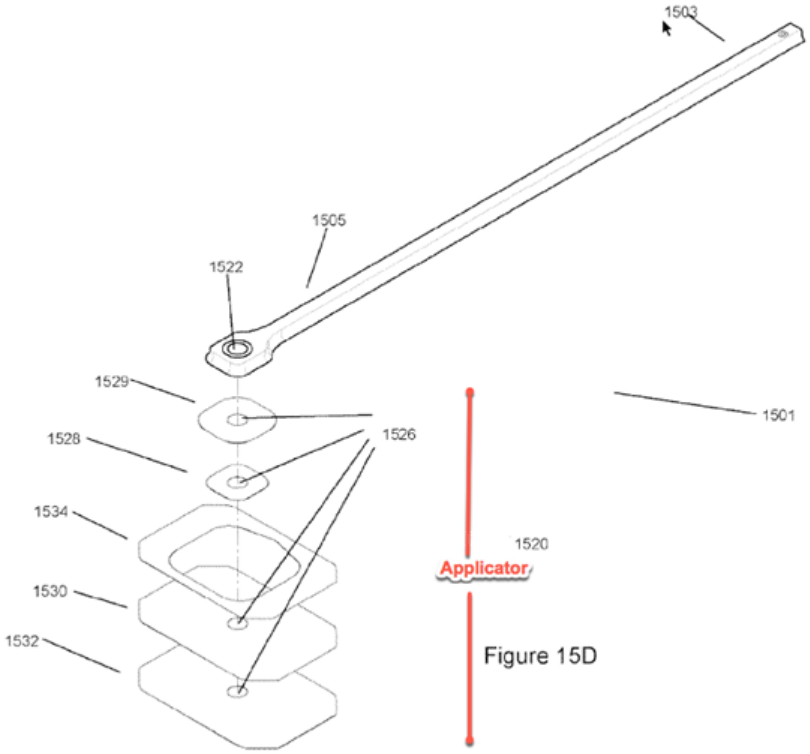


Figure 15D

5. (18.2) The "suction device"

Claim 18 requires a "suction device" that includes various structural limitations. A person of ordinary skill in the art attempting to identify support for these limitations in the specification of the '750 Patent would walk through each claim limitation and attempt to identify the support, if any, for each such limitation. (Ex. 1010, ¶59.)

a. (18.2.1) The "suction device" Requires A "fluid inlet" In The "attachment portion"

The "suction device" in Claim 18 requires "a fluid inlet being at least partially circumscribed by said attachment portion." The '750 Patent does not

recite a "fluid inlet" nor identify any structure in Figures 15A-D as a "fluid inlet." (Ex. 1001.) A person of ordinary skill in the art searching the '750 Patent for any disclosure that could plausibly relate to a "fluid inlet" would identify the "aperture" 1526 in Figures 15A-D as the only such disclosure. (Ex. 1001, 24:56-62.) As described in the '750 Patent, the aperture "can serve to fluidically connect the wound site to the source of negative pressure and to the air leak" and can also serve "as a conduit to draw out wound exudate from the wound site." (Ex. 1001, 24:56-62, Figure 15D (reproduced below).) (Ex. 1010, ¶60.)

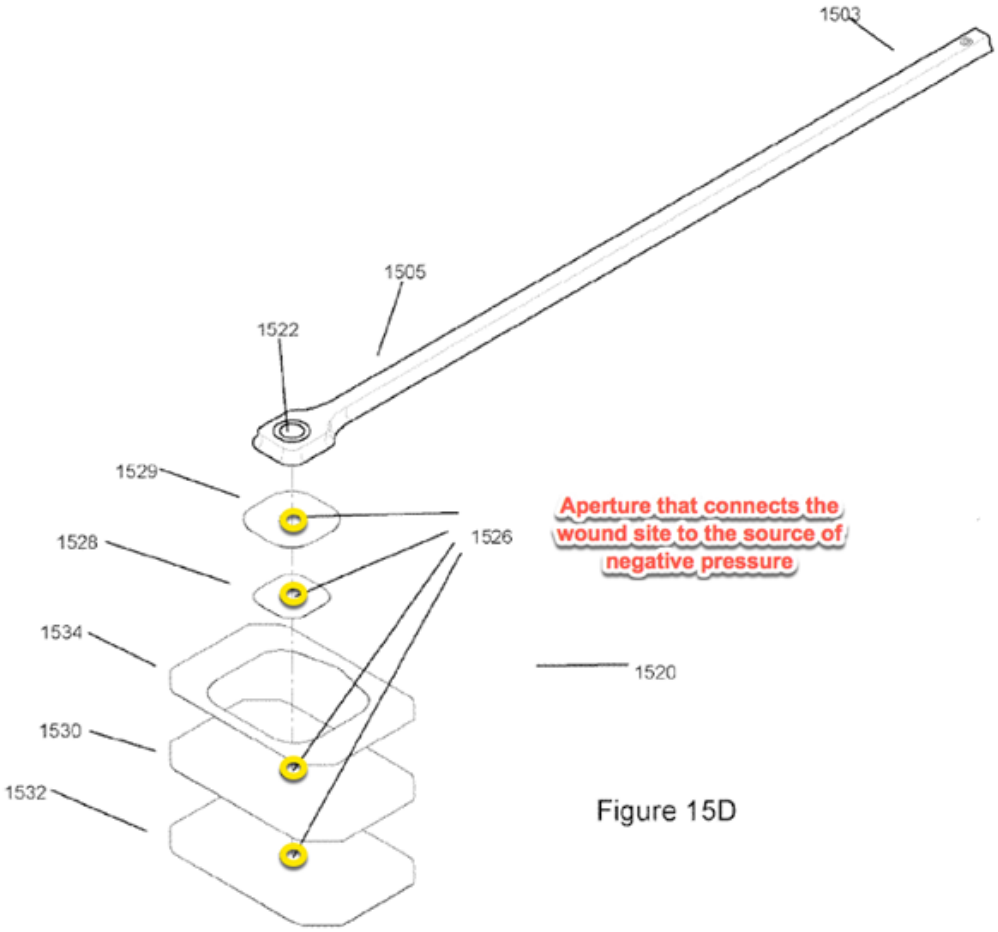


Figure 15D

b. (18.2.2) The "suction device" Also Requires "a fluid outlet"

The suction device in Claim 18 also requires "a fluid outlet." (Ex. 1001, claim 18.) The '750 Patent does not recite a "fluid outlet" nor identify any structure in Figures 15A-D as a "fluid outlet." (*See generally*, Ex. 1001.) A person of ordinary skill in the art searching the '750 Patent for any disclosure that could plausibly relate to a "fluid outlet" would identify the connector 1504 at the proximal end 1503 of the lower channel layer 1516. (Ex. 1001, 23:1-11, 25:42-56.) The "connector 1504" is the only disclosure in the '750 Patent that connects the suction device to negative pressure, which is necessary for operation as a NPWT device. The only disclosure in the '750 Patent that explains the functioning of the connector states that it is "provided at the proximal end" and is used to "connect the lower channel layer" to a source of negative pressure that draws fluid through the "bridge 1502" and away from the wound. (Ex. 1001, 23:2-11, Fig. 15C (reproduced below).) (Ex. 1010, ¶62-63.)

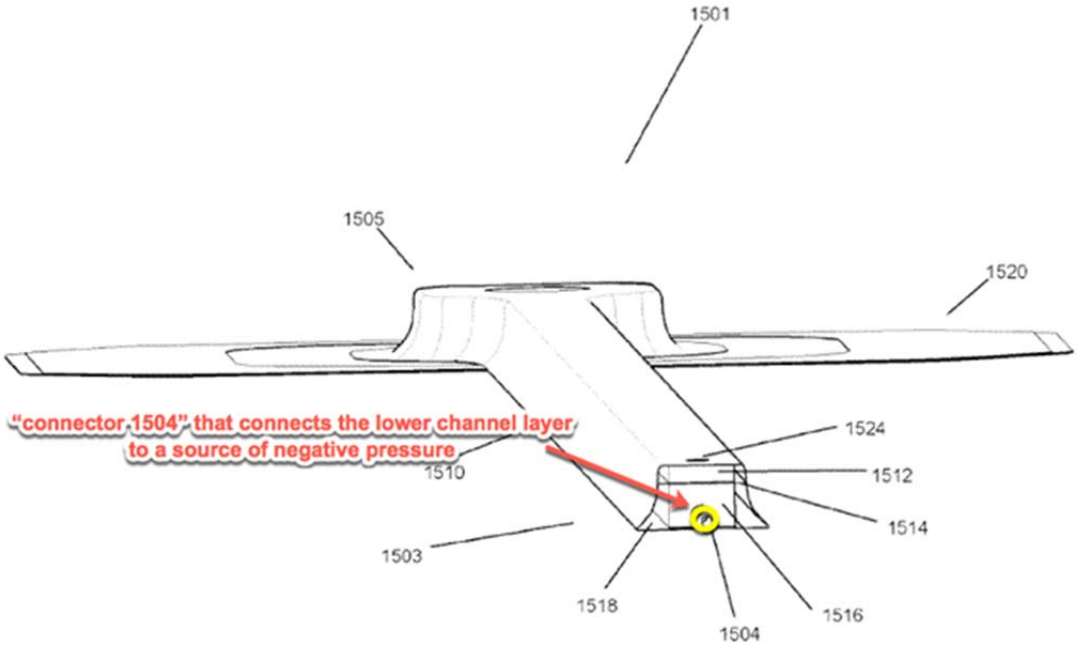


Figure 15C

Notably, the '750 Patent describes a system in which the "bridge 1502" includes two separate channel layers: an "upper channel layer 1512" and a "lower channel layer 1516." (Ex. 1001, 22:10-14.) The two channel layers each provide a separate function. The "lower channel layer 1516" is connected to a source of negative pressure to apply suction to a wound. (Ex. 1001, 23:1-11, 25:1-11, 49-51.) The "upper channel layer 1512" provides a constant flow of air through the system. (Ex. 1001, 23:26-43, 25:51-59.) (Ex. 1010, ¶64.)

So that suction can be applied properly, the two "channel layers 1512 and 1516" are separated from one another by an "intermediate layer 1514" and enclosed by upper and bottom layers (1510 and 1518). (Ex. 1001, 22:10-14, 23:1-

43.) This forms two distinct channels – one for suction and the other for the air leak. (Ex. 1001, 23:1-43, 25:49-59) (Ex. 1010, ¶65.)

Keeping these channels separate is important for the operability of the device. As described in the '750 Patent, air enters the system through the "air leak" and travels along the "upper channel 1512" to the wound site. It is then suctioned out through the "lower channel 1516." (*Id.*) The functioning of the system is illustrated in the figure below:

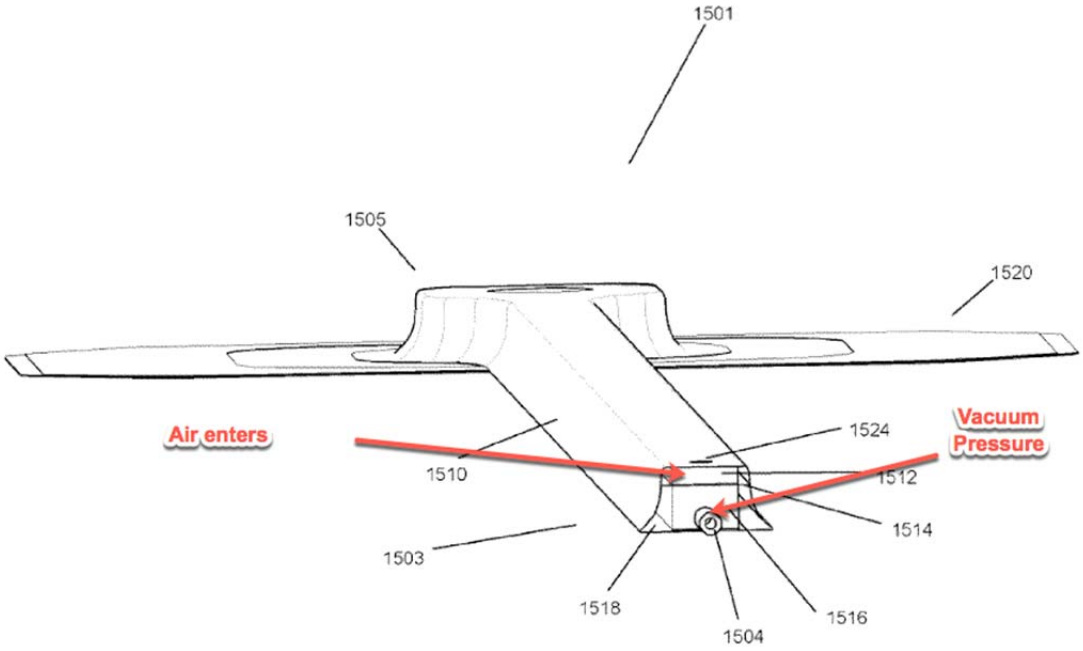


Figure 15C

(Ex. 1010, ¶66.)

c. (18.2.3)The "suction device" Requires "a connection portion adapted to . . . provide a fluid communication between said fluid inlet and said fluid outlet"

The '750 Patent does not recite a "connection portion" nor identify any structure in Figures 15A-D as a "connection portion." (Ex. 1010, ¶67.) A person of ordinary skill in the art searching the '750 Patent for any disclosure that could plausibly relate to a "connection portion" would identify the "bridge 1502." More specifically, a person of ordinary skill in the art would identify the "lower channel layer 1516" as the only disclosure in the '750 Patent that could create a "fluid communication" between the fluid inlet (the "aperture 1526") and the fluid outlet (the "connector 1504"). (Ex. 1001, 22:7-18, 25:49-56.) (Ex. 1010, ¶68.)

The bridge 1502 provides the connection between the "aperture 1526" and both the source of negative pressure at the connector 1504 and the source of the air leak 1524. The bridge 1502 comprises the upper and lower channel layers discussed above, and shown in Figures 15A and 15C. (Ex. 1010, ¶69.)

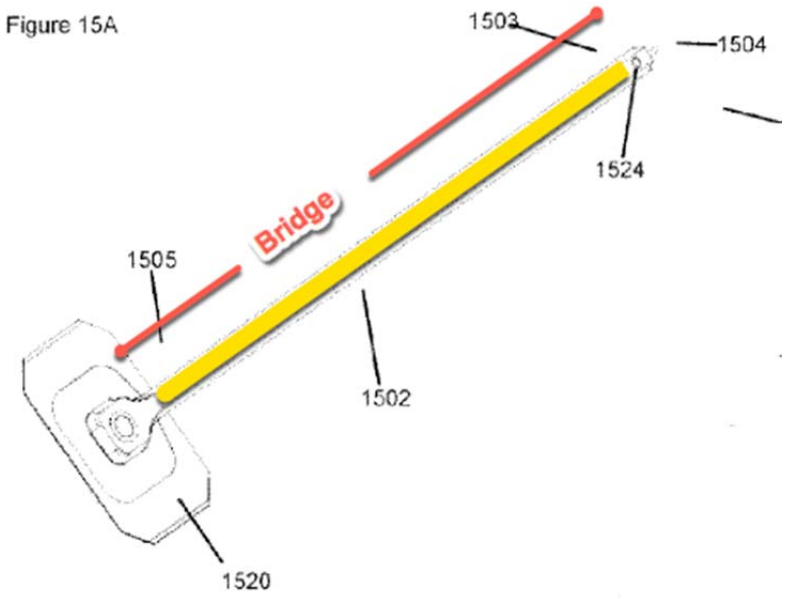


Figure 15A with bridge (1502) highlighted

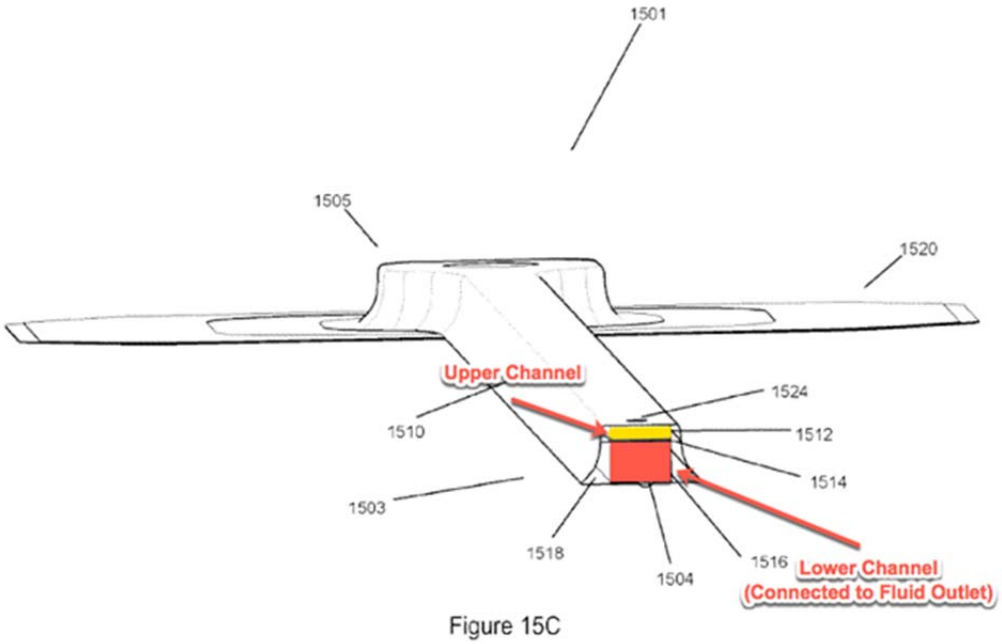


Figure 15C

Figure 15C with upper and lower channels (1516 and 1512) highlighted

As shown above and described in the '750 Patent, it is only the "lower channel layer" that is connected to the fluid outlet. It provides "fluid communication" between the two because the sides of the "upper layer 1510," the

"intermediate layer 1514" and the "lower layer 1518" create that channel. Consequently, a person of ordinary skill in the art would understand that the only disclosure supporting a "channel creating a fluid connection between [the] fluid inlet and [the] fluid outlet" is the "lower channel 1516" as defined by the intermediate layer, lower layer, and the sides of the upper layer. This disclosure is illustrated in the annotated figure below. (Ex. 1010, ¶70.)

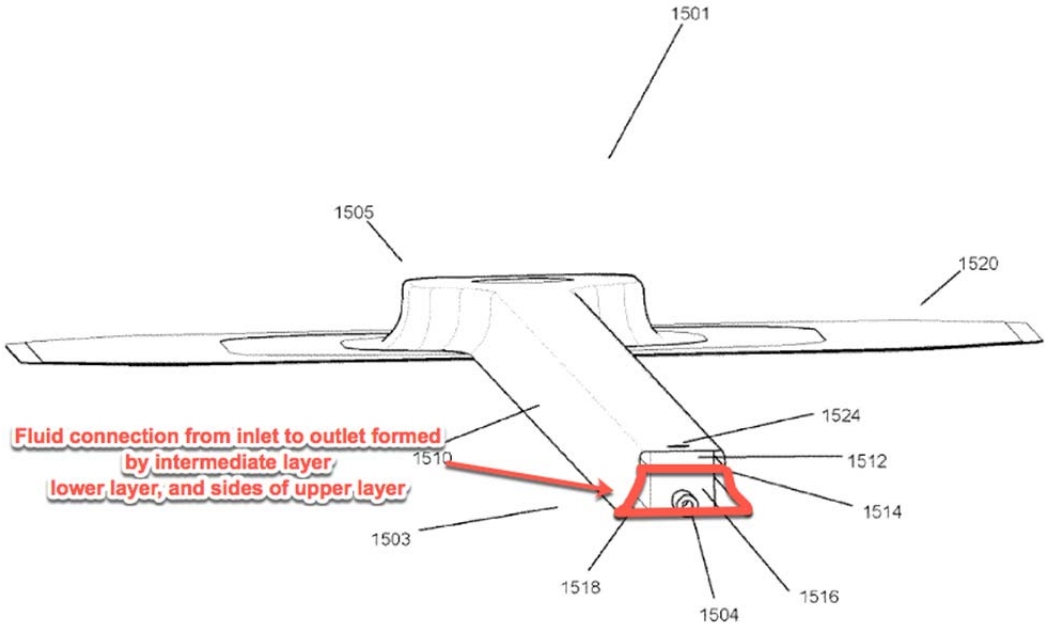


Figure 15C

6. (18.3) The "connection portion"

The claimed connection portion provides four additional limitations on the "connection portion" that make clear that the '750 Patent does not provide written description support for Claims 18-24. When viewed with the understanding one of

ordinary skill in the art would have of the disclosure that could plausibly support the "suction device" limitations, it becomes plain that there is no disclosure in the '750 Patent that can support several of the "connection portion" limitations, including the requirements that the "connection portion" include: an "inspection portion," a "duct wall comprising said inspection portion," and a "partition wall that extends partially from [the] duct wall." (Ex. 1010, ¶71.)

a. (18.3.1) There Is No Written Description Support For A "connection portion" That Includes "an inspection portion that is transparent to thereby facilitate the positioning of said suction device relative to said wound cover member"

The claimed "connection portion" requires "an inspection portion that is transparent to thereby facilitate the positioning of said suction device relative to said wound cover member." The '750 Patent does not recite a "connection portion" nor identify any structure in Figures 15A-D as a "connection portion." (Ex. 1010, ¶72.)

The '750 Patent further does not recite a connection portion with an "inspection portion." A person of ordinary skill in the art searching the '750 Patent for any disclosure that could plausibly support an "inspection portion" would identify the "viewing window 1522" as the only possible relevant disclosure. (Ex. 1010, ¶73.)

As discussed above, however, a person of ordinary skill in the art would also understand the only disclosure in the '750 Patent that could support the "connection portion" is the "lower channel 1516." The "lower channel 1516" is bounded by the sides of the upper layer and the intermediate and bottom layers. (Ex. 1010, ¶74.)

Because the "viewing window 1522" is only disclosed on the end portion of the top of the "upper layer" as shown in highlighted figure 15B below, it is not part of the "lower channel," and thus cannot be part of the structure that supports the claimed "connection portion." Indeed, the '750 Patent states that the "viewing window 1522" covers "the first aperture" of the apertures that lead to the wound site. (Ex. 1001, 25:8-11.) This first aperture is only disclosed to be over the top portion of the upper layer. (Ex. 1001, 25:8-11, Figs. 15B, 15D.) Consequently, the '750 Patent and all of its priority applications do not include written description that supports the claimed "inspection portion." (Ex. 1010, ¶75.)

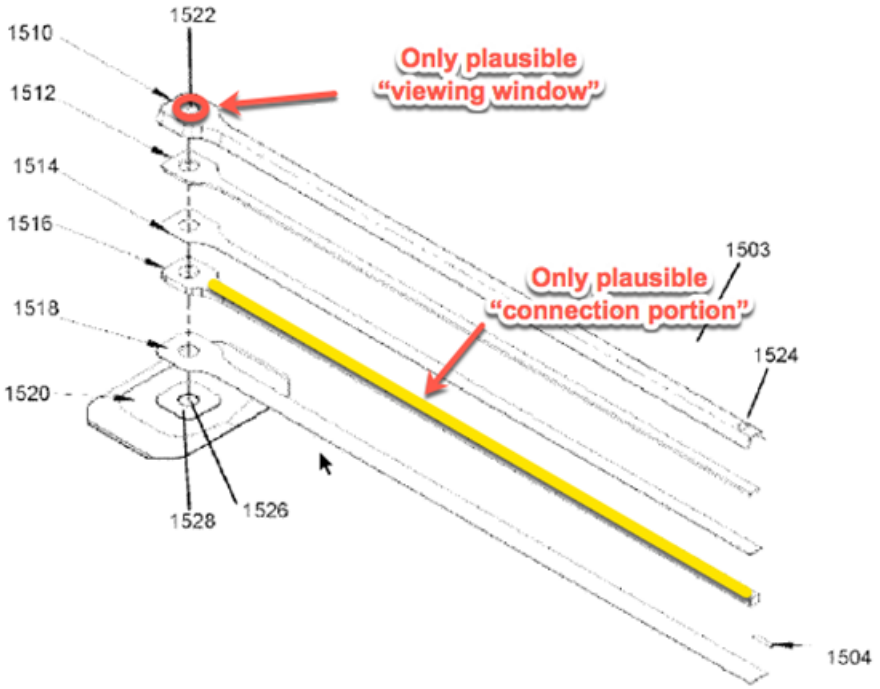


Figure 15B

b. (18.3.2) The "connection portion" Must Include A "duct wall" That "at least partially defines a connection duct from said inlet to said outlet"

The '750 Patent does not recite a "duct wall" nor identify any structure in Figures 15A-D that would be a "duct wall" that "defines a connection duct from said inlet to said outlet." (Ex. 1010, ¶76.) As discussed above in the claim construction section, a "duct" is a "pipe, tube, or channel for conveying a substance," and a "duct wall" is the wall of a duct. (Ex. 1010, ¶77.)

A person of ordinary skill in the art searching the '750 Patent for any disclosure that could plausibly support such a "duct wall" would identify one of the

four walls of the lower channel, as shown in highlighted Figure 15C (below) as the only possible relevant disclosure. (Ex. 1001, 22:7-18, 25:49-56.) It is these four walls (the sides of the upper layer, the bottom layer, and the intermediate layer) that cause the "lower channel" to channel wound exudate from the aperture to the source of negative pressure at the outlet. Nothing else in the '750 Patent or any of its priority applications could serve the function of providing a duct from inlet to outlet. (Ex. 1010, ¶78.)

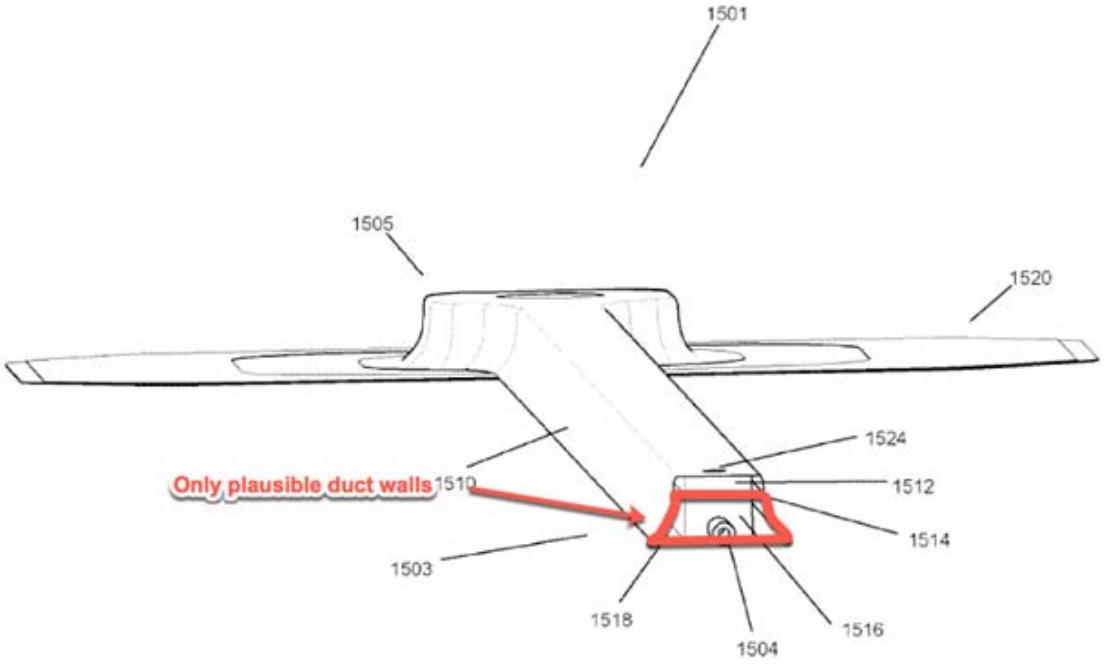


Figure 15C

c. (18.3.3) There Is No Disclosure Of "a duct wall" That Includes An "inspection portion"

Just as the '750 Patent includes no disclosure that supports a "connection portion" with an "inspection portion," the '750 Patent also does not disclose a "duct wall" with an "inspection portion." Claim 18 requires a "duct wall with an

inspection portion." As discussed above, a person of ordinary skill in the art would find the "viewing window 1522" to be the only plausible disclosure that could support an "inspection portion." (Ex. 1010, ¶79.)

As the '750 Patent makes clear, however, the "viewing window 1522" must be in the upper layer. However, as shown in annotated Figure 15C below, the only possible "duct walls" are entirely distinct from the portion of the upper layer that includes the "viewing window 1522." Indeed, the top wall of the upper layer has nothing to do with creating a fluid connection (or a connection duct) from inlet to outlet. Thus, there is no support in the '750 Patent or any of its priority applications for the claimed "duct wall" having an "inspection portion." (Ex. 1010, ¶80.)

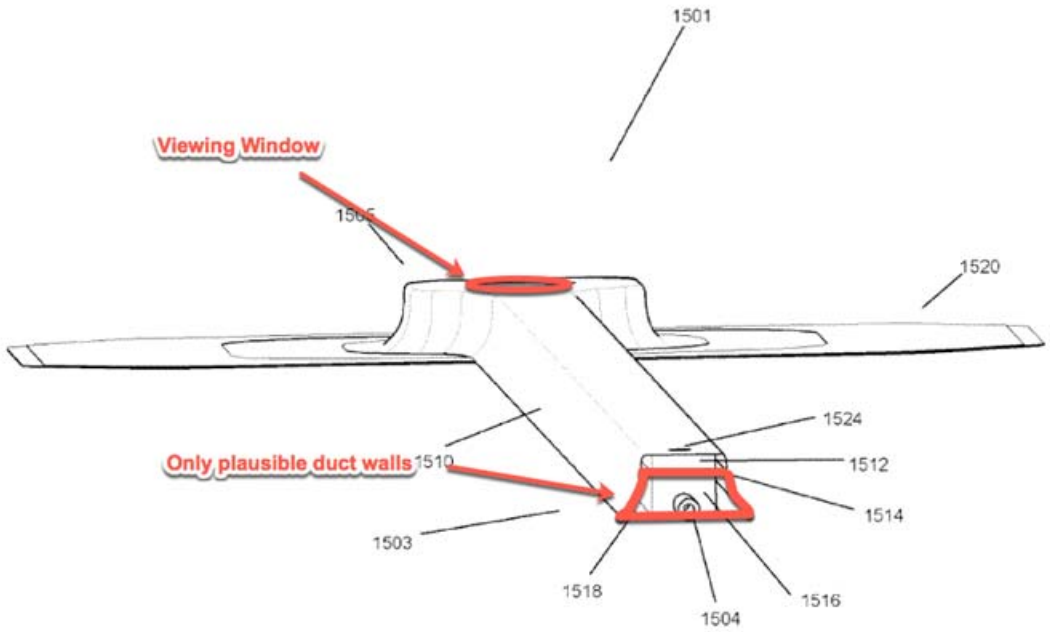


Figure 15C

d. (18.3.4) There Is No Disclosure That Supports "a partition wall extending at least partially from said duct wall"

Finally, the "connection portion" must have a "partition wall that extends at least partially from [the] duct wall." (Ex. 1001, claim 18.) There is no support for such a "partition wall" in the '750 Patent or any of its priority applications. The '750 Patent does not recite a "partition wall" nor identify any structure in Figures 15A-D that would be a "partition wall," particularly one that would "extend at least partially from [the] duct wall." (Ex. 1010, ¶81.)

Further, a person of ordinary skill in the art would find no disclosure in the '750 Patent that could be such a "partition wall." As discussed above in Section VII, a "partition wall" is a wall that divides. As shown in annotated Figures 15B and C, below, there is no such wall extending from anything that could plausibly be a "duct wall" in the '750 Patent. (Ex. 1001, claim 18.) (Ex. 1010, ¶82.)

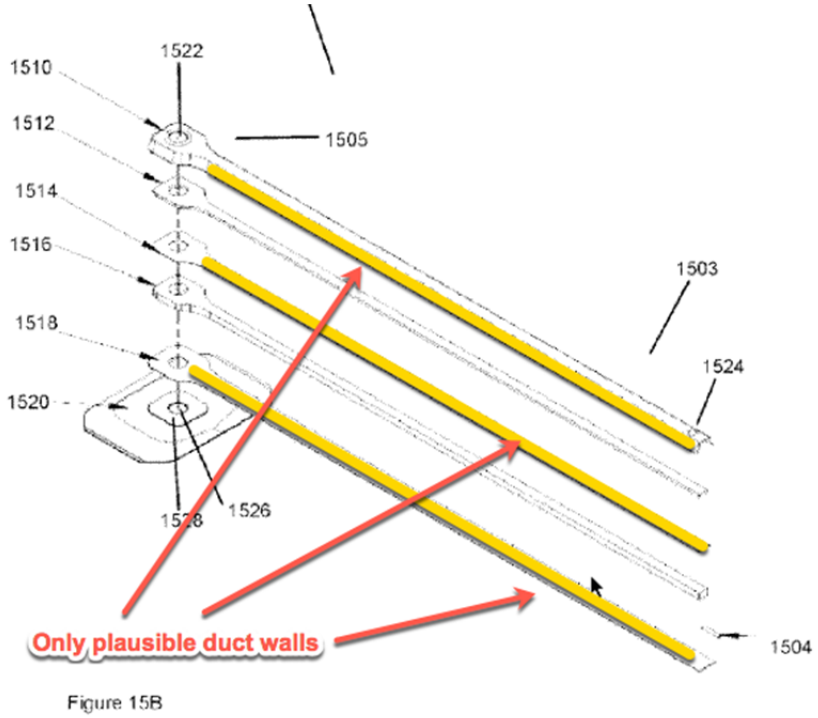


Figure 15B (plausible duct walls highlighted)

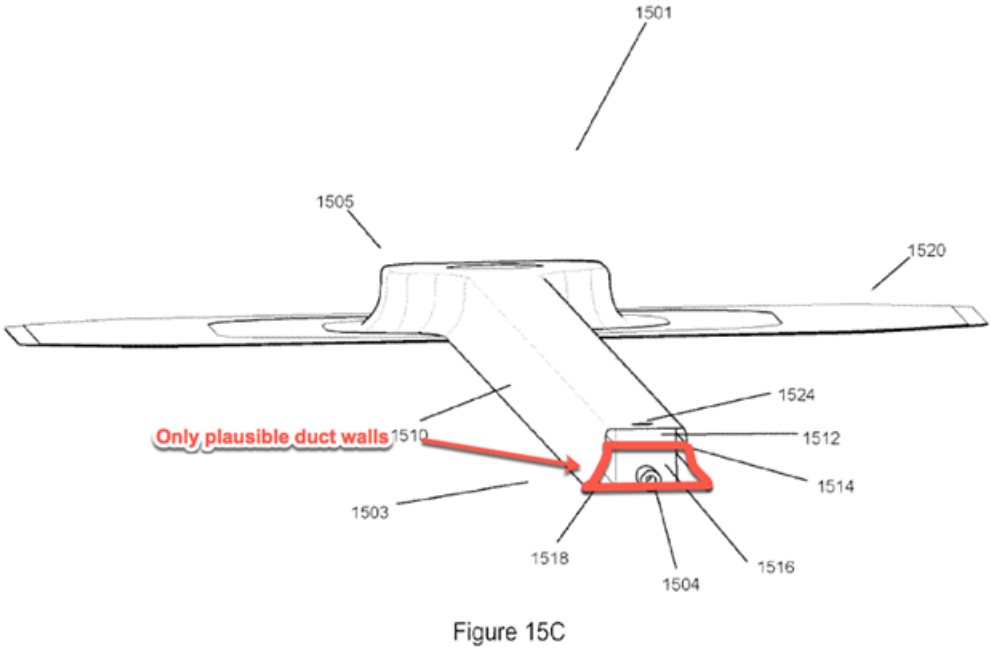


Figure 15C (plausible duct walls highlighted)

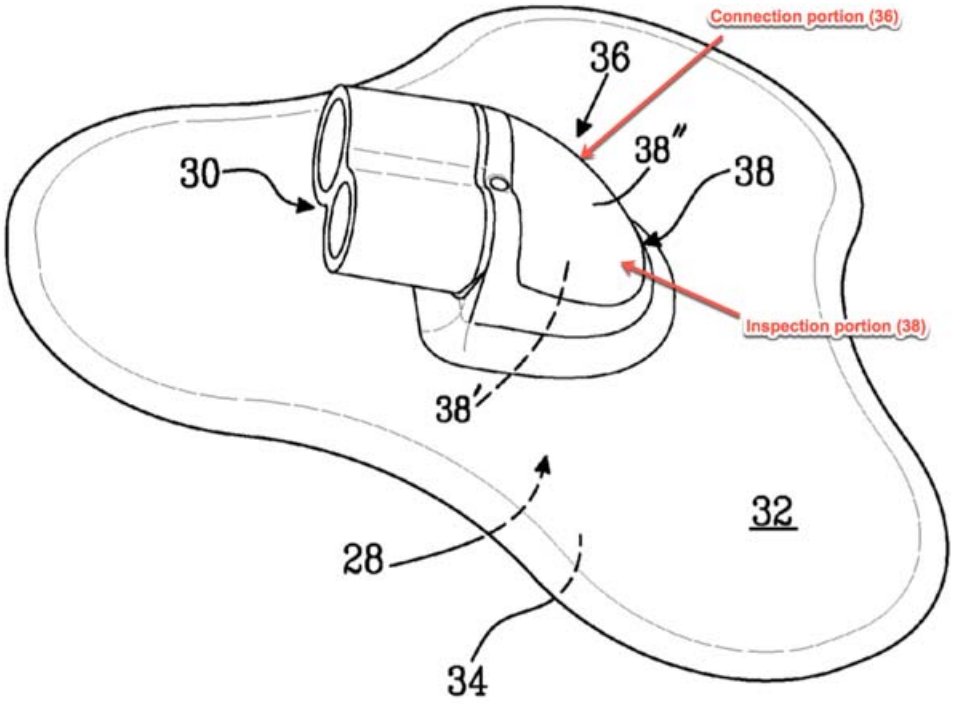
As can be seen here, there is nothing "extending" from the plausible "duct walls" at all, and certainly nothing that could be considered a "partition wall."

Consequently, there is no support for the claimed "partition wall" and thus Claim 18 is invalid for failing to comply with 35 U.S.C. § 112. (Ex. 1010, ¶83.)

7. Claim 18 Was Copied From An Application For A Completely Different Invention, Which Explains The Lack Of Written Description Support In The '750 Patent

The lack of support for claim 18 – particularly with respect to the lack of support for the claimed "connection portion comprising an inspection portion," "duct wall," and "partition wall" makes sense when considering that the applicants copied the claim verbatim from a different patent application filed by a different applicant and directed to a completely different invention. (Ex. 1010, ¶84.)

Specifically, Claim 18 was copied from Petitioner's application (the MHC Application). (Ex. 1008 and Ex. 1009, claim 1, p.212.) Figures 2 and 3 of the MHC Application illustrate the intended context of the claim terms that now appear in the '750 Patent, and explain what the terms that are unsupported in the '750 Patent would mean to a person of skill in the art in the proper context of the MHC Application. (Ex. 1010, ¶85.)



The MHC application was directed to a different NPWT device than the '750 Patent. As illustrated in annotated Figure 2 of the MHC Application (above) and the accompanying text, the MHC Application includes explicit discussion of the "connection portion" and "inspection portion" that appear in claim 18, but are never discussed in the '750 Application. As described in the MHC Application, the device has a single chamber over the wound site (the "connection portion 36") in which two tubes (one for the application of suction, the other to allow air to enter) meet. (Ex. 1008, ¶[0080].) That "connection portion 36" has an "inspection portion 38" that provides a window that allows viewing of the wound site. The text accompanying Figure 2 provides direct support for the "connection portion" and

"inspection portion," neither of which are present in the '750 Patent. (Ex. 1010, ¶86.)

Figure 3 (annotated, below) and accompanying text illustrates the "duct wall" and "partition wall" that are expressly discussed in the MHC Application, yet are also absent from the '750 Patent. (Ex. 1008, FIG. 3.) A "duct wall 40" defines "a connection duct" from the fluid inlet to the fluid outlet. A "partition wall 42" extends from the "duct wall 40," as shown in Figure 3. (Ex. 1008, FIG. 3.) (Ex. 1010, ¶87.)

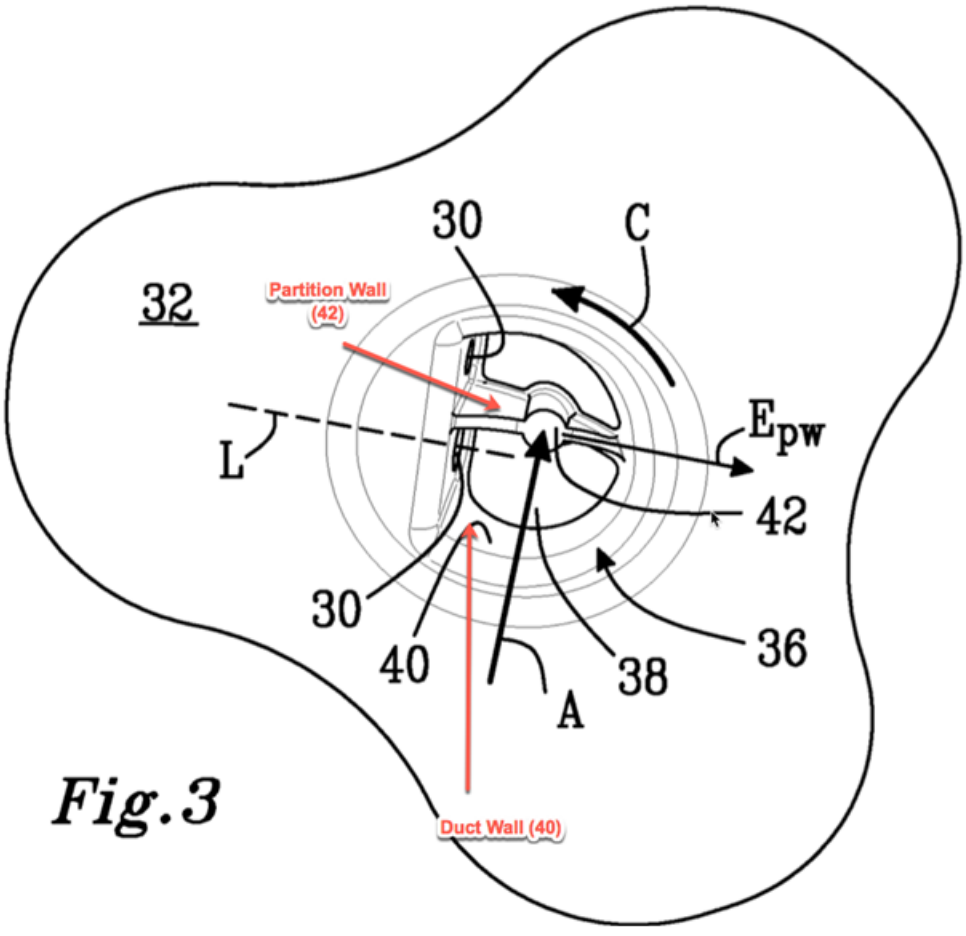


Fig.3

The partition wall reduces the risk of collapse of the connection portion, for example during installation of the device or during the negative pressure therapy. (Ex. 1008, ¶[0033].) The partition wall also allows for reduction in the wall thickness of the inspection portion while still maintaining structural integrity and improved viewing through the inspection portion. (Ex. 1008, ¶¶ [0033] – [0034].) The "partition wall 42" provides the added ability to prevent portions of the bandage that covers the wound from being sucked into the suction device. (Ex. 1008, ¶[0119].) (Ex. 1010, ¶88.)

The MHC invention uses essentially one unitary structure for the connection portion, inspection portion, duct walls, and connection duct, and such a structure contains the partition wall. Conversely, the '750 Patent is directed to a device that has multiple disparate parts for, *inter alia,* its bridge and visualization window. (Ex. 1010, ¶89.)

A person of ordinary skill in the art studying the MHC Application would conclude that there is explicit written description support in the MHC application for the elements that now appear in Claim 18. The MHC Application stands in stark contrast to the '750 Patent, which uses words without context, and without any indication to a person of ordinary skill in the art as to how those words relate to the disclosure in the '750 Patent. Consequently, a person of ordinary skill in the art would not understand the specification of the '750 Patent to demonstrate that

the inventors were in possession of the device set forth in Claim 18 as of its filing date. (Ex. 1010, ¶90.)

Thus, Claim 18 of the '750 Patent is invalid. Further, because none of the priority applications provide any additional support, Claim 18 is not entitled to an earlier priority date, and thus is eligible for this Post Grant Review proceeding, because it was filed after implementation of the AIA. (Ex. 1010, ¶91.)

8. Dependent Claims 19-24 Suffer From The Same Infirmities, And Are Also Invalid

Claims 19-24 each depend from independent claim 18. Each of these claims incorporates all of the limitations of the independent claims from which they depend. Further, none of the dependent claims narrows the scope of the independent claim limitations in a manner sufficient to bring them within the reach of the specification's disclosure. Thus, the limitations of each of the dependent claims lack written description support and are invalid under § 112(a) for the reasons discussed with respect to the independent claim 18. (Ex. 1010, ¶92.)

B. Ground 2: Claims 1-17 Are Invalid Under 35 U.S.C. § 112(a) For Lack Of Written Description

Claims 1-17 were also added to the '750 Patent in the February 16, 2016 amendment (after the '750 Patent's February 8, 2016 filing date). (Ex. 1002, p.111.) Like claims 18-24, there were no originally filed claims directed to the

subject matter of Claims 1-17. And, like claims 18-24, certain key words and phrases of claims 1-17 lack written description support. (Ex. 1010, ¶93.)

Claim 1 is reproduced below with the unsupported terms highlighted.

> 1. An apparatus to provide suction to a wound site comprising:
> **(1.1)** a suction adapter configured to be sealed to a wound cover covering a wound site, the suction adapter comprising:
> **(1.2)** an applicator configured to be positioned over an opening in the wound cover, the applicator comprising at least one aperture; and
> **(1.3)** a bridge portion connected to the applicator and comprising at least a first channel and a second channel extending parallel to an upper surface of the applicator, wherein at least one of the first channel and second channel is configured to provide suction to the wound site through the aperture in the applicator from a source of negative pressure;
> **(1.4)** a visualization window provided in an upper surface of the bridge portion over the at least one aperture in the applicator that provides **unobstructed visualization** from outside of the suction adapter, through the visualization window and through the aperture in the applicator;
> **(1.5)** wherein the bridge portion comprises material extending downwardly from the upper surface of the bridge portion to thereby connect the bridge portion to the applicator; and
> **(1.6) an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel**.

(Ex. 1010, ¶94.)

The disclosure of the ’750 Patent does not satisfy 35 U.S.C. § 112 for either the “unobstructed visualization” limitation or the “intermediate wall” limitations highlighted above. (Ex. 1010, ¶95.)

1. The '750 Patent Does Not Provide Written Description Support For The "unobstructed visualization" Limitation In Claims 1-17

Claim 1 requires "a visualization window . . . that provides unobstructed visualization." Claim 1 was added after the filing of the original '750 Patent in the amendment of February 16, 2016. (Ex. 1002, p.111.) (Ex. 1010, ¶96.)

The term "unobstructed visualization" does not appear anywhere in the specification or original claims of the '750 Patent. The specification does describe a "viewing window" at 24:65-25:12, but none of the disclosure of either the "viewing window" itself or its function describes something that provides an "unobstructed visualization." (Ex. 1001, 24:65-25:12.) (Ex. 1010, ¶97.)

At most, the specification refers to "targeting and visualization" and "ongoing monitoring" of the wound site. Neither the concept, nor the specific language, of "unobstructed visualization" appears anywhere in the '750 Patent. The '750 Patent also does not explain how to achieve "unobstructed visualization," as opposed to simply being able to "visualize" or "monitor" the wound site. One can target, visualize, or monitor even if the view is in some way obstructed. (Ex. 1010, ¶98.)

Because there is no written description support for "unobstructed visualization," claim 1 is therefore invalid under 35 U.S.C. § 112(a). Because

claim 1 is invalid, and claims 2-17 do not cure this invalidity, claims 2-17 are invalid for the same reason. (Ex. 1010, ¶99.)

All of the priority applications to the '750 Patent have either the same or less disclosure than that of the '750 Patent, and provide no additional disclosure regarding an "unobstructed visualization" than what is in the '750 Patent. Thus, solely for purposes of determining PGR eligibility, the effective filing date for claims 1-17 is deemed to be February 8, 2016 – the filing date of the '750 Patent. In addition to rendering claims 1-17 invalid, this provides an additional and independent reason for PGR eligibility over the reasons provided with respect to the lack of written description for claims 18-24. (Ex. 1010, ¶100.)

2. **There Is No Support For "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel" In Claims 1-17**

Nowhere is this concept, let alone the specific language, disclosed in the '750 Patent. (Ex. 1010, ¶101.) Claim 1 was added after the filing of the original application in the amendment of February 16, 2016. This clause is nowhere to be found in the specification or original claims of the '750 Patent. The specification discloses an intermediate layer 1514, downwardly extending material, and a first 1512 and second 1516 channel. But nowhere is this claimed orientation disclosed in the '750 Patent. (Ex. 1010, ¶¶102-103.)

The middle layer, which is allegedly the intermediate wall, is only described as "preferably being attached to the top and bottom layers." First, it makes no sense that the middle layer 1514 is attached to the bottom layer 1518. Then no channel is available between the middle layer 1514 and the bottom layer 1518. (Ex. 1010, ¶104.)

Second, nowhere is the arrangement of the intermediate wall "extending . . . from" the downwardly extending material, the perpendicular orientation, and the partitioning of the first channel from the second channel described in the specification of the '750 Patent. (Ex. 1010, ¶105.)

Figure 15C merely shows that the middle layer 1514 is between the upper layer 1510 and lower layer 1518. (Ex. 1001, FIG. 15C.) However, the extending from relationship, the perpendicular orientation, and the partitioning aspects are not shown. (Ex. 1010, ¶106.)

Moreover, the downwardly extending material from the upper layer 1510 does not extend straight down; it is curved. (Ex. 1001, FIG. 15C.) Therefore, it is not possible for the intermediate wall 1514 to extend perpendicularly from the downwardly extending material, which forms the side walls. The intermediate wall will be at an angle to the downwardly extending material and not perpendicular to that material. (Ex. 1010, ¶107.)

There is no written description support for this clause, and claim 1 is therefore invalid under 35 U.S.C. § 112(a). Because claim 1 is invalid, and claims 2-17 do not cure this invalidity, claims 2-17 are also invalid for the same reason. (Ex. 1010, ¶108.)

All of the priority applications to the '750 Patent have either the same or less disclosure than that of the '750 Patent, and provide no additional disclosure regarding the offending term than what is in the '750 Patent. Thus, solely for purposes of determining PGR eligibility, the effective filing date for claims 1-17 is deemed to be February 8, 2016 – the filing date of the '750 Patent. In addition to rendering claims 1-17 invalid, this provides an additional and independent reason for PGR eligibility over the reasons provided with respect to the lack of written description for claims 18-24. (Ex. 1010, ¶109.)

C. Ground 3: Claims 1-4 And 6-17 Are Anticipated By The Public Sale And/Or Public Disclosure Of SensaTRAC

As early as 2007, Kinetic Concepts, Inc. ("KCI") sold, offered for sale, and made the SensaTRAC system publicly available. SensaTRAC is a negative pressure wound treatment system that uses a vacuum pump to apply negative pressure to a wound through a polyurethane pad system. The pad system and vacuum pump of the SensaTRAC device are shown below. (Ex. 1010, ¶111.)

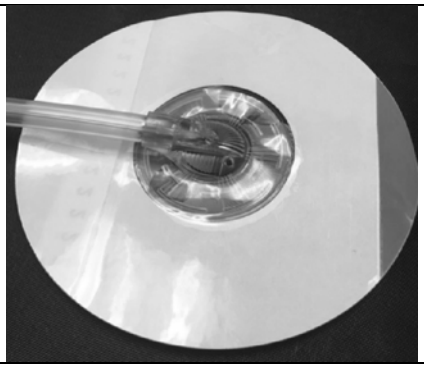
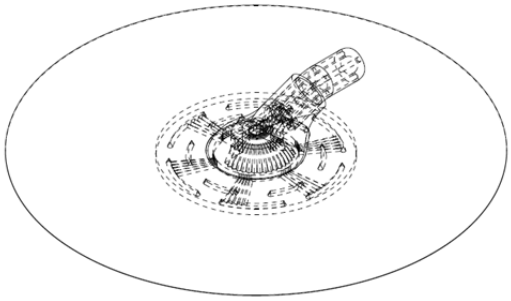
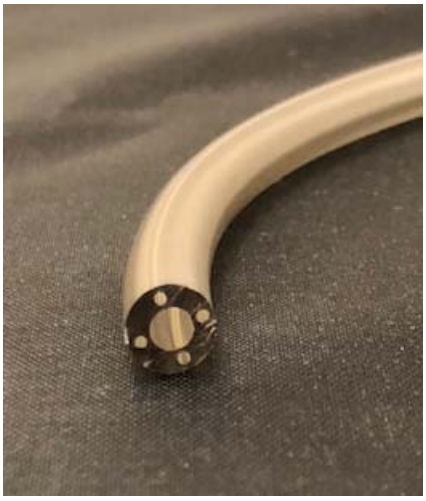
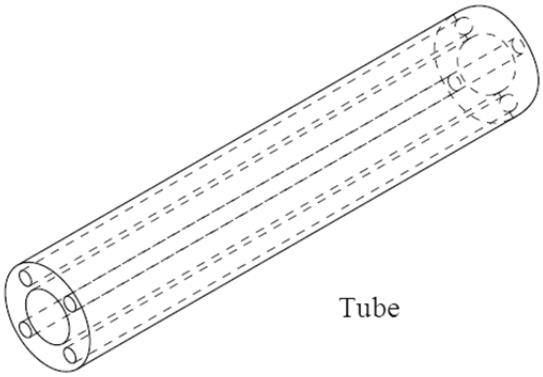
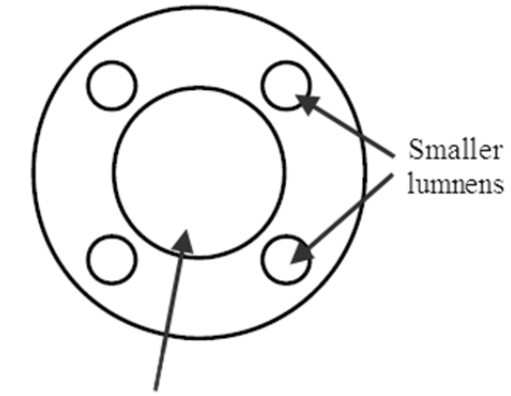
Vacuum Pump

Pad System, including a pad and tube

SensaTRAC, and in particular the pad system, anticipates claims 1-4 and 6-17 of the ’750 Patent. SensaTRAC discloses all of the elements of Claims 1-4 and 6-17. (Ex. 1010, ¶112.)

1. The SensaTRAC Negative Pressure Wound Therapy System

For the purposes of this petition, the most relevant aspect of the SensaTRAC is the pad that covers the wound site and the tubing that connects the pad to the vacuum source, i.e. pump. A photo of the pad and the tube are reproduced below, along with black-and-white line drawings of each to provide clarity. (Ex. 1010, ¶¶113, 274-307.)

Pad		
Tube		 

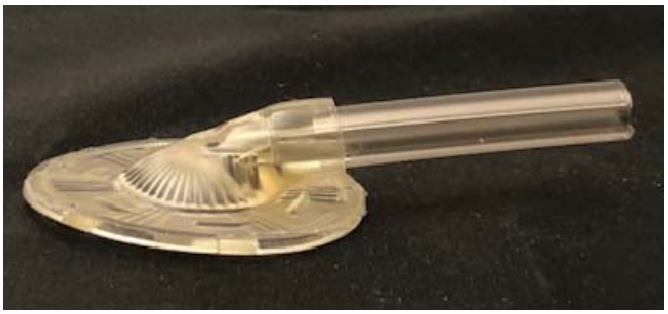
The images and black-and-white line drawings are each true and accurate representations of the pad and the tube. (Ex. 1010, ¶¶274-307.)

SensaTRAC is a device for providing negative pressure to a wound. SensaTRAC has been commercially available since June 14, 2007, in a kit, which

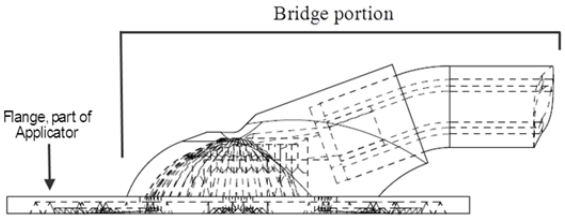
also includes a solid piece of foam with an open pore structure to be placed in the wound, and a plastic drape having adhesive coating on one side. The foam is placed in the wound, and a plastic drape, which acts as the wound cover, is placed over the foam and is attached to the skin surrounding the wound and foam to form an air tight seal around the wound and foam. A hole is then cut in the plastic drape above the foam and the pad of the SensaTRAC is applied over the hole. (Ex. 1011, ¶12.) (Ex. 1010, ¶114.)

SensaTRAC has an applicator, which includes a flange and an adhesive film, which is placed over the wound site and a bridge portion that couples the applicator to the source of negative pressure. The flange of the applicator and the bridge portion are shown below. (Ex. 1011, ¶13.) (Ex. 1010, ¶115.)

The images and black-and-white line drawings are each true and accurate representations of the applicator and bridge portion of the SensaTRAC. (Ex. 1011, ¶13.) (Ex. 1010, ¶116.)

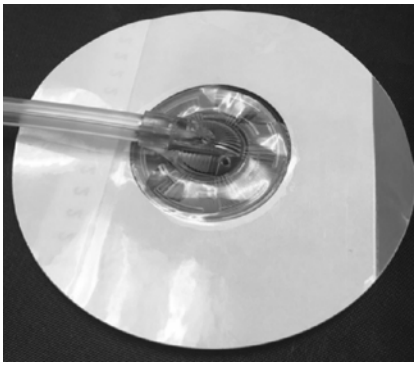


Flange (part of Applicator) and Bridge Portion

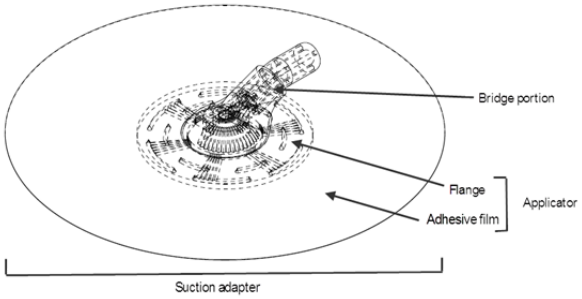


Flange (part of Applicator) and Bridge Portion

The applicator has a flange and an adhesive film. The images and black-and-white line drawings below are each true and accurate representations of the applicator, flange, and film. (Ex. 1011, ¶13.) (Ex. 1010, ¶116.)



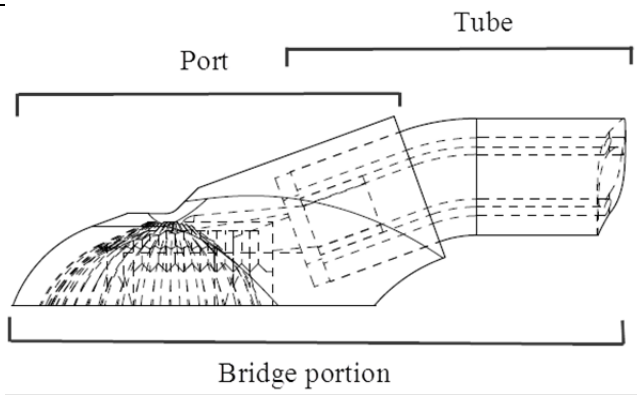
Applicator with Flange and Film

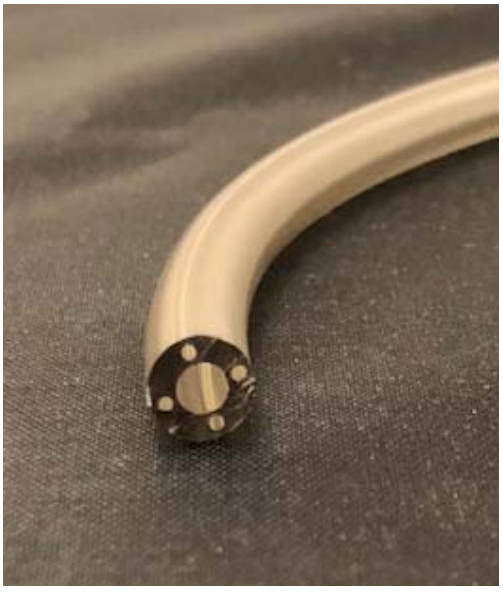


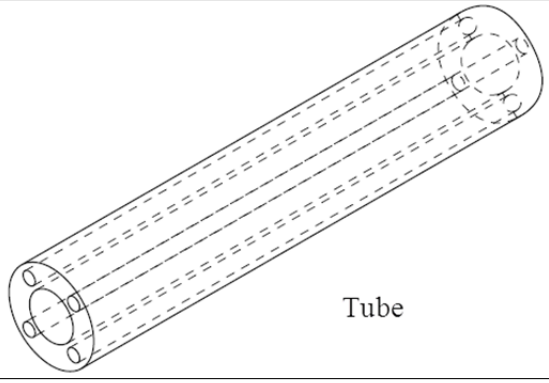
Applicator with Flange and Film

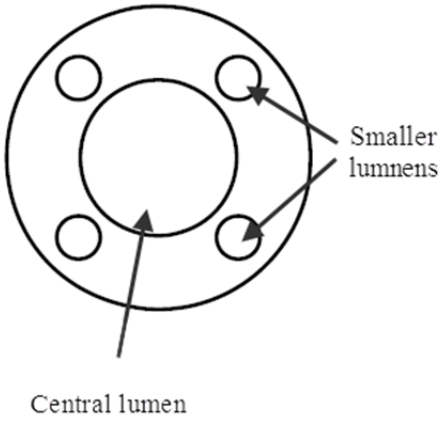
The bridge portion has a port and a tube. The tube is a multi-lumen tube with five lumens. The tube has one larger, central lumen that is connected to a negative pressure source (such as a vacuum pump), and is used as a conduit to provide suction to the wound. The four smaller lumens surround the larger central lumen and provide airflow from the pump into the opening of the applicator and the open space in the lower portion of the port. A valve is opened periodically in the pump to allow vented airflow to flow through the four smaller lumens and through air conduits in the port into the opening of the applicator and the open space in the lower portion of the port. Two smaller lumens of the tube are in fluid communication with a first air conduit of the port, and the other two smaller lumens are in fluid communication with a different second air conduit of the port.

Each air conduit, which is shown below, exits to the central opening of the applicator to provide a vented airflow from the pump into the interior of the port. The images and black-and-white line drawings are each true and accurate representations of the bridge portion and tube. (Ex. 1011, ¶14-16.) (Ex. 1010, ¶117.)









2. The SensaTRAC Negative Pressure Wound Treatment System Is Prior Art To The '750 Patent

The commercial product SensaTRAC was sold, offered for sale, and made available to the public by Kinetic Concepts, Inc. ("KCI") since June 14, 2007. KCI submitted a 510K filing (K062227) with the Food and Drug Administration ("FDA") on September 27, 2006, for V.A.C.® Therapy System, which includes a description of the T.R.A.C. technology. (Ex. 1027.) KCI has not filed any subsequent 510K filing related to T.R.A.C. technology, which indicates that the material and function of SensaTRAC has not changed since the initial 510K filing submitted on September 27, 2006. (Ex. 1011, ¶20.) There is no reason to believe that the design and function of SensaTRAC has been altered since its introduction to the market in June 14, 2007 to today. (Ex. 1011, ¶ ¶21-23.) (Ex. 1010, ¶118.)

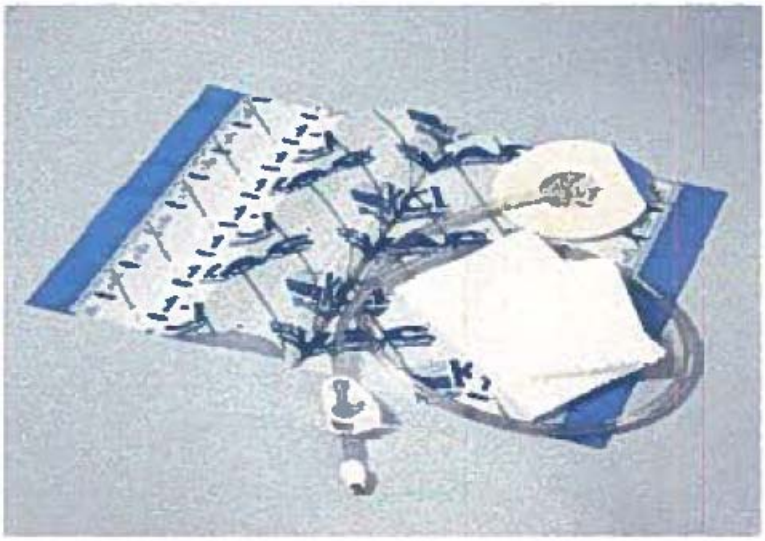
Exhibit 1019 is a KCI user's manual from December 2006, for Info V.A.C.® that includes a picture of SensaTRAC on the fourth page, as reproduced below. (Ex. 1010, ¶119.)

KCI filed an intent to use trademark application for a word mark for SENSAT.R.A.C. on April 20, 2006. (Ex. 1020.) The USPTO allowed the word mark on February 6, 2007. KCI provided a statement of use and a specimen on February 6, 2008, asserting that the first use in commerce took place on June 14, 2007. (Ex. 1020, p. 64-72) For the specimen, KCI provided a screenshot from their website showing KCI's website advertising the services of SensaTRAC, which included a picture of the SensaTRAC device, which is reproduced below. (Ex. 1010, ¶120.)

(Ex. 1020, p. 69-71.) (Ex. 1010, ¶120.)

As required, the statement of use included a declaration under 18 U.S.C. Section 1001 that the statements made on information and belief are believed to be true. (Ex. 1020, p. 67-68.) (Ex. 1010, ¶121.)

Exhibit 1021 is a presentation from KCI that on the third page states that SensaTRAC was introduced in 2007. The presentation includes a picture of the SensaTRAC device on the fifth page, as reproduced below. (Ex. 1010, ¶122.)



The website: https://www.itnonline.com/content/kci-launches-next-generation-wound-care-therapy-systems, dated August 30, 2007, is an article titled "KCI Launches Next Generation Wound Care Therapy Systems." The article recites that "The new InfoVAC includes: . . . SensaTRAC technology for

monitoring and maintaining target pressure at wound site; smaller and lighter than its predecessor." (Ex. 1024.) (Ex. 1010, ¶123.)

Exhibit 1025 is a KCI product catalog from 2009 that lists V.A.C. Dressings featuring SensaTRAC technology, as shown below. The product catalog also includes a picture of a SensaTRAC device on the second page, as reproduced below. (Ex. 1010, ¶124.)

Description	Part Number	Case Quantity
V.A.C. ATS® Therapy System	M82599968	N/A
V.A.C. Freedom® Therapy System	320000	N/A
V.A.C.® Dressings featuring T.R.A.C.™ Technology		

Description	Part Number	Case Quantity
Ease-of-Use (featuring SensaT.R.A.C.™ Technology)		
V.A.C.® Simplace™ Small Dressing	M8275041/10	10
V.A.C.® Simplace™ Small Dressing	M8275041/5	5
V.A.C.® Simplace™ Medium Dressing	M8275040/10	10
V.A.C.® Simplace™ Medium Dressing	M8275040/5	5
V.A.C.® GranuFoam™ Bridge Dressing	M8275042/10	10
V.A.C.® GranuFoam™ Bridge Dressing	M8275042/5	5
V.A.C.® GranuFoam™ Bridge XG Dressing	M8275044/5	5

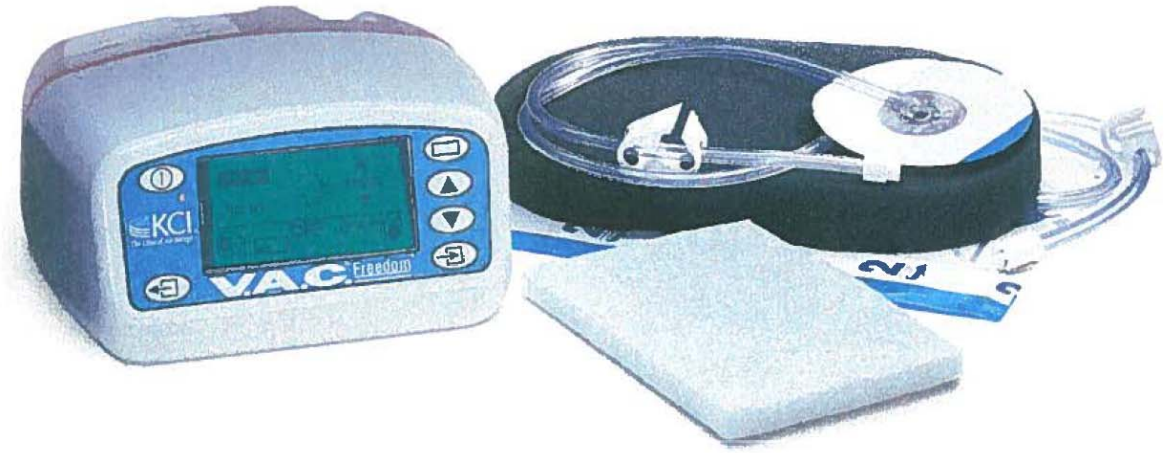
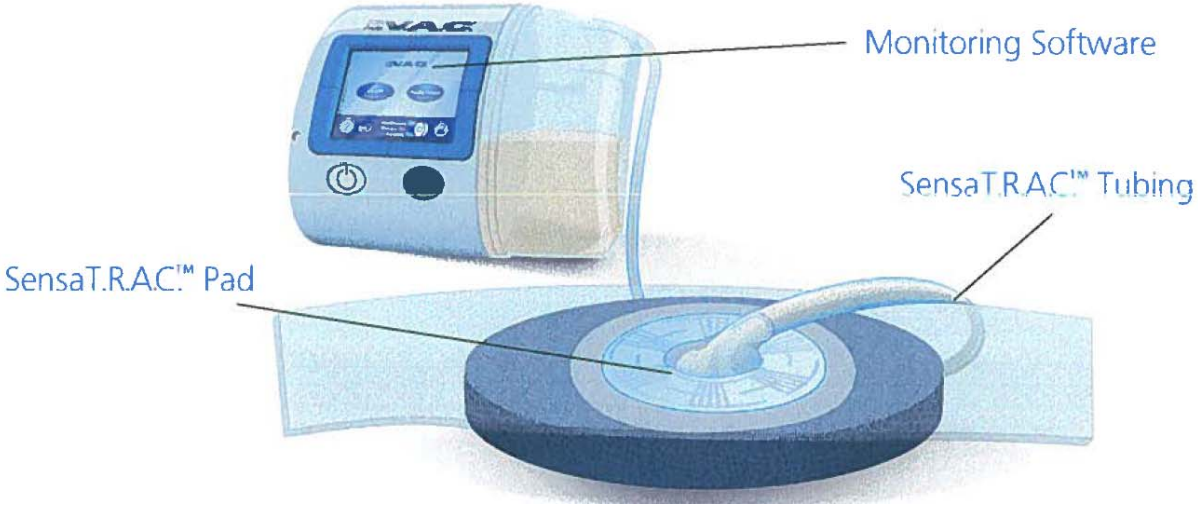
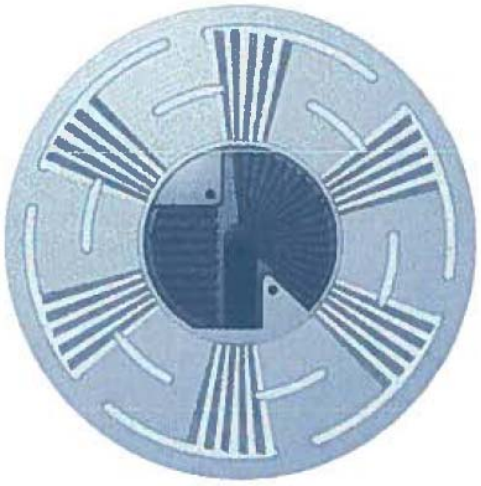
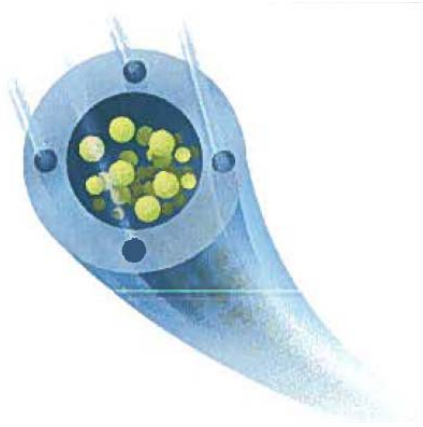


Exhibit 1026 is a KCI user's manual from March 5, 2010, for SensaTRAC Technology that includes a picture of the SensaTRAC device, the underside of the SensaTRAC device, and the tube of the SensaTRAC device, as reproduced below. (Ex. 1010, ¶125.)







As discussed above, the effective filing date for purposes of PGR eligibility determination of claims 1-17 of the '750 patent is deemed to be February 8, 2016. Even if the Board decides that claims 1-17 do not lack written description support, the earliest possible priority date (without admitting the '750 Patent is entitled to such priority) for claims 1-17 is May 7, 2010. That is the filing date for U.S. Provisional Application No. 61/332,440, which was the first presentation of figures corresponding to Figures 15A-D in the '750 patent.[2] SensaTRAC is thus prior art to the '750 patent under 35 U.S.C. 102(a)(1). Further, because it was a working device, it naturally would have enabled a person of skill in the art to make and use the SensaTRAC. (Ex. 1010, ¶126.)

[2] The '750 patent also claims priority to U.S. Provisional Application No. 61/289,358, filed on December 22, 2009, but there is no disclosure in this application that can support claims 1-17 in the '750 patent. Specifically, there are no figures or description in the specification that corresponds to Figures 15A-D in the '750 patent.

3. Claim 1

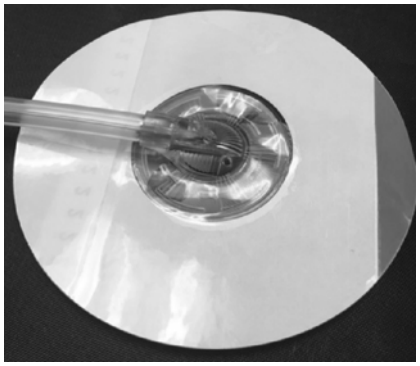
Claim 1 recites elements 1.1-1.6 below, and each element is specifically disclosed by SensaTRAC. (Ex. 1010, ¶127.)

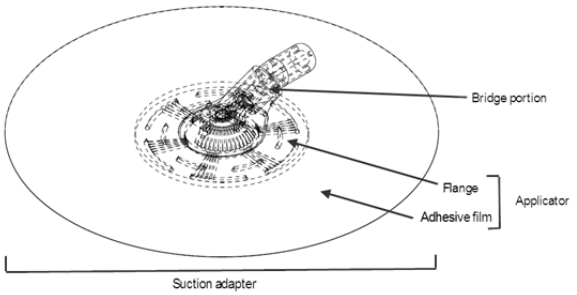
1 (Preamble) "An apparatus to provide suction to a wound site comprising:"

SensaTRAC teaches this limitation. SensaTRAC is an apparatus that, during use, provides suction and negative pressure to a wound site. (Ex. 1010, ¶¶128-129.)

1.1 "a suction adapter configured to be sealed to a wound cover covering a wound site, the suction adapter comprising:"

SensaTRAC teaches this limitation. SensaTRAC includes a suction adapter that, when used, is sealed to a plastic drape (wound cover) that covers a wound site. As shown below, the adapter includes an adhesive film that is applied on the upper surface of the flange, and is a part of the applicator, and attaches to the plastic drape (wound cover). The suction adapter includes an applicator and a bridge portion. The applicator is configured to seal the suction adapter to the plastic drape (wound cover). (Ex. 1010, ¶130.)



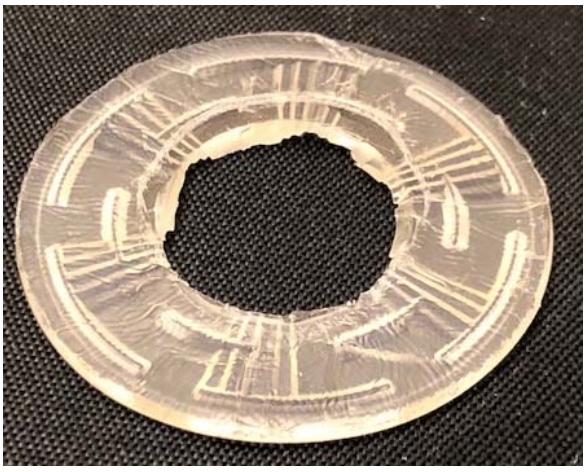


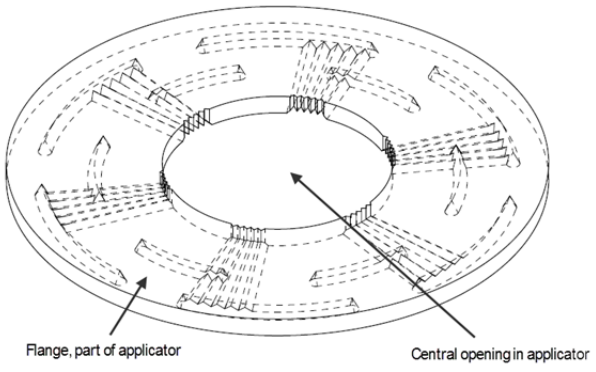
A skilled artisan would understand SensaTRAC's suction adapter and plastic drape to teach "a suction adapter configured to be sealed to a wound cover covering a wound site." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶131.)

1.2 "an applicator configured to be positioned over an opening in the wound cover, the applicator comprising at least one aperture; and"

SensaTRAC teaches this limitation. The term "applicator" is not explicitly defined in the '750 patent. It refers to a component that is configured to attach to the bridge portion, and configured to be placed over a wound site. (Ex. 1001, 24:36-38 and FIG. 15D.) (Ex. 1010, ¶132.)

As shown below, the bottom layer of SensaTRAC is an applicator having an opening (aperture) in the center of the flange. The applicator forms a circular perimeter around the central opening. The applicator is configured to be positioned over the hole that is cut in the plastic drape (wound cover). (Ex. 1010, ¶133.)

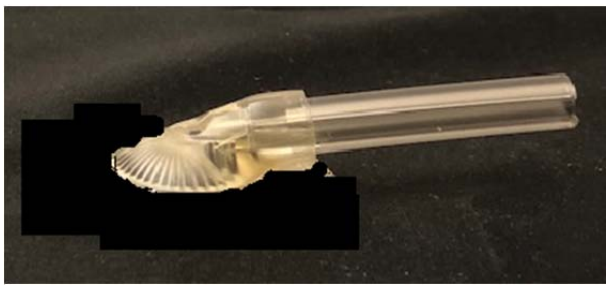


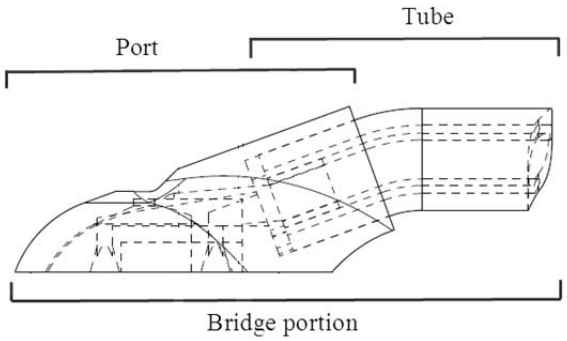


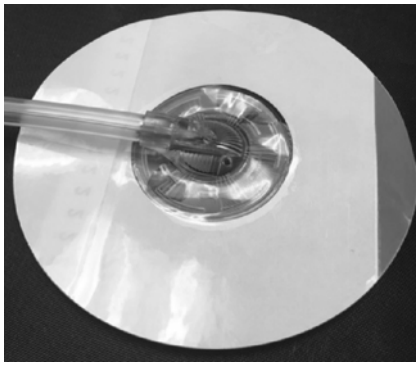
A skilled artisan would understand SensaTRAC's applicator to teach "an applicator configured to be positioned over an opening in the wound cover, the applicator comprising at least one aperture." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶134.)

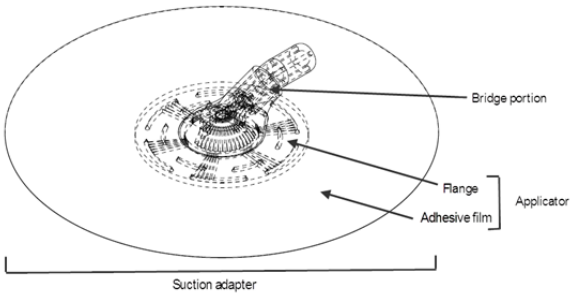
1.3 "a bridge portion connected to the applicator and comprising"

SensaTRAC teaches this limitation. The term "bridge portion" is not explicitly defined in the '750 patent. It refers to the component that is configured to attach to the applicator at one end and the vacuum pump at the other end and also having the recited claimed components. SensaTRAC includes such a bridge portion, as shown below. The bridge portion includes a port and a tube. The bridge portion is connected to the applicator as shown below. (Ex. 1010, ¶135.)





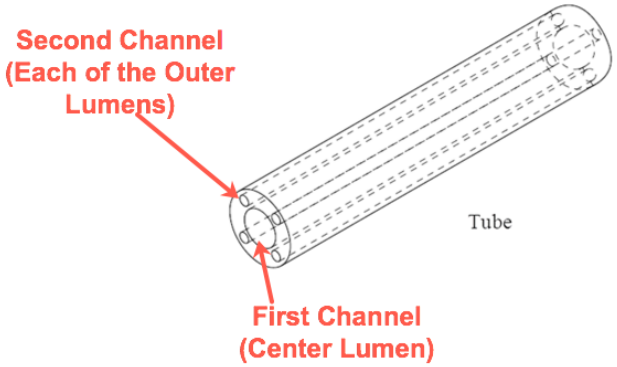




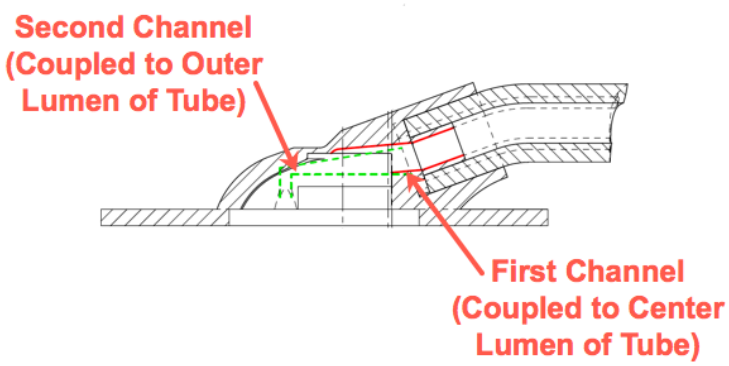
A skilled artisan would understand SensaTRAC's port and tube to teach "a bridge portion connected to the applicator." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶136.)

1.3.1 "at least a first channel and a second channel extending parallel to an upper surface of the applicator,"

SensaTRAC teaches this limitation in multiple ways. SensaTRAC has two sets of channels in the bridge portion that work together to couple the wound site to the source of negative pressure. The tube (discussed below in section A) has the first set, as shown in this figure. (Ex. 1010, ¶137.)



The port (discussed below in section B) has the second set of channels. As shown in the cross sections of the port below, channels run through the port to connect the lumens of the tube to the wound site. As shown here, the channel outlined in red is connected to the center lumen of the tube, and delivers negative pressure to the wound site. (Ex. 1010, ¶138.)



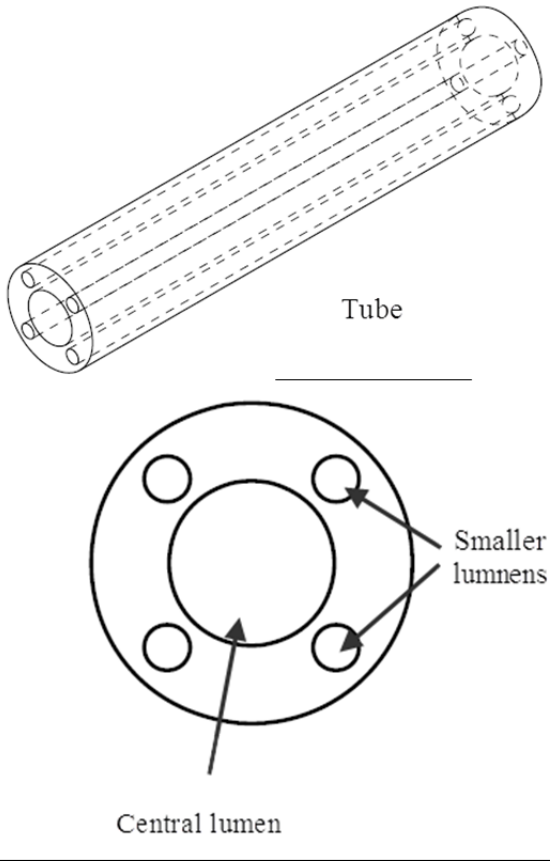
The channel shown in a hashed green line is coupled to the outer lumen of the tube, and provides an air vent to the wound site. (Ex. 1010, ¶139.)

In both the tube and the port, the channels extend parallel to an upper surface of the applicator, and thus teach this limitation. (Ex. 1010, ¶140.)

A. The Lumens (First and Second Channels) In The Tube Extend Parallel To The Upper Surface Of The Flange (Applicator)

The tube of the bridge portion of SensaTRAC has five lumens: a large, central lumen, and four smaller lumens in close proximity to and surrounding the central lumen, as shown below. Here, the central lumen corresponds to the first

channel and one of the four smaller lumens corresponds to the second channel. (Ex. 1010, ¶141.)

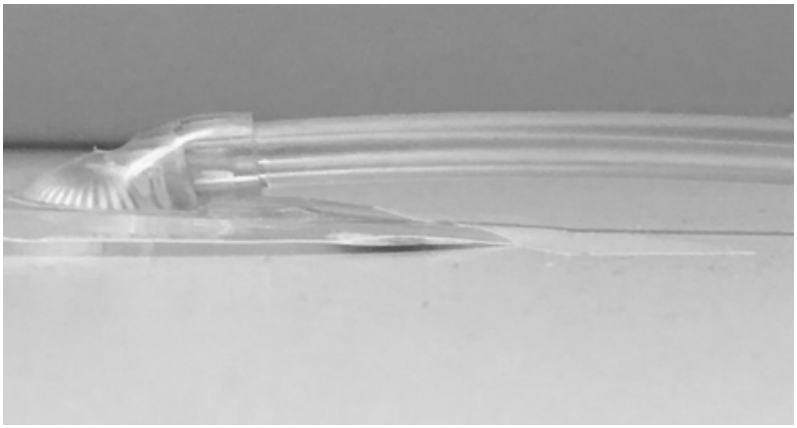


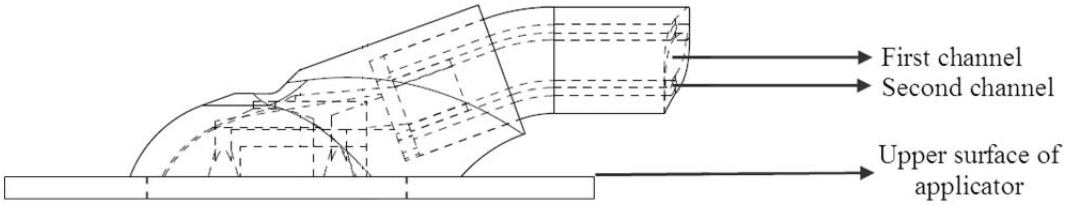
As described above, the central lumen of the tube is connected to a fitting in the port that allows suction from the wound, through the foam, though the opening in the applicator, through the port, through the tube via the central lumen, and to the pump. (Ex. 1010, ¶142.)

A skilled artisan would understand SensaTRAC's central lumen to teach the claimed first channel. A skilled artisan would also understand

SensaTRAC's outer lumens to teach the claimed second channel. (Ex. 1010, ¶143.)

A skilled artisan would also understand that at least under certain circumstances, the SensaTRAC's lumens would be parallel to the upper surface of the applicator. The tube is made of a flexible plastic material. The tube fitting in the port is on a slight upward angle that is substantially parallel to the upper surface of the applicator, as shown below. The tube exits the port on the slight upward angle that is substantially parallel to the upper surface of the applicator. Gravity makes the tube, which is made of a flexible plastic material, curve downwardly after it exits the port, resulting in the central lumen (first channel) and the smaller lumen (second channel) within the tube extending parallel to the supper surface of the applicator, as shown below. (Ex. 1010, ¶144.)





Thus, a skilled artisan would understand that SensaTRAC teaches first and second channels that are substantially parallel to the upper surface of the applicator. To the extent the channels are not completely parallel, the precise direction the channels run with respect to the applicator is a simple design choice that would be well within the understanding and skill of a person of ordinary skill in the art. Given the orientation of the applicator (along the skin and over the wound), the channels must at some point lead away from the wound site. Patients using NPWT are typically lying down, and the source of suction is on a table or cart at their bedside. Given that positioning, a skilled artisan would configure the

channels to run substantially parallel to the applicator, thus running substantially parallel to the patient's skin, and away from the wound site in the most direct possible way. As such, to the extent this aspect of SensaTRAC does not expressly disclose the channels as being parallel, it would have been obvious to a skilled artisan to modify the SensaTRAC channels in the tube to run parallel to the surface of the applicator such that "a first channel and a second channel extending parallel to an upper surface of the applicator." (Ex. 1010, ¶145.)

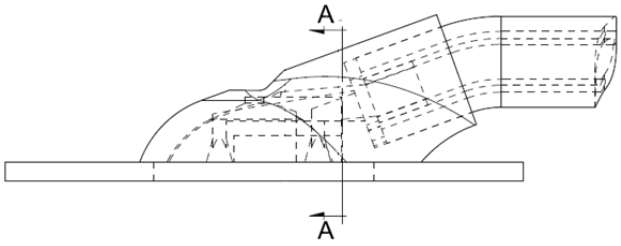
A skilled artisan would understand that the extensions of lumens in the tube and the flange in SensaTRAC teaches "a first channel and a second channel extending parallel to an upper surface of the applicator." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶146.)

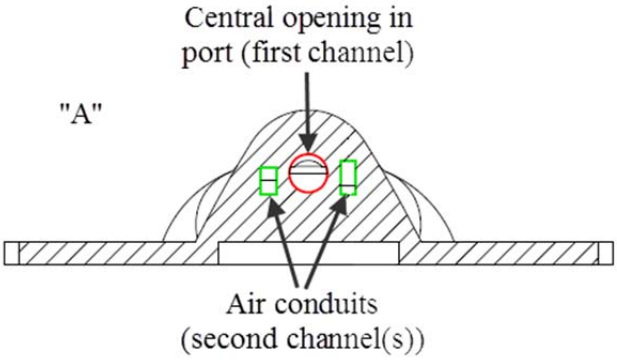
B. The Central Opening Of The Port (First Channel) And The Air Conduits (Second Channel(s)) Extend Parallel To The Upper Surface Of The Flange (Applicator)

The limitation "at least a first channel and a second channel extending parallel to an upper surface of the applicator" is also met by the arrangement of the central opening in the port (first channel) and either of the air conduits (second channel(s)) in the port, as shown below. (Ex. 1010, ¶147.)

The figure below on the right labeled "A" is a cross section of the figure below to the left along cut line A-A. The arrows along cut line A-A indicate the

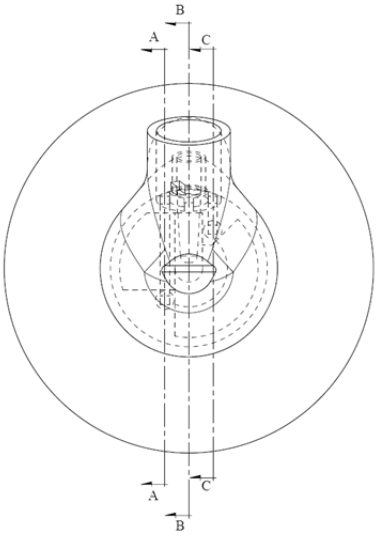
viewing direction of figure "A." The figures presented herein follow this conventional format. (Ex. 1010, ¶148.)

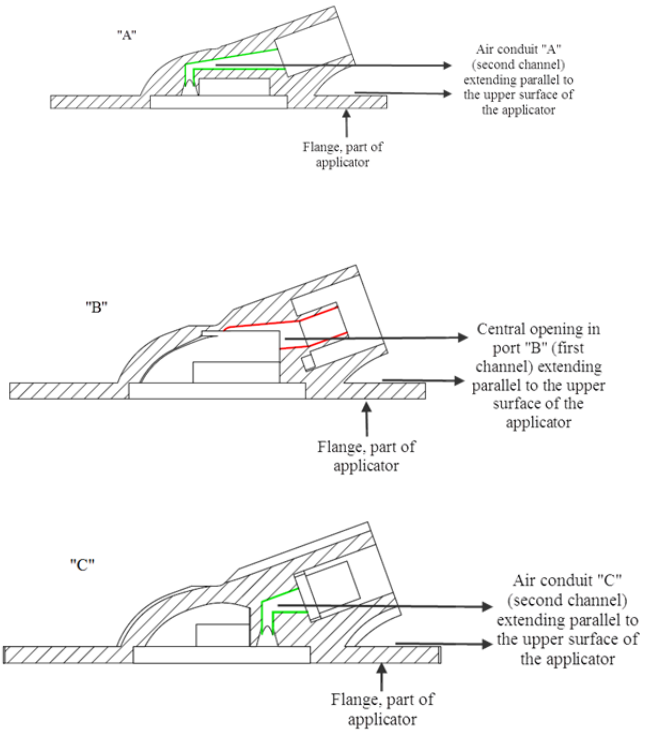




Red lines/circles in the drawings highlight the central opening in the port (first channel) and green lines in the drawings highlight the air conduits (second channel(s)), as shown above. (Ex. 1010, ¶149.)

As shown in the cross-sections below, the central opening in the port (first channel) and both of the air conduits (second channel(s)) extend parallel to an upper surface of the flange, which is a part of the applicator. (Ex. 1010, ¶150.)





A skilled artisan would understand that the central opening of the port, the air conduits, and the flange in SensaTRAC teaches "a first channel and a second channel extending parallel to an upper surface of the applicator." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶151.)

1.3.2 "wherein at least one of the first channel and second channel is configured to provide suction to the wound site through the aperture in the applicator from a source of negative pressure;"

SensaTRAC teaches this limitation. Both the central lumen of the tube and the central opening of the port that is connected to the central lumen of the tube are considered to be a part of the first channel. The central lumen of the tube (first

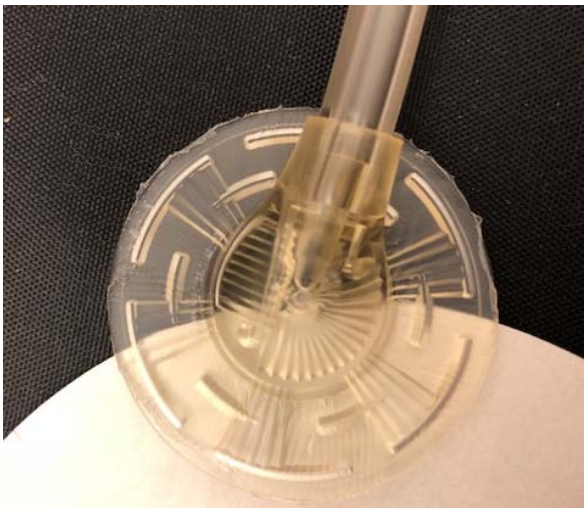
channel) of SensaTRAC is connected to a pump that provides the suction to the wound site. The suction and negative pressure is achieved when air is sucked from the wound site, through the opening in the applicator, through the interior of the port, through the central opening of the port, through the central lumen of the tube, and towards the pump. (Ex. 1010, ¶152.)

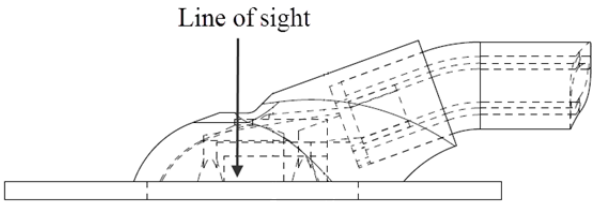
A skilled artisan would understand SensaTRAC's central lumen to teach a channel that provides suction to the wound site through the aperture in the applicator from a source of negative pressure. Accordingly, a skilled artisan would understand SensaTRAC to teach "at least one of the first channel and second channel is configured to provide suction to the wound site through the aperture in the applicator from a source of negative pressure." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶153.)

1.4 "a visualization window provided in an upper surface of the bridge portion over the at least one aperture in the applicator that provides unobstructed visualization from outside of the suction adapter, through the visualization window and through the aperture in the applicator;"

The term "unobstructed" is indefinite as discussed below. If the Board does not deem this term to be indefinite, then SensaTRAC teaches this limitation. The port of the bridge portion of SensaTRAC is made of a transparent material. The port of the bridge portion includes a transparent hollow dome structure where a part of the inner surface is a ruffled inner surface with protrusions. There is nothing between the inner surface of the dome and the opening of the applicator to block

the view. Thus, the view from the outside of the suction adapter through the dome and the opening in the applicator is unobstructed. A person can look through the dome from the outside through the opening of the applicator, as shown below. (Ex. 1010, ¶154.)



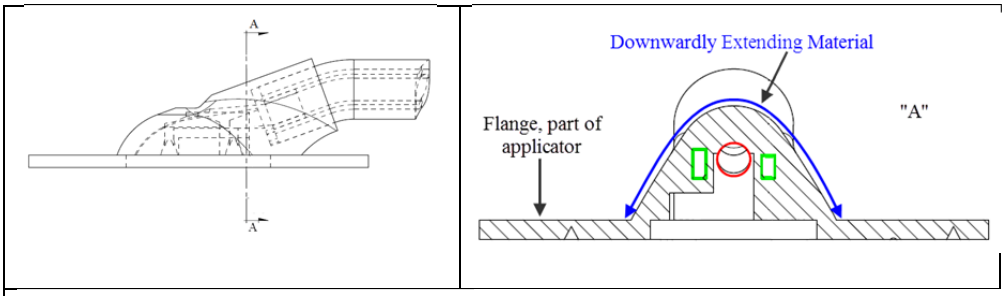


A skilled artisan would understand the transparent upper portion of SensaTRAC's suction adapter to teach "a visualization window provided in an upper surface of the bridge portion over the at least one aperture in the applicator that provides unobstructed visualization from outside of the suction adapter, through the visualization window and through the aperture in the applicator." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶155.)

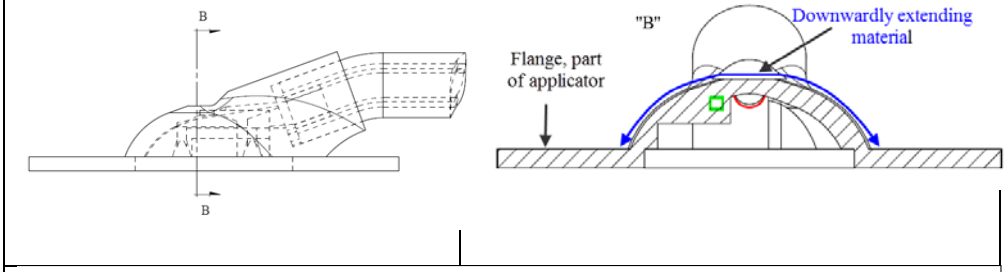
1.5 "wherein the bridge portion comprises material extending downwardly from the upper surface of the bridge portion to thereby connect the bridge portion to the applicator; and"

There are multiple ways SensaTRAC teaches this limitation. As shown below, there are multiple parts of the bridge portion of the SensaTRAC that extend downward from the upper surface of the bridge portion to the applicator. The figures on the right are the respective cross-sections of the figures on the left. (Ex. 1010, ¶156.)

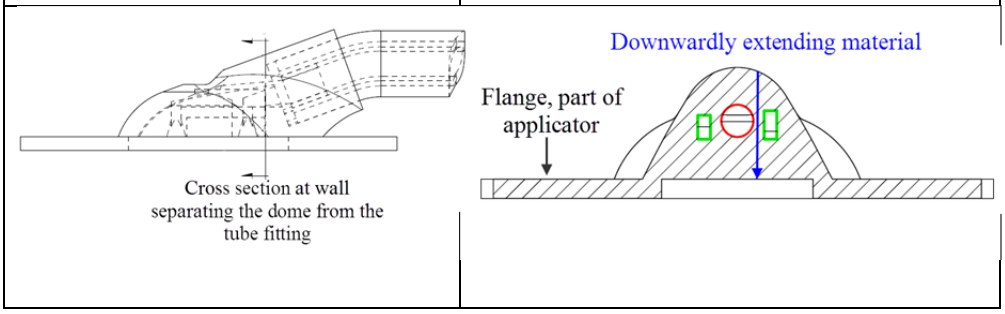
The outer portion of the bridge is "downwardly extending material" at "A"



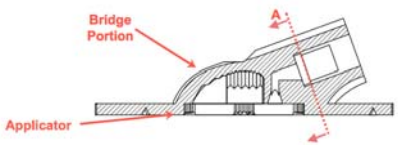
The outer portion of the bridge is "downwardly extending material" at "B"

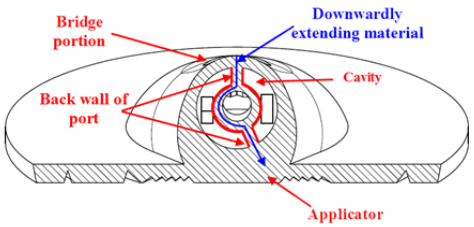


The wall that separates the dome from the tube fitting is "downwardly extending material"



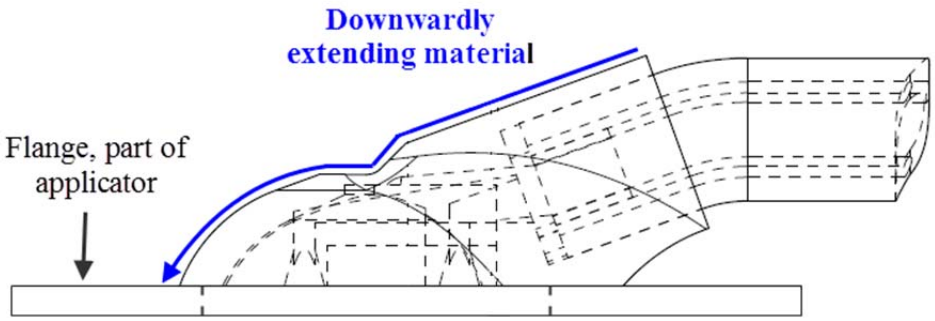
The wall at the back of the port is "downwardly extending material"

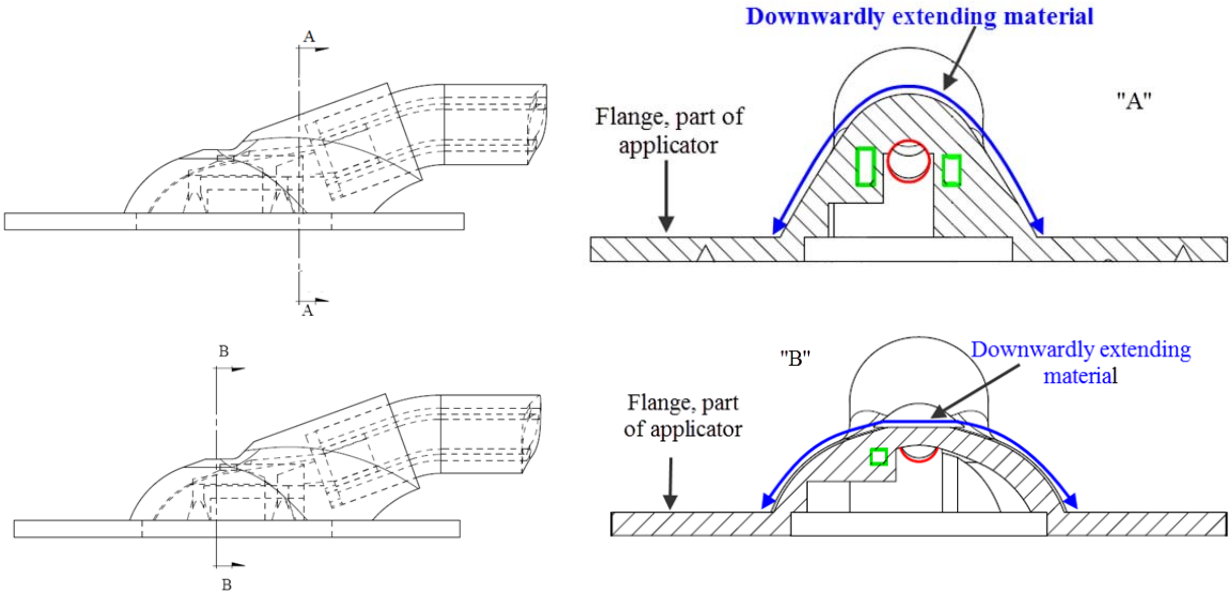




A. The Outside Of The Bridge Portion Is The Downwardly Extending Material

The port of the SensaTRAC is connected to the flange of the applicator such that the port encloses the central opening of the flange, as shown in the various views below. Material extends downwardly in all directions from the top surface of the port to connect to the flange of the applicator, such that the port encloses the central opening of the flange. (Ex. 1010, ¶157.)

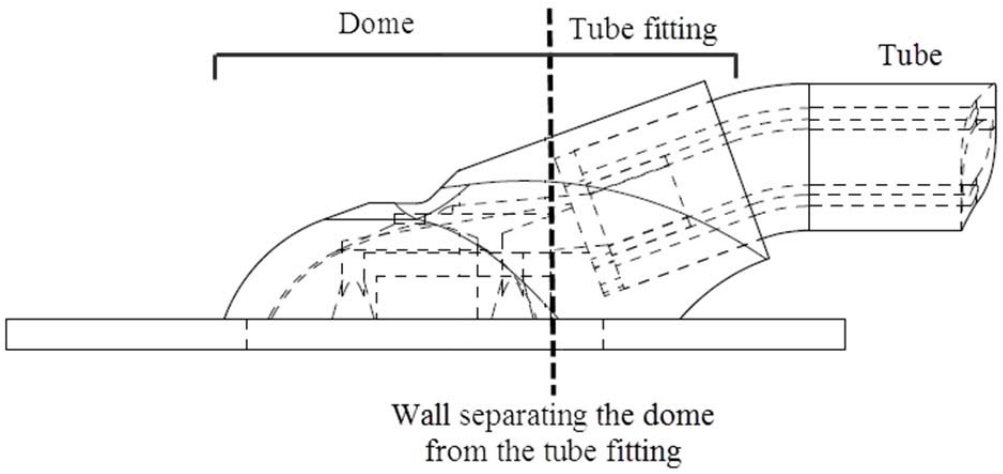


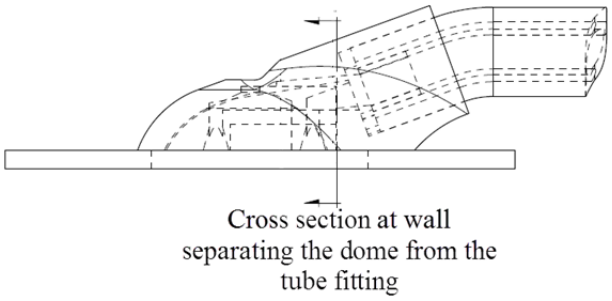


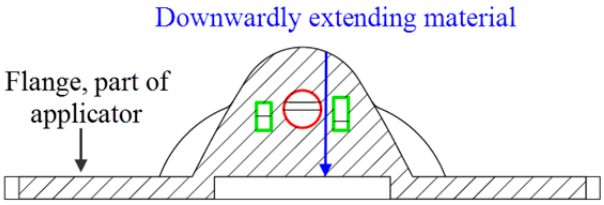
A skilled artisan would understand the upper surface of the port that connects to the flange of the SensaTRAC teaches "wherein the bridge portion comprises material extending downwardly from the upper surface of the bridge portion to thereby connect the bridge portion to the applicator." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶158.)

B. The Wall Separating The Dome From The Tube Fitting In The Port Is The Downwardly Extending Material

The port of the SensaTRAC has a dome and tube fitting. The wall that separates the dome from the tube fitting extends from the top surface to the port and connects to the flange, as shown in the various views below. (Ex. 1010, ¶159.)



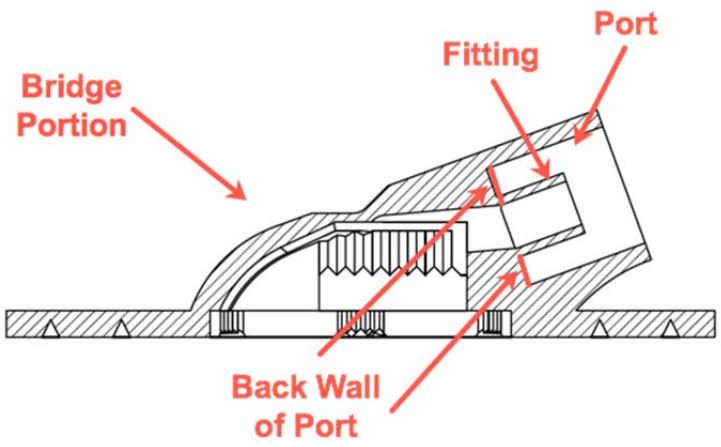




A skilled artisan would understand the wall that separates the dome from the tube fitting of the SensaTRAC teaches "wherein the bridge portion comprises material extending downwardly from the upper surface of the bridge portion to thereby connect the bridge portion to the applicator." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶160.)

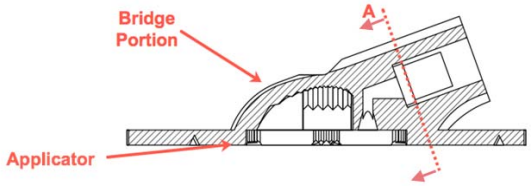
C. The Wall At The Rear Of The Port Is The Downwardly Extending Material

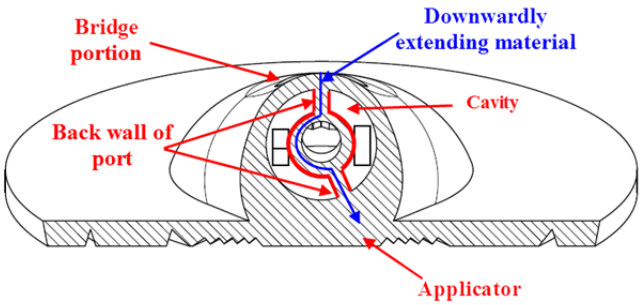
As discussed above, the SensaTRAC has a port where the tube mates with the applicator and bridge portion. The applicator and port are illustrated below. (Ex. 1010, ¶161.)



The illustration below is a cross section of the bridge portion cut away at the base of the fitting along the back wall of the port. This cross section (taken along dotted line A) illustrates the back wall of the port. (Ex. 1010, ¶162.)

As seen below, the back wall of the port extends down from the top of the bridge portion, around the opening in the port that leads to the opening of the applicator, and down to the applicator. (Ex. 1010, ¶163.)



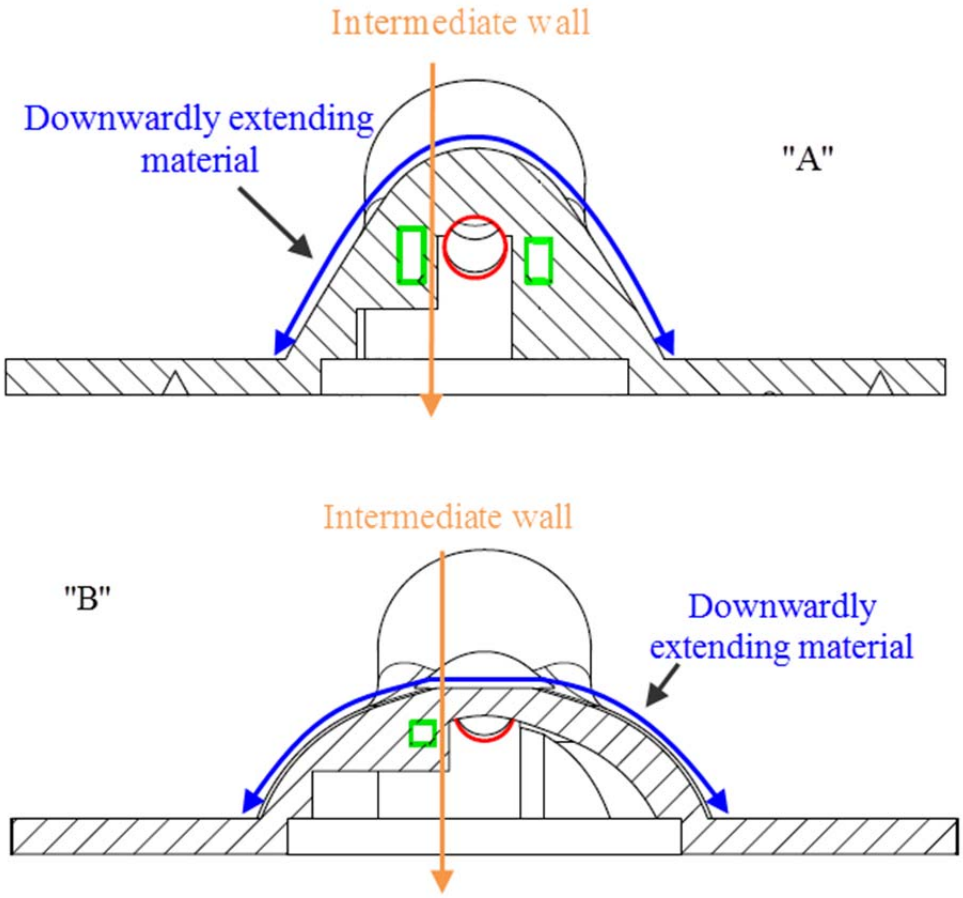


The back wall of the port also creates two cavities on either side of the wall. The cavities align with the outer lumens of the tube to provide an air path to the opening of the applicator. (Ex. 1010, ¶164.)

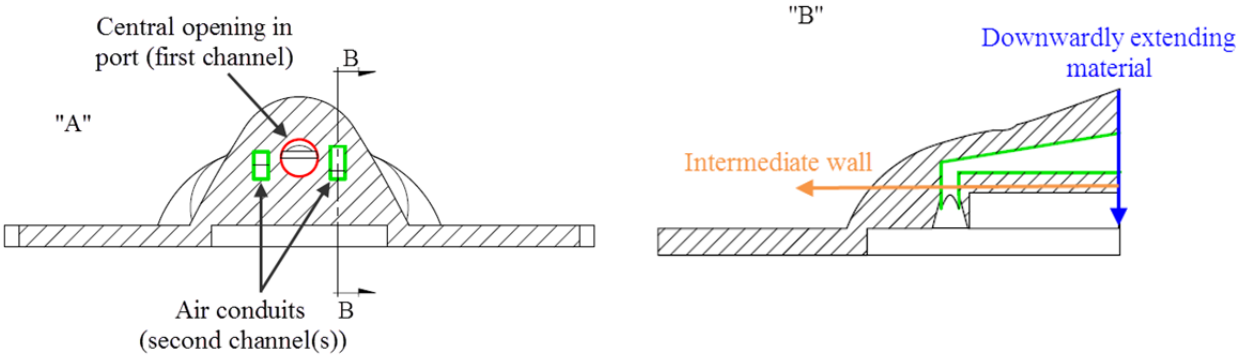
As illustrated above, the back wall of the port is "material extending downwardly from the upper surface of the bridge portion to thereby connect the bridge portion to the applicator." Consequently, a skilled artisan would understand SensaTRAC to disclose this limitation. (Ex. 1010, ¶165.)

1.6 "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel."

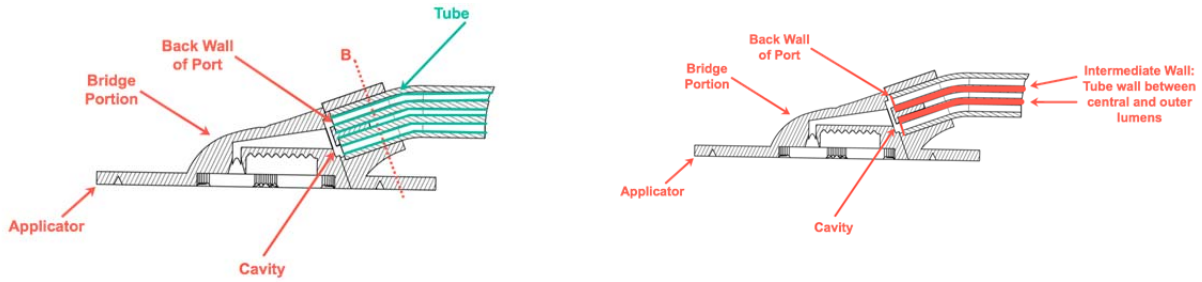
SensaTRAC also teaches this limitation in multiple ways that correspond to the multiple aspects of the SensaTRAC that satisfy the "downwardly extending material" limitation. First, where the downwardly extending material is the outer surface of the bridge portion, the "intermediate wall" is shown below. (Ex. 1010, ¶166.)



Second, where the downwardly extending material is the wall separating the dome portion from the tube fitting, the "intermediate wall" is shown below. (Ex. 1010, ¶167.)



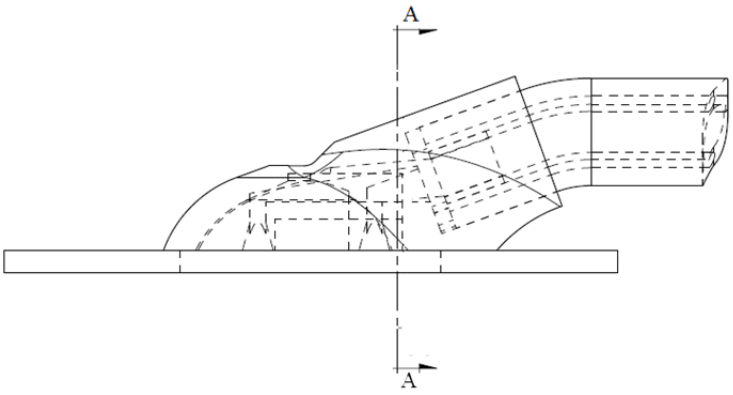
Finally, where the downwardly extending material is the wall at the rear of the port, the "intermediate wall" is shown below. (Ex. 1010, ¶168.)

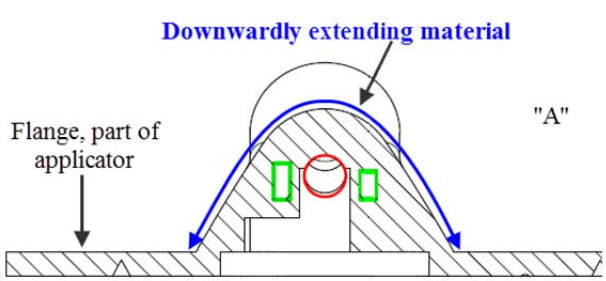


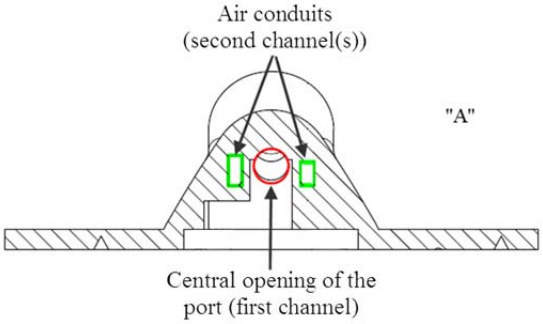
A. The Intermediate Wall Extends Perpendicularly From The Top Of The Bridge Portion (The Downwardly Extending Material) To Partition The First Channel From The Second Channel

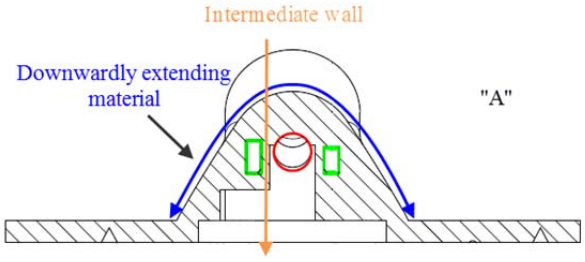
SensaTRAC teaches this limitation. Inside the dome of the port, each air conduit (second channel) is located within its own separate wall that extends from the ceiling of the dome. As shown below, each wall is an intermediate wall that partitions the central opening (first channel) of the port from the air conduits (second channel). Also as shown below, each intermediate wall extends

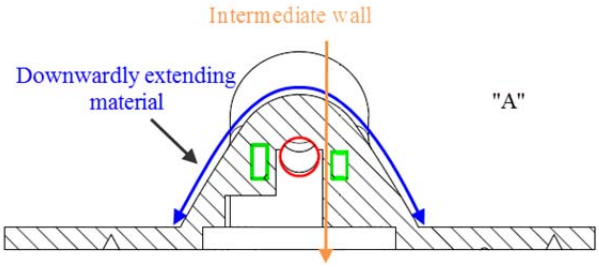
perpendicularly downwards towards the central opening of the applicator from the top of the dome, which is material that extends downwardly to connect the port to the flange of the applicator. (Ex. 1010, ¶169.)

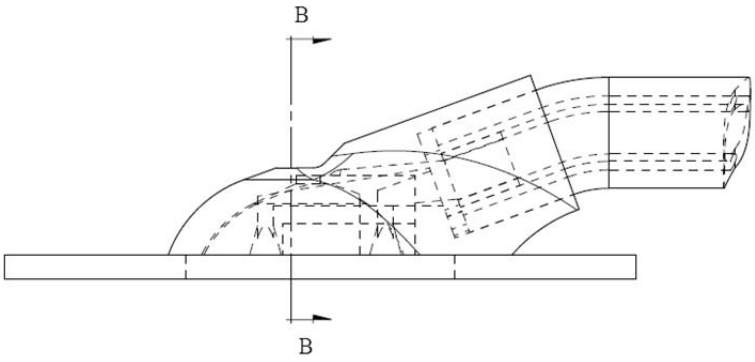


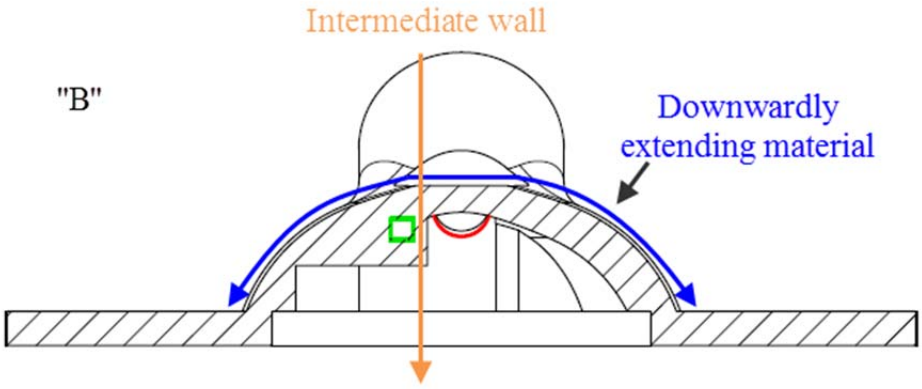












A skilled artisan would understand the port of the SensaTRAC teaches "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶¶170-171.)

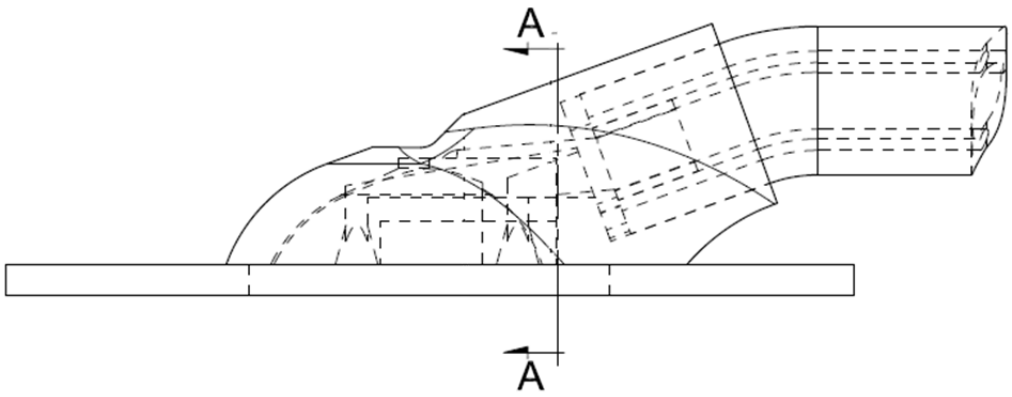
B. The Intermediate Wall Extends Perpendicularly From The Wall Separating The Dome From The Tube Fitting In The Port (The Downwardly Extending Material) To Partition The First Channel From The Second Channel

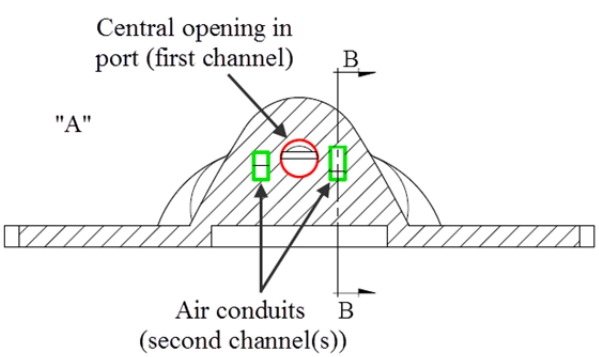
As shown below:

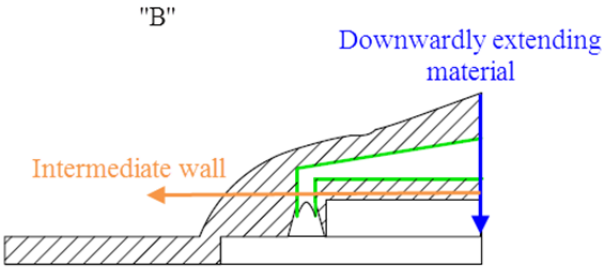
1. An air conduit exits within the dome of the port in the SensaTRAC device;
2. The air conduit is located within an intermediate wall that extends perpendicularly from the wall separating the dome from the tube fitting in the port; and
3. The intermediate wall partitions the central opening of the port (first channel) from the air conduit (second channel).

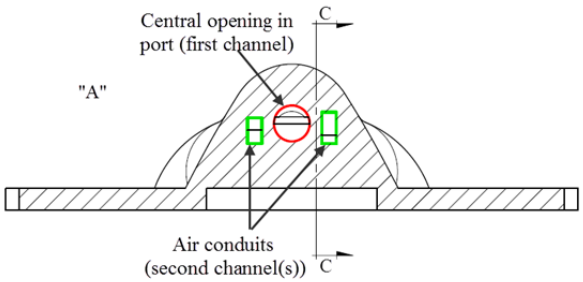
Cross-section "A" below is at the edge of the wall separating the dome from the tube fitting in the port. Cross-sections "B" and "C" are two separate cross-sections of cross-section "A" taken in two places. The first cross-section ("B") is taken across the air conduit. The second cross-section ("C") is taken between the central opening of the port and the air conduit. (Ex. 1010, ¶172.)

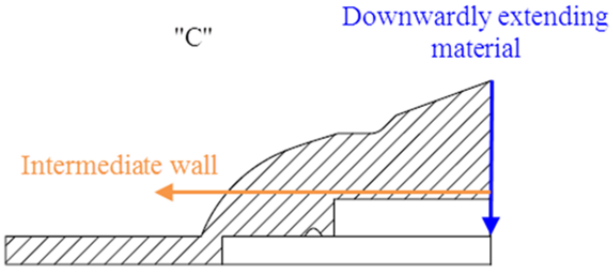
Cross-sections "B" and "C" show an intermediate wall that extends perpendicular from the wall separating the dome from the tube fitting in the port (downwardly extending material). The intermediate wall contains and partitions an air conduit (second channel) from the central opening of the port (first channel). (Ex. 1010, ¶173.)





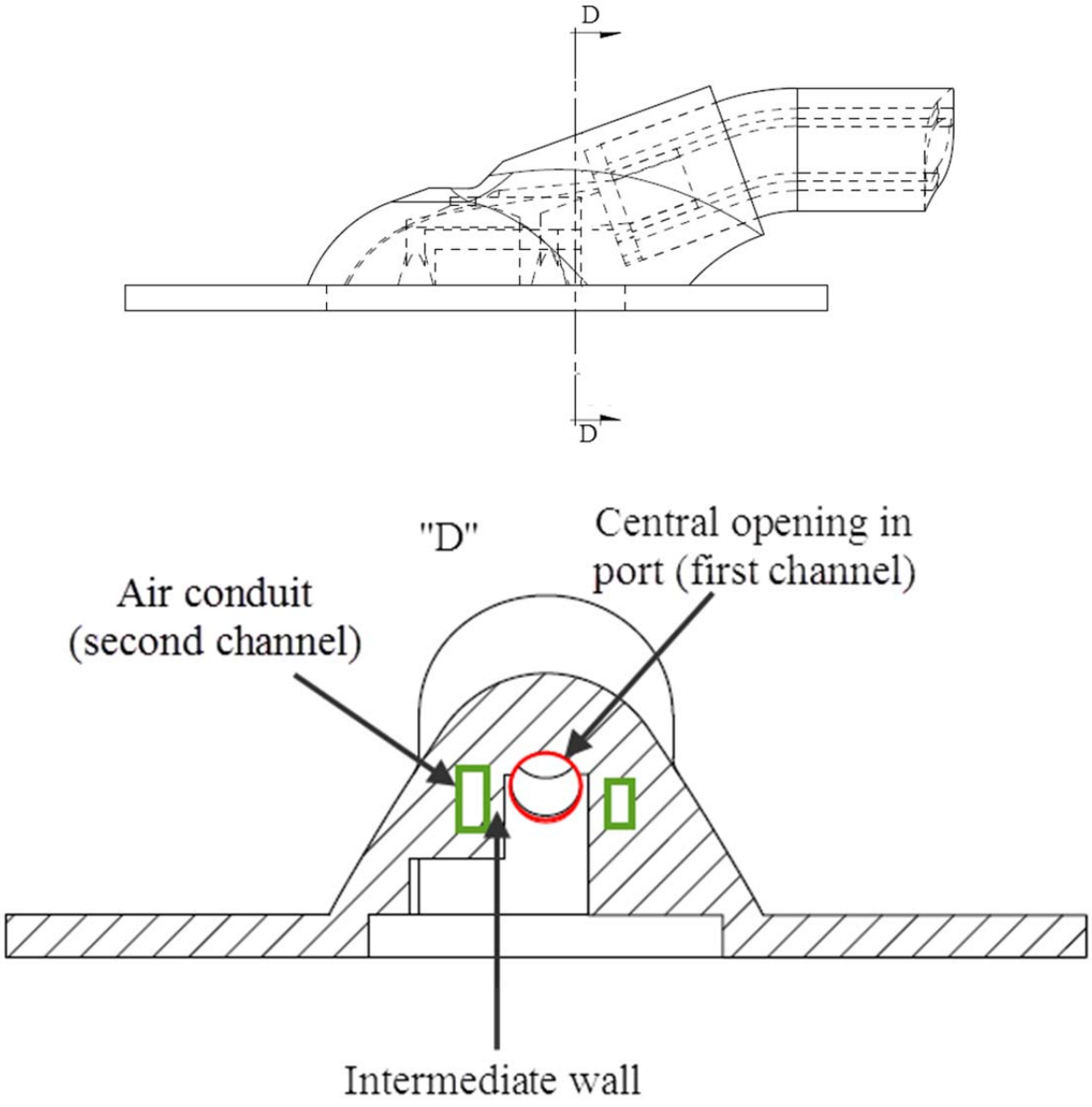






Cross-section "D" below shows a front view of the intermediate wall that contains and partitions an air conduit (second channel) from the central opening of the port (first channel), and extends perpendicular from the wall separating the

dome from the tube fitting in the port (downwardly extending material). (Ex. 1010, ¶174.)

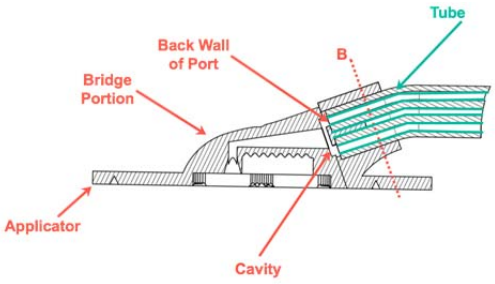


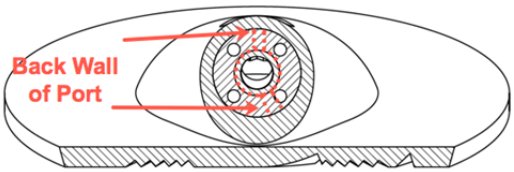
A skilled artisan would understand the port of the SensaTRAC teaches "an intermediate wall extending perpendicularly from the downwardly extending

material to partition the first channel from the second channel." Thus, SensaTRAC teaches this limitation. (Ex. 1010, ¶175.)

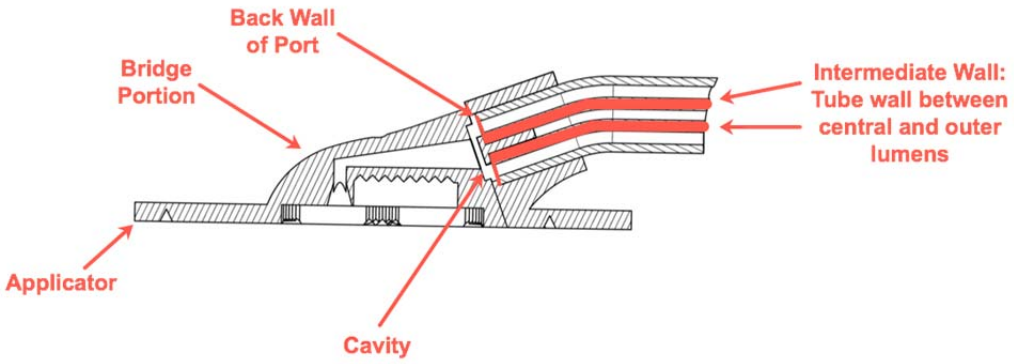
C. The Intermediate Wall Extends Perpendicularly From The Back Wall Of The Port To Separate The Central Lumen From The Outer Lumens

SensaTRAC also teaches this limitation. When the tube is inserted into the port, the fitting slides into the central lumen of the tube, and the end of the tube engages with the wall at the back of the port. A cross section of the bridge portion is shown below (taken along dotted line B with the tube in place). The dotted lines in the figure on the right illustrate the location of the back wall of the port as it engages with the tube. (Ex. 1010, ¶176.)





Once the tube is fitted in the port, the back wall of the tube engages with the material that separates the central lumen from the outer lumens as shown below. (Ex. 1010, ¶177.)



As shown above, the material that separates the outer lumens from the central lumen meets the back wall of the port at a right angle, and extends away from the back wall from the port, which is the downwardly extending material. Consequently, a skilled artisan would understand that SensaTRAC teaches "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel." (Ex. 1010, ¶178.)

Accordingly, SensaTRAC teaches all of the elements of claim 1, and therefore anticipates claim 1. (Ex. 1010, ¶179.)

4. Claim 2

Claim 2 recites the "apparatus of claim 1, wherein the visualization window comprises an at least partially transparent material." As described above, in the

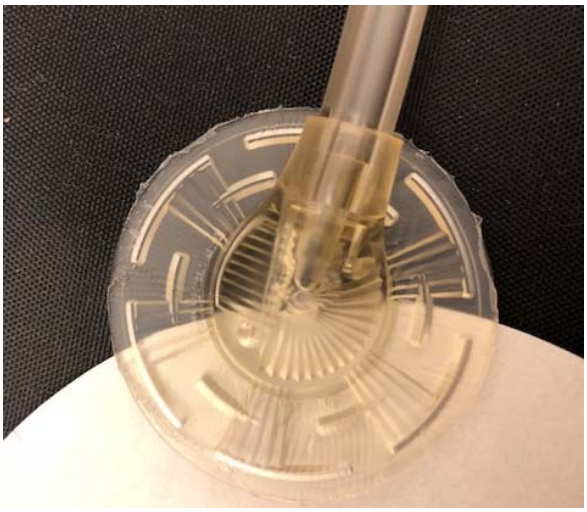
SensaTRAC, the port of the bridge portion includes a hollow dome structure, which is transparent, where a part of the inner surface is a ruffled inner surface with protrusions. (Ex. 1010, ¶180.)

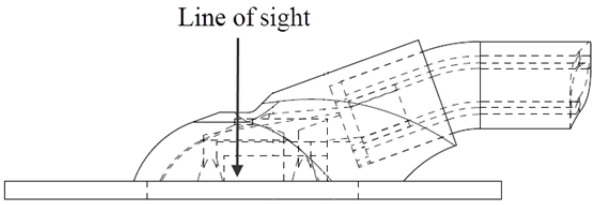
A skilled artisan would understand the transparent SensaTRAC material to teach a "visualization window [that] comprises an at least partially transparent material. (Ex. 1010, ¶181.)

Accordingly, claim 2 is anticipated by SensaTRAC. (Ex. 1010, ¶182.)

5. Claim 3

Claim 3 recites the "apparatus of claim 1, wherein the visualization window is configured to permit visualization of the wound site prior to sealing the suction adapter to the wound cover." As described above, in the SensaTRAC, the port of the bridge portion includes a hollow dome structure, which is transparent, where a part of the inner surface is a ruffled inner surface with protrusions. Thus, the view through the dome and the opening in the applicator is unobstructed. A person can look through the dome from the outside through the opening of the applicator onto the wound site prior to sealing the suction adapter to the wound cover, as shown in the figure below. (Ex. 1010, ¶183.)





Accordingly, claim 3 is anticipated by SensaTRAC. (Ex. 1010, ¶184.)

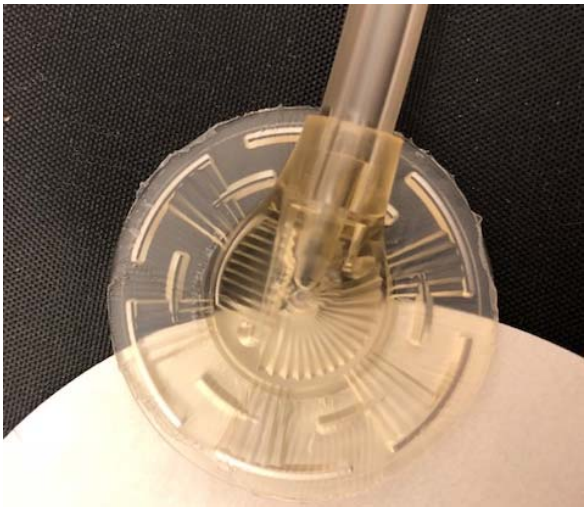
6. Claim 4

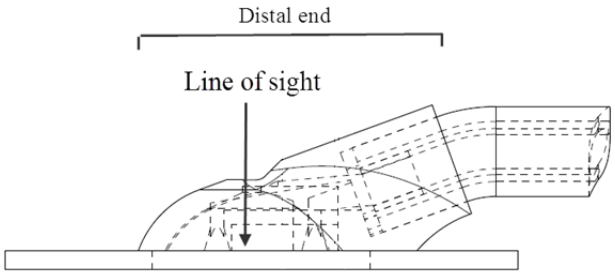
Claim 4 recites the "apparatus of claim 1, wherein the visualization window is configured to permit monitoring of the wound site while the apparatus is providing suction to the wound site." As described above, in the SensaTRAC, the port of the bridge portion includes a hollow dome structure, which is transparent, where a part of the inner surface is a ruffled surface with protrusions. Thus, the view through the dome and the opening in the applicator is unobstructed. A person can look through the dome from the outside through the opening of the applicator onto the wound site while the apparatus is providing suction to the wound site, as shown in the figure above under claim 3. (Ex. 1010, ¶185.)

Accordingly, claim 4 is anticipated by SensaTRAC. (Ex. 1010, ¶186.)

7. Claim 6

Claim 6 recites the "apparatus of claim 1, wherein the visualization window is positioned at a distal end of the bridge portion." As shown in the figure below, in SensaTRAC, the visualization window is located at the distal end of the bridge portion. The whole length of the tube in SensaTRAC is not shown in the photo or figure below The tube is about 35 inches long from the port to where it connects to the negative pressure source. (Ex. 1010, ¶187.)





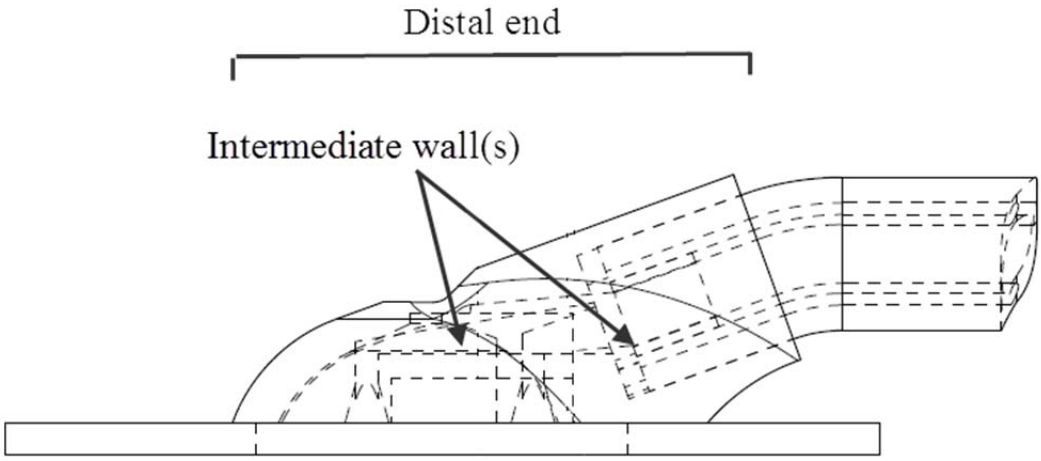
Accordingly, claim 6 is anticipated by SensaTRAC. (Ex. 1010, ¶188.)

8. Claim 7

Claim 7 recites the "apparatus of claim 1, wherein the intermediate wall is positioned at the distal end of the bridge portion." As shown in the figure below, in SensaTRAC, one intermediate wall is located at the distal end of the bridge portion. The whole length of the tube in SensaTRAC is not shown in the photo or

figure below The tube is about 35 inches long, and extends from the port and connects to the negative pressure source. (Ex. 1010, ¶189.)

Also, as shown below and described with respect to claim element 1.6, in SensaTRAC each air conduit is present in separate intermediate walls located within the dome of the port, which is at the distal end of the SensaTRAC device. (Ex. 1010, ¶190.)

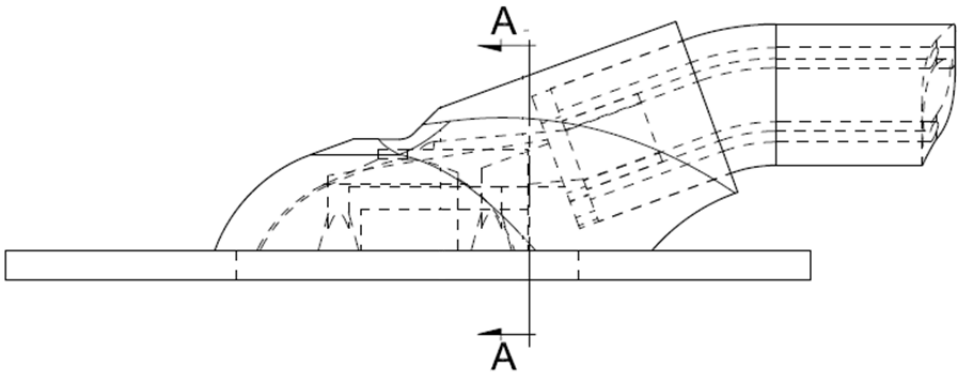


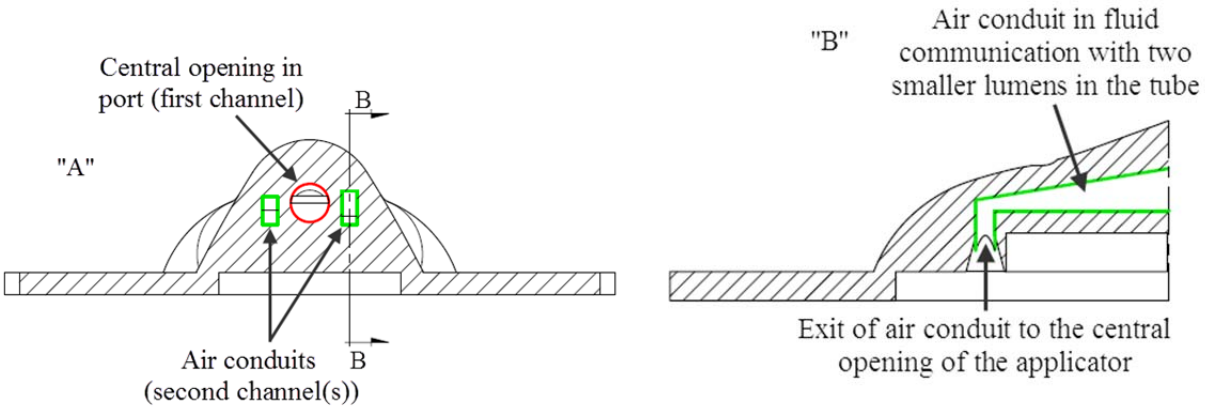
Accordingly, claim 7 is anticipated by SensaTRAC. (Ex. 1010, ¶191.)

9. Claim 8

Claim 8 recites the "apparatus of claim 1, wherein the first channel is configured to provide suction to the wound site and the second channel is configured to provide vented air to the wound site." As described above, the tube in SensaTRAC has one central lumen (first channel) that is connected to a negative pressure source, e.g. a pump, and is used as a vehicle to provide suction to the wound. The four smaller lumens (one smaller lumen being a second channel)

provide vented airflow from the pump via two air conduits in the port that exit into the opening of the applicator and the port, see the cross-section figure below. Two of the smaller lumens in the tube are in fluid communication with a one of the air conduits in the port, and the other two smaller lumens in the tube are in fluid communication with the other air conduit in the port. Accordingly, the central lumen in the tube is the first channel that is configured to provide suction to the wound site, and one of the smaller lumens is the second channel that is configured to provide vented air to the wound site. (Ex. 1010, ¶192.)

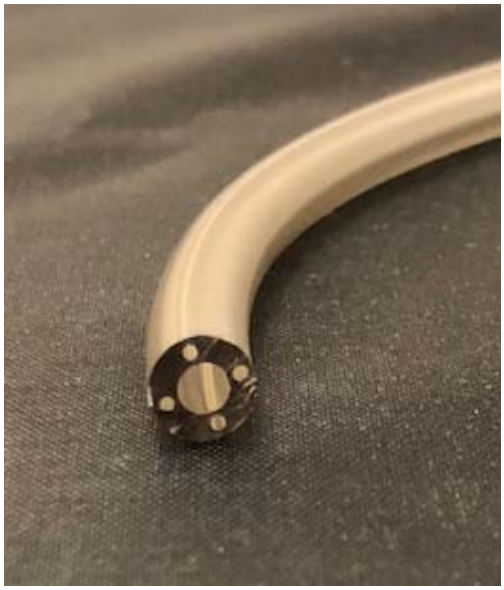


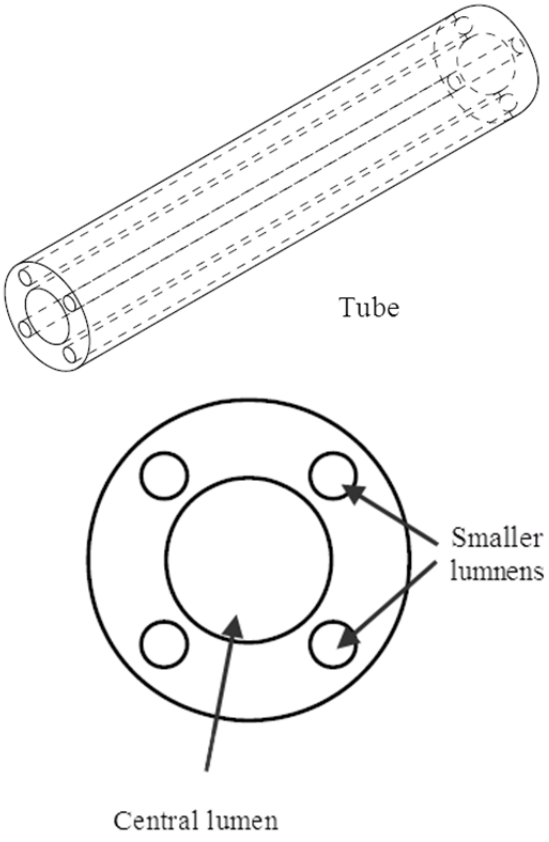


Accordingly, claim 8 is anticipated by SensaTRAC. (Ex. 1010, ¶193.)

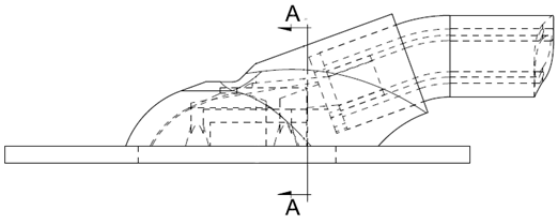
10. Claim 9

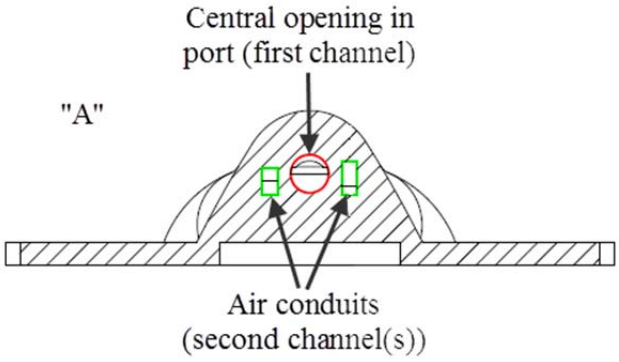
Claim 9 recites the "apparatus of claim 1, wherein the first channel and the second channel are formed as side by side conduits." "Side by side," under a dictionary definition, means, "beside one another." (Ex. 1018.). As shown in the figure below, the central lumen (first channel) and the smaller lumens (one smaller lumen being a second channel) are close and beside one another. (Ex. 1010, ¶194.)





As shown in the figure below, the central opening in the port (first channel) and the air conduits (second channel(s)) are close and beside one another. (Ex. 1010, ¶195.)



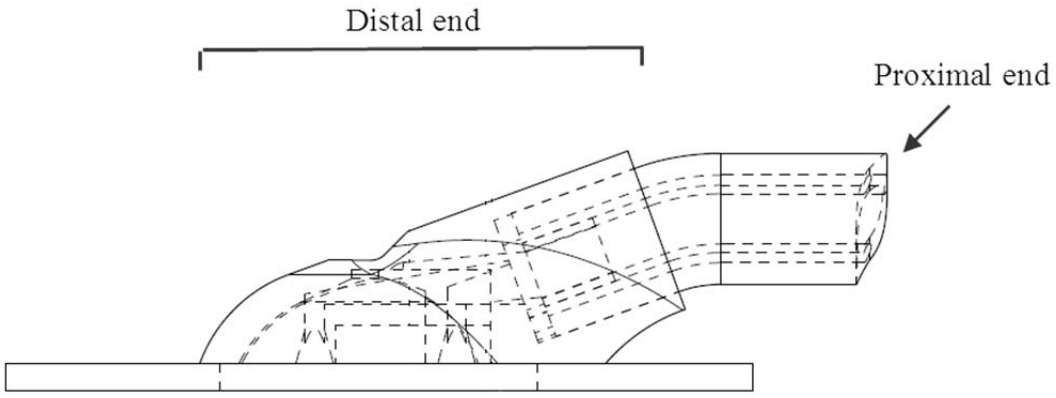


Accordingly, claim 9 is anticipated by SensaTRAC. (Ex. 1010, ¶196.)

11. Claim 10

Claim 10 recites the "apparatus of claim 1, wherein the bridge portion comprises a proximal end configured to provide fluid communication with the source of negative pressure and an enlarged distal end provided over the applicator, wherein the first and second channels extend between the proximal and distal ends." As described above, in SensaTRAC, the bridge portion includes a port and a tube. The port is enlarged relative to the tube. The port is located at the distal end of the bridge portion, see the figure below. The end of the tube, the proximal end of the bridge portion, is connected to the pump, see the figure below (not showing pump). The rest of tube, which includes the central lumen (first channel) and the smaller lumens (one smaller lumen being a second channel) extend

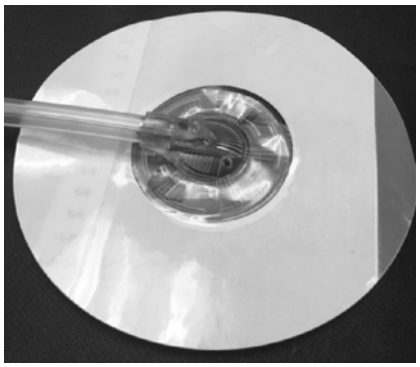
between the port (distal end) and the end of the tube (proximal end) that is connected to the pump. (Ex. 1010, ¶197.)

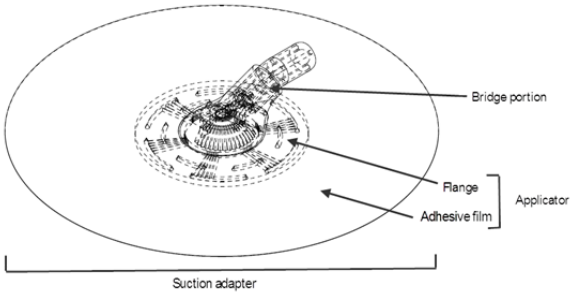


Accordingly, claim 10 is anticipated by SensaTRAC. (Ex. 1010, ¶198.)

12. Claim 11

Claim 11 recites the "apparatus of claim 10, wherein the applicator has an area that is larger than an area of the enlarged distal end of the bridge." As shown in the figure below, the applicator is larger than the port, which is the enlarged distal end of the bridge. (Ex. 1010, ¶199.)

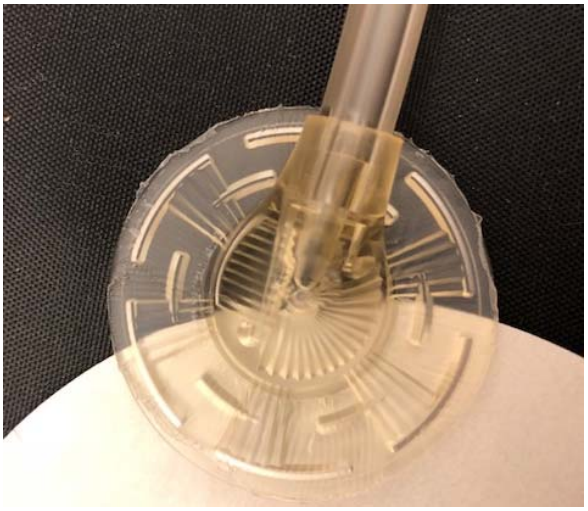


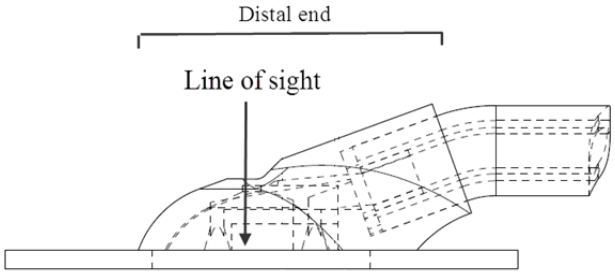


Accordingly, claim 11 is anticipated by SensaTRAC. (Ex. 1010, ¶200.)

13. Claim 12

Claim 12 recites the "apparatus of claim 10, wherein the visualization window is provided at the enlarged distal end." As discussed above, the port of the bridge portion is an enlarged distal end. As shown in the figure below, the visualization window is provided in the port of the bridge portion. (Ex. 1010, ¶201.)





Accordingly, claim 12 is anticipated by SensaTRAC. (Ex. 1010, ¶202.)

14. Claim 13

Claim 13 recites the "apparatus of claim 10, wherein the enlarged distal end of the bridge portion comprises an aperture positioned over the aperture in the applicator and configured to be positioned over the wound site to fluidically connect the wound site to the source of negative pressure." As discussed above, in

SensaTRAC, the applicator has a central opening, and the port having the hollow dome structure is placed above the central opening. The central opening of the applicator, and in turn the hollow dome structure, are positioned over the wound site to fluidically connect the wound site to the pump. (Ex. 1010, ¶203.)

Accordingly, claim 13 is anticipated by SensaTRAC. (Ex. 1010, ¶204.)

15. Claim 14

Claim 14 recites the "apparatus of claim 1, wherein the applicator further comprises an adhesive provided on a lower surface of the applicator, and wherein the adhesive is configured to seal the applicator to the drape." As discussed above, the adhesive film of the applicator has an adhesive on its lower surface that is configured to seal the applicator to the flexible plastic film (drape). (Ex. 1010, ¶205.)

Accordingly, claim 14 is anticipated by SensaTRAC. (Ex. 1010, ¶206.)

16. Claims 15-16

Claim 15 recites the "apparatus of claim 1, further comprising a wound cover for covering the wound site." Claim 16 recites the "apparatus of claim 15, wherein the wound cover comprises a drape." As discussed above, SensaTRAC is operated by first placing a foam in or over a wound. The foam is typically cut to have the same shape and size as the wound. A plastic drape (wound cover) is placed over the foam and is attached to skin surrounding the wound and foam to

form an air tight seal around the wound and foam. A skilled artisan would understand SensaTRAC's drape to be a wound cover and a drape, thus anticipating claims 15 and 16. (Ex. 1010, ¶207.)

17. Claim 17

Claim 17 recites the "apparatus of claim 1, wherein the intermediate wall extends substantially parallel to the first and second channels." As discussed above, in SensaTRAC, the tube includes a central lumen (first channel) and smaller lumens (one smaller lumen being a second channel). As discussed above, in SensaTRAC, the intermediate wall corresponds to the material between the central lumen (first channel) and the smaller lumens (one smaller lumen being a second channel). It is plain that the material between the central lumen (first channel) and the smaller lumens (one smaller lumen being a second channel) extend parallel to the both the central lumen (first channel) and the smaller lumens (one smaller lumen being a second channel).Accordingly, claim 17 is anticipated by SensaTRAC. (Ex. 1010, ¶208.)

Accordingly, in my opinion, claim 17 is anticipated by SensaTRAC. (Ex. 1010, ¶209.)

D. Ground 4: Claims 1-4 And 6-17 Would Have Been Obvious Over SensaTRAC

Even if any of the claims 1-4 and 6-17 are found not to be anticipated by the SensaTRAC device, to the extent there are minor differences in form between

claims 1-4 and 6-17 and the SensaTRAC disclosure, those differences would have been well within the knowledge and skill of a person of skill in the art, and thus would have been obvious design choices and/or obvious to try. (Ex. 1010, ¶210.)

E. Ground 5: Claim 5 Would Have Been Obvious Over SensaTRAC In View Of *Hu*

Claim 5 recites the "apparatus of claim 1, wherein the visualization window comprises polyurethane." The SensaTRAC device visualization window is made from a transparent material. It is known that polyurethane is a plastic material that can be transparent and is used in NPWT. Polyurethane does not provide a critical advantage over other transparent plastic materials. (Ex. 1010, ¶211.)

Application 12/626,426 to *Hu* (the '426 Application) was filed on November 25, 2009, and published as U.S. 2010/0137775 ("*Hu*") on June 3, 2010, and discloses the use of a transparent polyurethane port for use in NPWT. The '426 Application claims priority to U.S. Provisional Application 61/117,921 filed on November 25, 2008, and U.S. Provisional Application 61/117,920 filed on November 25, 2008. Accordingly, *Hu* is prior art to the '750 Patent under 35 U.S.C. 102(a)(2). (Ex. 1010, ¶212.)

Hu discloses a NPWT device. (Ex. 1012, Abstract.) The NPWT device in *Hu* has a port 700, which has an exterior wall 701 that is comprised of translucent material, as shown below. (Ex. 1012, ¶[0084], FIG. 7A.) (Ex. 1010, ¶213.)

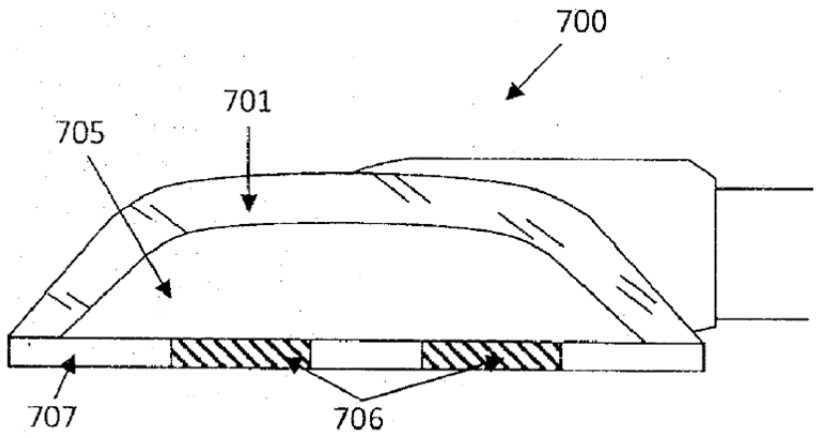


FIG. 7A

FIG. 4 of *Hu*, as reproduced below, shows an example of a reduced pressure treatment system 400 configured to permit selective viewing under a substantially opaque dressing 401. (Ex. 1012, ¶[0094].) Dressing 401 may be attached to port 402 as previously described. (Ex. 1012, ¶[0094].) Thus, for example, port 402 can be the port shown in FIG. 7A and described in ¶[0084]. Dressing 401 further comprises opaque flaps 403 which cover substantially transparent regions 404 of dressing 401. Transparent regions may comprise polyurethane, silicone, transparent hydrocolloid, hydrogel, copolyester, polyethylene or any other substantially transparent material known in the art. (Ex. 1012, ¶[0094].) Thus, one of ordinary skill in the art would have been motivated to use polyurethane as a material in the port of SensaTRAC, because *Hu* teaches that polyurethane can be used as a transparent material in a NPWT device where the port is translucent. (Ex. 1010, ¶214.)

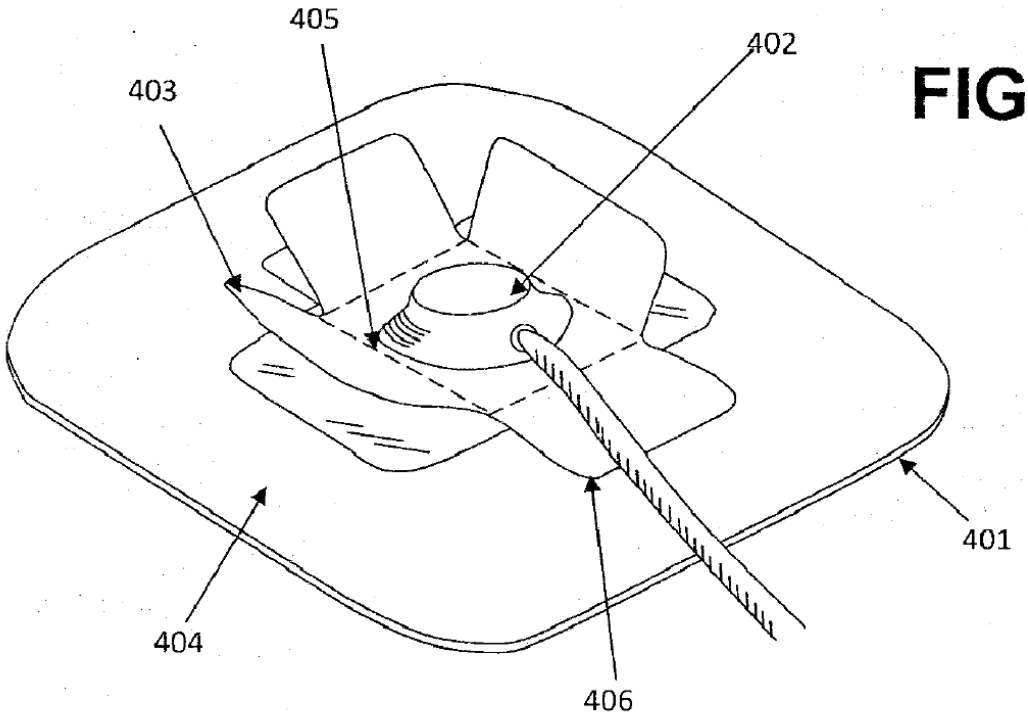


FIG. 4

Thus, as taught by *Hu*, it would have been obvious as a mere design choice for the visualization window to at least be made from some polyurethane, because polyurethane and other substantially transparent materials are interchangeable in a NPWT device visualization window. Thus, a skilled artisan would have been motivated to combine the transparent material taught in *Hu* with SensaTRAC to arrive at the polyurethane visualization window of claim 5. (Ex. 1010, ¶215.)

Accordingly, claim 5 would have been obvious over SensaTRAC in view of *Hu*. (Ex. 1010, ¶216.)

F. Ground 6: Claims 1-4 And 6-17 Would Have Been Obvious Over SensaTRAC In View Of *Vess*

1. Claim 1

The arguments below with respect to the combination of SensaTRAC and *Vess* are relevant to the discussion in Ground 3, Section 1.3.1(A), where the lumens (first and second channels) in the tube extend parallel to the upper surface of the flange (applicator). (Ex. 1010, ¶217.)

In the alternative, claim 1 would have been obvious over SensaTRAC in view of *Vess*. *Vess* was published September 10, 2009, which is, assuming the Board does not find that claims 1-17 lack written description support, before the alleged earliest effective priority date of the '750 patent of May 7, 2010. *Vess* is prior art to the '750 patent under 35 U.S.C. 102(a)(1). (Ex. 1010, ¶217.)

In the event that the Board decides that SensaTRAC does not anticipate the term "parallel" in the clause "at least a first channel and a second channel extending parallel to an upper surface of the applicator," *Vess* discloses this term. *Vess* discloses a parallel relationship between a channel and the upper surface of an applicator. (Ex. 1010, ¶218.)

SensaTRAC is applied as above for the anticipation analysis. As described above, in SensaTRAC, the tube fitting in the port is at an angle that is slightly inclined relative to the upper surface of the applicator. But, the direction of the

tube fitting in the port is a mere design choice. Moreover, the tubes exiting the port are parallel to the upper surface of the applicator. (Ex. 1010, ¶219.)

Vess discloses a wound dressing for use in vacuum wound therapy. (Ex. 1013, Abstract.) The wound dressing includes a cover layer 40 (applicator), which includes a backing layer 44 and a portal member 46 (bridge portion). The portal member 46 receives a vacuum tube 24 that is connected to a vacuum system 12. (Ex. 1013, ¶[0023].) As shown in FIG. 4 in *Vess*, the portal member 46 receives the vacuum tube 24 such that the channel in the vacuum tube 24 is parallel to an upper surface of the cover layer 40 (applicator) (Ex. 1013, FIG. 4.) (Ex. 1010, ¶220.)

Whether the tube and channels are received at the port in a parallel configuration or at a slight angle to the applicator is a mere design choice. The tubes and channels will run parallel to the applicator in any event. As such, in view of *Vess*, a skilled artisan would have been motivated to modify the port in SensaTRAC such that the tube and channels are received parallel to an upper surface of the applicator. A skilled artisan would have found such a modification to be routine. (Ex. 1010, ¶221.)

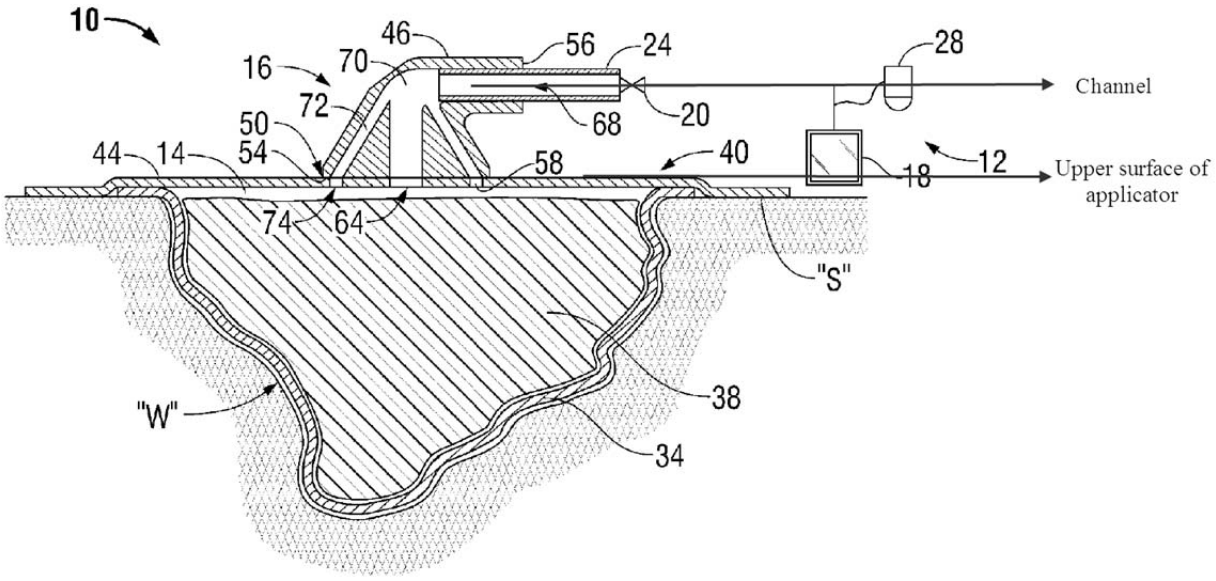


FIG. 4

Accordingly, claim 1 would have been obvious over SensaTRAC, in view of *Vess*. (Ex. 1010, ¶222.)

2. Claim 2

SensaTRAC discloses this limitation. *See* Ground 3, Claim 2, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶223.)

3. Claim 3

SensaTRAC discloses this limitation. *See* Ground 3, Claim 3, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶224.)

4. Claim 4

SensaTRAC discloses this limitation. *See* Ground 3, Claim 4, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶225.)

5. Claim 6

SensaTRAC discloses this limitation. *See* Ground 3, Claim 6, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶226.)

6. Claim 7

SensaTRAC discloses this limitation. *See* Ground 3, Claim 7, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶227.)

7. Claim 8

SensaTRAC discloses this limitation. *See* Ground 3, Claim 8, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶228.)

8. Claim 9

SensaTRAC discloses this limitation. *See* Ground 3, Claim 9, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶229.)

9. Claim 10

SensaTRAC discloses this limitation. *See* Ground 3, Claim 10, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶230.)

10. Claim 11

SensaTRAC discloses this limitation. *See* Ground 3, Claim 11, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶231.)

11. Claim 12

SensaTRAC discloses this limitation. *See* Ground 3, Claim 12, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶232.)

12. Claim 13

SensaTRAC discloses this limitation. *See* Ground 3, Claim 13, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶233.)

13. Claim 14

SensaTRAC discloses this limitation. *See* Ground 3, Claim 14, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶234.)

14. Claim 15

SensaTRAC discloses this limitation. *See* Ground 3, Claim 15, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶235.)

15. Claim 16

SensaTRAC discloses this limitation. *See* Ground 3, Claim 16, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶236.)

16. Claim 17

SensaTRAC discloses this limitation. *See* Ground 3, Claim 17, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Vess*. (Ex. 1010, ¶237.)

G. Ground 7: Claim 5 Would Have Been Obvious Over SensaTRAC In View Of *Vess* And In Further View Of *Hu*

In the alternative, claim 5 would have been obvious over SensaTRAC in view of *Vess*, and further in view of *Hu*, for the same reasons discussed above with respect to claims 1-4 and 6-17, and claim 5, respectively. (Ex. 1010, ¶238.)

H. Ground 8: Claims 1-4 And 6-17 Would Have Been Obvious Over SensaTRAC In View Of *Hirsch*

1. Claim 1

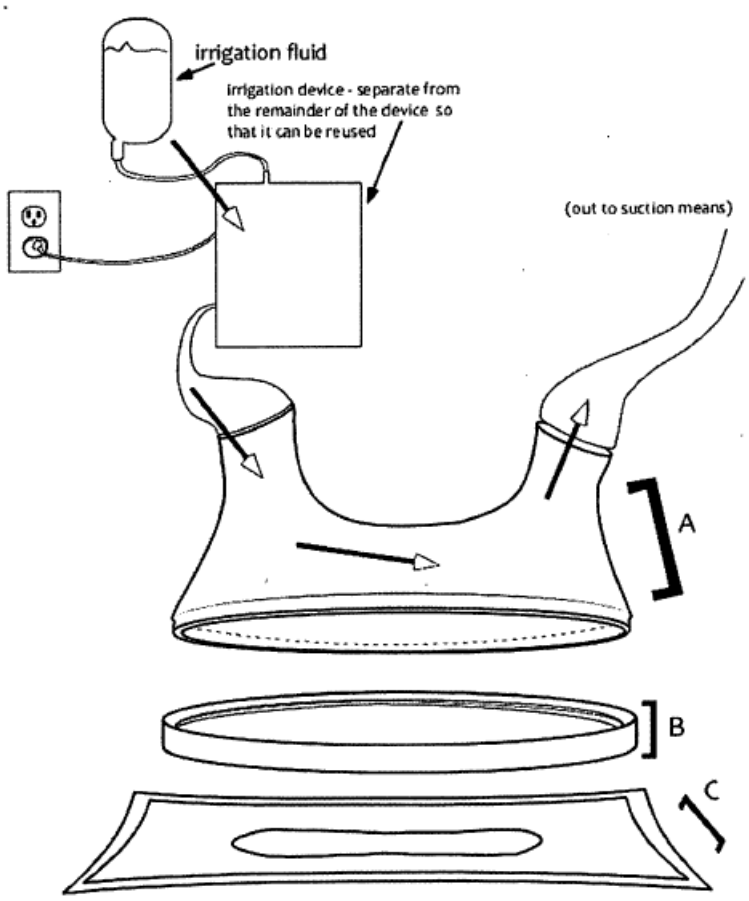
In the alternative, claim 1 would have been obvious over SensaTRAC in view of *Hirsch* (Ex. 1014). *Hirsch* became publically available on April 29, 2010, which is, assuming the Board does not find that claims 1-17 lack written description support, before the alleged earliest effective priority date of the '750 patent of May 7, 2010. *Hirsch* is U.S. Provisional Application No. 61/109,360, filed on October 29, 2008. U.S. Application No. 12/608,617 claims priority to *Hirsch*, and was published as U.S. Patent Publication No. 2010/0106108 on April 29, 2010. *Hirsch* is prior art to the '750 patent under 35 U.S.C. §102(a)(1) on April 29, 2010, and under 35 U.S.C. §102(a)(2) on October 29, 2008. (Ex. 1010, ¶239.)

In the event that the Board decides that SensaTRAC does not anticipate the term "unobstructed" in the clause "a visualization window provided in an upper surface of the bridge portion over the at least one aperture in the applicator that provides unobstructed visualization from outside of the suction adapter, through the visualization window and through the aperture in the applicator," *Hirsch* meets this term as it discloses an unobstructed visualization window. (Ex. 1010, ¶240.)

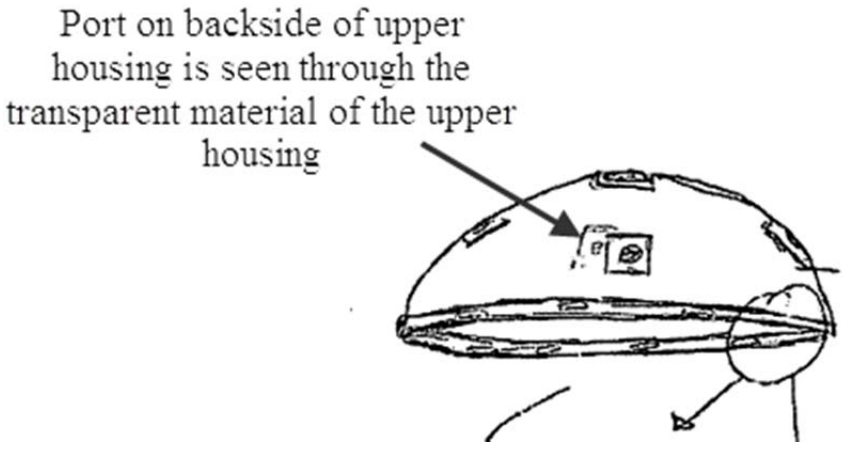
SensaTRAC is applied as above for the anticipation analysis. As described above, in SensaTRAC, the port of the bridge portion includes a hollow dome

structure, which is transparent, where a part of the inner surface is a ruffled inner surface with protrusions. (Ex. 1010, ¶241.)

Hirsch discloses a system for wound irrigation having base element and an upper housing element. (Ex. 1014, 7:27-30.) The upper housing element is constructed to also permit the application of negative pressure to the wound. (Ex. 1014, 11:30-31.) *Hirsch* discloses that the housing "defines a chamber continuous with a wound site," and can be made with materials without limitations to their transparency. (Ex. 1014, 5:22-26.) FIG. 1 in *Hirsch* shows the upper housing element A. FIG. 2 in *Hirsch* shows the upper housing element A is transparent and has smooth outer and inner surfaces. (Ex. 1014, FIG. 2.) As shown in FIG. 2, the housing includes five ports: one port on the top of the housing and four ports evenly spaced circumferentially around the housing (Ex. 1014, FIG. 2). The port on the backside of the housing can be seen, as shown in FIG. 2, through the transparent material of the upper housing. A skilled artisan would be motivated to combine the smooth hollow dome structure of *Hirsch*'s device that can be used for NPWT with SensaTRAC to arrive at a dome without obstructions, because this would make it easier to see through and ensure that the applicator is correctly applied over the hole cut out from the plastic drape. (Ex. 1010, ¶242.)



Hirsch FIG. 1



Hirsch FIG. 2 (partial)

Accordingly, claim 1 would have been obvious over SensaTRAC in view of *Hirsch*. (Ex. 1010, ¶243.)

2. Claim 2

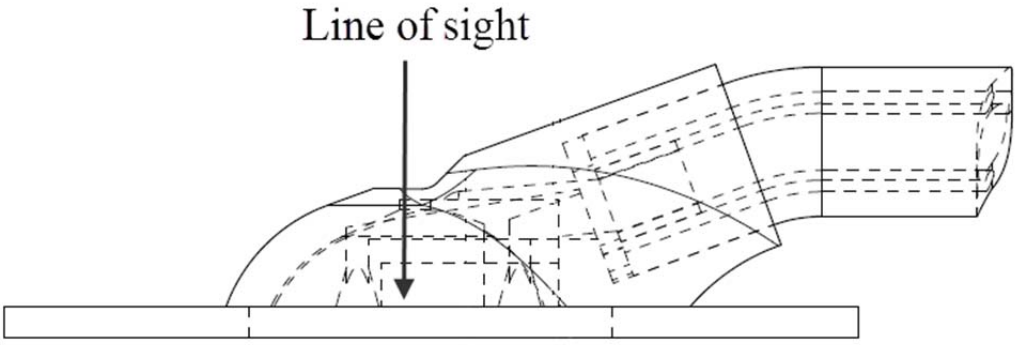
As described above, the port of the bridge portion includes a hollow dome structure, which is transparent, where a part of the inner surface is a ruffled inner surface with protrusions. (Ex. 1010, ¶244.)

In the alternative, as described above, SensaTRAC can be modified with a transparent hollow dome structure, as disclosed in *Hirsch*. (Ex. 1010, ¶245.)

Accordingly, claim 2 would have been obvious over SensaTRAC in view of *Hirsch*. (Ex. 1010, ¶246.)

3. Claim 3

As described above, the port of the bridge portion includes a hollow dome structure, which is transparent, where a part of the inner surface is a ruffled inner surface with protrusions. Thus, the view through the dome and the opening in the applicator is unobstructed. A person can look through the dome from the outside through the opening of the applicator onto the wound site prior to sealing the suction adapter to the wound cover, as shown in the figure below. (Ex. 1010, ¶247.)



In the alternative, as described above, SensaTRAC can be modified with a transparent hollow dome structure, as disclosed in *Hirsch*, which allows a person to view the wound site prior to sealing the suction adapter to the wound cover. (Ex. 1010, ¶248.)

Accordingly, claim 3 would have been obvious over SensaTRAC in view of *Hirsch*. (Ex. 1010, ¶249.)

4. Claim 4

As described above, the port of the bridge portion includes a hollow dome structure, which is transparent, where a part of the inner surface is a ruffled surface with protrusions. Thus, the view through the dome and the opening in the applicator is unobstructed. A person can look through the dome from the outside through the opening of the applicator onto the wound site while the apparatus is providing suction to the wound site, as shown in the figure above. (Ex. 1010, ¶250.)

In the alternative, as described above, SensaTRAC can be modified with a completely transparent hollow dome structure, as disclosed in *Hirsch*, which allows a person to monitor the wound site while the apparatus is providing suction to the wound site. (Ex. 1010, ¶251.)

Accordingly, claim 4 would have been obvious over SensaTRAC in view of *Hirsch*. (Ex. 1010, ¶252.)

5. Claim 6

SensaTRAC discloses this limitation. *See* Ground 3, Claim 6, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶253.)

6. Claim 7

SensaTRAC discloses this limitation. *See* Ground 3, Claim 7, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶254.)

7. Claim 8

SensaTRAC discloses this limitation. *See* Ground 3, Claim 8, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶255.)

8. Claim 9

SensaTRAC discloses this limitation. *See* Ground 3, Claim 9, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶256.)

9. Claim 10

SensaTRAC discloses this limitation. *See* Ground 3, Claim 10, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶257.)

10. Claim 11

SensaTRAC discloses this limitation. *See* Ground 3, Claim 11, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶258.)

11. Claim 12

SensaTRAC discloses this limitation. *See* Ground 3, Claim 12, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶259.)

12. Claim 13

SensaTRAC discloses this limitation. *See* Ground 3, Claim 13, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶260.)

13. Claim 14

SensaTRAC discloses this limitation. *See* Ground 3, Claim 14, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶261.)

14. Claim 15

SensaTRAC discloses this limitation. *See* Ground 3, Claim 15, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶262.)

15. Claim 16

SensaTRAC discloses this limitation. *See* Ground 3, Claim 16, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶263.)

16.Claim 17

SensaTRAC discloses this limitation. *See* Ground 3, Claim 17, above. Consequently, a skilled artisan would have found this feature obvious in view of the combination of SensaTRAC and *Hirsch*. (Ex. 1010, ¶264.)

I. Ground 9: Claim 5 Would Have Been Obvious Over SensaTRAC In View Of *Hirsch* In Further View Of *Hu*

In the alternative, claim 5 would have been obvious over SensaTRAC in view of *Hirsch*, and further in view of *Hu*, for the same reasons discussed above with respect to claims 1-4 and 6-17, and claim 5, respectively. (Ex. 1010, ¶265.)

J. Ground 10: Claims 1-4 And 6-17 Would Have Been Obvious Over SensaTRAC In View Of *Vess* And In View Of *Hirsch*

In the alternative, claims 1-4 and 6-17 would have been obvious over SensaTRAC in view of *Vess*, and further in view of *Hirsch*, for the same reasons discussed above with respect to claims 1-4 and 6-17. (Ex. 1010, ¶266.)

K. Ground 11: Claim 5 Would Have Been Obvious Over SensaTRAC In View Of *Vess* And In View Of *Hirsch* And In Further View Of *Hu*

In the alternative, claim 5 would have been obvious over SensaTRAC in view of *Vess*, and *Hirsch*, and further in view of *Hu*, for the same reasons discussed above with respect to claims 1-4 and 6-17, and claim 5, respectively. (Ex. 1010, ¶267.)

L. Ground 12: Claims 1-17 Are Invalid Under 35 U.S.C. § 112(b) Because The Term "Unobstructed" Is Indefinite

Claims 1-17 all require a visualization window that provides "unobstructed visualization from outside of the suction adapter, through the visualization window and through the aperture in the applicator." Neither the specification nor the claims explain the conditions under which visualization can be "unobstructed." Consequently, a skilled artisan would not understand the meaning of the term "unobstructed" in the context of the '750 Patent, and as such, claims 1-17 are invalid as indefinite. (Ex. 1010, ¶268.)

"[C]laims are required to be cast in clear – as opposed to ambiguous, vague, indefinite – terms." *In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014). A claim

is indefinite if it "contains words or phrases whose meaning is unclear" *Packard* at 1314 or is "amenable to two or more plausible claim constructions" *Ex parte Miyazaki*, 89 USPQ2d 1207, 1211 (BPAI 2008) (precedential).

1. The Specification Never Mentions Or Explains The Term "Unobstructed"

It is unclear what "unobstructed" means. As discussed above, unobstructed appears only in claim 1 in the context of the visualization window, and never appears in the specification. Claim 1 requires "a visualization window . . . that provides unobstructed visualization from outside of the suction adapter, through the visualization window and through the aperture in the applicator." (Ex. 1010, ¶269.)

There are multiple possible interpretations for "unobstructed." For example, "unobstructed" visualization could be plausibly interpreted to mean a variety of things, including: (1) an unblocked view of the wound site with no intermediate elements present below the visualization window to through the aperture in the applicator, (2) a path that includes some intermediate elements so long as the wound is visible through all of those elements, or (3) a path that contains some obstructions visible through the window, so long as there is some way to look through the window and see the wound site. Thus, this term is subject to at least three alternative constructions. As discussed above, the specification does not explain the meaning of unobstructed because the word "unobstructed" does not

appear in the original specification or claims. Thus, claim 1 is indefinite. Because dependent Claims 2-17 do not cure the indefiniteness of claim 1, Claims 2-17 are also indefinite. (Ex. 1010, ¶270.)

In the alternative, if the claims are not deemed indefinite, the only appropriate claim construction for this term must be limited to the first definition above, that is, where there is an unblocked view of the wound site, as that is the only example shown in the figures. Figures 15A-D disclose a series of apertures from the viewing window to the aperture in the applicator. There is no further element or material present in the apertures or between the apertures; that is, the view from the visualization window to through the aperture in the applicator does not pass through anything but empty space. (Ex. 1010, ¶271.)

As discussed above, the dictionary definition of "obstruct" is "to block or close up by an obstacle" or "to cut off from sight." (Ex. 1015.) Any element or material in the viewing line of sight from outside the suction adaptor through the visualization window to the aperture in the applicator would in some manner block by being an obstacle or cut off from sight and would not be "unobstructed." (Ex. 1010, ¶272.)

Therefore, if Claims 1-17 are not indefinite, they must be interpreted to mean that "unobstructed" requires there to be an absence of any element from the visualization window to through the aperture in the applicator. (Ex. 1010, ¶273.)

IX. Conclusion

This petition has demonstrated that MHC will more likely than not prevail in its challenge of the patentability for claims 1-24 of the ’750 patent. MHC respectfully requests that trial for post-grant review on the ’750 patent be instituted and that claims 1-24 be canceled.

Dated: February 9, 2018

By: /s/ Mitchell A. Katz

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CERTIFICATION OF COMPLIANCE

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Post-Grant Review totals 17,848, excluding the cover page, signature block, and parts exempted by 37 C.F.R. §42.24(a). This word count was made by using the built-in word count function tool in the Microsoft Word software Version 2010 used to prepare the document.

The undersigned further certifies that this Petition complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and typestyle requirements of 37 C.F.R. § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14 point font.

Dated: February 9, 2018 Respectfully submitted,

By: /s/ *Mitchell A. Katz*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 9,642,750 and supporting materials (Exhibits 1001-1029, Exhibit Listing Document, and Power of Attorney) have been served this 9th day of February, 2018, by FedEx® mail delivery service® on Patent Owner at the correspondence address for the attorney of record for the '750 patent shown in USPTO PAIR:

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