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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 Patent 9,642,750 B2

Before LINDA E. HORNER, JAMES J. MAYBERRY, and JASON W. MELVIN, *Administrative Patent Judges*.

MELVIN, Administrative Patent Judge.

DECISION Denying Institution of Post-Grant Review 37 C.F.R. § 41.208

I. INTRODUCTION

Petitioner, Mölnlycke Health Care AB ("MHC"), filed a Petition (Paper 3, "Pet.") requesting post-grant review of all 24 claims of U.S. Patent No. 9,642,750 B2 (Ex. 1001, "the '750 patent"). Patent Owner, Smith & Nephew, Inc., filed a Preliminary Response. Paper 8 ("Prelim. Resp."). Pursuant to 35 U.S.C. § 324 and 37 C.F.R. § 42.4(a), we have authority to determine whether to institute review.

A post-grant review may not be instituted unless "the information presented in the petition . . . if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). For the reasons set forth below, we conclude that Petitioner has not adequately demonstrated that the '750 patent is eligible for post-grant review. We, therefore, do not institute post-grant review of any claim of the '750 patent.

A. RELATED MATTERS

Petitioner identifies the following applications that claim priority to the '750 patent's filing date: U.S. Patent Application No. 15/198,690, filed June 30, 2016 (issued as US 9,999,547 B2 on June 19, 2018); U.S. Patent Application No. 15/256,349, filed September 2, 2016 (issued as US 9,974,695 B2 on May 22, 2018); and U.S. Patent Application No. 15/681,165, filed August 18, 2017. Pet. 3.

B. The '750 Patent

The '750 patent is directed to apparatuses and methods for negativepressure wound therapy. Ex. 1001, 1:20–25. Such therapy is employed for

"treatment of open or chronic wounds that are too large to spontaneously close or otherwise fail to heal." *Id.* at 1:29–32. The Specification explains:

Negative pressure wound treatment systems currently known in the art commonly involve placing a cover that is impermeable to liquids over the wound, using various means to seal the cover to the tissue of the patient surrounding the wound, and connecting a source of negative pressure (such as a vacuum pump) to the cover in a manner so that an area of negative pressure is created under the cover in the area of the wound.

Id. at 1:32–39. Although the patent discloses a number of embodiments, the parties agree that the embodiment of Figures 15A–15D are relevant to the issues raised in the Petition. *See* Pet. 20; Prelim. Resp. 10–11. Figures 15A and 15B are reproduced below:

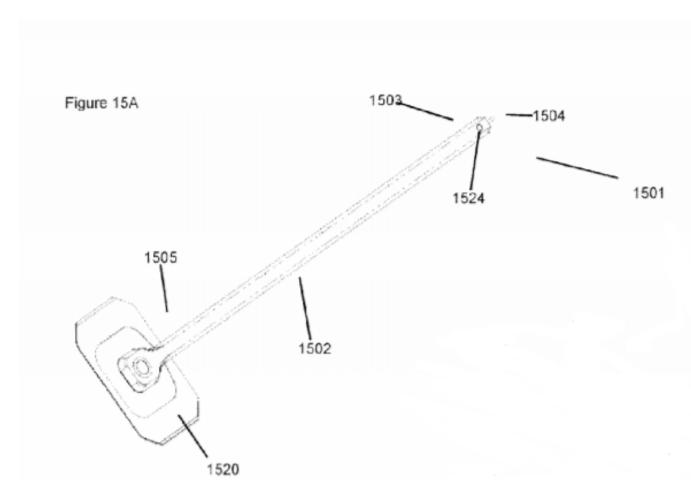


Figure 15A illustrates a "negative pressure wound treatment system 1501 comprising a flexible suction adapter." Ex. 1001, 22:1–3. The illustrated system comprises "a bridge 1502 having a proximal end 1503 and a distal end 1505 and an applicator 1520 at the distal end 1505 of the bridge 1502." *Id.* at 22:7–10.

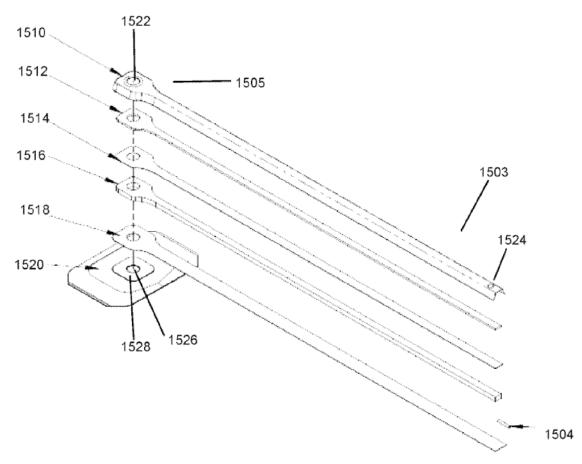


Figure 15B

Figure 15B illustrates an exploded view of the flexible suction adapter, showing a bridge that comprises "an upper channel layer 1512 sandwiched between an upper layer 1510 and an intermediate layer 1514, with a lower channel layer 1516 sandwiched between the intermediate layer 1514 and a bottom layer 1518." *Id.* at 22:10–14. The upper layer of the bridge includes a "viewing window 1522 that permits targeting and visualization of the wound site prior to placement of the system 1501 as well as ongoing monitoring of the wound site during the course of treatment." *Id.* at 24:65–25:2. The Specification describes that, preferably, the viewing window "is at least partially transparent." *Id.* at 25:8–11. "[A] connector 1504 is provided at the proximal end 1503 which may be used to connect the lower channel layer 1516 to a source of negative pressure," thus permitting "wound exudate to be suctioned away from the wound and for negative pressure to be applied to the wound site." *Id.* at 23:1–11.

C. CHALLENGED CLAIMS

Challenged claims 1 and 18 are independent, illustrative of the claimed subject matter, and reproduced below:

- 1. An apparatus to provide suction to a wound site comprising:
 - a suction adapter configured to be sealed to a wound cover covering a wound site, the suction adapter comprising:
 - an applicator configured to be positioned over an opening in the wound cover, the applicator comprising at least one aperture; and
 - 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;
 - 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;

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

Ex. 1001, 52:2–29.

18. A suction device for a negative pressure wound therapy system,

said suction device comprising an attachment portion adapted to be attached to a wound cover member,

said suction device comprising a fluid inlet being at least partially circumscribed by said attachment portion,

said suction device also comprising a fluid outlet,

- said suction device further comprising 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,
 - said connection portion comprising 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 a duct wall at least partially defining a connection duct from said inlet to said outlet,

said duct wall comprising said inspection portion,

said connection portion comprising a partition wall extending at least partially from said duct wall.

Id. at 53:9–26.¹

D. PROPOSED GROUNDS OF UNPATENTABILITY

Claim(s)	Basis	Reference(s)
1–24	§ 112(a) written description	n/a
1-4 and 6-17	§ 102	SensaTRAC ³
1-4 and 6-17	§ 103	SensaTRAC
5	§ 103	SensaTRAC and Hu ⁴
1-4 and 6-17	§ 103	SensaTRAC and Vess ⁵
5	§ 103	SensaTRAC, Vess, and Hu
1–4 and 6–17	§ 103	SensaTRAC and Hirsch ⁶
5	§ 103	SensaTRAC, Hirsch, and Hu
1–4 and 6–17	§ 103	SensaTRAC, Vess, and Hirsch

Petitioner asserts the following grounds of unpatentability:²

¹ We have formatted the language of claim 18 by adding line breaks and indentation to help clarify the claimed structures. Our formatting does not indicate any additional restriction or relationship of any type beyond the unformatted claim that appears in the '750 patent.

² The America Invents Act included revisions to, *inter alia*, 35 U.S.C. §§ 102, 103, and 112 effective on March 16, 2013. If the '750 patent is eligible for post-grant review, the AIA versions of those sections apply.

³ Petitioner relies on the "public sale, offer for sale, and/or public disclosure of SensaTRAC in 2007" (Exs. 1019–1029). Pet. 5; *accord id.* at 46–59.

⁴ U.S. Patent Application Publication No. US 2010/0137775 A1 (Ex. 1012).

⁵ U.S. Patent Application Publication No. US 2009/0227968 A1 (Ex. 1013).

⁶ U.S. Patent Application Publication No. US 2010/0106108 A1 and U.S. Provisional Patent App. No. 61/109,360 (Ex. 1014).

Claim(s)	Basis	Reference(s)
5	§ 103	SensaTRAC, Vess, Hirsch, and Hu
1–17	§ 112(b) definiteness	n/a

Pet. 5–6. Petitioner also relies on the Declaration of Dr. Michael Helmus (Ex. 1010) and the Declaration of Carianne Nilsson (Ex. 1011).

II. DISCUSSION

A. CLAIM CONSTRUCTION

The Board interprets unexpired claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.200(b); see Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, we generally give a claim term its "ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question" at the time of the invention when "read in view of the specification." In re Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007) (internal quotation and citation omitted). The specification may impose a specialized meaning, departing from the ordinary and customary meaning, by defining a term with reasonable clarity, deliberateness, and precision. In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Further, a party in a post-grant review may prove "the existence of a 'clear and unmistakable' disclaimer" that narrowed a term's definition in the prosecution history of a challenged patent. TriVascular, Inc. v. Samuels, 812 F.3d 1056, 1063-64 (Fed. Cir. 2016) (quoting Elbex Video, Ltd. v. Sensormatic Elecs. Corp., 508 F.3d 1366, 1371 (Fed. Cir. 2007)).

1. "unobstructed visualization"

Petitioner argues that the term "unobstructed visualization" is indefinite but that, if we determine otherwise, it should be construed as "an unblocked view of the wound site." Pet. 12. Petitioner also asserts that the term requires "an unblocked view of the wound site with no intermediate elements present below the visualization window to [*sic*] through the aperture in the applicator" such that "the view . . . does not pass through anything but empty space." *Id.* at 117–18. Patent Owner characterizes Petitioner's proposed construction as unhelpful but does not propose a different construction at this stage. Prelim. Resp. 14–15 ("[U]nder any conceivable construction, the specification fully discloses the claimed invention."). We adopt Petitioner's construction for purposes of this decision.

2. <u>"duct wall"</u>

Petitioner asserts that the term "duct wall" should be construed as the wall of "a pipe, tube, or channel that conveys a substance." Pet. 12–13. Patent Owner does not challenge Petitioner's proposed construction at this stage. Prelim. Resp. 14. We adopt Petitioner's construction for purposes of this decision.

3. <u>"partition wall"</u>

Petitioner asserts that a "partition wall" should be construed as "an interior dividing wall." Pet. 13. Patent Owner does not challenge Petitioner's proposed construction at this stage. Prelim. Resp. 14. We adopt Petitioner's construction for purposes of this decision.

B. ELIGIBILITY FOR POST-GRANT REVIEW

Post-grant review is available for a patent that issues from an application "that contains or contained at any time . . . a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after" March 16, 2013. *See* Leahy-Smith America Invents Act, Pub L. No. 112-29 ("AIA") §§ 3(n)(1), 6(f)(2)(A), 125 Stat. 284, 293, 311 (2011), available at https://go.usa.gov/xQA4b; 35 U.S.C. § 100(i). Petitioner bears the burden of proving that the challenged patent is subject to the first-inventor-to-file provisions of the AIA and eligible for post-grant review. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 54, 9–10 (PTAB Dec. 28, 2016).

Petitioner submits that because applications on which the '750 patent relies for an effective filing date do not provide written-description support for the issued claims, no claim of the '750 patent is entitled to an effective filing date before the actual filing date of the application for the '750 patent, February 8, 2016.⁷ Pet. 7–8, 14–46. Thus, Petitioner contends, the claims are eligible for post-grant review. *Id.*

Patent Owner responds that disclosures supporting the claims of the '750 patent were submitted by May 7, 2010, and maintained in the chain of

⁷ Because the '750 patent issued from a continuation application (Ex. 1001, [63]), the question of its effective filing date is the same as the question of whether the claims have adequate written-description support in the Specification of the '750 patent under § 112. We therefore address the issue of effective filing date by reference to the Specification of the '750 patent.

applications leading to that for the '750 patent. Prelim. Resp. 16–52. Thus, Patent Owner argues, the claims are ineligible for post-grant review. *Id*.

The dispute spawns two arguments—one for each independent claim of the '750 patent. If Petitioner is correct about either independent claim, the patent is available for post-grant review as described above. *See, e.g.*, *Inguran, LLC v. Premium Genetics(UK) Ltd.*, PGR2015-00017, Paper 8, 6–7 (PTAB Dec. 22, 2015).

To satisfy the written-description requirement under 35 U.S.C. § 112(a), the specification must "reasonably convey[] to those skilled in the art that the inventor had possession" of the claimed invention as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). An adequate description does not require any particular form of disclosure or that the specification recite the claimed invention *in haec verba*, but must do more than render the claimed invention obvious. *Id.* at 1352.

1. <u>Claim 1</u>

Petitioner asserts the following limitations in claim 1 lack writtendescription support in the Specification: "a visualization window . . . that provides unobstructed visualization" and "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel." Pet. 8, 41–46. Because, as described below, we do not agree with Petitioner's contentions, we conclude that the language of claim 1 is adequately supported by the Specification and therefore by the applications to which the '750 patent claims benefit of an earlier filing date.

a. "unobstructed visualization"

Petitioner recognizes that the Specification "refers to 'targeting and visualization' and 'ongoing monitoring' of the wound site" but asserts such disclosure is insufficient to support a claim to "unobstructed visualization" because "[o]ne can target, visualize, or monitor even if the view is in some way obstructed." Pet. 43 (citing Ex. 1010 ¶ 98). Patent Owner responds that Petitioner "gives undue emphasis on the word 'unobstructed' as if that adjective requires specific structures (or lack thereof), when in reality it merely emphasizes that the user must be able to see the wound through the window." Prelim. Resp. 28–29 (citing Ex. 2001 ¶ 54).

As noted above, the Specification describes the "viewing window 1522" as a structure that "permits targeting and visualization of the wound site" and that is "at least partially transparent." Ex. 1001, 24:65–25:11. Additionally, a series of apertures leave open space below the visualization window. *Id.* at Fig. 15B, 25:3–6. The viewing window and open space are consistent with Petitioner's construction of the term, which requires an unblocked view with no intermediate elements. *See supra* at 9. Accordingly, we conclude that the Specification supports a claim to a "visualization window . . . that provides unobstructed visualization."

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

Petitioner argues that the Specification does not support claim 1's language requiring "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel." According to Petitioner, "the downwardly extending material from the upper layer 1510 does not extend straight down; it is curved" and, "[t]herefore, it is not possible for the intermediate wall 1514 to extend

perpendicularly from the downwardly extending material, which forms the side walls." Pet. 45 (citing Ex. 1001, Fig. 15C; Ex. 1010 ¶¶ 106–107). Patent Owner responds that the upper layer depicted in Figure 15C has "straight, vertical portions . . . from which the intermediate layer extends across the width of the bridge." Prelim. Resp. 33 (citing Ex. 1001, Fig. 15C; Ex. 2001 ¶ 62). Patent Owner argues further that even if the figures did not depict an intermediate layer extending at precisely ninety degrees, the exact angle is "irrelevant to the design of the device or its performance, particularly when the materials used are pliable." *Id.* at 33–34 (citing Ex. 2001 ¶ 63).

We agree with Patent Owner. Although no textual description indicates the intermediate layer extends at precisely ninety degrees, Figure 15C depicts the intermediate layer 1514 extending perpendicularly from the sides formed from the downwardly extending portion of the upper layer 1510. Ex. 1001, Fig. 15C. We therefore conclude that the Specification supports a claim to "an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel."

2. <u>Claim 18</u>

Petitioner asserts the following limitations in claim 18 lack writtendescription support in the Specification: "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." Pet. 7, 16–37. Because, as described below, we do not agree with Petitioner's contentions, we conclude that the language of claim 18 is adequately supported by the Specification, and therefore by the applications to which the '750 patent claims benefit of an earlier filing date.

Petitioner asserts that a person of ordinary skill in the art would identify the "bridge 1502" as relating to the connection portion, and further that such a person would identify only the "lower channel layer 1516" as the claimed connection portion, because only the lower channel layer "could create a 'fluid communication' between the fluid inlet (the 'aperture 1526') and the fluid outlet (the 'connector 1504')." Pet. 27 (citing Ex. 1001, 22:7– 18, 25:49–56; Ex. 1010 ¶ 68). Petitioner's identification of the lower channel layer (or lower portion of the bridge) as the claimed connection portion leads to several arguments regarding lack of written-description support. Because the "viewing window 1522" described in the Specification is contained in the upper portion of the bridge (not the lower channel layer), Petitioner argues that the described connection portion does not include an inspection portion. Pet. 30–32. In that same way, Petitioner argues that the Specification does not describe a "duct wall comprising an inspection portion" because the only "duct wall" could be in the lower portion of the bridge, which creates a fluid connection from inlet to outlet. Pet. 33–34. Finally, Petitioner relies on the same understanding of the connection portion to argue that the described duct wall could not include "a partition wall extending at least partially" from the duct wall. Pet. 35–36.

Patent Owner challenges Petitioner's view of the claimed "connection portion," arguing that the term reads on the entire "assembled bridge 1502" described in the Specification. Prelim. Resp. 42–44. We conclude that Patent Owner has the more persuasive view of the Specification and claim language.

Most significantly, the claim states that the connection portion is "adapted to . . . provide a fluid communication between said fluid inlet and

said fluid outlet." The claim does not limit the connection portion to provide *only* that fluid communication, and therefore we have no reason to conclude that the connection portion must not include any other structures. In that regard, we agree with Patent Owner that the connection portion may include structures beyond the recited elements. *See id.* at 43–44 (citing Ex. 2001 ¶ 79); *cf. AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1244–45 (Fed. Cir. 2001) ("When a claim uses an 'open' transition phrase, its scope may cover devices that employ additional, unrecited elements."; "[T]he word 'comprising' is an open transition phrase."). The Specification describes that the "bridge 1502" is a structure with a proximal end and a distal end and that is made from layers arranged to convey fluids between the ends. Ex. 1001, 22:7–36. We conclude that description supports that the bridge is a structure consistent with the plain and ordinary usage of the term "connection portion."

Patent Owner also points out that claim 18 requires the connection portion include a "duct wall at least partially defining a connection duct" from the fluid inlet to outlet, and that limiting the connection portion to the "lower channel layer 1516" as Petitioner seeks would effectively read the "connection duct" out of the claim. Prelim. Resp. at 44 (citing Ex. 2001 ¶ 80); *see* Pet. 27. We agree with Patent Owner that the claimed connection portion is not limited to the "lower channel layer 1516" and that the claim cannot be interpreted such that the connection portion is synonymous with the connection duct. Under Patent Owner's view, the connection portion reads on the entire assembled bridge and therefore includes the entire "upper layer 1510." *See* Prelim. Resp. 42–43. We conclude that view is consistent with the Specification, which describes the upper layer 1510 as a single

structure covering the entire bridge (i.e., the claimed connection portion). Ex. 1001, 22:10–14, 23:11–13, Fig. 15C. Petitioner does not adequately justify dividing the upper layer into regions and excluding from the claimed "connection portion" all but the region used to form the duct wall.

The foregoing understanding of the connection portion resolves each of the written-description challenges to claim 18 raised by Petitioner. The parties do not dispute that the described "viewing window 1522" is contained within the upper layer. Pet. 31; Prelim. Resp. 46. As discussed above, we read the connection portion as including the entire upper layer. Thus, we conclude that the Specification describes a "connection portion comprising an inspection portion."

Similarly, the parties do not dispute that a portion of the upper layer 1510 forms a "duct wall at least partially defining a connection duct" from the fluid inlet to fluid outlet. *See* Pet. 33 (identifying "the sides of the upper layer"); Prelim. Resp. 48 (citing Ex. 2001 ¶¶ 90–91). Although Petitioner takes the view that the "duct wall" includes only the portion of the upper layer relevant to the duct allowing flow from the fluid inlet to outlet and therefore does not include the viewing window (Pet. 33–34), we conclude otherwise. The Specification discloses that the "upper layer 1510 may comprise additional material extending downward, preferably at least of the thickness of the bridge 1502." Ex. 1001, 23:11–13. It discloses that the upper layer is a single structure attached to the lower layer and intermediate layer and that such attachment forms a duct at least partially from the upper layer. *Id.* at 22:27–36, 23:13–23, Fig. 15C. We conclude that, understanding the claimed duct wall as the "upper layer 1510" described in the Specification, the duct wall comprises the inspection portion as claimed.

Finally, that same understanding of the duct wall—that the Specification describes the "upper layer 1510" as the claimed "duct wall" leads to the conclusion that the "intermediate layer 1514" is within the connection portion and acts as a partition wall extending at least partially from the duct wall, as claimed. *See* Ex. 1001, Fig. 15C; Prelim. Resp. 50 (citing Ex. 2001 ¶¶ 94–95). The claim language does not require that the partition wall divides the claimed duct into particular sections. Rather, applying Petitioner's proposed construction (*see supra* at 9), the claim requires that the connection portion include "an interior dividing wall" that extends at least partially from the duct wall. Because the intermediate layer described in the Specification does serve as an interior dividing wall dividing the connection portion into two ducts—and does extend (perpendicularly) from the duct wall, the Specification indicates that the inventors were in possession of the claimed invention.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not demonstrated that claim 1 or 18 of the '503 patent is entitled to an effective filing date on or after March 16, 2013. Because Petitioner addressed only those independent claims, Petitioner has not made an adequate showing that any challenged claim of the '750 patent is subject to the first-inventor-to-file provisions of the AIA and, thus, Petitioner fails to show any challenged claim is eligible for post-grant review.

IV. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 324(a), the Petition for post-

grant review is *denied*.

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