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**Datasheet for the decision
of 18 October 2021**

Case Number: T 0460/18 - 3.2.02

Application Number: 11714148.1

Publication Number: 2547375

IPC: A61M1/00

Language of the proceedings: EN

Title of invention:

DELIVERY-AND-FLUID-STORAGE BRIDGES FOR USE WITH REDUCED-
PRESSURE SYSTEMS

Patent Proprietor:

KCI Licensing, Inc.

Opponent:

Smith & Nephew, Inc.

Relevant legal provisions:

RPBA Art. 12(4)

EPC Art. 123(2), 84, 56

Keyword:

Request submitted with the statement of grounds of appeal -
admitted (yes)
Added subject-matter (no)
Lack of clarity (no)
Inventive step (yes)

Decisions cited:

T 0725/18



Beschwerdekammern

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Case Number: T 0460/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 October 2021

Appellant: Smith & Nephew, Inc.
(Opponent) 1450 Brooks Road
Memphis, TN 38116 (US)

Representative: Appleyard Lees IP LLP
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Halifax HX1 2HY (GB)

Respondent: KCI Licensing, Inc.
(Patent Proprietor) P.O. Box 659508
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Representative: Simmons & Simmons
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 19 December
2017 rejecting the opposition filed against
European patent No. 2547375 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Dennler
N. Obrovski

Summary of Facts and Submissions

- I. The opponent filed the appeal against the opposition division's decision to reject its opposition against the contested patent.
- II. In that decision, the opposition division held, *inter alia*, that the subject-matter of claim 1 of the patent as granted did not contain subject-matter extending beyond the content of the application as filed from which the patent had been granted, published as WO 2011/115908 A1 ("the application as filed"). Moreover, the subject-matter of claim 1 as granted was found to be novel and to involve an inventive step over the following documents:
- D1:** WO 2009/002260 A1
D2: US 2007/0167927 A1
- III. The appellant/opponent ("the appellant") requested that the decision under appeal be set aside and that the patent be revoked.
- IV. The respondent/patent proprietor ("the respondent") requested that the patent be maintained either in amended form on the basis of the claims of the main request filed with the submission dated 6 January 2021, or as granted, as a first auxiliary request.
- V. Claim 1 of the **main request** ("claim 1") reads as follows (amendments with respect to claim 1 as granted highlighted by the Board):

A reduced-pressure treatment system (100) for applying reduced pressure to a tissue site on a patient, the reduced-pressure treatment system comprising:

a reduced-pressure source (120) for supplying reduced pressure;

a treatment manifold (109) for placing proximate the tissue site and adapted to distribute reduced pressure to the tissue site;

a sealing member (161, 315) for placing over the tissue site, wherein the sealing member is adapted to form a fluid seal, and wherein the sealing member has a treatment aperture; and

a delivery-and-fluid-storage bridge (102) having a first longitudinal end (110) and a second longitudinal end (112) and a first side (103) and a second, patient-facing side (105), wherein the delivery-and-fluid-storage bridge (102) at least partially fluidly couples the treatment manifold (109) and the reduced-pressure source (120), the delivery-and-fluid-storage bridge (102) comprising:

a delivery manifold (138) extending along a length of the delivery-and-fluid-storage bridge (102) for delivering reduced pressure through the delivery-and-fluid-storage bridge, the delivery manifold comprising a first material,

an absorbent layer (140) proximate the delivery manifold and adapted to receive, absorb, and store liquids within the delivery-and-fluid-storage bridge, the absorbent layer comprising a second material, and wherein the first material and the second material have differing properties,

a first encapsulating layer (148) and a second encapsulating layer (150) at least partially enclosing the delivery manifold (138) and the absorbent layer (140),

wherein a first aperture (152) is formed on the first side (103) of the delivery-and-fluid-storage bridge proximate the first longitudinal end (110), the first aperture (152) is fluidly coupled to the reduced-pressure source (120), and

wherein a second aperture (154) is formed on the second side (105) of the delivery-and-fluid-storage bridge proximate the second longitudinal end (112), the second aperture (154) is fluidly coupled to the treatment manifold (109) over the treatment aperture in the sealing member, and characterised in that the delivery-and-fluid-storage bridge (102) further comprises a conduit (164) disposed between the first encapsulating layer (148) and the second encapsulating layer (150), wherein the conduit (164) extends substantially along the longitudinal length of the delivery-and-fluid-storage bridge (102) from the first longitudinal end (110) to the second longitudinal end (112) to facilitate measurement of pressure proximate the tissue site and to monitor pressure at the second longitudinal end (112) of the delivery-and-fluid-storage bridge (102).

VI. The **appellant's arguments**, as far as relevant for the present decision, can be summarised as follows.

Admittance of the main request

The main request corresponded to the respondent's previous first auxiliary request, filed for the first time on appeal with the reply to the statement of grounds of appeal. During the oral proceedings before the Board, the appellant requested that the main request not be admitted into the proceedings pursuant to Article 12(4) RPBA 2007, since it could and should have been filed in the first-instance proceedings. In

support of this request, the appellant referred to decision T 725/18.

Added subject-matter

The appellant's written objections under Article 123(2) EPC concerned the feature of claim 1 as granted whereby "the conduit (164) extends substantially along the length of the delivery-and-fluid-storage bridge (112)". In claim 1 of the main request, this feature has been amended to read "the conduit (164) extends along the longitudinal length of the delivery-and-fluid-storage bridge (102) from the first longitudinal end (110) to the second longitudinal end (112)".

During the oral proceedings before the Board, the appellant argued that the amended feature of claim 1 whereby the conduit extended "from the first longitudinal end to the second longitudinal end" of the bridge was not directly and unambiguously derivable from the application as filed. Paragraph [0042] of the description of the application as filed was concerned only with the point at which the conduit terminated. No clear, unambiguous disclosure was made of the point from which the conduit started. In particular, nowhere in paragraph [0042] was it stated that the conduit extended "from the first longitudinal end".

Lack of clarity

The amendments made in claim 1 with respect to claim 1 as granted introduced a lack of clarity open to objection under Article 84 EPC:

- (a) First, the wording "extends (...) from (...) to (...)" could be interpreted either as a definition

of the end points of the conduit or simply as a definition of part of the extent of the conduit. It was thus not clear whether the conduit was to be construed as being located entirely within the bridge or whether an extension of the tube outside the bridge at either end would still fall within the scope of the claim.

- (b) Second, claim 1 referred both to "a length of the delivery-and-fluid-storage bridge" and to "the longitudinal length of the delivery-and-fluid-storage bridge". It was not clear whether these were intended to be references to the same thing or whether there were two different lengths defined in the claim.

Inventive step

The subject-matter of claim 1 lacked inventive step in view of the combination of D1 with D2.

D1 disclosed a reduced-pressure treatment including a soft, padded bridge to convey a vacuum so as to avoid discomfort for the patient, like the bridge in the contested patent. The subject-matter of claim 1 differed from this known system only on account of the conduit provided within the bridge as defined in the characterising portion. The effect of this distinguishing feature was that pressure could be monitored within the bridge, especially at the tissue site to be treated, and therefore the technical problem was how to apply a reduced pressure while simultaneously monitoring the pressure being applied.

D2 related to the monitoring of pressure at a wound site in a similar reduced-pressure treatment system.

From this document, the person skilled in the art would have learnt that it was advantageous to combine a pressure monitoring conduit with the reduced-pressure delivery conduit. In the light of D2, the person skilled in the art would thus have obviously incorporated this kind of pressure monitoring conduit into the padded bridge of D1 in a way that maintained the advantages described in D1. Hence, the person skilled in the art starting from D1 would have arrived at the claimed subject-matter without exercising inventive skill.

- VII. The **respondent's arguments**, as far as relevant for the present decision, can be summarised as follows.

Admittance of the main request

The respondent had filed the earlier first auxiliary request, on which the main request was now based, with its reply to the statement of grounds of appeal, i.e. at the earliest possible stage of the appeal proceedings. This request was aimed at overcoming the appellant's objections raised in the statement of grounds of appeal. In view of the course of the first-instance proceedings, which had been concluded with the rejection of the opposition, the respondent could not have been expected to file this request earlier. Furthermore, the amendments made in this request were not complex. The main request, which corresponded to this earlier first auxiliary request, was therefore to be admitted.

Added subject-matter

Claim 1 was not concerned with the location where the conduit started. The feature that the conduit extended

"from the first longitudinal end to the second longitudinal end of the delivery-and-storage bridge" was supported by the statement in paragraph [0042] of the application as filed that the conduit "could either terminate proximate the first longitudinal end (...) or could continue to the second longitudinal end". The requirements of Article 123(2) EPC were therefore met.

Lack of clarity

Objection (a) was unfounded because claim 1 was not concerned with any features of the conduit other than its extension from the first to the second end and its ability to perform the required functions.

Regarding objection (b), it was clear from the wording of claim 1 that "longitudinal length" was a reference to "length".

Claim 1 was therefore clear.

Inventive step

It was accepted that the subject-matter of claim 1 differed from the system disclosed in D1 only on account of the conduit as defined in the characterising portion.

However, the person skilled in the art starting from D1 would not have considered D2, especially because this document disclosed conventional tubings which the soft bridge of D1 was aimed at avoiding. In addition, even if the person skilled in the art had done so, combining D2 with D1 would not have led to the claimed solution. There was nothing in D2 that suggested incorporating a conduit within the bridge of D1 as required by claim 1.

Hence, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

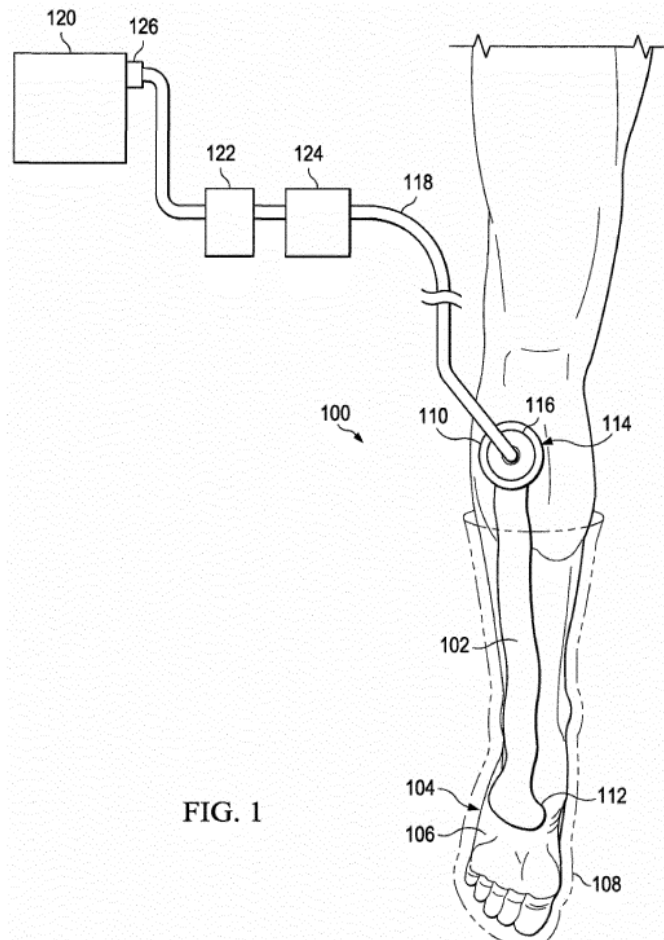
1. Subject-matter of the contested patent

1.1 The patent generally concerns treatment systems for reduced-pressure therapy. In this kind of therapy, reduced pressure is applied to a tissue site, for example a wound, in order to remove fluids that may exude from it and to promote faster healing and increased tissue growth (paragraph [0003]).

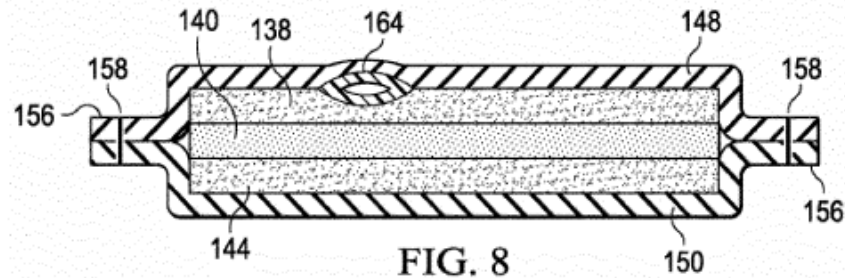
1.2 Applying reduced pressure may be problematic when access to the tissue site is limited, for example when the tissue site (104) is on the sole of a foot (106) covered by an orthopaedic device, such as an offloading boot (108) as illustrated in Figure 1 reproduced below. The patent aims at facilitating the application of reduced pressure in situations like this.

To this end, the patent provides a low-profile delivery-and-fluid-storage bridge (102) adapted to convey reduced pressure between a first longitudinal end (110), typically placed at a location with more convenient access (in this example, outside the offloading boot), where it can be coupled to a reduced-pressure source (120) via a reduced-pressure interface (116), and a second longitudinal end (112) placed in the vicinity of the tissue site (104) to be treated. Hence, in contrast to harder conventional tubings, reduced pressure can be applied to the tissue site even when using an orthopaedic device, without causing

undesirable pressure which could lead to the formation of ulcers. This increases patient comfort and enhances the reliability of the reduced-pressure supply (paragraphs [0015]-[0017] and [0019]).



- 1.3 As shown in the cross-section depicted in Figure 8 reproduced below, the delivery-and-fluid-storage bridge (102) comprises at least one delivery manifold (138, 144) extending along the length of the bridge for delivering reduced pressure through the bridge, and an absorbent layer (140) to receive and store wound exudates. Both are encapsulated between two encapsulating layers (148, 150) (paragraphs [0025] and [0029]).



1.4 In addition, the bridge further comprises a conduit (164) disposed between the encapsulating layers and extending along the length of the bridge, to facilitate the measurement of pressure proximate the tissue site and monitor pressure at the second longitudinal end (paragraphs [0034]-[0035]). The pressure measured at the second longitudinal end can be compared with the pressure at the reduced-pressure source to determine the pressure drop across the system and, in turn, the saturation of the bridge (paragraph [0035]).

2. Admittance of the main request

- 2.1 The main request is identical to the first auxiliary request filed by the respondent with its reply to the statement of grounds of appeal.
- 2.2 Pursuant to Article 12(4) RPBA 2007, which applies in this case by virtue of the transitional provisions of Article 25(2) RPBA 2020, without prejudice to the Board's power to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings, everything presented by the parties in the statement of grounds of appeal or reply to the statement of grounds must be taken into account by the Board if and to the extent it relates to the case under appeal and meets the requirements in Article 12(2) RPBA.

The main request at issue incorporates amendments aimed at overcoming the appellant's objections under Article 123(2) EPC raised in the statement of grounds of appeal (section 3). Since these objections had already been raised in the notice of opposition (points 12-16), the request could have been presented in the opposition proceedings and, as a consequence, the Board has the discretionary power to hold the request inadmissible.

- 2.3 The appellant argued that the Board should exercise its discretion and hold the request inadmissible, referring to decision T 725/18, in which the deciding Board did not admit into the appeal proceedings two requests that could have been filed in the opposition proceedings.

However, decisions - and discretionary decisions in particular - are based on the specific facts underlying each individual case. The facts underlying decision T 725/18, concerning an appeal against the revocation of a patent, are different from those underlying the appeal in this case, which is against the rejection of an opposition.

Since the opposition was rejected in the case in hand, the opposition division would not have decided on the request under consideration even if it had been filed as an auxiliary request in the opposition proceedings. Hence, submitting this request upon appeal had no impact on whether or not the Board could have reviewed a decision of the opposition division in this respect.

Furthermore, the amendments concerned are not technically complex and address the objections of added subject-matter without raising any new issues.

Lastly, the request was filed at the earliest possible stage of the appeal proceedings, namely with the reply to the statement of the grounds of appeal.

Under these circumstances, the Board decided to admit the main request.

3. Added subject-matter

3.1 In dispute between the parties is whether the feature of claim 1 whereby the conduit extends "from the first longitudinal end to the second longitudinal end" of the delivery-and-fluid-storage bridge is directly and unambiguously derivable from the application as filed, especially from paragraph [0042].

3.2 Paragraph [0042] discloses two alternative configurations of the conduit, namely that "the conduit 164 *could either terminate proximate the first longitudinal end 110 of the delivery-and-fluid-storage bridge 102 or could continue the longitudinal length 132 of the delivery-and-fluid-storage bridge 102 to the second longitudinal end 112*" (emphasis added by the Board).

While in the second configuration the conduit is explicitly disclosed as extending "to the second longitudinal end" as defined in claim 1, there is indeed no explicit disclosure of the location *from where the conduit extends*.

3.3 However, a plain reading of the sentence above shows that the conduit runs along the longitudinal length of the bridge *in the direction of the second longitudinal end*, as implied by the term "continue". Since, in the

second configuration, the conduit does not "terminate [at a location] proximate the first longitudinal end 110", but "continue[s]" from this location, the person skilled in the art understands that the location *from where the conduit extends* must necessarily be farther from the second longitudinal end than said location "proximate the first longitudinal end". The person skilled in the art therefore concludes that the conduit implicitly extends "from the first longitudinal end" of the delivery-and-fluid-storage bridge.

- 3.4 This conclusion is supported by the conduit's function of monitoring pressure at the second longitudinal end, disclosed in paragraphs [0042]-[0043] of the application as filed.

Paragraphs [0026]-[0027] disclose that the first longitudinal end is typically placed at a location with convenient access, for example outside an offloading boot, whereas the rest of the bridge may extend within the boot. The person skilled in the art therefore understands that the conduit for monitoring pressure at the second longitudinal end must extend at least from the first longitudinal end in order to fluidly couple said second longitudinal end to a location outside the boot that is suitable for accommodating a pressure feedback device, or a connection to that device.

- 3.5 Therefore, contrary to the appellant's argument, the Board concludes that the claimed feature whereby the conduit extends "from the first longitudinal end to the second longitudinal end" of the delivery-and-fluid-storage bridge is directly and unambiguously derivable from the application as filed. The requirements of Article 123(2) EPC are therefore met.

4. Lack of clarity

The clarity objections raised by the appellant do not convince the Board.

Regarding objection (a), the expression "from the first longitudinal end (110) to the second longitudinal end (112)" added in claim 1 clearly limits the definition of the conduit by specifying its extent *within the delivery-and-fluid-storage bridge*. The possibility that the conduit may not be entirely contained within the bridge is not excluded by this claim wording and does not result in a lack of clarity, contrary to the appellant's view.

Regarding objection (b), the person skilled in the art would clearly recognise from the wording of claim 1 that the expressions "a length of the delivery-and-fluid-storage bridge" in line 3 and "the longitudinal length of the delivery-and-fluid-storage bridge" in the last paragraph refer to the same length, namely the longitudinal length L of the bridge connecting the first and second longitudinal ends, as illustrated in Figure 2 (paragraphs [0019] and [0024]). This interpretation is also in line with the description of the patent as a whole, in which the only length disclosed is the longitudinal length L.

The Board therefore concludes that claim 1 is clear (Article 84 EPC).

5. Inventive step starting from D1 in combination with D2

5.1 It is common ground that D1 discloses the features of the preamble of claim 1, namely:

A reduced-pressure treatment system (see Figures 1 and 4 reproduced below) for applying reduced pressure to a tissue site on a patient, the reduced-pressure treatment system comprising:

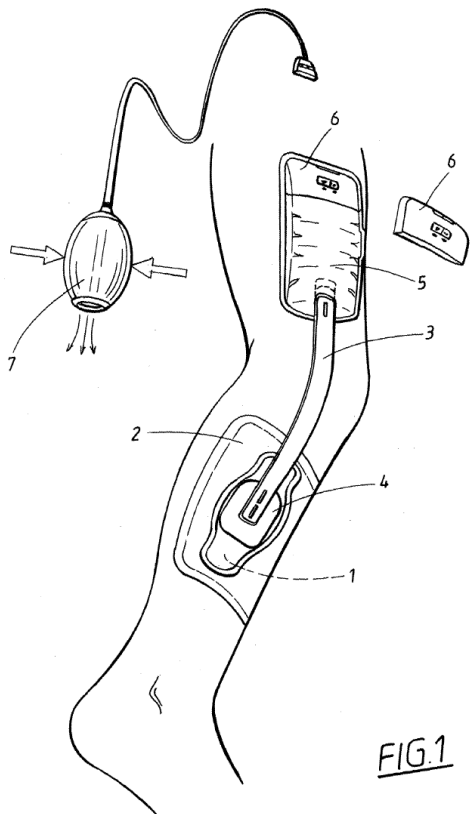


FIG.1

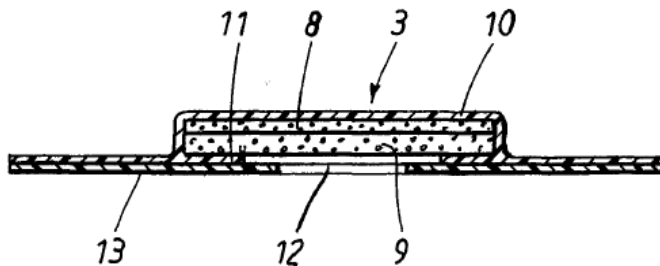


FIG.4

a reduced-pressure source (5, 6; page 11, lines 11-26) for supplying reduced pressure;

a treatment manifold (1; Figure 18) for placing proximate the tissue site and adapted to distribute reduced pressure to the tissue site;

a sealing member (2) for placing over the tissue site, wherein the sealing member is adapted to form a

fluid seal, and wherein the sealing member has a treatment aperture (16; Figure 5); and

a delivery-and-fluid-storage bridge (tube 3; page 10, lines 17-20) having a first longitudinal end (close to the collecting receptacle 5) and a second longitudinal end (4) and a first side and a second, patient-facing side (Figure 4), wherein the delivery-and-fluid-storage bridge at least partially fluidly couples the treatment manifold and the reduced-pressure source (page 10, lines 17-20), the delivery-and-fluid-storage bridge comprising:

a delivery manifold (8) extending along a length of the delivery-and-fluid-storage bridge (102) for delivering reduced pressure through the delivery-and-fluid-storage bridge (page 13, lines 10-12), the delivery manifold comprising a first material,

an absorbent layer (9) proximate the delivery manifold and adapted to receive, absorb, and store liquids within the delivery-and-fluid-storage bridge, the absorbent layer comprising a second material, and wherein the first material and the second material have differing properties (page 13, lines 14-15),

a first encapsulating layer and a second encapsulating layer at least partially enclosing the delivery manifold and the absorbent layer (page 12, line 12: "the tube casing consists of two plastics films made of a soft elastic plastic"),

wherein a first aperture (see e.g. opening shown in Figure 16; page 18, lines 30-31) is formed on the first side of the delivery-and-fluid-storage bridge proximate the first longitudinal end, the first aperture is fluidly coupled to the reduced-pressure source, and

wherein a second aperture (12) is formed on the second side of the delivery-and-fluid-storage bridge

proximate the second longitudinal end, the second aperture is fluidly coupled to the treatment manifold over the treatment aperture in the sealing member (Figure 18).

5.2 The subject-matter of claim 1 thus differs from the system known from D1 on account of *a conduit disposed between the first encapsulating layer and the second encapsulating layer, wherein the conduit extends along the longitudinal length of the delivery-and-fluid-storage bridge from the first longitudinal end to the second longitudinal end to facilitate measurement of pressure proximate the tissue site and to monitor pressure at the second longitudinal end of the delivery-and-fluid-storage bridge, as defined in the characterising portion of claim 1. This is not contested by the parties.*

5.3 Even if the appellant's formulation of the objective technical problem to be solved were accepted (i.e. how to apply reduced pressure while simultaneously monitoring the pressure being applied), the person skilled in the art starting from D1 would not have arrived at the claimed subject-matter without an inventive step.

5.3.1 As the appellant submitted, it is true that D2 discloses (Figure 1) a reduced-pressure treatment system which comprises, in addition to a first tube 101 for conveying reduced pressure to a porous dressing 102 at a wound site to be treated, a second tube 106 coupling the dressing to a pressure transducer 108 for monitoring the pressure at the wound site (paragraph [0031]). D2 further teaches that, instead of being a separate tube as illustrated in Figure 1, this second tube 106 can be conveniently combined with the first

tube 101 into a single multi-lumen tube, as disclosed in paragraphs [0035]-[0036] and illustrated in Figures 5F and 6E reproduced below (see reduced-pressure delivery lumen 127, 606 and pressure monitoring lumen 130, 607; paragraphs [0036]-[0038]).

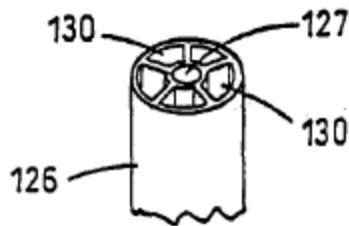


Fig. 5F

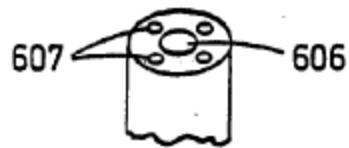


Fig. 6E

However, as pointed out by the appellant itself, D1 clearly describes the relatively rigid plastic tubing traditionally used in these treatment systems as being unsatisfactory for connecting the tissue site to the reduced-pressure source (page 3, lines 6-14), in view of the pressure points they may cause. This is why D1 provides the soft, padded bridge 3 as a replacement for that traditional tubing in the region of the treatment site, so as to avoid discomfort to the patient (page 4, lines 8-9; page 12, lines 29-31; page 24, lines 19-23).

The tubes disclosed in D2 thus belong to the very type of tubing that D1 recommends avoiding in the vicinity of the tissue site. For this reason, the Board is not convinced by the appellant's assertion that the person skilled in the art starting from D1 would have considered D2 for a solution to the formulated problem.

In this respect, it is irrelevant that D1 may contain implicit pointers towards monitoring pressure at the tissue site, as the appellant argued. Moreover, this view is not contradicted by the disclosure in D1 that the soft, padded bridge 3 may "[merge] into a

conventional silicone tube before it is coupled to the collecting receptacle" (page 24, last paragraph) - i.e. that the bridge 3 is compatible with existing hard silicone tubing, as argued by the appellant. This statement suggests at most that a conventional tube could be used in the connection region between the bridge and the collecting receptacle, where chafing issues are less critical. However, using a multi-lumen tube to connect the collecting receptacle to the bridge, while leaving the bridge unchanged, would clearly not solve the technical problem referred to above.

The appellant's inventive-step attack thus fails to convince the Board for this reason alone.

- 5.3.2 Furthermore, even if the person skilled in the art had considered D2, they would not have arrived at the subject-matter of claim 1 in an obvious manner.

On one hand, replacing the padded bridge 3 *as a whole* with a multi-lumen tube including a pressure monitoring lumen and a reduced-pressure delivery lumen as disclosed in D2 would have gone against the very teaching of D1 that this relatively rigid tubing should be avoided, as discussed in point 5.3.1 above. The person skilled in the art would therefore not have envisaged any such modification. Moreover, this would have destroyed the flat, low-profile encapsulated configuration of the padded bridge of D1, thus leading away from the claimed subject-matter.

On the other hand, without hindsight the person skilled in the art would not have been prompted by the particular designs of multi-lumen tubes disclosed in D2 to specifically include a pressure monitoring conduit

between the two encapsulating layers of the bridge of D1, i.e. *within the reduced-pressure delivery lumen*:

- (a) From the design of Figure 6E, according to which pressure monitoring lumens are "located within the walls" of a thick multi-lumen tube (paragraph [0037]), the person skilled in the art would not have extrapolated that this kind of monitoring conduit could be provided "within the walls" of the bridge of D1, i.e. within the thickness of the encapsulating layers, not least because the layers are formed of thin plastics films (page 12, line 12).

What is more, even if the person skilled in the art had done so, the resulting conduit would have been provided within the thickness of one of the encapsulating layers and not, as argued by the appellant, formed by attaching an additional sheet to the inner surface of said encapsulating layer. Therefore, the conduit would in no way have extended *between the two encapsulating layers*, i.e. within the delivery lumen of the bridge as required by claim 1. In this respect, the Board agrees with the respondent that Figure 8 of the contested patent shows the conduit 164 being located not "within the walls" of the bridge but rather within its lumen.

- (b) In the design of Figure 5F, the delivery lumen and the pressure monitoring lumens are merely juxtaposed. Hence, on this basis the person skilled in the art would at most have positioned an additional pressure monitoring conduit *outside* the layers of the bridge of D1 and thus would not have arrived at a bridge as defined in claim 1 either.

6. From the above considerations, the Board concludes that the subject-matter of claim 1 involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Claims: claims 1-13 of the main request filed with the submission dated 6 January 2021

Description: description of the patent specification

Drawings: drawings of the patent specification

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated