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Datasheet for the decision of 25 February 2025

Case Number: T 0126/23 - 3.2.02

Application Number: 16787539.2

Publication Number: 3365039

IPC: A61M1/00, A61M39/08

Language of the proceedings: EN

Title of invention:
WOUND DRESSING

Patent Proprietor:
ConvaTec Limited

Opponent:
Smith & Nephew, Inc.

Relevant legal provisions:
EPC Art. 123(2), 84, 54(2), 56
RPBA 2020 Art. 13(1)

Keyword:
Amendments - allowable (yes)
Claims - clarity (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0003/14

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Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0126/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 February 2025

Appellant: (Opponent)	Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 (US)
Representative:	HGF HGF Limited 1 City Walk Leeds LS11 9DX (GB)
Respondent: (Patent Proprietor)	ConvaTec Limited GDC First Avenue Deeside Industrial Park Deeside Flintshire CH5 2NU (GB)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 6 December 2022 concerning maintenance of the European Patent No. 3365039 in amended form.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	N. Obrovski

Summary of Facts and Submissions

I. The appeal was filed by the opponent against the interlocutory decision of the opposition division finding that the request before it designated auxiliary request 2 met the requirements of the EPC.

II. Oral proceedings before the board took place on 25 February 2025.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 15 as specified in its letter of 2 January 2025.

III. Claims 1 and 7 of the main request (i.e. the request found to meet the requirements of the EPC in the decision under appeal) read as follows:

"1. A negative pressure wound therapy dressing comprising a drainage tube (12), wherein the drainage tube comprises a tube (14) knitted or braided from a monofilament yarn characterized in that the tube knitted or braided from a monofilament yarn is surrounded by an impermeable sheath, wherein the impermeable sheath comprises one or more sheets (15a, 15b) of an impermeable material, wherein the knitted or braided tube is sandwiched between two sheets of the impermeable material, and the sheets are sealed

together at each side such that the knitted or braided tube is held between the sheets."

"7. A knitted or braided tube suitable for use in a negative pressure wound therapy dressing, wherein the tube is knitted or braided from monofilament yarn, one end of the tube is connectable to a body of the negative pressure wound therapy dressing, and the other end of the tube is attached to a connector by which the dressing can be coupled to a source of negative pressure, characterized in that the tube is surrounded by an impermeable sheath, wherein the impermeable sheath comprises one or more sheets (15a, 15b) of an impermeable material, wherein the knitted or braided tube is sandwiched between two sheets of the impermeable material, and the sheets are sealed together at each side such that the knitted or braided tube is held between the sheets."

IV. The following documents are relevant to the present decision:

D1 US 2010/0324516 A1
D2 WO 2011/087871 A2
D3 WO 2013/175306 A2
D4 WO 2009/002260 A1

V. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

Added subject-matter

Claims 1 and 7 comprised added subject-matter.

The original claim 5 did not provide a basis for an impermeable sheath comprising two sheets. The original

claim 6 did not refer to the sheath of the original claim 1 and thus could not provide a basis for the restriction that the sheath had to be comprised of two sheets of the impermeable material. Therefore, the only possible basis for claim 1 of the main request was on page 2, lines 26 to 32, of the application as filed. However, claim 1 represented an intermediate generalisation that resulted in added subject-matter because, firstly, this passage only provided a basis for an impermeable material formed of two sheets, whereas claims 1 and 7 of the main request encompassed both a single sheet and more than two sheets of impermeable material; and because, secondly, claims 1 and 7 of the main request did not specify that the sheets of the impermeable material surrounded the knitted or braided tube.

Claim 7 also comprised added subject-matter in relation to the feature "one end of the tube is connectable", because the application as filed did not suggest that the connection of the tube to the dressing was reversible.

Clarity

It was unclear whether claim 1 was intended to cover an arrangement in which the impermeable sheath comprised one sheet, two sheets or a plurality of sheets of impermeable material. Claim 1 encompassed the option of using a single sheet or multiple sheets of impermeable material to form the sheath while having the tube additionally sandwiched between two sheets provided within the sheath, especially as the specification stated that the sheath could have any suitable form. The modification of the article "an" to "the" when applied to the sheets of the impermeable material

fundamentally altered the interpretation of the claims. Moreover, the retention of the language of the granted claim 5 was redundant by virtue of the amendments derived from the features extracted from the description.

Novelty over D2

The appealed decision stated that a tube required at least one main through-going lumen inside an outer wall structure. This was incorrect, in particular because an outer wall structure was not a prerequisite for the tube of claims 1 and 7 in view of paragraph [0019] of the specification. Instead, a tube was a one-piece structure having a channel.

Claims 1 and 7 were not novel over D2. Three embodiments of D2 anticipated the subject-matter of these claims.

In the embodiment of Figure 15, the channel layer 1516 consisted of a wicking fabric suitable for channelling wound exudate away from the wound and also for transmitting negative pressure. Therefore, the channel layer 1516 was a one-piece structure having a channel and thus a "tube" as required by the independent claims.

In the embodiment of Figures 55A to 55J, the bridge 5502 was a drainage tube and the proximal end of the channel layer 5516 had a cylindrical shape and included a pre-made cavity that received the connector 5506. This proximal end of the channel layer 5516 was a hollow cylindrical structure that anticipated the tube comprised in the drainage tube.

The ovoid openings shown in Figure 56A and described in paragraph [0231] of D2 also anticipated a tube.

Inventive step starting from D1

The subject-matter of claims 1 and 7 was obvious when starting from D1, either from the embodiment of Figure 3 or from the embodiment of Figure 10B.

The embodiment of Figure 3 anticipated all of the features of claim 1 except that the sheath was made from two sheets. The problem solved was providing an alternative sheath or an alternative way of manufacturing the sheath.

D1 disclosed that the outer sleeve 32 could be fabricated from various polymer and elastomeric materials. These materials were generally provided in the form of a sheet, and it would be the most straightforward option to manufacture the outer sleeve 32 from two sheets. The connection to the wound dressing was not relevant to the manufacturing of the sheath. Hence, the subject-matter of claims 1 and 7 was obvious in view of D1 alone.

Claims 1 and 7 also lacked an inventive step in view of D1 (embodiment of Figure 3) in combination with D2, D3 or D4. D1 disclosed in the embodiment of Figure 10B an impermeable sheath having a layered structure, thus encouraging alternatives to the embodiment of Figure 3 of D1 and the use of a sheath such as that in D2, D3 or D4.

D2 described in the embodiment of Figures 55A to 55J a lower channel layer 5516 sandwiched between an intermediate layer 5514 and a bottom layer 5518. The

layers 5514 and 5518 were of impermeable material and were welded together during assembly. The attachment of the channel layer 5516 to the connector 5506 in Figure 55E of D2 was similar to the attachment of the conduit 30 to the connector 40 in D1.

D3 addressed similar problems to those addressed by D1 and disclosed a fluid passage constructed from flexible film layers, teaching that two film layers could be used as a sheath.

D4 disclosed in Figure 3 an impermeable sheath formed by two plastic films connected along the edges of the tube to form a casing. D4 emphasised the benefits of such a sheath in the context of pliability. The outer sleeve of D1 could readily be replaced with the casing of D4 without any modification. In D4, the connection to the wound dressing worked in the same way as the connection using an adhesive-coated thin film as mentioned in paragraph [0064] of D1.

Starting from the embodiment of Figure 10B of D1, paragraph [0075] of D1 disclosed that the elongate wick 104 could be constructed from the same materials as the conduit 30 and thus be formed as a knitted or braided tube such as that described in paragraph [0057] and shown in Figure 6D. In the embodiment of Figure 10B, the wick 104 was surrounded by the lining 103 and the wick cover 106, taking into account that "partly surrounding" fell within the scope of the claims. The embodiment of Figure 10B thus disclosed all of the features of claims 1 and 7 except possibly the use of a monofilament yarn. The use of monofilament yarns was part of common general knowledge, however, and did not involve an inventive step.

Rule 80 EPC

The amendment to include the features of the granted claim 5 was not occasioned by a ground for opposition if claim 1 only encompassed two sheets of impermeable material. Therefore, the main request did not comply with the requirements of Rule 80 EPC.

VI. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

Added subject-matter

Claim 1 was based on the original claims 1, 5 and 6 and on page 2, lines 26 to 32, of the application as filed. Claim 7 was based on the original claims 11, 15 and 16, and on the same passage of the application as filed. The person skilled in the art would understand that the sheets of impermeable material of the original claims 5 and 6 were the same sheets as the sheets of page 2, lines 26 to 32, of the application as filed. Moreover, claim 1 implicitly required that two sheets of impermeable material surrounded the tube; there was thus no intermediate generalisation.

As regards the term "connectable" in claim 7, the application as filed disclosed that the tube "will be connected" (page 3, lines 16 to 19), and there was no technical difference between the two.

Clarity

The addition of the subject-matter from page 2, lines 26 to 32, did not add any further lack of clarity not already present in the original combination of claims 1+5+6 as granted and claims 9+13+14 as granted.

Claims 1 and 7 of the main request recited the language of the granted claims exactly, except for the change of "an impermeable material" to "the impermeable material".

Novelty over D2

The subject-matter of claims 1 and 7 was novel over D2.

The normal meaning of a tube was a hollow cylindrical structure, and this meaning would be applied when interpreting the claims. This meaning was not negated by paragraph [0019] of the specification, which only described the structure of the material forming the outer wall of the tube.

The wicking fabric of the channel layer 1516 of Figure 15 was neither a hollow cylindrical structure nor had at least one main through-going lumen inside an outer wall structure. Therefore, it did not anticipate a tube.

The pre-made cavity in the layer 5516 of Figures 55A-J was an aperture, not a tube with openings at both ends.

The objection based on the ovoid openings of Figure 56A was late filed and should not be admitted into the proceedings.

Inventive step starting from D1

The subject-matter of claims 1 and 7 was inventive.

The embodiment of Figure 3 of D1 failed to anticipate several features. Even if only the distinguishing features of having the tube sandwiched between two

sheets and the sheets sealed together at each side were taken into consideration, and if it was assumed that these features merely provided an alternative sheath, the prior art still would not lead to the claimed invention.

D1 did not disclose the use of two sheets in the embodiment of Figure 3. The embodiment of Figure 10B related to a different arrangement serving a different purpose and did not comprise the two distinguishing features or provide any incentive to modify the device of Figure 3. Using two sheets in the embodiment of Figure 3 would also require further modifications. Therefore, the claimed solution was inventive over D1 (embodiment of Figure 3) alone.

D2 to D4 disclosed specific multi-layer arrangements and would not be combined with D1. In D1, the fibrous core extended into the wound dressing, unlike in D2 to D4. This resulted in differences in the way the sheath or outer layers were attached to the cover layer. The layers of each of D2 to D4 comprised other features, e.g. an upper layer with an air leak in D2; an orifice and an enlarged circular shape in D3; two inner strands of different material and a widened portion for attachment to the sealing film in D4. There were thus incompatibilities between D1 and each of D2 to D4.

As to the objection starting from the embodiment of Figure 10B of D1, D1 did not disclose that the elongate wick 104 was a tube, let alone a tube knitted or braided from a monofilament yarn. The reference to paragraph [0075] related to the materials, but D1 did not disclose the combination of Figure 10B with the arrangement of Figure 6D. Moreover, in the embodiment of Figure 10B, the lining 103 was only partially along

the elongate wick 104. Thus, the elongate wick 104 was neither surrounded by an impermeable sheath nor sandwiched between two sheets of impermeable material such that it was held between the sheets.

Rule 80 EPC

The objection under Rule 80 EPC should not be admitted into the proceedings. It could and should have been raised during the first-instance proceedings.

Reasons for the Decision

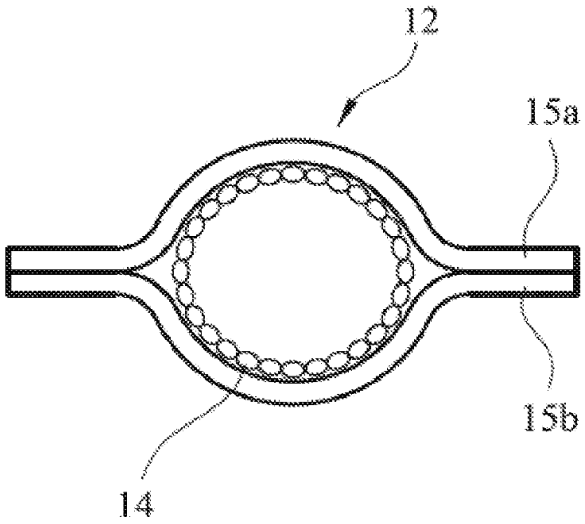
1. Patent

1.1 The opposed patent relates to wound dressings for negative pressure therapy.

1.2 Such dressings typically use a drainage tube connected to a negative pressure source, allowing the wound fluid to be drawn away. The patent addresses the shortcomings of conventional plastic tubes, such as the limited flexibility and resiliency thereof (see paragraphs [0002] and [0006] of the specification).

1.3 The patent has two independent claims. The first is directed to a negative pressure wound therapy dressing comprising a drainage tube, and the second to a knitted or braided tube suitable for use in a negative pressure wound therapy dressing.

1.4 Figure 2 of the specification, which is reproduced below, shows a cross-sectional view of a drainage tube 12, formed of a knitted tube 14 that is sealed between two sheets 15a, 15b of impermeable material.



2. Main request - Article 123(2) EPC

2.1 Claim 1 of the main request is based on the original claims 1, 5 and 6 and on page 2, lines 26 to 32, of the application as filed, the latter passage providing a basis for the feature "the sheets are sealed together at each side such that the knitted or braided tube is held between the sheets". Claim 7 is based on the original claims 11, 15 and 16 and the same passage of the application as filed.

2.2 The appellant argued that if page 2, lines 26 to 32, of the application as filed were considered as a possible basis, then claims 1 and 7 of the main request represented an unallowable intermediate generalisation due to the omission of two restrictions, namely that the sheets of the impermeable material surround the tube and that there are exactly two sheets surrounding the tube.

The board holds that the first alleged omission (that the sheets of impermeable material surround the tube) results from an incorrect claim construction. When

interpreting claims 1 and 7 of the main request in a technically meaningful manner, it is immediately apparent that the "sheets" of the feature "wherein the knitted or braided tube is sandwiched between two sheets of the impermeable material" are the same sheets that are "sealed together" and are "sheets of an impermeable material" comprised in the impermeable sheath previously defined in claim 1. This interpretation is further supported by, for example, paragraphs [0013], [0018] and [0030] of the patent specification; notably, the specification does not deal with sheets that are *not* comprised in the sheath.

Claims 1 and 7 require the tube to be surrounded by an impermeable sheath and sandwiched between two sheets (of the sheath) and the (two) sheets to be sealed together at each side such that the tube is held between the sheets, thus implying that the sheets of the impermeable material surround the tube. The allegedly omitted feature is therefore implied by claim 1.

As regards the allegedly omitted restriction to exactly two sheets, which the appellant derived from the expression "formed of two sheets" on page 2, line 30, the board holds that this does not result in added subject-matter either. This is because the feature added to claim 1, of the sheets being sealed together at each side such that the tube is held between the sheets, is not inextricably linked to having exactly two sheets forming the sheath, as other sheets can be included while maintaining this construction.

2.3 In connection with claim 7, the appellant argued that the application as filed did not disclose that one end of the tube is "connectable" to a body of the dressing.

However, page 3, lines 16 to 17, of the application as filed discloses that one end of the tube "will be connected", thereby implying that one end of the tube is connectable. Both this passage and the subsequent paragraph leave open whether or not the connection is reversible. There is thus no added subject-matter in connection with the term "connectable" in claim 7.

2.4 It follows that the main request complies with Article 123(2) EPC.

3. Main request - Article 84 EPC

3.1 The appellant submitted that it was unclear whether claim 1 covered an arrangement in which the impermeable sheath comprised one sheet, two sheets or a plurality of sheets of impermeable material. According to the appellant, this lack of clarity had been introduced because claim 1 expressly required the sheets to form components of the impermeable sheath.

However, claim 5 as granted already includes this requirement. By virtue of the dependency of the granted claim 6 on the granted claim 5, the alleged lack of clarity would already have been present in claim 6 as granted. Furthermore, the alleged lack of clarity regarding the number of sheets is not altered by modifying the term "an impermeable material" (in the granted claim 6) to "the impermeable material" (in claim 1 of the main request); nor is it altered by the amendment based on the description indicating that the sheets are sealed together, an amendment that only details how the two sheets that sandwich the tube (i.e. the two sheets of the original claim 6) are arranged.

Hence, the alleged lack of clarity may not be examined (see the order of G 3/14).

3.2 The appellant also argued that the retention of the language of the granted claim 5 ("one or more sheets") was redundant in view of the required sealing arrangement using two sheets, thus resulting in a lack of compliance with Article 84 EPC.

For the reasons noted in relation to claim 1 of the main request in section 2.2 above, the sheets of claim 6 as granted are to be construed as sheets of the sheath. Since claim 6 as granted requires "two sheets", the alleged redundancy was already present in the combination of claims 5 and 6 as granted, and therefore this issue may not be examined either.

3.3 As regards the dependent claims 5 and 11 of the main request, the appellant asserted that, by virtue of dependency, the feature "the impermeable sheath is a polyurethane sheath" was limited to a single sheet of impermeable material and therefore caused a lack of clarity.

Claims 7 and 15 as granted include the feature "the impermeable sheath is a polyurethane sheath". Claim 7 as granted depends on any preceding claim and thus also on claim 6 as granted, which requires two sheets which, as noted above, are sheets of the sheath. Hence, the alleged lack of clarity in claim 5 of the main request due to the dependency is also present in claim 7 as granted (as far as it depends on claim 6) and therefore cannot be examined. Likewise, the alleged lack of clarity in claim 11 of the main request is also present in claim 15 as granted (as far as it depends on

claim 14) and therefore this issue may not be examined either.

3.4 In summary, none of the objections raised under Article 84 EPC can be examined.

4. Main request - novelty over D2

4.1 Embodiment of Figure 15

4.1.1 The appellant argued that the channel layer 1516 of Figure 15 is a tube within the meaning of claims 1 and 7.

The channel layer 1516 is a substantially flat and elongate layer/piece of wicking fabric, e.g. a knitted polyester 3D fabric (page 31, paragraph [0152]). Such a piece of wicking fabric does not anticipate a tube.

The appellant argues that a tube within the meaning of the claims does not need to have a through-going lumen inside an outer wall structure, referring to a passage of paragraph [0019] of the specification to support this argument.

This passage of paragraph [0019], in the general part of the description, states that pressure may be applied through the material of the tube, which in the tube 14 shown in Figure 2 would be through the material/wall of the tube 14. This, however, does not modify the meaning that a person skilled in the art would assign to the term "tube" in the context of the specification.

The definition of "tube" indicated by the appellant, namely a one-piece structure having a channel, is too broad and includes structures such as a piece of foam,

which cannot be considered to be a tube. This is the case for the channel layer 1516, which is a foam-like structure which, despite its ability to channel fluids through it, cannot be considered a tube within the meaning of claims 1 and 7.

Therefore, the channel layer 1516 of D2 does not anticipate a tube within the meaning of claims 1 and 7.

4.2 Embodiment of Figures 55A to 55J

4.2.1 Figures 55A to 55J relate to a system with a multi-layer bridge 5502. The appellant stated that a portion of the lower channel layer 5516 anticipated a tube within the meaning of claim 1, namely the portion of its distal end shown in Figure 55E, which has a substantially cylindrical shape and includes an opening ("pre-made cavity" in the second sentence of paragraph [0222]) to accommodate the channel connector 5506.

As noted by the respondent, the pre-made cavity is an aperture, and the distal end portion with the cavity does not have openings at either end. Indeed, the cavity formed in the layer 5516 is a blind hole of limited depth that is used to receive a connector, rather than a through-hole passing completely through the material of the layer 5516. Making a blind hole in a material does not result in a tube, just as a coffee mug would not be considered a tube even if it is cylindrical and hollow. This is true even if the walls of the cavity are made of a material permeable to the liquids, like the layer 5516 of D2.

The distal end of layer 5516 with such a blind hole can therefore not be regarded as anticipating a tube within

the meaning of claims 1 and 7. Hence, the objection is not convincing.

4.3 Embodiment of Figure 56A

4.3.1 With its letter dated 26 January 2024, the appellant argued that the ovoid openings shown in Figure 56A and described in paragraph [0231] of D2 anticipated a tube.

This represents a new line of argument supported by new facts. Contrary to what is required under Article 13(1), third sentence, RPBA, the appellant did not provide any reasons for submitting this amendment at such a late stage of the appeal proceedings, nor is any such reason apparent to the board. The board has thus decided not to admit this amendment under Article 13(1) RPBA.

4.4 In summary, none of the objections relating to a lack of novelty prejudices the maintenance of the patent on the basis of the main request.

5. Main request - inventive step starting from D1

5.1 Starting from the embodiment of Figure 3

5.2 D1 discloses in the embodiment of Figure 3 (or, to be more precise, in the embodiment of Figures 1, 3 and 6D) a negative pressure wound therapy dressing having an exudate conduit 30 with an outer sleeve 32 defining a lumen 33. A fibrous core 38 is disposed within the lumen 33. According to the appellant objection, regards the fibres enclosed as outer bundle 46d as illustrated in Figure 6D corresponded to the tube within the meaning of claim 1, and the outer sleeve 32 corresponded to the sheath.

5.3 It is common ground that this embodiment does not disclose the outer sleeve 32 as being manufactured from two sheets. Therefore, it at least does not disclose the features that "the knitted or braided tube is sandwiched between two sheets of the impermeable material" and "the sheets are sealed together at each side such that the knitted or braided tube is held between the sheets".

5.4 The problem to be solved by these features can be considered to be to provide an alternative sheath/ sleeve.

5.5 The appellant argued that the subject-matter of claims 1 and 7 was obvious in view of D1 alone.

D1 discloses in paragraph [0046] that the outer sleeve 32 may be fabricated from flexible polymer and/ or elastomeric materials. The appellant asserted that since these materials were generally provided in the form of a sheet, it would be obvious to manufacture the outer sleeve 32 from two sheets.

This assertion is speculative and not supported by any evidence. The aforementioned materials can be provided in different forms, e.g. as pellets. In the absence of any indication or incentive to do so in D1, the person skilled in the art would not manufacture the outer sleeve 32 from two sheets sealed together at each side. Moreover, the conduit 30 of D1 is shown to have a curved cross-section, without any sharp edges on its outer part (see, for example, Figures 3 and 7). Making the outer sleeve 32 from two sheets sealed together at each side would result in a different cross-section, comparable to that of Figure 3 of D4, and would thus

require further modifications, for example to the attachment of the conduit 30 to the connector 40 as shown in Figure 3. It follows that the objection relating to a lack of inventive step in view of D1 alone is not convincing.

5.6 The appellant submitted that the subject-matter of claims 1 and 7 lacked an inventive step in view of D1 in combination with D2, D3 or D4.

5.6.1 In D1, the conduit 30 is bent before its proximal end 34 to allow its insertion through the cover layer 24 so that the fibres 42 can extend in the insertion direction from the proximal end 34 into the reservoir 14 (see Figures 1, 3 and 7; see also the last sentence of paragraph [0049] and the first sentence of paragraph [0064]; paragraph [0064] is erroneously referred to in the minutes of the oral proceedings before the board as paragraph 62).

5.6.2 Each of D2 to D4 discloses a negative pressure wound therapy device having a flat layered/laminated structure for transmitting reduced pressure. The structures of D2 to D4 comprise one or more fibrous inner layers, but neither this fibrous inner layer nor any other part of the structure is inserted through the dressing's cover layer. Instead, in each of D2 to D4, the fluid connection to the dressing is achieved by having the layered structure with the fibrous inner layer overlaying an opening formed in the dressing's cover layer (see Figure 55D of D2, Figure 1B of D3 and Figure 4 of D4).

Although they serve substantially the same purpose as the conduit 30 of D1, the structures of D2 to D4 and their connection to the respective wound dressing are

different from the conduit 30 and its connection to the wound dressing 12. These differences are also reflected in the respective sleeves/sheaths. The outer sleeve 32 of D1 radially covers the fibrous core 38 without any variation along the length of the sleeve 32. Instead, the outer layers of the laminated structures of D2 to D4 are provided with features for their intended use, such as openings at certain locations and variations of shape/width along its length (see, for example, D2: Figure 55D and paragraphs [0221] and [0224]; D3: Fig. 5C and B35; D4: Figures 2 and 4 and page 12, lines 15 to 20).

5.6.3 Replacing the outer sleeve 32 would require further adaptations to result in a functional conduit and connection in the system of D1. For instance, if it were replaced by the outer layers disclosed in any of D2 to D4, it would not be apparent how the insertion through the dressing's cover layer in the manner contemplated by D1 would work (see, for example, Figure 1), nor what would happen with the enlarged portions of the outer layers of D2 to D4.

5.6.4 In support of the combination of D1 with any of D2 to D4, the appellant submitted that D1 also disclosed in the embodiment of Figure 10B a layered structure.

However, D1 does not disclose using the layered structure of Figure 10B for the conduit of Figure 3. Instead, that embodiment only describes an alternative way to establish fluid communication between a fluid conduit 54 and a wick 104 of a bridging dressing 102. Hence, the disclosure of Figure 10B is not relevant to the assessment of whether or not the person skilled in the art would have considered the teaching of D2 to D4 when modifying the outer sleeve 32 of D1.

5.6.5 In support of the combination of D1 with D2 (i.e. with the sheath said to be formed by the layers 5514 and 5518 of the embodiment of Figures 55A to 55J), the appellant argued at the oral proceedings that the attachment of the channel layer 5516 to the connector 5506 in Figure 55E of D2 was similar to the attachment of the distal end 36 to the connector 40 in D1.

However, there are relevant differences between D1 and D2 as regards the attachment to the respective connectors, particularly in the part which is most relevant to the objection, namely the sheath. In D2, the layers 5514, 5516 and 5518 change shape in the region approaching the connector 5506, which is sandwiched between the layers 5514 and 5518 which extend well beyond the end of the channel layer 5516 and the connector 5506 (see Figure 55E of D2). Meanwhile, in D1, the conduit 30 and its outer sleeve 32 do not change as they approach the connector 40 (see Figures 1 and 7 of D1), which is provided after the end of the conduit 30 and its outer sleeve 32.

5.6.6 In support of the combination of D1 with D4, the appellant argued at the oral proceedings that the outer sleeve 32 of D1 could readily be replaced with the casing 10 of D4 without any modification.

The board is not persuaded by this argument. Firstly, D4 describes the side of the tube 3 which is closer to the wound, but no details are given about the other side of the tube. The different cross-section resulting from the two films forming the casing 10 (see Figure 3

of D4) would require modifications for the attachment of the conduit 30 to the connector 40 of D1.

As regards the connection to the wound dressing, in D4 the underside of the casing 10 is provided with a bonding agent 13 in the widened portion 4 surrounding the opening 12, so that it can be attached to the upper side of the sealing film 2 (see D4, Figures 1 to 4, and page 12, lines 15 to 20). This construction works in D4 because the tube 3 rests on the upper surface of the sealing film 2 and this contact surface can be used for the attachment. In D1, the conduit 30 does not lie on top of the cover layer 24 but is instead inserted through it, for example using a thin film to seal the connection as disclosed in paragraph [0064].

If, in the conduit 30 of D1, the outer sleeve 32 were replaced with the casing 10 of D4, the modified conduit (hereinafter referred to as 30') would not work without further modifications. If an attempt was made to insert the end of the modified conduit 30' through the cover layer 24 as shown in Figure 1 of D1, this would be precluded by the widened portion 4 of the casing that would surround the end of the conduit 30'. Moreover, having such a widened portion 4 with adhesive inserted within the cover layer 24 would make no sense in any case.

5.6.7 For the reasons set out above, the person skilled in the art starting from D1 would not consider replacing the outer sleeve 32 of D1 with the sheath (i.e. outer layers) of any of the structures of D2 to D4.

6. Main request - inventive step in view of D1 alone (embodiment of Figure 10B)

6.1 Figure 10B shows an alternative embodiment to the bridging dressing 102 of Figure 10A used to provide fluid communication from the wound "w" to a remote location "r" without the use of a fluid port to receive the conduit 54. The embodiment of Figure 10B includes, *inter alia*, a lining 103, an elongate wick 104 and a wick cover 106a.

6.2 The appellant argued that the wick 104 anticipated the tube of claim 1, and that the wick cover 106 and the lining 103 anticipated the sheath. The appellant submitted that the use of a monofilament yarn was the only conceivable difference between claim 1 and the embodiment of Figure 10B (see point 8.19 of the appellant's letter of 26 January 2024).

The board does not share the appellant's assessment and agrees with the respondent that further features of claim 1 are not disclosed in the embodiment of Figure 10B.

D1 does not disclose implementing the wick 104 of Figure 10B with the particular construction shown in Figure 6D (i.e. as a "tube"). The appellant refers to paragraph [0075] which discloses, in connection with Figure 10A, that the wick 104 "may be constructed from materials suitable for use as ... exudate conduit 30". This can be taken as a reference to the materials listed in paragraph [0054]. However, there is no reference to the fibre bundle arrangements of Figures 6A to 6J, let alone to the particular arrangement of Figure 6D. Hence, even taking into account the disclosure in paragraph [0075], the wick 104 in the embodiment of Figure 10B does not anticipate a tube.

With respect to the sheath, the appellant submitted that in the embodiment of Figure 10B the wick was surrounded by the lining 103 and the wick cover 106. However, Figure 10B defines an alternative only for the part of Figure 10A on the left, showing the fluid port 55. This is clear from the curved sign used on the right-hand side of Figure 10B, together with the first sentence of paragraph [0081]. That is, the embodiment of Figure 10B includes the arrangement shown on the right-hand side of Figure 10A. It can be seen on Figure 10A that the lining 103 stops before the contact layer 18 and that a substantial part of the wick 104 extends beyond the lining 103. Therefore, the embodiment of Figure 10B does not disclose the feature that the wick 104 is "surrounded" by a sheath, nor that the wick is "sandwiched" between the sheets 103, 106a, or that the sheets 103, 106a are sealed together at each side such that the wick is "held between the sheets".

6.3 There are thus several additional distinguishing features in addition to the distinguishing feature identified by the appellant. It follows that the objection relating to a lack of inventive step in view of the embodiment of Figure 10B of D1 alone is not convincing.

7. Main request - admittance of the objection relating to a lack of compliance with Rule 80 EPC

7.1 With its letter dated 26 January 2024, the appellant raised a new objection under Rule 80 EPC.

Contrary to what is required under Article 13(1), third sentence, RPBA, the appellant did not provide any reasons for submitting this amendment at such a late stage of the appeal proceedings, nor is any such reason apparent to the board. Moreover, this amendment is not suitable for resolving the issues raised for lack of *prima facie* relevance. The inclusion of claims 5 and 6 as granted (noting that claim 6 depends on claim 5) has a limiting effect and is thus occasioned by a ground for opposition.

The board has therefore decided not to admit the objection under Article 13(1) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated