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Datasheet for the decision of 25 June 2021

Case Number: T 2410/17 - 3.2.02

Application Number: 09721153.6

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Language of the proceedings: EN

Title of invention:
VACUUM PORT FOR VACUUM WOUND THERAPY

Patent Proprietor:
Smith & Nephew, Inc.

Opponent:
KCI Licensing, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Prior art disclosure erroneous (no)
Novelty
Inventive step

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
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Case Number: T 2410/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 June 2021

Appellant: (Opponent)	KCI Licensing, Inc. 12930 IH-10 West San Antonio TX 78249 (US)
Representative:	K. Cordina Simmons & Simmons City Point One Ropemaker Street London EC2Y 9SS (GB)
Respondent: (Patent Proprietor)	Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 (US)
Representative:	H. M. Chung A. Hines S. Turberville HGF 1 City Walk Leeds LS11 9DX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 October 2017 rejecting the opposition filed against European patent No. 2254647 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	W. Sekretaruk

Summary of Facts and Submissions

I. The appeal was filed by the opponent against the Opposition Division's decision to reject its opposition against the contested patent.

II. In this decision the Opposition Division had found, *inter alia*, that the subject-matter of claim 1 of the patent as granted was new and involved an inventive step over the document US 2007/0167926 A1 (D3).

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 appeal be dismissed and that the patent be maintained as granted (main request) or, as an auxiliary measure, that the patent be maintained in amended form on the basis of the claims of auxiliary request 1 or 2, both filed on 8 January 2021. An amended description adapted to the claims of auxiliary request 1 was filed during the oral proceedings before the Board held on 25 June 2021.

V. Claim 1 of the **main request** (claim 1 as granted) reads as follows:

A wound dressing (16) for use in a vacuum wound therapy treatment comprising:

a cover layer (44) for positioning over a wound (W) to define a reservoir in which a reduced pressure may be maintained over the wound (W);

a portal member (30,30A,30B) for securement to an outer surface of the cover layer mounted relative to an aperture (56) in the cover layer (44), the portal member (30,30A,30B) defining a fluid passage for fluid coupling with a reduced pressure supply conduit (24) for creating the reduced pressure within the reservoir, wherein the aperture (54,56) in the cover layer permits fluid communication between the reservoir and the reduced pressure supply conduit (24); and
a filter screen (58,58A,59,60) incorporated into the portal member (30,30A,30B) and mounted relative to the fluid passage, the filter screen (58,58A,59,60) dimensioned to minimize passage of tissue particles of predetermined dimension through the fluid passage of the portal member (30,30A,30B).

VI. Claim 1 of **auxiliary request 1** additionally comprises the following features:

a filler (38), wherein the filler (38) comprises an absorbent material configured to collect wound exudate; and
a contact layer (34 configured to be in direct contact with the wound (W) and to allow fluids to pass through.

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

Main request - novelty over D3

The wound dressing disclosed in Figure 1 of D3 comprised all the features of claim 1 as granted. In particular, film 17 was explicitly disclosed in paragraph [0421] as being "fluid-impermeable" so that it constituted a cover layer within the meaning of claim 1, adapted to define a reservoir in which a

reduced pressure may be maintained over the wound. Contrary to the respondent's allegation, there was no reason to suspect an error in paragraph [0421]. In particular, the fact that film 17 was fluid-impermeable did not prevent the embodiment of Figure 1 from working as described. This embodiment was based on a completely different fluid circulation scheme compared to the embodiment of Figure 2, for which film 17 had to be porous. In the embodiment of Figure 1, fluid impermeability of film 17 was even desirable to avoid exudate remaining trapped in foam 18, which would prejudice the removal and treatment of wound exudate aimed at by the device. The subject-matter of claim 1 was therefore not new over D3.

Auxiliary request 1 - novelty over D3

D3 disclosed in paragraph [0132] that it could be advantageous to limit the remaining wound space under the backing layer with a filler. According to paragraph [0135], a suitable filler could be a foam, such as the resilient foam 41 described for the embodiment of Figure 7. In this embodiment, the foam was separated from the wound bed by a fluid-permeable contact layer 6 (paragraphs [0441]-[0442]).

In view of the wording of paragraph [0132], this disclosure did not apply only to the embodiment of Figure 7, but applied to all the embodiments of D3, including that of Figure 1. Thus, a filler and a contact material as defined in claim 1 were implicitly disclosed in D3 in combination with the other features of the wound dressing of Figure 1. The subject-matter of claim 1 was therefore not new over D3.

Auxiliary request 1 - inventive step in view of D3

If the subject-matter of claim 1 were found to be new over D3, similar arguments as those put forward in the novelty attack showed that it did not involve an inventive step.

Indeed, the filler and the contact layer (which were the only differentiating features of claim 1) solved two independent partial technical problems: to avoid voids in the wound chamber and to provide a suitable contact layer with the wound. The person skilled in the art starting from the embodiment of Figure 1 would have found obvious solutions to these problems in the passages of D3 cited in the novelty attack and would have therefore arrived at the subject-matter of claim 1 without exercising an inventive step.

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

Main request - novelty over D3

The person skilled in the art considering D3 as a whole would have understood that the disclosure in paragraph [0421] that the film 17 was fluid-impermeable was manifestly erroneous. In particular, making the film 17 fluid-impermeable would prevent the wound dressing from being resiliently deformable and conformable as it should be. The person skilled in the art would have instead understood from the whole disclosure of D3 that the film had in fact to be porous, as consistently disclosed for all the other embodiments, especially those of similar construction (for example the dressing shown in Figure 2). The subject-matter of claim 1 was therefore new over D3.

Auxiliary request 1 - novelty over D3

Paragraphs [0132] and [0135] concerned only wound dressings of the type shown in Figures 5-7 and 10, where cleansing means were formed as a conformable cleansing chamber containing a cleansing fluid and specifically designed to remain in close vicinity of the wound bed. For example, in the embodiment of Figure 7, cleansing fluid contained in the chamber was repeatedly moved in and out of the chamber by squeezing the latter against the wound bed via a rigid dome 50. A filler enclosed within the cleansing chamber enabled it to remain in close contact with the wound bed, which was desirable for this type of dressing.

By contrast, the wound dressings shown in Figures 1-4 had a very different construction. The cleansing chamber was instead confined within a central boss 11 (paragraph [0420]) and consistently shown in the figures with a space between the film 17 and the wound bed left unfilled. Wound exudate was sucked into the cleansing chamber.

Hence, paragraphs [0132] and [0135] did not apply to the embodiment of Figure 1. A filler and a contact layer were therefore not directly and unambiguously disclosed in combination with the embodiment of Figure 1. It resulted that the subject-matter of claim 1 was new over D3.

Auxiliary request 1 - inventive step in view of D3

For similar reasons as put forward in support of novelty, the person skilled in the art considering D3 would not have applied the teaching of paragraphs [0132] and [0135] to the embodiment of Figure 1. This

would have made no technical sense. In particular, a filler comprising an absorbent material configured to collect wound exudate would have prevented exudate from being sucked into the cleansing chamber and treated as described in D3. This would have reduced the effectiveness of the exudate treatment. Thus, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. **Subject-matter of the patent**

The patent relates to a wound dressing for use in a vacuum wound therapy treatment. In such a treatment, reduced pressure is applied to a wound to remove fluids exuding from the wound (wound exudate) and promote faster healing and increased tissue growth (paragraphs [0003]-[0004]).

A wound dressing (16) according to claim 1 of the patent as granted is illustrated in Figure 1 reproduced below. It comprises a cover layer (44) to be adhered over the wound (W) to create a reservoir in which a reduced pressure may be maintained, and a portal member (30) secured to the cover layer which defines a fluid passage between the reservoir and a reduced pressure supply conduit (24) (paragraph [0016]). A filter screen (58, 59, 60) is incorporated into the portal member to inhibit the migration of large tissue particles through the portal member, which may otherwise create a restriction or blockage of the reduced pressure supply conduit (paragraph [0019], Figure 8).

In the illustrated embodiment, the wound dressing further includes a filler (38) comprising an absorbent

material to collect wound exudate (paragraphs [0023], [0025]). The filler is separated from the wound bed by a contact layer (34) allowing fluids to pass through (paragraphs [0023], [0024]).

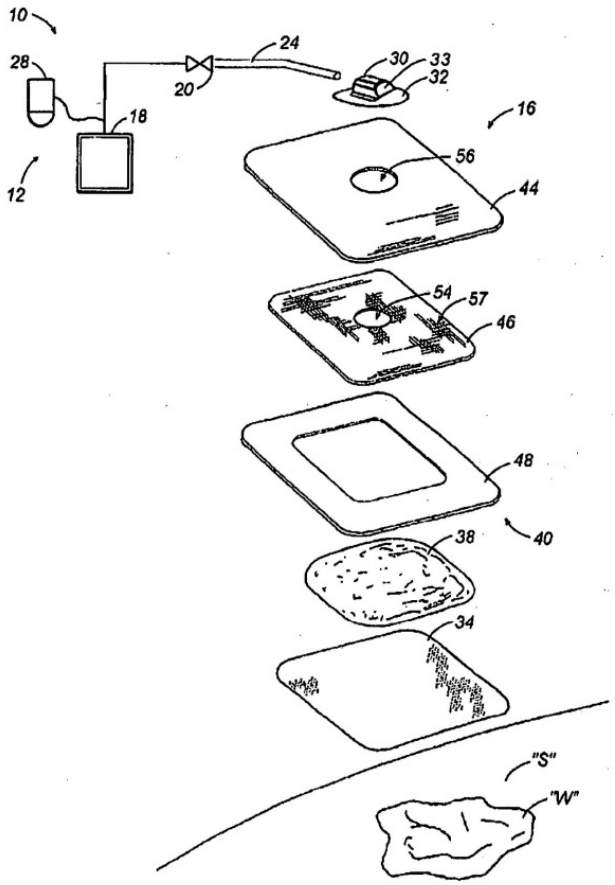

FIG. 1

2. **Main request - novelty over D3**

2.1 It is not disputed between the parties that Figure 1 of D3, reproduced below, discloses:

a wound dressing (paragraph [0002]) *for use in a vacuum wound therapy treatment* (syringe 7 is adapted to apply a reduced pressure to the wound site) *comprising:*

- a cover layer for positioning over a wound (film 17 attached to the boss 11; paragraph [0421]);

- *a portal member* (boss 11) *for securement to an outer surface of the cover layer* (Figure 1) *mounted relative to an aperture* (necessarily provided) *in the cover layer, the portal member defining a fluid passage for fluid coupling with a reduced pressure supply conduit* (pipe 19 connecting the boss 11 with syringe barrel 20; paragraph [0422]) *for creating the reduced pressure within the reservoir* (as the syringe piston 22 is being withdrawn; paragraph [0423]), *wherein the aperture in the cover layer permits fluid communication between the reservoir and the reduced pressure supply conduit* (implicit)*; and*

- *a filter screen* (porous film 12, permeable membrane 13; paragraph [0420]) *incorporated into the portal member and mounted relative to the fluid passage, the filter screen dimensioned to minimize passage of tissue particles of predetermined dimension through the fluid passage of the portal member* (paragraphs [0148], [0151]).

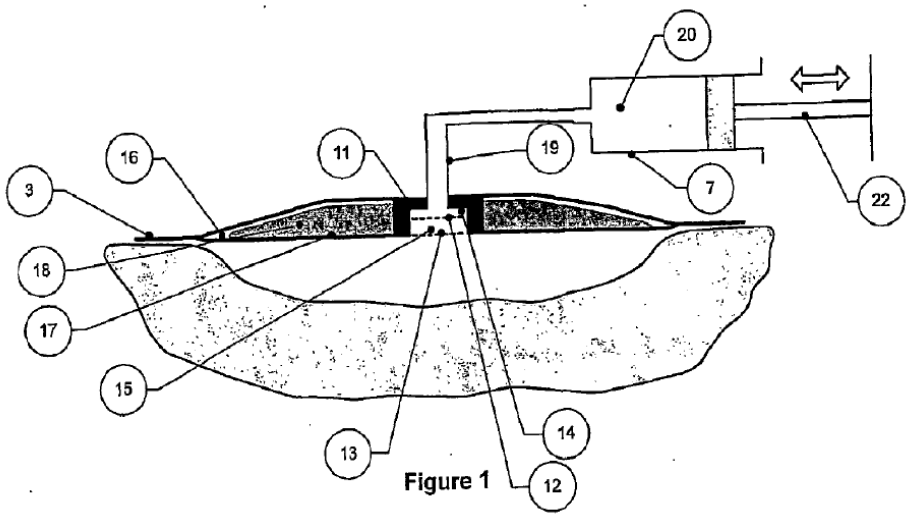

Figure 1

2.2 As argued by the appellant, the film 17 is explicitly disclosed in paragraph [0421] as being fluid-impermeable. This makes it adapted to *define a*

reservoir in which a reduced pressure may be maintained over the wound, as required by claim 1.

2.3 The respondent contested this view, arguing that the disclosure of paragraph [0421] was manifestly erroneous. The person skilled in the art considering D3 as a whole would have recognised this and understood that the film 17 could not be fluid-impermeable, but was in fact porous as consistently disclosed for the other embodiments (especially those of similar construction illustrated in Figures 2-4, 8, 9; see for example paragraphs [0427], [0429] and [0440], which all refer to "the porous film (17)").

2.4 The respondent's argument does not convince the Board, which sees no reason to regard the disclosure of paragraph [0421] as erroneous.

2.4.1 The respondent submitted that, if the film 17 were fluid-impermeable as disclosed in paragraph [0421], the annular chamber 16 enclosing foam 18 would form an incompressible sealed unit, which would prevent the wound dressing from being resiliently deformable and conformable as it should be (paragraph [0028]). Therefore, the film 17 could not be fluid-impermeable as a matter of technical reality.

The Board disagrees.

Firstly, given that the backing layer 3 itself is disclosed as "capable of forming a relatively fluid-tight seal or closure" over the wound (paragraph [0070]), applying the respondent's argument to the sealed cavity formed under the wound dressing would lead to the same conclusion that the conformability of the wound dressing is prejudiced (irrespective of the

nature of the film 17). This conclusion is clearly in contradiction with the disclosure of D3.

Secondly, while the behaviour mentioned by the respondent might be observed if the annular chamber were inflated "like a balloon", to use the respondent's comparison, the person skilled in the art would understand that the expected conformability of the dressing implicitly presupposes that any internal chamber of the dressing that is sealed should be inflated at an appropriate filling pressure level to ensure that the dressing can easily deform. The Board therefore sees no technical incompatibility between the necessary conformable character of the dressing and the fluid-impermeable nature of the film 17.

2.4.2 Furthermore, even if the description of D3 suggests similarities in construction between the different embodiments described, the person skilled in the art does not derive from D3 that the film 17 is identical in all the embodiments. In this respect, the use of the definite article "the" in the expression "the porous film (17)" relating to the embodiment of Figure 2 in paragraph [0427] is not, in the Board's view, a direct and unambiguous disclosure that that porous film and the film referred to in paragraph [0421] for the embodiment of Figure 1 are the same or are both porous.

Indeed, the film 17 does not have the same function in all of the embodiments, and the Board finds it plausible that, consequently, it may be constructed differently:

(a) in the embodiments of D3 for which the film 17 is explicitly disclosed as porous, for example that of Figure 2, the film forms part of the fluid flow

path to return cleansed wound exudate back to the wound (paragraph [0427]);

(b) by contrast, in the embodiment of Figure 1, exudate is removed from the wound and injected back through the cleansing chamber 15 (paragraph [0423]), where it is treated (paragraph [0420]). It is not intended that exudate moves through the film 17.

Hence, whereas there is a technical reason in the embodiment of Figure 2 for the film 17 to be porous, no such reason exists in the embodiment of Figure 1. In other words, the film 17 does not have to be porous in the embodiment of Figure 1.

What is more, for the same reason, the fact that the film 17 is fluid-impermeable as disclosed in paragraph [0421] does not hinder the exudate treatment described for the embodiment of Figure 1. In fact, as argued by the appellant, the fluid-impermeable nature of the film 17 can even improve the effectiveness of the exudate treatment in the embodiment of Figure 1 by avoiding that exudate remains trapped in foam 18 instead of being sucked into the cleansing chamber 15 and treated there.

2.5 In the Board's view, there is therefore no reason to depart from the explicit disclosure of paragraph [0421] that the film 17 is fluid-impermeable.

It follows that the subject-matter of claim 1 as granted is not new over D3 (Article 54(1) and (2) EPC).

3. **Auxiliary request 1**

3.1 Compared to claim 1 as granted, claim 1 of auxiliary request 1 additionally stipulates that the wound dressing comprises a filler, wherein the filler comprises an absorbent material configured to collect wound exudate, and a contact layer configured to be in direct contact with the wound and to allow fluids to pass through.

3.2 *Novelty over D3*

3.2.1 In view of the conclusion above that the film 17 is fluid-impermeable, the embodiment shown in Figure 1 of D3 indisputably does not comprise a contact layer configured to be in direct contact with the wound and to allow fluids to pass through. Nor does it comprise a filler comprising an absorbent material configured to collect wound exudate.

3.2.2 The appellant argued that such a filler and contact layer were disclosed in D3 as optional additional features for all the embodiments described in that document, including that illustrated in Figure 1. Paragraph [0132] disclosed indeed that it could be advantageous to fill the remaining wound space under the backing layer with a filler. Paragraph [0135] presented the foam 41 described for the embodiment of Figure 7 as a suitable filler. As further disclosed in paragraphs [0441] and [0442], a cleansing fluid was absorbed in that foam 41, which meant that the foam was absorbent and could collect wound exudate, and the foam was separated from the wound bed by a fluid-permeable film 6, which constituted a contact layer. It resulted that claim 1 lacked novelty over D3.

3.2.3 This line of argument does not convince the Board.

The Board shares the respondent's view that the disclosure of paragraph [0132] and the examples of fillers given in paragraph [0135] (in particular that shown in Figure 7 cited by the appellant, reproduced below) relate specifically to a type of wound dressing in which cleansing means are formed as a conformable cleansing chamber containing a cleansing fluid and designed to remain in close vicinity of the wound bed. For example, in the embodiment of Figure 7, cleansing fluid contained in the chamber 5 is repeatedly moved in and out of the chamber by squeezing the latter against the wound bed via a rigid dome 50. A filler 41 placed within the chamber enables it to remain in contact with the wound bed, which is desirable for this type of dressing.

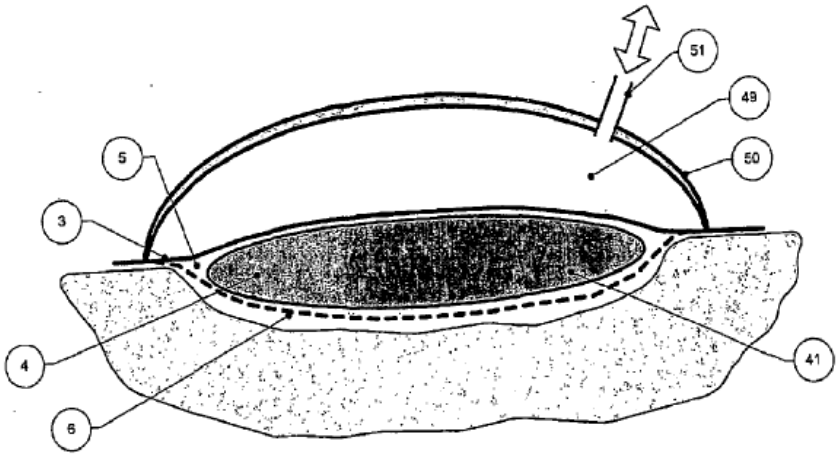

Figure 7

This is in strong contrast to the wound dressings of Figures 1-4, which have a very different construction. In these embodiments, wound exudate is sucked into a cleansing chamber confined within a central boss 11 (paragraph [0420]). As consistently disclosed in these figures, the cleansing chamber is placed outside of the wound space, with space between the film 17 and the wound bed left unfilled.

In view of these differences, the Board does not see in the paragraphs cited by the appellant any direct and unambiguous disclosure of the specific arrangement of a filler and a contact layer as disclosed in Figure 7, in combination with the wound dressing of Figure 1.

3.2.4 The same conclusion is reached when accepting the appellant's argument that the disclosure of paragraph [0132], due to the use of the expression "especially", is not limited to chambers "in which the cleansing fluid is contained" (i.e. to embodiments of the type illustrated in Figure 7) but also applies to the embodiment of Figure 1.

Indeed, the appellant's interpretation of the "chamber" and the "remaining wound space volume" mentioned in paragraph [0132] is not correct. In the Board's view, the "chamber" meant here is not any chamber of the dressing, but rather the cleansing chamber, as it follows from the preceding paragraphs (e.g. paragraph [0120]). The "remaining wound space volume under the backing layer" is therefore the wound space volume under the backing layer which is not occupied by the cleansing chamber.

In the embodiment of Figure 1, the cleansing chamber 15 is confined within a recess of the boss 11 (paragraph [0420]). The "remaining wound space volume under the backing layer" (which the second sentence of paragraph [0132] teaches to limit with a filler) thus includes the annular chamber 16. The foam 18 which "fill[s]" this annular chamber (paragraph [0421]) therefore represents a filler within the meaning of paragraph [0132].

It follows that the embodiment of Figure 1 already comprises a filler as disclosed in paragraph [0132]. Therefore, the disclosure of this paragraph, even applied to the embodiment of Figure 1, cannot amount to the disclosure of an additional filler provided in the dressing, as claimed by the appellant.

3.2.5 The Board concludes that the subject-matter of claim 1 of auxiliary request 1 is new over D3 (Article 54(1) and (2) EPC).

3.3 *Inventive step in view of D3*

3.3.1 The appellant's inventive-step attack is based on similar arguments as put forward under the novelty objection discussed above. In the appellant's opinion, the person skilled in the art starting from the embodiment of Figure 1 of D3 would arrive, in the light of the passages cited above, in particular paragraph [0132], at the subject-matter of claim 1 without exercising an inventive step.

3.3.2 As discussed in point 3.2.4 above, the appellant's line of argument is based on an incorrect interpretation of paragraph [0132]. As established above, a proper interpretation of this paragraph would not lead the person skilled in the art applying this teaching to the wound dressing of Figure 1 to provide the latter with an additional filler as required by claim 1.

3.3.3 Furthermore, as argued by the respondent, including a filler comprising an absorbent material configured to collect wound exudate and a contact layer as defined in claim 1 (hence both necessarily placed below the fluid-impermeable film 17) would lead to wound exudate being trapped in the absorbent material of the filler instead

of being sucked into the cleansing chamber and cleansed there. This would reduce the effectiveness of the exudate treatment aimed at by the wound dressing of Figure 1. Thus, the person skilled in the art would not have reasonably considered such a modification.

3.3.4 The Board concludes that the subject-matter of claim 1 of auxiliary request 1 involves an inventive step (Article 56 EPC).

3.4 *Further objections*

The appellant had no further objections against the claims of auxiliary request 1 or against the adapted description filed by the respondent during the oral proceedings before the Board on 25 June 2021. The Board had no objections either.

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 1-21 of auxiliary request 1 filed on 8 January 2021

Description: description pages 2-6 filed during the oral proceedings before the Board on 25 June 2021

Drawings: Figures 1-11 of the patent specification

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated