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**Datasheet for the decision  
of 14 July 2021**

**Case Number:** T 0103/17 - 3.2.02

**Application Number:** 11156201.3

**Publication Number:** 2345436

**IPC:** A61M1/00, A61F13/02

**Language of the proceedings:** EN

**Title of invention:**

Dressing for applying reduced pressure to and collecting and storing fluid from a tissue site

**Patent Proprietor:**

KCI Licensing, Inc.

**Opponents:**

BSN medical GmbH  
Smith & Nephew Research Centre

**Headword:**

**Relevant legal provisions:**

EPC Art. 83, 54(2), 54(3), 56

**Keyword:**

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 0103/17 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 14 July 2021**

**Appellant:** KCI Licensing, Inc.  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
8 November 2016 concerning maintenance of the  
European Patent No. 2345436 in amended form.**

**Composition of the Board:**

|                 |                     |
|-----------------|---------------------|
| <b>Chairman</b> | M. Alvazzi Delfrate |
| <b>Members:</b> | A. Martinez Möller  |
|                 | N. Obrovski         |

## **Summary of Facts and Submissions**

- I. The appeals lie from the decision of the Opposition Division concerning maintenance of European Patent No. 2345436 in amended form according to auxiliary request 1 as filed during the oral proceedings before the Opposition Division.
- II. The patent proprietor and opponent 2 appealed against the decision.
- III. Oral proceedings before the Board were held by videoconference on 14 July 2021.

Opponent 1 was not present at the oral proceedings, as announced with its submission dated 08 June 2021. Opponent 1 had not submitted any requests in writing.

Opponent 2 requested that the decision under appeal be set aside and the patent be revoked.

The patent proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or any of the first to sixth auxiliary requests, all filed with the statement of grounds of appeal.

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

E1: WO 2007/030601 A2  
E4: WO 2005/123170 A1  
E5: WO 2009/066106 A1  
E28: WO 2007/133618 A2

E31: WO 2009/009467 A1

E32: Press release by Bio-Chem Valve, Inc., 28 December 2006: "Miniature 4 $\mu$ L Micro Pump cycles at rates to 4 Hz." ([http://news.thomasnet.com/print\\_friendly.html?prid=501837](http://news.thomasnet.com/print_friendly.html?prid=501837))

E33: Press release by Micropump, Inc., 11 May 2004: "Ultra-Low Flow Pump utilizes external gear technology" ([http://news.thomasnet.com/print\\_friendly.html?prid=451530](http://news.thomasnet.com/print_friendly.html?prid=451530))

E34: Press release by Bio-Chem Valve, Inc., 12 January 2007: "Micro Pump dispenses high-purity or aggressive fluids" ([http://news.thomasnet.com/print\\_friendly.html?prid=503951](http://news.thomasnet.com/print_friendly.html?prid=503951))

V. Claim 1 of the main request reads as follows:

"A reduced pressure dressing (1804) for applying reduced pressure treatment to a tissue site, the reduced pressure dressing comprising:

an interface layer (1920) adapted to be positioned at the tissue site (1808);

an absorbent layer (1928) in fluid communication with the interface layer to absorb liquid from at least one of the interface layer and the tissue site;

a diverter layer (1932) adjacent the absorbent layer, the diverter layer formed from a substantially fluid-impermeable material, the diverter layer including a plurality of apertures in fluid communication with the absorbent layer to increase an amount of time that the absorbent layer is able to distribute reduced pressure;

a pump (1810) in fluid communication with the plurality of apertures of the diverter layer to deliver a reduced pressure to the tissue site;

a cover (1944) positioned over the pump, the diverter layer, the absorbent layer, and the interface layer to maintain the reduced pressure at the tissue site; and

a liquid-air separator (1940) positioned between the diverter layer and the pump to inhibit liquid from entering the pump."

- VI. The arguments by opponent 2 (opponent 1 did not make any substantive submission in appeal), as far as relevant to the decision, may be summarised as follows:

*Main request - sufficiency of disclosure*

Claim 1 required the absorbent layer to "distribute" reduced pressure. It was not disclosed how the absorbent layer could distribute any pressure, nor did a distribution of pressure by the absorbent layer make sense.

*Main request - novelty*

Document E5 was prior art under Article 54(3) EPC and disclosed all the features of claim 1. While the figures of E5 did not show a cover positioned over a pump, the passage on page 3, lines 23-25 reciting that certain embodiments included an integrated pump indicated that other embodiments not shown in the figures and having a pump included within the dressing were part of the disclosure.

Document E1 in its embodiment of Figure 6 also anticipated the subject-matter of claim 1. The capillary layer 206 was a diverter layer within the meaning of claim 1 and was necessarily formed from a fluid-impermeable material in order to permit controlled directional flow of a liquid. The packing layer 208 anticipated both the absorbent layer and the liquid-air separator of claim 1 because it provided the functionality assigned to both elements in accordance with claim 1.

Document E28 disclosed a reduced pressure dressing within the meaning of claim 1. The liquid collector 1242 in the embodiment of Figure 15, which showed all the features of claim 1 except for the cover positioned over the pump, was necessarily made of a fluid-impermeable material, like the diverter layer of claim 1. E28 likewise disclosed a cover positioned over the pump as shown in Figures 6 and 7. Document E28 thus anticipated all the features of claim 1.

*Main request - inventive step*

The feature of the liquid-air separator defined the only distinguishing feature over the dressing of E1. This feature was obvious in view of E4. The subject-matter of claim 1 was thus not inventive in view of E1 and E4.

The subject-matter of claim 1 was not inventive when starting from the embodiment of Figure 5 of E31 either. The only distinguishing feature was the cover positioned over the pump. Micropumps were part of the common general knowledge in the art and their use within the dressing of E31 in order to render it portable did not involve an inventive step. Documents



E32, E33 and E34 each disclosed a micropump. The subject-matter of claim 1 was thus also rendered obvious by combining E31 with E32, E33 or E34.

VII. The patent proprietor's arguments, as far as relevant to the decision, may be summarised as follows:

*Main request - sufficiency of disclosure*

The objection that an absorbent layer could not distribute reduced pressure was a clarity objection which could not be examined. The word "distribute" in the context of claim 1 meant that the reduced pressure could pass through the absorbent layer. This was to be seen in the context of the problem addressed by the invention, of the absorbent layer blocking the transmission of reduced pressure upon absorbing liquid.

*Main request - novelty*

Document E5 was not prior art under Article 54(3) EPC because claim 1 of the main request was entitled to its priority from document P1 and E5 was not entitled to its earlier priority date. Moreover, document E5 did not disclose a cover positioned over a pump: in all the examples, the pump was positioned outside the cover. The wording "an integrated pump" on page 3, lines 23-25 of E5 did not mean that the pump was under the cover but that it was attached to the dressing.

There was no suggestion in document E1 that the capillary layer would divert flow. Nor did E1 provide any information on the material from which the capillary layer 206 was formed; in particular it did not disclose that it was formed from a fluid-impermeable material. Fluid-permeable materials would

also permit controlled directional flow of a liquid. Claim 1 defined the absorbent layer and the liquid-air separator as two separate entities. The packing layer 208 could thus not anticipate both entities.

The objection of lack of novelty in view of E28 relied upon the example of Figure 15, which showed the pump positioned over the cover. Figures 6-7 and 9 related to different embodiments, and there was no suggestion in E28 that the placement of the pump below the cover would apply to the embodiment of Figure 15. The liquid collector 1242 in Figure 15 was not a diverter layer within the meaning of claim 1, and was not formed from a fluid-impermeable material.

*Main request - inventive step*

E1 did not disclose a liquid-air separator and a diverter layer as defined in claim 1. The combination of E1 and E4 thus did not lead to the claimed invention.

E31 did not disclose a cover positioned over the pump and a liquid-air separator as defined in claim 1. The subject-matter of claim 1 thus involved an inventive step.

**Reasons for the Decision**

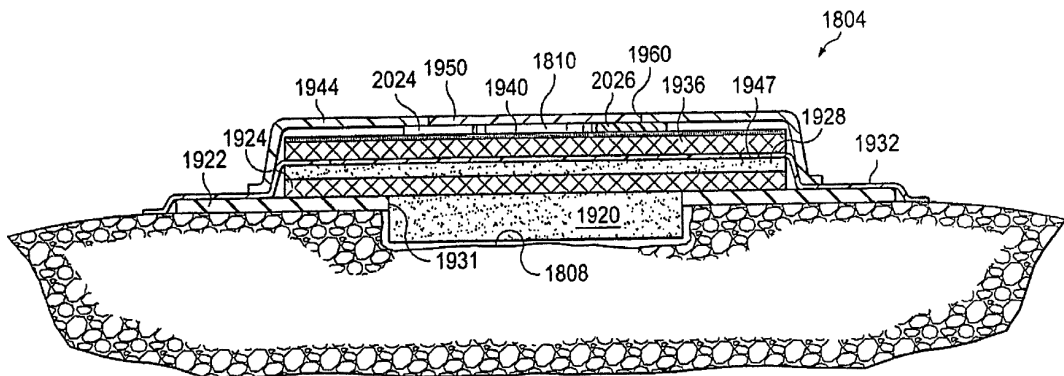
1. The invention

The invention relates to a dressing for applying a reduced pressure treatment to a tissue site. Subjecting a tissue site to reduced pressure augments and

accelerates the growth of new tissue at the tissue site.

Dressings for applying a reduced pressure are used in the treatment of wounds to promote healing. During the reduced pressure treatment, the treated wound usually produces exudate which is drained from the tissue site towards the dressing by the applied reduced pressure.

The claimed dressing comprises an interface layer (1920), an absorbent layer (1928), a diverter layer (1932), a pump (1810), a cover (1944) and a liquid-air separator (1940). An example thereof is shown in Figure 19 of the patent specification, which is reproduced below.



In the dressing of the invention, the liquid (exudate) drained from the tissue site progressively saturates the absorbent layer. A fluid-impermeable diverter layer including a plurality of apertures is used to transmit the reduced pressure generated by the pump to the absorbent layer while encouraging the flow of reduced pressure and liquid towards regions of the absorption layer which would otherwise collect less liquid. This allows a larger portion of the absorbent layer to be used to absorb liquid and thus allows the dressing to be used for a longer period of time without having to

dispose of it (see paragraphs [0041]-[0045] and [0071]-[0078] of the patent specification).

2. Main request - sufficiency of disclosure

Distribution of reduced pressure by the absorbent layer occurs when the reduced pressure is transmitted through the absorbent layer. This transmission depends not only on the properties of the absorption layer but, for each portion of the absorption layer, also on the amount of liquid that it has already absorbed while in use. Hence reduced pressure is indeed distributed by the absorbent layer as defined in claim 1. The amount of liquid and hence the degree of saturation in the different portions of the absorption layer while in use are themselves influenced by the apertures provided in the fluid-impermeable diverter layer (see paragraphs [0041]-[0045] and [0071]-[0078] of the patent specification).

It follows that the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

3. Main request - novelty

3.1 Novelty over E5

E5 discloses in the embodiments of Figures 1 and 4 a reduced pressure dressing with a pump. However, contrary to what is required by the present claim 1 ("a cover (1944) positioned over the pump"), the pump in these drawings is mounted on top of the cover (see also page 9, lines 32-34).

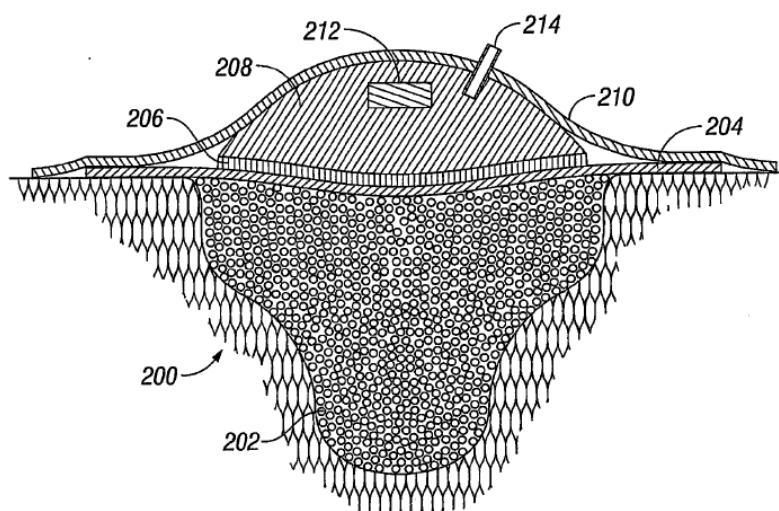
It is true that E5 also discloses on page 3, lines 23-25 that it is an aim of certain embodiments to provide a wound dressing which includes an "integrated pump". However, an "integrated pump" is not necessarily a pump provided within the cover of the dressing. Indeed, this wording could refer to a pump attached to the dressing, as shown in the drawings of E5.

Hence E5 does not directly and unambiguously disclose a cover positioned over the pump within the meaning of claim 1.

In view of this conclusion, there is no need to assess whether and to what extent E5 is prior art under Article 54(3) EPC.

### 3.2 Novelty over E1

3.2.1 E1 discloses in its embodiment of Figure 6 (reproduced hereafter) a wound dressing 200 including a bead packing 202, contact layer 204, capillary layer 206, packing layer 208, micropump 212 and occlusive layer 210.



3.2.2 E1 describes the capillary layer 206 on page 15, lines 9-11 as follows:

*"Capillary layer 206 includes a plurality of capillary fibers defining microchannels that permit controlled directional flow of a liquid, e.g., to permit drainage of the exudates from the wound."*

The structure of the capillary layer 206 offers some resistance to flow and inherently diverts this flow to some extent when directing it through the microchannels defined in said layer. Thus, contrary to the proprietor's submission, it is regarded as a diverter layer.

E1 is silent as to the material of capillary layer 206. The capillary layer 206 of E1 permits a controlled directional flow of a liquid: from the layer where the liquid reaches the capillary layer 206, i.e. from contact layer 204, towards the packing layer 208. This directional flow is controlled by the microchannels defined by the fibres in the capillary layer 206 as used in the reduced pressure dressing of E1. Contrary to what has been asserted by opponent 2, there is no indication in E1 nor is it derivable from its disclosure that the controlled directional flow of a liquid by the capillary layer would require the material forming the capillary layer to be substantially fluid-impermeable.

It follows that E1 does not directly and unambiguously disclose, explicitly or implicitly, a "diverter layer formed from a substantially fluid-impermeable material" as required by claim 1.



paragraphs, serves to collect and retain liquid. This also applies to the example in paragraph [42] of the liquid collector being a composite structure of polyester fibres with superabsorber fibres distributed within the structure and used to absorb liquid. The function of absorbing and retaining liquids conflicts with the diverter layer of claim 1 being formed from a substantially fluid-impermeable material. Hence the liquid collector 1242 is not fluid-impermeable and E28 does not disclose a "diverter layer formed from a substantially fluid-impermeable material".

3.3.3 Opponent 2 pointed out that in the embodiments of Figures 6 or 7 the pump is positioned within the cover. It is however not permissible, when establishing the disclosure of a prior art document, to combine items belonging to different embodiments described in the prior art document unless such combination has been specifically disclosed. E28 does not disclose or suggest combining the features from the embodiment of Figure 15 and the positioning of the cover and the pump of the embodiments of Figures 6 or 7. Hence said positioning of the cover and pump from the embodiments of Figures 6 or 7 cannot be taken into account when assessing novelty over the dressing of the embodiment of Figure 15.

3.3.4 For the above reasons, the subject-matter of claim 1 is novel over E28.

4. Main request - inventive step

At the oral proceedings, in respect of inventive step the parties merely referred to their written submissions.



4.1 Inventive step in view of E1 and E4

The submission by opponent 2 that the subject-matter of claim 1 was rendered obvious in view of E1 and E4 was based on the assumption that the liquid-air separator defined the only distinguishing feature over E1.

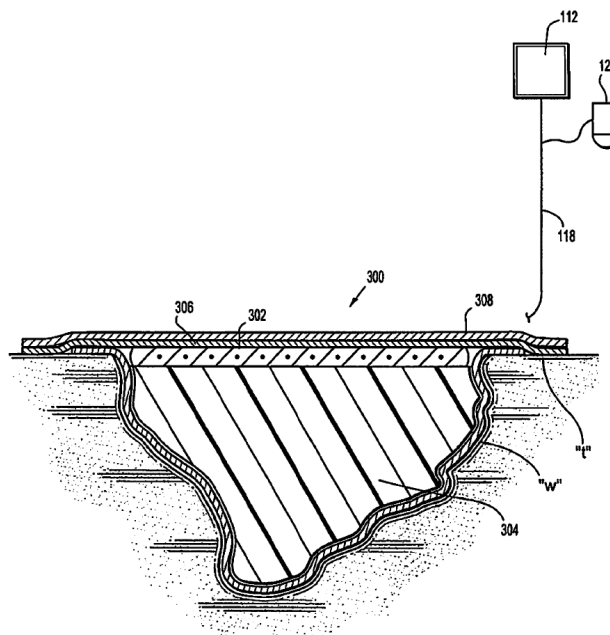
As established under point 3.2 above, this assumption is incorrect because the feature of a diverter layer formed from a substantially fluid-impermeable material defines an additional distinguishing feature over E1.

No objection starting from E1 and based on the two identified distinguishing features was submitted. Nor does the Board see any reason why it would have been obvious to provide the dressing of E1 with both said distinguishing features. In these circumstances the Board has no reason to question the presence of an inventive step starting from this document.

It follows that the subject-matter of claim 1 involves an inventive step when starting from E1.

4.2 Inventive step in view of E31 and one of E32, E33, E34 or the common general knowledge

4.2.1 E31 in Figure 5 (reproduced hereafter) discloses a wound dressing apparatus 300 for applying reduced pressure treatment, comprising a supplemental member 302, an inner member 304, an adhesive member 306 and an outer member 308 (see paragraph [0035]). A subatmospheric pressure source 112 is connected to the wound dressing apparatus by means of tubing 118.



It is undisputed that E31 does not disclose the feature of a cover positioned over the pump within the meaning of claim 1. Contrary to the opinion of opponent 2, this is not the only distinguishing feature.

4.2.2 In the communication under Article 15(1) RPBA dated 29 April 2021, the Board had already indicated that E31 did not disclose that the supplemental member 302, which according to opponent 2 represented a diverter layer within the meaning of claim 1, was formed from a fluid-impermeable material.

The Board pointed out that paragraph [0035] of E31 disclosed that the supplemental member 302 could be a gauze material such as KERLIX®, a material further defined in paragraph [0022]. Paragraph [0022] of E31 indicates that KERLIX® is an antimicrobial dressing. Neither paragraph [0022] nor paragraph [0035] allow the conclusion that KERLIX® or the supplemental member 302 are fluid-impermeable. Hence the feature that the diverter layer is formed from a substantially fluid-

impermeable material defines an additional distinguishing feature over E31.

- 4.2.3 The submission by opponent 2 that the subject-matter of claim 1 lacked inventive step starting from E31 was based on the assumption that the cover positioned over the pump defined the only distinguishing feature. No lack of inventive step starting from E31 and addressing this additional distinguishing feature was argued. Nor does the Board see any reason why it would have been obvious to provide the dressing of E31 with both distinguishing features. In these circumstances, the Board has no reason to question the presence of an inventive step.

It follows that the subject-matter of claim 1 involves an inventive step when starting from E31.

5. Main request - amendment of the description

The patent proprietor introduced a new paragraph [0003] of the description, replacing previous paragraphs [0003]-[0010], to align the description with claim 1 of the main request.

Opponent 2 did not raise any objections to this amendment, and nor does the Board have any objections to it.

## **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: 1-17 according to the main request filed with the statement of grounds of appeal
- description: paragraphs 1-2 and 11-110 of the patent specification and paragraph 3 as filed during the oral proceedings before the Board
- drawings: figures 1-20 of the patent specification

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated