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**Datasheet for the decision
of 6 July 2021**

Case Number: T 0850/17 - 3.2.02

Application Number: 11156200.5

Publication Number: 2345438

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:

Paul Hartmann AG
Smith and Nephew, Inc.

Headword:

Relevant legal provisions:

EPC Art. 76(1), 123(2), 83, 56

Keyword:

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Inventive step - (yes)

Decisions cited:

T 0605/97, G 0003/14

Catchword:



Beschwerdekammern

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Chambres de recours

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Case Number: T 0850/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 July 2021

Appellant: Paul Hartmann AG
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
7 February 2017 concerning maintenance of the
European Patent No. 2345438 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeals lie from the interlocutory decision of the Opposition Division concerning maintenance of the European Patent No. 2345438 in amended form according to auxiliary request 4 as filed during the oral proceedings before the Opposition Division.

The disputed patent had been granted on the basis of European application number 11156200.5 ("the application as filed"), which was a divisional application of European application number 09717511.1 ("the earlier application").

- II. Both opponents appealed against the decision.

The patent proprietor also appealed against the decision, but subsequently withdrew its appeal with its submission dated 25 May 2021.

- III. Oral proceedings before the Board were held by videoconference on 6 July 2021. Opponent 2 was not present, as announced with its submission dated 25 June 2021.

The appellants (opponent 1 and opponent 2) requested that the decision under appeal be set aside and the patent be revoked.

The respondent (patent proprietor) requested that the appeals be dismissed and the patent be maintained as upheld by the Opposition Division (main request), or alternatively on the basis of the first or second

auxiliary request, both filed with the submission dated 25 May 2021.

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

D2: US-A-2004/0030304

D7: US-A-2007/0265586

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

"A reduced pressure dressing (104) adapted to distribute a reduced pressure to a tissue site (108), the dressing comprising:
an interface layer (220) adapted to be positioned at the tissue site;
an absorbent layer (228) made from a super absorbent fiber in fluid communication with the interface layer to absorb liquid from at least one of the interface layer and the tissue site;
a pump (110) in fluid communication with the absorbent layer to deliver the reduced pressure to the tissue site; and
a cover (244);
the dressing comprises a diverter layer (232) between the absorbent layer and the pump for diverting the reduced pressure allowing the absorption capabilities of the absorbent layer to be more fully utilized, the diverter layer formed from a substantially gas-permeable, liquid impermeable material, and wherein the cover is positioned over the diverter layer to maintain the reduced pressure at the tissue site, wherein the diverter layer includes a plurality of apertures to transmit the reduced pressure from the pump to the absorbent layer, and wherein at least one of the

apertures is larger than another of the apertures..
[sic]"

VI. The appellants' arguments, as far as relevant to the decision, may be summarised as follows:

Amendments

The feature concerning the "super absorbent fiber" and the feature "at least one of the apertures is larger than another of the apertures" were only disclosed in specific embodiments comprising further features which had not been included in claim 1. Moreover, neither these two features nor the feature "for diverting the reduced pressure allowing the absorption capabilities of the absorbent layer to be more fully utilized" were disclosed in combination with a diverter layer being formed from a gas-permeable and liquid-impermeable material. Thus neither the application as filed nor the earlier application as filed (of which the application was a divisional) disclosed the subject-matter of claim 1.

Sufficiency of disclosure

The opposed patent did not teach which materials were considered to be "substantially gas-permeable, liquid impermeable". Moreover, a gas-permeable material transmitted the reduced pressure without causing any diversion of reduced pressure. The skilled person would thus not know how to provide a diverter layer which was made from a gas-permeable material and at the same time was "for diverting the reduced pressure allowing the absorption capabilities of the absorption layer to be more fully utilized" as required by claim 1.

Inventive step

The subject-matter of claim 1 was rendered obvious in view of D2 and D7. It would have been obvious starting from the dressing of D2 to use super-absorbent fibers for the absorbent layer (paragraphs [0041]-[0042] and [0046] in D7) and a gas-permeable material for the diverter layer (paragraph [0049] in D7). Production of the dressing of D2 would inevitably have led to apertures of different sizes. Moreover, it would be sufficient for claim 1 to have a single aperture which was slightly larger than the others: without any qualification in claim 1 as to how much larger an aperture was, no technical effect was achieved. Furthermore, D2 disclosed in paragraph [0037] that clogging caused by the exuded fluids and the accompanying debris caused the flow to deteriorate. It would thus have been an obvious choice in the dressing of D2 to use apertures of different sizes to account for the different sizes of particles present in the debris.

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

Amendments

Claim 1 resulted from the addition of three features to clause 65 of the application as filed (Article 123(2) EPC), or claim 65 of the earlier application as filed (Article 76(1) EPC). The three features had a basis in the explanations provided for the embodiment of Figures 1-4 on pages 7 to 20 on which clause 65 relied. Also page 13, lines 21-31 disclosed a diverter layer being formed from a gas-permeable and liquid-impermeable

material together with the functional feature added to clause 65.

Sufficiency of disclosure

Gas-permeable, liquid-impermeable materials were well-known to a person skilled in the art. The description provided numerous examples of how a plurality of apertures could be provided in the diverter layer to enhance the transmission of reduced pressure and to divert the reduced pressure so as to allow the absorption capabilities of the absorbent layer to be more fully utilised.

Inventive step

The subject-matter of claim 1 involved an inventive step over the combination of D2 and D7. D2 disclosed all apertures of the diverter layer being of the same size. That the production of the dressing of D2 would lead to marginal variations in the sizes of the apertures because of manufacturing tolerances related to an alleged prior use which had not been submitted as prior art. When approaching the claim with a mind willing to understand, it was clear that said marginal size variations did not meet the requirements of claim 1. Providing an aperture larger than the other apertures resulted in the technical effect of preferentially diverting flow. D7 did not disclose any apertures. There was thus no disclosure leading the person skilled in the art towards the subject-matter of claim 1.

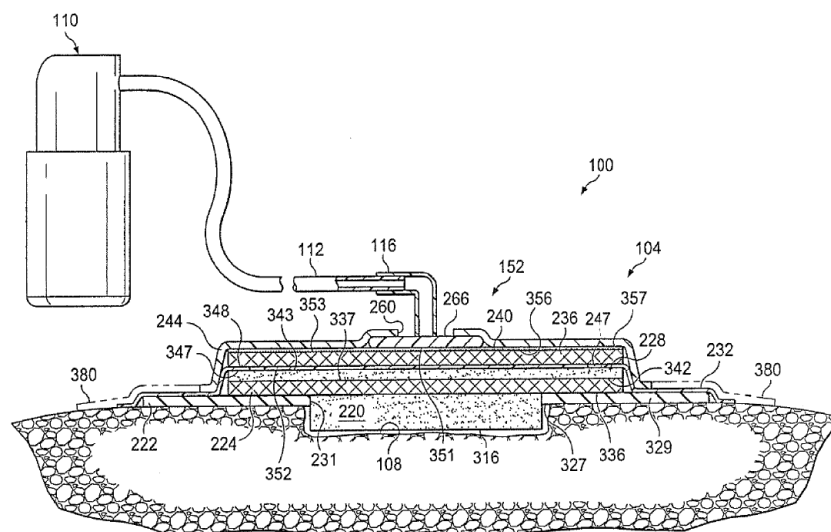
Reasons for the Decision

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 site.

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

The claimed dressing comprises an interface layer (220), an absorbent layer (228), a pump (110), a cover (244) and a diverter layer (232). An example thereof is shown in Figure 2 of the patent specification, which is reproduced below.



2. Amendments

2.1 The application as filed extensively describes the embodiment of Figures 1-4 on pages 7 to 20, detailing the function of each layer of the dressing and several related optional features. Other embodiments (Figs. 10, 17 and 18) are not presented with a comparable level of detail. They instead rely on the corresponding explanations provided for the embodiment of Figures 1-4, as confirmed by several references to it (see page 22, lines 10-11; page 25, lines 19-30; and page 28, lines 20-22). The same applies to the embodiments defined by the clauses on pages 33-40, which likewise rely on the disclosure of the corresponding layers provided on pages 7-20.

2.2 Claim 1 of the main request is based on clause 65 (disclosed on page 40 of the description as originally filed), which defines all the features of claim 1 except:

(a) "made from a super absorbent fiber";

(b) "for diverting the reduced pressure allowing the absorption capabilities of the absorbent layer to be more fully utilized"; and

(c) "wherein the diverter layer includes a plurality of apertures to transmit the reduced pressure from the pump to the absorbent layer, and wherein at least one of the apertures is larger than another of the apertures".

2.3 Feature (a) is disclosed as an optional feature of the absorbent layer on page 12, lines 19-20. It is true that this passage relates to the embodiment of Figures

1-4 which comprises layers which are not included in the dressing of claim 1, e.g. the seal layer 222 and the first manifold layer 224 mentioned on page 12, lines 15-17. However, the feature that the absorbent layer is made from a super absorbent fiber relates to the ability of the absorbent layer to absorb liquid, and is unrelated to the presence of these additional layers. This is also clear from clauses 3, 11 and 28, which disclose the feature in embodiments which do not comprise any of these additional layers. Hence the addition of feature a) to clause 65 without these additional layers does not contravene Article 123(2) EPC.

- 2.4 Similar considerations apply to feature (c), which finds a basis on page 20, lines 5-8 (describing Figure 4) in view of page 22, lines 1-3, and which is likewise disclosed in clauses 16, 34 and 52 without the particular configuration of apertures shown in Figure 4.
- 2.5 It is uncontested that the functional feature (b) has a basis in the application as filed (see page 13, lines 21-22; page 14, lines 6-12; page 26, lines 15-18; clauses 19, 37 and 55).
- 2.6 As established above, clause 65 relies on the explanations of the corresponding layers provided on pages 7 to 20 relating to the embodiment of Figures 1-4. These explanations on page 13, lines 21-31 comprise the feature of a diverter layer formed from a substantially gas-permeable, liquid-impermeable material as defined in clause 65.

The three features (a), (b) and (c) are disclosed as part of these explanations on pages 7 to 20 and relate

to the absorbent layer and the diverter layer, both comprised in the dressing of clause 65. Claim 1 thus has a basis in clause 65 and in the passages mentioned for each of the three features. Hence the requirements set out in Article 123(2) EPC are met.

2.7 The reasoning provided for Article 123(2) EPC likewise applies for Article 76(1) EPC if the references to clauses are replaced by references to the corresponding claims in the earlier application as filed (European application No. 09717511.1, published as WO 2009/111657).

2.8 It follows that claim 1 of the main request does not contain subject-matter extending beyond the content of the application as filed or of the earlier application as filed.

3. Sufficiency of disclosure

3.1 It is undisputed that gas-permeable, liquid-impermeable materials were well-known to a person skilled in the art at the priority date.

Whether the person skilled in the art would be left in doubt as to exactly what defines a substantially gas-permeable material relates to an allegedly unclear scope of protection conferred by the claim. Said alleged lack of clarity was however present in claim 1 as granted and may thus not be examined (see G 3/14, order).

3.2 Paragraph [0042] of the contested patent discloses that the diverter layer "may still include a pattern of holes for transmitting a greater volume of liquid or gas than that permitted by the gas-permeable material

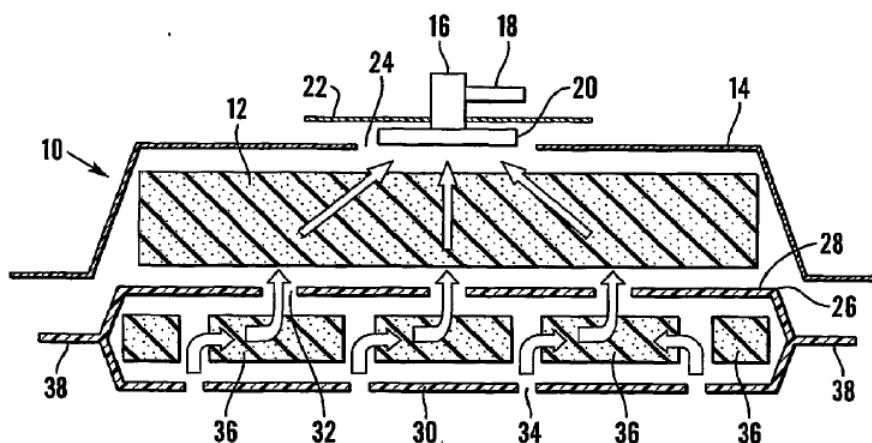
of which the diverter layer 232 is constructed". That is to say, a higher transmission of reduced pressure is achieved through the holes than through the gas-permeable material, causing a diversion of the reduced pressure. Hence, contrary to what was submitted by the appellants, a person skilled in the art following the disclosure in the contested patent is able to provide a diverter layer which is made from a gas-permeable material and which diverts the reduced pressure.

3.3 Furthermore, paragraphs [0041]-[0046] and [0071]-[0076] of the contested patent describe how the provision of apertures in the diverter layer and the diversion of reduced pressure is used to direct the liquid from the tissue site towards a larger portion of the absorbent layer, resulting in the storage of a greater volume of liquid from the tissue site and allowing the absorption capabilities of the absorption layer to be more fully utilised.

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

4. Inventive step

4.1 Document D2 in its embodiment of Figure 1 (reproduced hereafter) discloses a wound dressing 10 comprising among other things an elastomeric drape 14, an upper foam layer 12, and a lower foam layer 36 placed within an elastomeric envelope 38 formed by an upper sheet 28 and a lower sheet 30 (see paragraphs [0029]-[0040] of D2). The dressing further comprises a connector 16 for connection to a negative-pressure source.



4.2 It is undisputed that D2 defines a valid starting point for assessing inventive step of the subject-matter of claim 1.

4.3 As regards the feature of claim 1 "wherein at least one of the apertures is larger than another of the apertures", D2 discloses that the upper sheet layer 28 has holes (holes 32 in Figure 1 and paragraphs [0036]-[0037]), but does not disclose that these holes are of different sizes.

Even if, as submitted by the appellants, a dressing produced following the teaching of D2 were to be considered as a starting point, and even if such a dressing included marginal differences in the size of the holes caused by manufacturing tolerances, it is the view of the Board that "larger than" as applied to the size of the apertures in claim 1 must be interpreted as going beyond mere measuring errors and/or manufacturing tolerances (cf. T 605/97, point 6.2 of the reasons).

Hence the feature "wherein at least one of the apertures is larger than another of the apertures" defines a distinguishing feature over D2.

- 4.4 The technical effect of this distinguishing feature is to preferentially divert flow through the region of the absorbent layer adjacent to the at least one larger aperture.

The amount of preferential diversion of flow caused by the at least one larger aperture will depend on how much larger this aperture is. However, the difference in size primarily concerns the *magnitude* of the technical effect rather than *whether* such a technical effect is achieved vis-à-vis the dressing of D2.

- 4.5 The objective technical problem solved by the invention on the basis of this technical effect is how to better utilise the transmission capability of the absorbent layer.

- 4.6 Neither D2 nor D7 provides any teaching towards using apertures of different sizes as defined in claim 1 in order to address this objective technical problem.

D2 discusses the problem of clogging of the medium through which the exuded fluid flows, i.e. clogging of the foam layers, along the direct path towards the vacuum source. The holes in the upper sheet layer 28 address this problem by dispersing the vacuum and de-localizing the flow (paragraph [0037] in D2). In D2 there is however no relationship between the size of the holes 32 and the size of the particles comprised in the debris accompanying the exuded fluid. Hence, even if the debris accompanying the wound exudate comprised particles of different sizes, the person skilled in the art would have no motivation to provide holes of different sizes in the dressing of D2.

D7 was cited by the appellants in connection with the materials for the absorbent and diverter layers and does not disclose or suggest a diverter layer including apertures of different sizes.

4.7 It follows that the subject-matter of claim 1 involves an inventive step when starting from D2 in combination with D7.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated