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**Datasheet for the decision
of 3 August 2023**

Case Number: T 1878/19 - 3.2.06

Application Number: 10747361.3

Publication Number: 2470135

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A61M27/00

Language of the proceedings: EN

Title of invention:
RE-EPITHELIALIZATION WOUND DRESSINGS AND SYSTEMS

Patent Proprietor:
KCI Licensing, Inc.

Opponent:
Pajaro Limited

Headword:

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - added subject-matter (yes)

Decisions cited:

T 0012/81, T 3035/19, T 0330/05

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1878/19 - 3.2.06

D E C I S I O N
of Technical Board of Appeal 3.2.06
of 3 August 2023

Appellant: KCI Licensing, Inc.
(Patent Proprietor) P.O. Box 659508
San Antonio, TX 78265 (US)

Representative: Simmons & Simmons
City Point
One Ropemaker Street
London EC2Y 9SS (GB)

Appellant: Pajaro Limited
(Opponent) 12 New Fetter Lane
London
EC4A 1JP (GB)

Representative: Bird & Bird LLP
Maximiliansplatz 22
80333 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
30 April 2019 concerning maintenance of the
European Patent No. 2470135 in amended form.**

Composition of the Board:

Chairman M. Harrison
Members: M. Dorfstätter
W. Ungler

Summary of Facts and Submissions

- I. In its interlocutory decision the opposition division found that, account being taken of the amendments made by the patent proprietor during the opposition proceedings, the European patent No. 2 470 135 met the requirements of the EPC.
- II. Appeals were filed by the patent proprietor and the opponent respectively. As they are both appellants, they will be referred to as 'proprietor' and 'opponent' in the following.
- III. The proprietor requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the main request or the first auxiliary request, both filed with letter of 30 August 2019, or that the opponent's appeal be dismissed (second auxiliary request).
- IV. The opponent requested that the decision under appeal be set aside and the European patent be revoked.
- V. The Board issued a summons to oral proceedings and a subsequent communication, in which it indicated *inter alia* that it considered that Article 123(2) EPC was contravened by claim 1 of all requests.
- VI. Oral proceedings were held, at the end of which the parties confirmed their initial requests as stated above.
- VII. Claim 1 of the main request reads as follows (with the contentious amended features underlined by the Board):

"A re-epithelialization dressing (102) for use with reduced pressure to treat a wound site (106), the dressing (102) comprising:
a moist tissue-interface layer (126) for disposing against the wound site (106), the moist tissue-interface layer (126) providing a moisture balance, the moist tissue-interface layer (126) being a hydrogel layer and having a first side (136) and a second, tissue-facing side (138), and wherein a plurality of apertures (140) are formed with a uniform pattern through the moist tissue-interface layer (126);
a manifold member (130) for distributing reduced pressure, the manifold member (130) having a first side (152) and a second, tissue-facing side (154), wherein the manifold member (130) is a porous foam;
a sealing member (132), the sealing member (132) having a first side (158) and a second, tissue-facing side (160); and
wherein the manifold member (130) is disposed between the sealing member (132) and the moist tissue-interface layer (126)."

The main request further comprises independent claim 6, which is however not relevant for the present decision and is thus not reproduced here.

VIII. Claim 1 of the first auxiliary request reads as for claim 1 (and claim 6) of the main request but is formulated to include the alternatives defined in those independent claims in a single claim.

IX. Claim 1 according to the second auxiliary request (i.e. the request which was found to meet the requirements of the EPC by the opposition division) is identical to claim 1 of the main request. In this request, the

subject-matter of the second independent claim (i.e. claim 6 of the main request) has been deleted.

- X. The arguments of the proprietor may be summarised as follows:

Claim 1 of the main request did not contravene Article 123(2) EPC.

The alternatives presented in the description were not all to be classified as "lists". Furthermore, there were pointers to the claimed alternatives in the application as filed such that if they were selections, their selection did not result in added subject-matter.

The claimed combination of features did not constitute an unallowable intermediate generalisation either. These features did not need to be extracted from the variants of the single embodiment in which they were shown. They were not inextricably linked with the other features shown in the figures, nor was any other feature necessary. Any further feature was thus optional and did not need to be included in the claim.

- XI. The arguments of the opponent may be summarised as follows.

Claim 1 of the main request contravened Article 123(2) EPC.

To derive the subject-matter of claim 1 from the description of the application as filed, several selections out of several lists had to be made, for which selections there was no pointer. Furthermore, there was no basis in the application as filed for the combination of the features so selected.

Likewise, claim 1 constituted an unallowable intermediate generalisation of the embodiments shown in the figures. The figures presented many more features in combination than what was claimed. The amended features could thus not be extracted from the embodiment.

XII. Further arguments of the parties are dealt with below under "Reasons".

Reasons for the Decision

1. *Main request - Article 123(2) EPC*

The amendments made in claim 1 of the main request introduce subject-matter that extends beyond the content of the application as filed, contrary to Article 123(2) EPC.

1.1 As argued by the opponent, claim 1 of the main request was amended vis-à-vis claim 1 of the application as filed in the following aspects:

- the moist tissue-interface layer was specified as being for disposing against, rather than adjacent to, the wound site
- the moist tissue-interface layer was further specified as being a hydrogel layer
- the apertures were defined as being formed with a uniform pattern
- the manifold member was defined as being a porous foam.

It was undisputed by the parties that the application as filed lacks an explicit disclosure of an embodiment including the combination of these features without

further features being described in combination therewith. It was also undisputed that at least each of the latter three features was described as such (albeit with alternatives being mentioned).

According to well-established case law of the boards of appeal, a single feature may normally be taken from a single list and incorporated into a filed claim without contravening Article 123(2) EPC. If features from more than a single list are combined there generally needs to be a pointer for each of the selections made such that the combination of selected features can be considered disclosed by the application as filed. An original disclosure might also be within the content of the application as filed if a particular combination of features is presented together in the application, such as in the described embodiments.

1.2 The Board finds that each of the following:

- using hydrogel as the moist tissue-interface layer,
- forming the plurality of apertures through the moist tissue-interface layer with a uniform pattern, and
- using a porous foam for the manifold member

constitutes a selection from a list of features in the application, for which selection there is no pointer. This holds not only for the individual selections but also for the combination of selections made.

With reference to T 12/81, the proprietor argued that two alternatives do not establish a list of sufficient length and that a skilled person did not need to make a selection. They would instead understand that the two alternatives were disclosed as separate embodiments.

With reference to T 3035/19, the proprietor further argued that the combination of features resulting from selections in two or more lists introduced added subject-matter only in the absence of a pointer to that particular combination. Still further, and with reference to T 330/05, the proprietor argued that a concretisation of a feature already present in the claims of the application as filed did not require any unforeshadowed selection.

These arguments are however not found convincing, at least not in the circumstances of the present case. An individual list may be short and even only comprise two alternatives. Yet, it further adds to the number of choices a skilled person already has to make to arrive at the claimed subject-matter. The decisive question is thus not how long an individual list is, to be classified as a "list", but merely from the fact that alternatives are present among which the particular combination of features is to be selected. Further it has to be questioned whether there is a pointer not only to each individual selected feature, but also to the specific combination of the selected features. As regards the proprietor's argument of a "concretisation", the Board does not find this convincing if, as in the present case, the general feature of the claim in the application as filed can be concretised in several ways which are presented as mere alternatives without any specific preference to one or the other being given (as will be explained below for each contentious feature).

1.2.1 *Selection of hydrogel as the material for the moist tissue-interface layer*

The proprietor argued that claim 1 of the application as filed already included a reference to the moist tissue-interface layer. The definition that this layer was a hydrogel layer was thus allegedly a mere concretisation, for which there was a pointer in the description, notably on page 9, lines 1ff., stating that:

"The moist tissue-interface layer 126 may be, for example, a water-based material, such as hydrogel or hydrocolloid."

The proprietor further argued that hydrogel was the first and foremost material mentioned and that the order in which the two alternatives of hydrogel and hydrocolloid were presented thus constituted a pointer to the use of hydrogel. Other materials were presented in lines 15ff., which, according to the proprietor, were not presented on an equal level but were intended for the more specific use for deeper wounds or difficult shapes.

The Board does not accept this. The use of hydrogel is not presented as preferred over the use of any other material capable of providing the necessary fluid balance in the moist tissue-interface layer. Since claim 1 is not limited to a particular use, it embraces any application, including deep wounds and difficult shapes. A reader of the application as filed is not particularly pointed to the use of hydrogel. If at all they are pointed to hydrogel only to the same extent as they are pointed to the other mentioned materials, notably hydrocolloid (page 9, line 3), hydrophilic

foam, film-coated perforated non-woven material, hydrogel-impregnated foam, hydro-active dressing material, or other material (all on page 9, lines 16-18).

Although hydrogel is indeed mentioned first on page 9 of the application as filed, this mentioning is preceded by the general statement that "[t]he moist tissue-interface layer 126 may be made from numerous materials". Hydrogel (and hydrocolloid) is then given as an example for a water-based material which, in turn, is also only presented as an example. The reader of page 9 is thus presented with the clear information that any of these mentioned materials can be used for the moist tissue-interface layer and none is preferred over the other. In fact, nothing is derivable from the order in which the alternatives are presented. It is immanent for a list that one alternative appears on top of the list just as another appears at its bottom (which is also not less preferred merely by being at that location). With no further indication that the order has a meaning, no further information about preference or importance can be gleaned therefrom.

Therefore, the use of hydrogel as the material for the moist tissue-interface layer represents a first selection from a list for which there is no clear pointer in the application as filed.

1.2.2 *Selection of a uniform pattern for forming the plurality of apertures through the moist tissue-interface layer*

The proprietor referred to the description as filed (page 8, lines 9-11) which contains the following statement:

"The first plurality of apertures 140 may be formed with a uniform pattern or may be random and may have uniform or varied diameters."

It argued that "uniform" or "random" were only two alternatives since the second half-sentence did not relate to the apertures but established two further alternatives relating to the diameter. Further, the figures all contained a uniform pattern which was a clear pointer towards this alternative.

The Board does not accept that the above-cited statement relates to only two alternatives. As the information about the pattern and the diameters relate to characteristics of the apertures, they cannot be separated from each other. As also argued by the opponent, the sentence thus includes information about four possibilities to configure the first plurality of apertures in the moist tissue-interface layer:

- uniform pattern with uniform diameters (this being the one depicted in the figures),
- uniform pattern with varied diameters,
- random pattern with uniform diameters, or
- random pattern with uniform diameters.

These four possibilities form a further list from which a selection needs to be made in order to arrive at the claimed subject-matter.

The Board also does not accept that the figures are a clear pointer for selecting the first alternative on the list above. Figures simply show the features of an embodiment described in the application or they represent (as in the contested patent) the embodiment

on their own. Indeed the figures show a uniform pattern (and, notably, also a uniform diameter), but this is construed as a specific embodiment of the general teaching in the description. Other embodiments are not given. It is immediately apparent that the alternatives with randomly arranged apertures and/or varied diameters are not less preferred merely because they are not depicted. In the present case, there is thus no basis to assign any importance to not depicting alternatives in the figures which are mentioned in the description.

Therefore, forming the first plurality of apertures with a uniform pattern represents another selection from a list, for which there is no clear pointer in the application as filed.

1.2.3 *Selection of a porous foam for the manifold member*

The proprietor argued that claim 1 as filed already contained the feature of a manifold member for distributing reduced pressure and that "porous foam" was just a concretisation of this feature. Porous foam was mentioned on page 12, line 2, of the application as filed. Its selection thus did not require an "unforeshadowed selection" in the sense of T 330/05, Reasons 3.1.

This is, however, also not accepted. Porous foam is presented as only one alternative amongst a longer list of possible materials for the manifold member. The list is spelt out on page 11, line 21 to page 12, line 1, of the application as filed. It reads:

"The manifold member 130 may include, for example, without limitation, devices that have structural

elements arranged to form flow channels, such as, for example, cellular foam, open-cell foam, porous tissue collections, liquids, gels, and foams that include, or cure to include, flow channels. The manifold member 130 may be porous and may be made from foam, gauze, felted mat, or any other material suited to a particular biological application."

That this represents a list of sufficient length was not contested by the proprietor, but it was argued that there was a pointer towards porous foam due to the way it was mentioned on page 12. This juncture immediately follows the one reproduced above and reads as follows:

"In one illustrative, non-limiting embodiment, the manifold member 130 is a porous foam and includes a plurality of interconnected cells or pores that act as flow channels."

Leaving aside the question as to whether the further feature of a plurality of interconnected cells or pores acting as flow channels is inextricably linked to porous foam, porous foam is not presented as being preferred or otherwise pointed to, as was also argued by the opponent. It is not the only example described in more detail either. The statement on page 12, lines 1-4, is introduced by the wording "in one illustrative, non-limiting embodiment". As an alternative, non-woven material is mentioned in the same paragraph (page 12, lines 5-7). It has the following wording:

"In one non-limiting illustration, a manifold member 130 is formed of a non-woven material, such as a non-woven material available from Libeltex BVBA of Belgium."

The Board thus concludes that neither of the two alternatives is preferred or more pointed to than the other. Again, these two materials are each considered as representing a different embodiment, whereby any one material is not preferred over any other material mentioned in the list on page 11.

Therefore, using porous foam for the manifold member represents yet another selection from a list, for which there is no clear pointer in the application as filed.

1.2.4 In addition to the individual selections from the lists not being pointed to, there is even less of a pointer in the application as filed towards the combination of selections made in claim 1. The Board thus concludes that the subject-matter of claim 1 is not derivable from the general description of the application as filed.

1.3 As to the proprietor's further line of argument that the various embodiments could be used as a basis for deriving the claimed subject-matter, the Board considers that the combination of features of claim 1 represents an unallowable intermediate generalisation of the embodiments shown in and described with respect to the figures.

1.3.1 *Specifying that the moist tissue-interface layer is for disposing "against", rather than "adjacent to", the wound site*

The proprietor argued that it was derivable from the application as a whole that the moist tissue-interface layer was provided for contact with the wound. This already followed from the expression "interface". Furthermore, it was a general principle supported by

all the drawings. The amendment from "adjacent" to "against" was nothing to be extracted from the drawings but a mere clarification of the original intention upon filing the application.

This is not convincing. It was uncontested by the parties that the meaning of "adjacent to the wound site" differs from "against the wound site" in that the latter implies contact whilst the former does not require contact. As acknowledged by the proprietor, the application as filed does not include the wording "against the wound site". The only mention of the word "against" is, as cited by the opponent, on page 15, line 12, but this refers to the relative smooth surface of the moist tissue-interface layer against the tissue-site. It was also not contested that this passage cannot form the basis for the amendment.

There is however no other potential basis for the moist tissue-interface layer being disposed against the wound site than the drawings, which however show further features of this layer in combination. These further features, such as for example the shape, size, orientation and distance of the apertures therethrough, are not defined in claim 1. Since the Board does not accept that the term "interface" necessarily implies a direct contact, the use of the feature of being disposed against the wound site in claim 1 needs to be isolated from the context in which this is presented in the drawings.

Specifying that the moist tissue-interface layer is for disposing against the wound site without including the further features of this layer as shown in the figures thus results in an inadmissible intermediate generalisation.

1.3.2 *Selection of a uniform pattern for forming the plurality of apertures through the moist tissue-interface layer*

The proprietor argued that the feature of a uniform pattern was derivable from the application as filed separately from the other features shown in the drawings. These features, including the whole support layer were described as being optional and could thus be omitted.

This is not accepted. As argued by the opponent, the figures clearly show that the uniform pattern of the first apertures in the moist tissue-interface layer corresponds to the pattern of the plurality of apertures in the support layer. There is thus a clear technical functional and structural relationship between these two patterns in the figures. Any statement in the description that the support layer is optional does not refer to the embodiment shown. If this were followed, the first apertures being formed with a uniform pattern would then also be "optional". With several features being declared merely optional in the description, the embodiment cannot be considered anything more than what is explicitly shown in the figures. The embodiments of the application as filed thus all comprise a support layer with a second plurality of apertures. These apertures, which line up with the first layer, are thus functionally linked to the first plurality of apertures and cannot thus be simply omitted when considering the information conveyed by the embodiment depicted in the drawings. It is true that at several junctures of the description the support layer is described as being "optional" or "may be included" in the dressing, as argued by the

proprietor. However, no information can be derived from the application as filed as to what the moist tissue-interface layer would look like without a support layer being provided, let alone whether the pattern for forming the plurality of apertures therethrough would be uniform.

Specifying that a first plurality of apertures are formed with a uniform pattern through the moist tissue-interface layer without including the second plurality of apertures through the support layer and formed in a corresponding configuration and in alignment with the apertures in the tissue-interface layer as shown in the figures thus represents an inadmissible intermediate generalisation, if the figures are taken as the pointer or basis for the amendments in claim 1.

1.3.3 *Selection of a porous foam for the manifold member*

The proprietor argued that page 12, lines 1-2, of the application as filed provided a pointer for the manifold member shown in the figures being a porous foam and that the plurality of interconnected cells or pores mentioned in that sentence were not inextricably linked with the porous foam.

This is not accepted. It cannot be determined whether the material for the manifold of the embodiment shown in the figures is a porous foam or a non-woven material or any other material from the list given on page 11, lines 21-25. The statement on page 12, lines 1-2 to which the proprietor referred, is not specifically linked to any figure.

The proprietor further argued that channels in the porous foam were implicit since the manifold was

defined as being for distributing pressure. The question as to whether not including the plurality of interconnected cells or pores acting as flow channels in the claim also constitutes an unallowable intermediate generalisation can be left unanswered by the Board. The embodiment shown in the figures does not clearly comprise a manifold of foam, since an open-cell foam is merely mentioned as one of several alternatives in the description. There is thus no specific embodiment shown in the figures that clearly comprises a foam manifold from which the claimed subject-matter could potentially be generalised.

- 1.4 Contrary to the requirement of Article 123(2) EPC, the subject-matter of claim 1 of the main request is thus neither directly and unambiguously derivable from the general teaching of the description of the application as filed nor from the embodiments as depicted in the figures. The main request is thus not allowable.

2. Auxiliary requests

Claim 1 of the first auxiliary request includes, in one alternative, the subject-matter of claim 1 of the main request. Claim 1 of the second auxiliary request is identical to claim 1 of the main request. The conclusions reached for the main request thus apply equally to the auxiliary requests. The proprietor also did not argue that these requests could result in a different conclusion being reached.

None of the auxiliary requests is thus allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



D. Grundner

M. Harrison

Decision electronically authenticated