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Datasheet for the decision of 25 February 2021

Case Number: T 1576/17 - 3.2.06

Application Number: 09748589.0

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IPC: A61F13/00, A61M1/00

Language of the proceedings: EN

Title of invention:
DRESSING REDUCED-PRESSURE INDICATORS AND SYSTEMS

Patent Proprietor:
KCI Licensing, Inc.

Opponent:
Smith and Nephew, Inc.

Headword:

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - main request, first auxiliary request - no

Decisions cited:

Catchword:

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Boards of Appeal

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Case Number: T 1576/17 - 3.2.06

D E C I S I O N
of Technical Board of Appeal 3.2.06
of 25 February 2021

Appellant: (Opponent)	Smith and Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 (US)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Respondent: (Patent Proprietor)	KCI Licensing, Inc. P.O. Box 659508 San Antonio, TX 78265 (US)
Representative:	Simmons & Simmons City Point One Ropemaker Street London EC2Y 9SS (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 May 2017 concerning maintenance of the European Patent No. 2490637 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. An appeal was filed by the appellant (opponent) against the interlocutory decision of the opposition division in which it found that European patent No. 2 490 637 in an amended form met the requirements of the EPC.

II. The appellant requested that the decision under appeal be set aside and the patent be revoked.

III. With letter of 24 January 2018 the respondent (patent proprietor) requested that the appeal be dismissed or, auxiliarily, that the patent be maintained in amended form according to a first auxiliary request.

IV. The Board issued a summons to oral proceedings and a subsequent communication containing its provisional opinion, in which it indicated *inter alia* that the invention defined in claim 1 of both requests on file appeared not to meet the requirements of Article 83 EPC.

V. With letter of 12 November 2020 the respondent submitted further arguments refuting the Board's preliminary opinion regarding Article 83 EPC.

VI. Oral proceedings before the Board were held by video conference on 25 February 2021. The requests of the parties were as follows:

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

The respondent requested that the appeal be dismissed (main request), auxiliarily that the patent be

maintained in amended form on the basis of the first auxiliary request filed with letter dated 24 January 2018.

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

A reduced-pressure dressing (112) for treating a tissue site (102) on a patient with reduced pressure, the dressing (112) comprising:
a dressing bolster (114) for providing a reduced-pressure treatment space over a tissue site;
a sealing member (116) for covering the dressing bolster (114) and a portion of the patient's epidermis (106);
a reduced-pressure interface (138) coupled to the sealing member (116) for providing reduced pressure to the dressing bolster (114);
a dressing reduced-pressure indicator (101) fluidly coupled to the dressing bolster (114) proximate the dressing bolster (114), wherein the dressing reduced-pressure indicator (101) comprises:
a moving member (152) that is adapted to move under reduced pressure, and
a visual indicator (154) associated with the moving member (152)
wherein the moving member (152) comprises an indicator sealing member (170) over a convex member (172); and
wherein the visual indicator (154) comprises the indicator sealing member (170) changing appearance as the indicator sealing member (170) approximates the convex member (172)
wherein the convex member (172) having an interior surface (174) with a first color; and
wherein the indicator sealing member (170) having a second color which changes appearance to a third color as the indicator sealing member (170) approximates the

interior surface (174) of the convex member (172)."

Claim 1 of the first auxiliary request reads as for claim 1 of the main request except for the final feature starting with 'wherein' reading as follows:

"wherein the indicator sealing member (170) having a second color, different to the first color, which changes appearance to a third color, different to the first and second colors, as the indicator sealing member (170) approximates the interior surface (174) of the convex member (172)."

VIII. The appellant's arguments relevant to the present decision may be summarised as follows:

The invention according to claim 1 of the main request could not be carried out by the skilled person contrary to the requirements of Article 83 EPC. The skilled person would be unable to provide an indicator sealing member over a convex member which could approximate an interior surface of the convex member, as claimed. The objection was not a problem of the clarity of claim 1 as what was claimed could be clearly understood. Instead the problem lay in the skilled person being unable to carry out what was clearly defined in the claim. Not every protrusion from a surface could be described as being convex and no definition of this was provided in the patent. The description was also silent as regards an interior surface of the convex member. Consequently the skilled person was not taught by the patent as a whole how the indicator sealing member could approach the interior surface of the convex member. Even Figure 11 did not assist the skilled person since this did not reflect the normal understanding of what a convex shaped member was. The

scope of claim 1 was thus far broader than the sole example of the invention in the description. Should functional features in the claim be used to assist the understanding of the dressing reduced-pressure indicator, these even contradicted the structural features due to the indicator sealing member having to approximate the interior surface of the convex member whilst simultaneously being positioned above the convex member.

Claim 1 of the first auxiliary request failed to overcome the objection under Article 83 EPC to the main request.

IX. The respondent's arguments relevant to the present decision may be summarised as follows:

The requirements of Article 83 EPC were fulfilled by claim 1 of the main request. The appellant's objections amounted to a clarity objection rather than one of sufficiency. Despite certain terms of claim 1 being somewhat unusual, if these were correctly construed, the invention could undoubtably be carried out by the skilled person.

Firstly considering claim 1 without reference to the description, the term 'convex member' would just be understood by the skilled person as defining a protrusion of any shape extending outwardly from a surface, rather than being limited to a mathematically convex protrusion. The 'interior surface' of such a 'convex member' would be understood as the surface defined by a hollow or a recess formed into the otherwise continuous surface of the convex member. As a result, the indicator sealing member being positioned over the convex member would approximate the interior

surface of the convex member when a reduced pressure was applied to the dressing. As a further result of the interior surface of the convex member being sandwiched under reduced pressure conditions between the indicator sealing member and the convex member, the surface could also be seen as an 'interior surface'. The function of the indicator sealing member approximating the interior surface of the convex member in order to display a colour change also clarified the claimed arrangement of physical features and assisted the skilled person in understanding and carrying out the invention according to claim 1.

If the skilled person referred to the description for guidance on carrying out the claimed invention, the Figure 11 embodiment provided one example of this, with a convex member that protruded outwards and had an interior surface defined on a hemispherical recess in the convex member. The convex member extended upwards from the planar portion of the body 171 of Figure 11. The reference sign 172 in the figure, whilst pointing to the hemispherical line additionally labelled as the surface of the convex member 174, should actually be interpreted to stop short of this line to indicate the convex member itself. As a consequence, Figure 11 was consistent with claim 1. An embodiment which did not enable the indicator sealing member to approximate both the convex member and the interior surface of the convex member was clearly not within the scope of claim 1, since the claimed approximation to the interior surface was simply a further limitation of the claim which additionally defined the colour changes.

For the same reasons as those presented for the main request, the first auxiliary request also met the requirements of Article 83 EPC.

Reasons for the Decision

Main request

1. *Article 83 EPC*

The invention according to claim 1 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, contrary to the requirements of Article 83 EPC.

1.1 Considering the invention defined in claim 1 alone, the skilled person would be unable to construct the claimed 'dressing reduced-pressure indicator'. Whilst providing both a convex member with an interior surface and an indicator sealing member over the convex member would be unproblematic for the skilled person, they would be at a loss as to how the indicator sealing member, in the arrangement as claimed, could approximate the interior surface of the convex member.

1.1.1 The Board holds that, seen generally, an interior surface of a body must be a surface enclosed to at least some degree by the body itself. In the context of a 'convex member', if this were seen as an essentially two-dimensional body with an upwards protrusion of a generally convex shape, the interior surface would be that on the lower surface of the two-dimensional body i.e. that having an essentially concave shape. This would be the only surface which could be considered to be enclosed to some degree by the body itself and thus the only surface which could reasonably be understood to be an interior surface of a convex member. The surface on the opposite side of the convex member to

the interior surface, i.e. the upper surface of the two-dimensional body would not reasonably be referred to as an 'interior surface', not least since it would not be at all enclosed by the convex member. As a consequence, with the indicator sealing member being defined as being 'over' the convex member in claim 1, the skilled person would not know how to enable the indicator sealing member to approach the convex member from below which would be required in order to satisfy the claimed definition of the 'indicator sealing member approximates the interior surface of the convex member'.

1.1.2 The respondent argued that the claimed 'interior surface of the convex member' would be understood from the wording of the claim alone as the surface defined by a hollow or a recess formed in the upper surface of the convex member (for ease of later reference, this will be called the 'hollow embodiment'). This example of how the claimed interior surface could be understood is, however, a very specific embodiment not suggested to the skilled person by the terminology 'interior surface of a convex member' defined in the claim. Additionally, as explained in point 1.1.1, the interior surface of a convex member would be seen as the lower surface in the example described there. If a hollow or recess were then imagined in the upper surface, this would be formed in the exterior surface of the convex member such that even the surface within the hollow or recess would still be the exterior surface of the convex member. The argument that the skilled person would envisage the claimed invention with a hollow in the upper surface of the convex member is thus in no way suggested by the claim language, and the Board finds that this would not be reasonably interpreted as

an interior surface by the skilled person.

1.1.3 The respondent's contention that the 'hollow embodiment' would enable the skilled person to carry out the invention because the surface of the hollow would be sandwiched between the indicator sealing member and the convex member, thereby fulfilling the 'interior surface' condition of claim 1, is not accepted. Claim 1 defines the interior surface solely in relation to the convex member - 'the convex member having an interior surface' - not additionally in relation to the indicator sealing member. The skilled person would therefore not reasonably consider a sandwiching of a surface between the indicator sealing member and the convex member as therefore resulting in the surface being an 'interior surface'. Even if the respondent's definition for the 'interior surface' were accepted, this would directly contradict the skilled person's understanding, as indicated in point 1.1.1 above, of what the interior surface of a convex member is, such that they would be left in considerable doubt as to how the claimed interior surface of the convex member should be realised.

1.1.4 The respondent further argued that the function of the indicator sealing member approximating the interior surface of the convex member in order to realise a colour change would, in case any doubt existed, enable the skilled person to understand and thus carry out the claimed physical arrangement of the dressing reduced-pressure indicator. Whilst the colour change associated with an indicator sealing member approximating the coloured interior surface of a convex member can be understood, this fails to teach the skilled person how the indicator sealing member, arranged over the convex member in the claimed invention can approximate the

interior surface of the convex member. Being 'over' the convex member, the skilled person would be unable to envisage how the indicator sealing member could possibly approximate the interior surface of the convex member i.e. that surface on the underside of the convex member (see point 1.1.1). Since it is located 'over' the convex member, it would naturally approximate its exterior surface rather than the interior surface.

1.1.5 The respondent's contention that the appellant's objections merely related to a lack of clarity in the claim, rather than an inability to carry out the invention, is also not accepted. The features included in claim 1 and their relative positioning and required interactions are clear from the wording of the claim:
- an indicator sealing member over a convex member;
- the indicator sealing member changing appearance as it approximates the convex member;
- the convex member having an interior surface with a first color; and
- a second color of the indicator sealing member changing appearance to a third color when it approximates the interior surface of the convex member.
The elements of the individually claimed features are clear and can certainly be understood by the skilled person, as is their indicated interaction in order to indicate the presence of a reduced pressure in the dressing. The difficulty lies in how to resolve the contradiction in a way that the indicator sealing member can be realised so that it lies over the convex member, yet, in response to a reduced pressure of the dressing, can approximate the interior surface of the convex member. This therefore relates to an inability to carry out the claimed invention, rather than a lack of clarity of the claim as a result of its features and

their interaction.

1.1.6 In summary therefore, when considering claim 1 alone, the skilled person is not taught how to carry out the claimed invention.

1.2 When consulting the description and figures in order to resolve the inability to carry out the invention, the skilled person is still unable to do so. The sole figure offering any guidance as to how the claimed invention could be realised is Figure 11, which depicts an embodiment of the invention allegedly comprising, through labelling of the elements, *inter alia* a convex member 172, an indicator sealing member 170 and a surface 174 of the convex member (see paragraphs [0042] to [0044]). Despite the structure in Figure 11 being described as an embodiment of the invention, how the convex member is to be interpreted with the indicator sealing member approximating its interior surface remains a mystery for the skilled person.

1.2.1 Figure 11 indicates the convex member 172 as being realised by a hemispherical depression 'formed in' the base or body 171, with the surface of this depression labelled with lead line from 174 being indicated as being the same surface of the convex member labelled with lead line from 172. However, the hemispherical depression would never be considered as a 'convex member' by the skilled person due to this depression being of a concave rather than a convex form. Whilst a concave form could indeed be labelled as convex when viewed from the 'other side' of the concave surface, this is not how a convex shape is technically understood: the shape is defined as viewed from the outside of the body i.e. from above the surface 174 in Figure 11, not through a hypothetical observation of

the same shape from the opposite side i.e. from inside the body 171 of Figure 11. The hemispherical depression in the body 171 would thus logically be understood as defining a concave member, not a convex member.

1.2.2 The respondent's interpretation of Figure 11, that the outwardly projecting part of the body 171 is the convex member is not accepted. An element which outwardly protrudes from a surface does not automatically satisfy the requirements to be called a convex element. A convex element must, in the Board's view, have at least a semblance of a convex shape to it, even if not purely, mathematically convex. In the Board's view, the respondent's examples of a frustrum or a pyramid being a convex element stretches the definition beyond its reasonable limits. Without further detail qualifying the form of the frustrum or pyramid, indicating at least a degree of mathematical convexity to the element when viewed objectively, the Board cannot accept that the skilled person would view this outwardly projecting part of body 171 as a convex element or member.

1.2.3 Furthermore, the respondent's interpretation is not consistent with paragraph [0042] of the patent which describes the convex member 172 as being 'formed in a base or body 171'. The interpretation of the entirety of body 171 forming the convex member is thus not consistent with the description of the Figure 11 embodiment itself. Even if, as argued at oral proceedings, the convex member were interpreted as that part of the body which protruded from the planar base of the body 171 (albeit shown anyway as a single body), such a protruding portion still fails to be of a convex shape which the skilled person would reasonably interpret as the claimed convex member.

1.2.4 In this regard the respondent also argued that the reference numeral line 172 incorrectly terminated at the surface 174 and should in fact indicate the general upwards protrusion of the member from the planar surface of the body 171. This seems to be mere conjecture on the part of the respondent. Even if followed, this would not help the skilled person to carry out the claimed invention due to their inability to determine what in Figure 11 should be the convex member and how the indicator sealing member could approximate the 'interior surface' of such convex member (see also points 1.2.2 to 1.2.3 above). Lastly it should be noted that element 174 is not described as being the interior surface, but merely as 'surface 174'.

1.2.5 Thus, in summary, the respondent's contention that the embodiment of Figure 11 indicated how the invention according to claim 1 was to be carried out is not accepted. Figure 11 fails to depict an embodiment which would assist the skilled person in this task:
Firstly, it fails to depict what the skilled person would reasonably view as a convex member (see points 1.2.2 to 1.2.4);
Secondly, it does not disclose anything that the skilled person could reasonably regard as the claimed interior surface of the convex member. As already held in respect of the 'hollow embodiment' in point 1.1.2, the surface 174 does not satisfy the claimed requirement of being an interior surface of the convex member, the term 'interior surface' also in fact being used nowhere in the description of the present patent (apart from in paragraph 0033 where it is correctly used to described a 'convex interior surface' of a collapsible wall, in the normal meaning of the term 'convex'). In trying to interpret the invention of

claim 1 using Figure 11, the skilled person would not be assisted at all due to the 'convex member' and the 'interior surface' of the convex member not being clearly identifiable in this embodiment; and
Thirdly, in failing to allow a clear identification of the convex member and its interior surface, the Figure 11 embodiment further fails to indicate how the indicator sealing member can approximate the unidentifiable interior surface of the undefined convex member.

1.2.6 It thus follows that, even in the light of the description and figures of the patent, the invention of claim 1 cannot be carried out by the skilled person.

1.2.7 The requirements of Article 83 EPC are therefore not met and the main request is not allowable.

First auxiliary request

2. *Article 83 EPC*

2.1 Claim 1 differed from claim 1 of the main request solely through the further specification of the second color being different to the first color and the third color being different to the first and second colors. As such, the amendments had no impact on the finding with respect to the main request of the disclosure lacking sufficiency.

2.2 When specifically asked on this matter, the respondent confirmed that it had no further arguments in support of the first auxiliary request in regard to Article 83 EPC.

2.3 The Board therefore finds that, for the same reasons as for the main request, the invention according to claim 1 of the first auxiliary request cannot be carried out by the skilled person.

2.4 The requirements of Article 83 EPC are therefore not met such that the first auxiliary request is also not 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