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Datasheet for the decision of 31 March 2022

Case Number: T 2059/17 - 3.2.02

Application Number: 04778864.1

Publication Number: 1663380

IPC: A61M35/00

Language of the proceedings: EN

Title of invention:
NEGATIVE PRESSURE WOUND TREATMENT DRESSING

Patent Proprietor:
KCI Licensing, Inc.

Opponent:
Smith and Nephew, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56, 83, 84, 123(2), 123(3)
RPBA Art. 13(2)

Keyword:

Late-filed request - admitted (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)
Amendments - added subject-matter (no) - broadening of claim (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2059/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 31 March 2022

Appellant: (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)
Respondent: (Opponent)	Smith and Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 (US)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 July 2017 revoking European patent No. 1663380 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	N. Obrovski
	A. Martinez Möller
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor filed an appeal against the decision of the opposition division to revoke European patent No. 1 663 380.

II. Oral proceedings before the board were held on 31 March 2022 in the absence of the respondent (opponent).

III. The appellant (patent proprietor) requested as a main request that the decision be set aside and that the patent be maintained in amended form on the basis of the claims of the former first auxiliary request filed with the submission dated 10 March 2022.

The respondent had requested in writing that the appeal be dismissed and that the auxiliary requests filed with the statement of grounds of appeal not be admitted into the proceedings. It had also requested that the case be remitted to the opposition division if further prior-art objections had to be considered.

IV. Claim 1 of the main request reads as follows.

"A wound dressing for use under negative pressure, comprising:

a porous polymer foam concave pad adapted for placement in a wound on an extremity;

an occlusive wrapping adapted for positioning over and around the porous polymer foam concave pad, wherein said occlusive wrapping comprises a porous polymer foam fluid manifold having a receiving site and fluid

communicator arms extending distally from the receiving site, and an occlusive drape which is made of a vapor permeable polyurethane material, surrounding said porous polymer foam fluid manifold, wherein the occlusive drape has a wound facing layer and an outer layer and wherein a wound contact region of the wound facing layer is fenestrated, and an adhesive on at least an edge of said occlusive drape for sealing said occlusive wrapping to the area surrounding the wound; and

a fluid communication port through at least a layer of said occlusive drape for communicating fluid from said porous polymer foam fluid manifold to a source of negative pressure,

wherein the occlusive wrapping is folded along its centreline and its lower edges are bonded together to form a pouch for receiving at least a portion of the extremity."

V. The following documents are referred to in the present decision.

VP-C : WO 2005/009488 A2 (original application as filed)

VP-7 : D. Dill-Müller, A. Bonowitz, A. Wagner, W. Tilgen; "Vakuumassistierter Wundverschluss nach Exzision eines malignen Melanoms an der Ferse mit dem Fersenschaum (V.A.C.®-Heel-Dressing)", published in a special edition of the German Zentralblatt für Chirurgie in May 2004

VI. The respondent's arguments can be summarised as follows.

Added subject-matter

Claim 1 did not meet the requirements of Article 123(2) EPC for the following reasons.

The application as filed (VP-C) did not disclose that the concave pad was adapted for placement in a wound. Instead, it was stated in paragraph [0026] of VP-C that the pad had to be trimmed to the areal dimensions by the user before it was adapted to be placed in the wound.

A fluid communication port extending through at least a layer of the occlusive drape was not disclosed in combination with the embodiments of Figures 1A to 5 of VP-C, on which claim 1 was based. In these embodiments, the fluid communication port was positioned over the receiving site and adhesively bonded to the dressing (Figure 4G).

The feature that the occlusive wrapping is folded along its centreline and that its lower edges are bonded together to form a pouch could not be derived directly and unambiguously from VP-C. Paragraphs [0008] and [0027] only disclosed that a pouch could be formed in use. In the course of the application of the dressing, the surgeon had to fold the wrapping and bond the lower edges together. Hence, VP-C only described the suitability of the wrapping to form a pouch, which was different from the structural limitation of the wrapping forming a pouch.

Furthermore, claim 1 in its entirety constituted an unallowable intermediate generalisation. There was an inextricable link between

- any of the features "the fluid manifold is made from porous polymer foam", "the occlusive drape is made of a vapor permeable polyurethane material" and "the wound contact region of the wound facing layer is fenestrated", and the configuration of the fluid communicator arms terminating in loops or fingers;

- the specific shape of the manifold having a wound contact region and a receiving site and the fluid communication port being attached to the receiving site;

- the wound-facing layer and the outer layer being sealed along their periphery and the feature "the occlusive drape is made of a vapor permeable polyurethane material";

- the wrapping comprising a fingerhold and first and second removable liners and the feature "the occlusive wrapping is folded along its centreline and its lower edges are bonded together to form a pouch for receiving at least a portion of the extremity".

The omission of the additional features in claim 1 constituted an unallowable intermediate generalisation.

Extension of protection

The replacement of the feature "the occlusive drape is formed from an occlusive material" with the feature "the occlusive drape is made of a vapor permeable polyurethane" shifted and broadened the scope of protection. The occlusive property could be achieved in different ways, and not necessarily by means of the material forming the drape.
Furthermore, the contradiction between the wrapping

being occlusive and the drape being made of a vapour-permeable material inadmissibly extended the scope of the claim.

By the replacement of the feature "a contoured pad adapted for placement in a wound" with "a concave pad adapted for placement in a wound" the protection conferred by the patent was extended, since the contour of the pad defined by its outer edge no longer needed to be suited for placement in the wound.

Clarity

The features that the drape is occlusive and that it is made of vapour-permeable polyurethane were mutually exclusive, since the drape could not be both occlusive and permeable.

Moreover, it was not clear whether concavity was used to refer to the shape of the pad's boundary or of the pad's surface. Nor was it clear how the specification of the pad being concave could be distinguished from the inherent concavity of the foam material.

Hence, claim 1 lacked clarity.

Sufficiency of disclosure

The person skilled in the art did not know how to carry out the two contrary teachings, namely that both the pad and the wound contact region of the occlusive wrapping should contact the wound.

Hence, the invention was not sufficiently disclosed to be carried out by the person skilled in the art, contrary to the requirements of Article 83 EPC.

Inventive step in view of VP-7 and the public prior use of the V.A.C Heel Dressing

VP-7 and the public prior use could be used as the closest prior art, from which the subject-matter of claim 1 differed in that the pad was concave.

For the person skilled in the art it would have been obvious to provide the pad with a concave shape such that the pad conformed with the wound on the extremity.

Therefore, the subject-matter of claim 1 lacked an inventive step.

Admittance of the auxiliary requests filed with the statement of grounds of appeal

The auxiliary requests should be rejected as inadmissible since their claims entailed different lines of argumentation and did not converge.

VII. The appellant's arguments can be summarised as follows.

Admittance of the first auxiliary request filed with the submission dated 10 March 2022.

The request was filed at the earliest possible point in time, namely after the board had issued its view concerning the features "contoured vs. concave" and "over and around". Since this matter concerning the feature "over and around" was decided in favour of the appellant in the opposition division's decision, an earlier filing of this request would have been neither appropriate nor practical.

Inventive step in view of VP-7 and the public prior use of the V.A.C Heel Dressing

The subject-matter of claim 1 involved an inventive step, since neither VP-7 nor the public prior use disclosed a concave pad.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to a wound dressing for use under negative pressure that is adapted to be applied to wounds located on an extremity of the patient such as the heel.

The wound dressing comprises a concave pad (26) which is placed in a wound (Figure 4A). An occlusive wrapping (10) is positioned over and around the pad (26, Figures 4B and 4C). The occlusive wrapping comprises a fluid manifold (14) having a receiving site (20) and fluid communicator arms (22) extending distally from the receiving site (Figure 2). The fluid manifold is surrounded by an occlusive drape (16) having an outer layer (16b) and a wound-facing layer (16a, Figure 1A). A wound contact region (17) of the wound-facing layer is fenestrated (19, Figure 1B). The occlusive wrapping can be sealed to the area surrounding the wound by means of an adhesive on at least an edge of the occlusive drape (16). The wound dressing further comprises a fluid communication port (18) through at

least a layer of the occlusive drape for communicating fluid from the fluid manifold to a source of negative pressure.

Before the wound dressing is placed on the wound, the occlusive wrapping is folded along its centreline and its lower edges are bonded together to form a pouch (30) for receiving the heel (Figure 5).

2. Admittance of the main request

The main request was filed as the first auxiliary request on 10 March 2022 and differed from the previous first auxiliary request filed with the statement of grounds of appeal through the insertion of "and around" after "over". Since it was filed after notification of the summons its admittance is subject to the provisions of Article 13(2) RPBA 2020.

In the communication under Article 15(1) RPBA the board expressed the view that, from the plurality of the respondent's objections as to added subject-matter, only the one relating to the feature "over and around" was relevant. The significance of this issue, which was decided in favour of the appellant in the appealed decision and was not presented as a prominent objection in the reply to the statement of grounds, was rendered objectively apparent for the first time by the board's communication. Moreover, when applying Article 13(2) RPBA 2020, a Board may also rely on the criteria referred to in Article 13(1) RPBA 2020. In this regard, the amendment immediately overcomes the issue raised, does not give rise to new objections and is not detrimental to procedural economy. The alleged lack of convergence with higher ranking requests as raised by the respondent is no longer relevant either, since the

request under consideration became the new main request.

In conclusion, the Board exercised its discretion under Article 13(2) RPBA to admit the request.

3. Added subject-matter

3.1 As to the feature "contoured pad in a wound on an extremity", the board considers that it can be derived from VP-C (paragraph [0007], lines 4 to 5) that the pad is adapted for placement in a wound even without being trimmed to the areal dimensions thereof.

As to the feature "fluid communication port", the board considers that claim 1 does not require the port to extend through a layer of the drape but merely requiring the fluid communication to be established through the drape when the port is connected to the wrapping. Hence, in VP-C and in claim 1, the fluid communication port is a separate component which can be attached to the receiving site when the dressing is secured to the patient's heel (Figure 4G).

As to the feature "folded along its centreline", the board considers the structural limitation defined in this feature to be disclosed in Figure 5 and paragraph [0020] of VP-C.

Hence, none of the features mentioned above add subject-matter.

3.2 As to the issue of unallowable intermediate generalisation, the board considers that there is no inextricable link between

- any of the features "the fluid manifold is made from porous polymer foam", "the occlusive drape is made of a vapor permeable polyurethane material" and "the wound contact region of the wound facing layer is fenestrated" (disclosed in paragraphs [0025] and [0023] of VP-C), and the configuration of the fluid communicator arms. The function of communicating fluid and vacuum between the wound contact region 17 and the receiving site 20, effectuated by the fluid manifold and the occlusive drape, is not inextricably linked to the specific shape of the arms.

- the specific shape of the manifold having a wound contact region and a receiving site and the fluid communication port being attached to the receiving site. Figures 1B and 2 disclose the wound contact region and the receiving site without the fluid communication port being attached to it. In fact, it appears from Figures 4A to 4G that the fluid communication port is not attached to the receiving site until the occlusive wrapping has been secured to the heel of the patient.

- the wound-facing layer and the outer layer being sealed along their periphery and the feature "the occlusive drape is made of a vapor permeable polyurethane material". The occlusive drape can be made of vapour-permeable polyurethane irrespective of the layers being sealed along their periphery.

- the wrapping comprising a fingerhold and first and second removable liners and the feature "the occlusive wrapping is folded along its centreline and its lower edges are bonded together to form a pouch for receiving at least a portion of the extremity". The occlusive wrapping can be folded along its centreline to form a

pouch irrespective of the provision of a fingerhold to facilitate grasping or removable liners to protect the adhesive backing.

Hence, the omission of the features

- the fluid communicator arms either terminate in loops having openings for viewing the wound perimeter or in fluid communicator fingers extending distally from the fluid communicator arms,
- the wound-facing layer and the outer layer are sealed along their periphery to secure the fluid manifold within the wound-facing layer and the outer layer of the drape,
- the fluid communication port is attached to the receiving site,
- the occlusive wrapping comprises a fingerhold to facilitate grasping the pouch and holding it in place,
- the occlusive wrapping comprises a (first) removable liner covering an adhesive backing on the outer layer and having a finger tab, and
- the occlusive wrapping comprises a second removable liner adhering to the receiving site to protect the adhesive on the wound-facing layer

in claim 1 does not constitute an unallowable intermediate generalisation.

3.3 Consequently, claim 1 meets the requirements of Article 123(2) EPC.

4. Extension of protection

4.1 The board agrees with the opposition division (point 17.3 of the decision) that the feature "made of a vapor permeable polyurethane" further specifies the

occlusive drape. Hence, there is no contradiction between the wrapping being occlusive and the drape being made of a vapour-permeable material. In this context, the term "occlusive" implies that the material of the drape is occlusive at least to the extent required in the present invention.

4.2 In the board's view, the term "contoured" means "shaped to fit the outline of something". Hence, in the context of the present patent, "contoured" means "shaped to fit the outline of a contoured body part", such as a patient's heel. Therefore, since "contoured" represents a broader definition of shape which encompasses "concave", the scope of the claim has not been extended.

4.3 Hence, the requirements of Article 123(3) EPC are met.

5. Clarity

As mentioned above (point 4.1), the requirements that the drape be occlusive and that it be made of vapour-permeable polyurethane are not mutually exclusive.

From the wording of the claim, which refers to a "polymer foam concave pad", it is clear that the wording "concave" refers to the whole pad, i.e. to the shape of its surface, irrespective of a possible concavity of it boundary or an inherent concavity due to its porosity. This understanding of the claim is also supported by Figures 3B and 3C of the patent, which show a concave pad.

Hence, claim 1 does not lack clarity.

6. Sufficiency of disclosure

It is clear from the patent at column 5, lines 50 to 52, that the pouch formed by the occlusive wrapping is placed over the wound and the pad. From Figures 4B and 2 it can be derived that the wound contact region 17 (i.e. the region around the loops 22) contacts the wound with the pad. Hence, there is no contradictory teaching.

The requirements of Article 83 EPC are met.

7. Inventive step in view of VP-7 and the public prior use

The board agrees with the respondent that neither the wound dressing of VP-7 nor the public prior use has a concave pad.

Due to its concavity, the claimed pad can be placed over a flat wound on a curved surface. Hence, the problem to be solved can be regarded as to improve treatment of wounds on a concave part of the body.

VP-7 and the public prior use relate to the treatment of deep wounds, wherein one or more flat pads are placed in the wound. The person skilled in the art would not have been prompted by this prior art to modify the dressing such that it included a concave pad. The board thus holds that, starting from this prior art, the provision of a concave pad would not be obvious.

Therefore, the subject-matter of claim 1 involves an inventive step over VP-7 and the public prior use.

8. The impugned decision was only based on the requirements of Articles 123(2) and 123(3) EPC and inventive step starting from the public prior use to which VP-7 relates. In addition to the issues considered in the present decision a number of patentability objections in view of the prior art were raised in opposition and not considered in the contested decision. The respondent had requested that the case be remitted to the opposition division if further prior-art objections had to be considered.

Not remitting the case to the opposition division would necessitate the board having to examine all further legal requirements in both first-instance and last-instance proceedings and effectively replace the opposition division rather than reviewing the contested decision in a judicial manner (Article 12(2) RPBA 2020). It thus follows that "special reasons" within the meaning of Article 11 RPBA 2020 present themselves.

Hence, the board remits the case to the opposition division for further prosecution.

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 for further prosecution on the basis of the main request,

i.e. the former first auxiliary request filed with the submission dated 10 March 2022.

The Registrar: The Chairman:

N. Schneider M. Alvazzi Delfrate

Decision electronically authenticated