

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 31 March 2022**

Case Number: T 2053/17 - 3.2.02

Application Number: 10176295.3

Publication Number: 2253353

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, 76(1), 83, 84, 123(3)

RPBA Art. 12(4)

Keyword:

Inventive step - (yes)

Divisional application - added subject-matter (no)

Sufficiency of disclosure - (yes)

Claims - clarity (yes)

Late-filed request - admitted (yes)

Amendments - broadening of claim (no)

Decisions cited:

T 2059/17

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 2053/17 - 3.2.02

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

Appellant: 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)

Respondent: Smith and Nephew, Inc.
(Opponent) 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. 2253353 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. 2 253 353.
- 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 that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of the main request or one of the first to fourth auxiliary requests, all 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, the wound dressing having a porous polymer foam concave pad adapted for placement in a wound, the wound dressing characterized by:

an occlusive wrapping (10) adapted for positioning over and around the porous polymer foam concave pad, wherein the occlusive wrapping has a receiving site and a wound contact region displaced from the receiving site, and wherein the occlusive wrapping is for allowing negative

pressure to be delivered to the receiving site and transported to the wound contact region for application to the wound;

wherein the occlusive wrapping (10) comprises:

an occlusive drape (16) having a wound-facing layer (16a) and an outer layer (16b),

a unitary fluid manifold (14) having a part positioned at the receiving site and a part positioned at the wound contact region, the parts being connected to each other such that negative pressure applied at the part positioned at the receiving site is transported to the part positioned at the wound contact region, wherein the fluid manifold (14) is made of a porous polymer foam material,

wherein the fluid manifold (14) is enclosed within the occlusive drape between the wound-facing layer and the outer layer,

a plurality of fenestrations (19) formed on the occlusive drape (16) at the wound contact region, and an adhesive on at least an edge of the occlusive drape (16) for sealing the occlusive wrapping (10) to the area surrounding the wound; and

a fluid communication port (18) through at least a layer of the occlusive drape (16) for communicating fluid from the fluid manifold (14) to a source of negative pressure."

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

VP-C : WO 2005/009488 A2 (original parent 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 in its entirety constituted an unallowable intermediate generalisation in respect of the originally filed parent application VP-C. 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 "a plurality of fenestrations are formed on the occlusive drape at the wound contact region" 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 fluid manifold being enclosed within the occlusive drape between the wound-facing layer and the outer layer, and the wound-facing layer and the outer layer being sealed along their periphery;
- the fluid manifold being unitary and the exact shape of the manifold;
- the features of the wrapping being adapted to be folded along its centreline to form a pouch, and the

wrapping comprising a fingerhold and first and second removable liners.

Furthermore, the combination of the features "polymer foam" and "concave" could not be derived from the parent application as originally filed.

The application as originally filed did not disclose that the occlusive wrapping had a receiving site and a wound contact region. Instead, the receiving site was a part of the fluid manifold.

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).

Extension of protection

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.

Hence, claim 1 did not meet the requirements of Article 123(3) EPC.

Clarity

It was not clear whether concavity was used to refer to the shape of the pad's boundary or of the pad's

surface, and how the specification of the pad being concave could be distinguished from the inherent concavity of the foam material.

Hence, claim 1 lacked clarity (Article 84 EPC).

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.

The person skilled in the art was not taught how the occlusive wrapping would be able to deliver negative pressure to the receiving site.

The patent did not enable the person skilled in the art to carry out the invention.

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

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 main 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 feature "over and around". Since this matter 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.

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 has a receiving site (20) and a wound contact region displaced from the receiving site (Figure 1B). The occlusive wrapping allows negative pressure to be

delivered to the receiving site and transported to the wound contact region for application to the wound. The occlusive wrapping comprises an occlusive drape (16) having an outer layer (16b) and a wound-facing layer (16a, Figure 1A), and a unitary fluid manifold (14) having a part positioned at the receiving site and a part positioned at the wound contact region, the parts being connected to each other such that negative pressure applied at the part positioned at the receiving site is transported to the part positioned at the wound contact region. The fluid manifold is made of porous polymer foam material and is enclosed within the occlusive drape between the wound-facing layer and the outer layer. At the wound contact region, a plurality of fenestrations (19) are formed on the occlusive drape (Figure 1B). The occlusive wrapping further comprises an adhesive on at least an edge of the occlusive drape for sealing the occlusive wrapping to the area surrounding the wound, and a fluid communication port (18) through at least a layer of the occlusive drape (16) for communicating fluid from the fluid manifold to a source of negative pressure (Figure 4G).

2. Admittance of the main request

The main request corresponds to the second auxiliary request filed with the statement of grounds of appeal. It was thus filed at the earliest possible point of the appeal proceedings, in accordance with Article 12(4) RPBA 2007. The alleged lack of convergence with higher ranking requests as raised by the respondent is no longer pertinent since the request is now the main request.

Under these circumstances the board exercised its discretion under Article 12(4) RPBA 2007 to admit the

request.

3. Added subject-matter

The patent in suit was filed as a divisional application of the parent application VP-C, to which reference is made in the following paragraphs.

3.1 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 "a plurality of fenestrations are formed on the occlusive drape at the wound contact region" (disclosed in paragraphs [0025] and [0023]), and the configuration of the fluid communicator arms terminating in loops or fingers. 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 only attached to the receiving site after the occlusive wrapping has been secured to the heel of the patient.

- the fluid manifold being enclosed within the occlusive drape between the wound-facing layer and the outer layer, and the wound-facing layer and the outer layer being sealed along their periphery. The occlusive drape can be made of vapour-permeable polyurethane irrespective of the layers being sealed along their periphery.

- the fluid manifold being unitary and the exact shape of the manifold. The exact shape of the manifold is considered irrelevant for effectively transporting the negative pressure through the unitary manifold. Furthermore, paragraph [0024] mentions different shapes of the unitary fluid manifold.

- the features of the claim and the wrapping being adapted to be folded along its centreline to form a pouch, and the wrapping comprising a fingerhold and first and second removable liners. The occlusive wrapping can be applied to the patient's extremity without being folded along its centreline to form a pouch, and without having 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 is adapted to form a pouch when it is folded along its centreline and the lower edges are bonded together,
- 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.

3.2 The board considers that the feature "polymer foam concave pad" can be derived from paragraph [0025] of VP-C, referring to Figures 3A-3D and mentioning the porous polymer foam material, in connection with Figures 3B and 3C, showing a concave pad.

Figures 1B and 5 of VP-C disclose the feature that the occlusive wrapping has a receiving site 20.

As to the feature "fluid communication port", the board considers that claim 1 does not require that the port extend through a layer of the drape but merely that the fluid communication 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).

3.3 It follows from the above that claim 1 meets the requirements of Article 76(1) EPC.

4. Extension of protection

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

Consequently, claim 1 of the main request complies with Article 123(3) EPC.

5. Clarity

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 its 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 10 to 12, 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.

Furthermore, it is disclosed in paragraph [0029] that negative pressure is delivered via the flexible tube 42 and the fluid communication port 18 from a negative pressure source 44 to the receiving site of the occlusive wrapping. Hence, the occlusive wrapping allows the negative pressure to be transported from the negative pressure source to the wound via the receiving site and the wound contact region.

The requirements of Article 83 EPC are met.

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

The board agrees with the respondent that neither the wound dressing of VP-7 nor the public prior use have 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. Hence, the board holds that, starting from this prior art, providing 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 76(1) and 123(3) EPC. In addition to the issues considered in the impugned 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 prior-art objections other than the one related to VP-7 and the public prior use - which had been dealt with in the impugned decision in the parallel case on EP 1 663 380 (see T 2059/17) 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 take the place of 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 filed with the submission dated 10 March 2022.

The Registrar:

The Chairman:



N. Schneider

M. Alvazzi Delfrate

Decision electronically authenticated