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**Datasheet for the decision  
of 9 October 2019**

**Case Number:** T 0610/14 - 3.2.02

**Application Number:** 03808617.9

**Publication Number:** 1578477

**IPC:** A61M1/00

**Language of the proceedings:** EN

**Title of invention:**

A dressing assembly for a closed wound or incision

**Patent Proprietor:**

KCI Licensing, Inc.

**Opponent:**

Smith and Nephew, Inc.

**Headword:**

**Relevant legal provisions:**

EPC Art. 100(c), 123(2), 100(b), 83, 100(a), 54, 56

**Keyword:**

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 0610/14 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 9 October 2019**

**Appellant:** Smith and Nephew, Inc.  
(Opponent) 1450 Brooks Road  
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**Respondent:** KCI Licensing, Inc.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 17 January 2014  
rejecting the opposition filed against European  
patent No. 1578477 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** S. Böttcher  
D. Ceccarelli

## **Summary of Facts and Submissions**

- I. The opponent lodged an appeal against the decision of the Opposition Division, dispatched on 17 January 2014, to reject the opposition against European patent No. EP 1 578 477.
- II. Opposition was filed against the patent as a whole and based on grounds for opposition under Articles 100(a), (b) and (c) EPC.
- III. Notice of appeal was filed by the appellant/opponent on 13 March 2014. The appeal fee was paid on the same day.
- IV. The statement setting out the grounds of appeal was received on 27 May 2014.
- V. The parties were summoned to oral proceedings by letter dated 5 July 2019.
- VI. The following documents are referred to in this decision:  
  
D2: WO-A-01/85248  
D6: US-A-4,899,762  
D7: "New Techniques in Wound Management: Vacuum-Assisted Wound Closure", Laurence X. Webb, J. Am. Acad. Orthop. Surg., Vol. 10, No. 5, September/October 2002, pages 303 to 311
- VII. Oral proceedings took place on 9 October 2019.

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

The respondent (patent proprietor) requested that the decision under appeal be set aside and that the patent be

maintained on the basis of one of the main request and first auxiliary request, both filed with letter dated 6 September 2019.

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

"A dressing assembly (302) for a closed wound or incision (304), which comprises:  
an external patient interface including an external fluid transfer component (314), said external fluid transfer component (314) being adapted for transferring fluid from the closed wound or incision (304);  
said external patient interface including an over-drape (316) placed over said external fluid transfer component (314) in contact with a surrounding skin surface;  
a re-closeable seal strip (324) connected to said over-drape (316) and having a closed position sealing same and an open position providing access to said external fluid transfer component (314) therethrough;  
a pair of side drapes (312) each located along a respective side of said wound or incision (304) between said external fluid transfer component (314) and the patient's skin;  
a pressure source (28) connected to the external fluid transfer component (314); and  
an internal fluid transfer component (310) for location in said wound or incision in fluidic communication with said external fluid transfer component (314)."

IX. The appellant's arguments, in so far as relevant to the present decision, can be summarised as follows:

*Claim 1 - added subject-matter (Article 123(2) EPC)*

The combination in claim 1 of "a pressure source connected to the external fluid transfer component" and

"a pair of side drapes each located along a respective side of said wound or incision between said external fluid transfer component and the patient's skin" could not be directly and unambiguously derived from the application as filed. Claim 1 was based on a combination of two discrete embodiments, namely the combination of claim 1 with claims 3 and 4 and the combination of claim 1 with claim 9. However, claim 9 was not dependent on claims 3 and 4. It could not be derived from the application as filed that the embodiment comprising the pair of side drapes but no pressure source (embodiment VII, page 24, line 18 to page 25, line 13, Figures 17 to 22) could be combined with one of the embodiments comprising a pressure source but no side drapes (e.g. embodiment IX, page 27, line 8 to page 28, line 9, Figures 28 and 29; embodiment X, page 28, line 10 to page 31, line 6, Figures 30 to 37; and embodiment XII, page 32, line 1 to page 33, line 6, Figure 41).

The tissue closure system of embodiment VII was assembled by placing one component after the other on the wound site (page 24, line 22 to page 23, line 4), whereas embodiments IX, X and XI comprised a pre-assembled external dressing, wherein a foam piece was enclosed in a sheath (Figures 28, 30 and 41). Hence, embodiments IX, X, and XI were technically incompatible with embodiment VII, and the skilled person would not seriously contemplate combining one of the embodiments having a pre-assembled dressing and a pressure source connected to this dressing with the embodiment having a separate over drape to be placed over the foam piece and no pressure source.

Furthermore, the description disclosed various embodiments of dressings having a pressure source. However, when a pressure source was present, it was not always connected to the external fluid transfer

component. For instance, in the embodiment of Figures 1 to 8 the pressure source was connected to the drain tube 50 arranged in the wound, and in the embodiment of Figure 10, the pressure source was connected to the third fluid transfer component 58a. Thus, although various arrangements for coupling the dressing to a pressure source were mentioned in the description, the specific arrangement of the pressure source as defined in claim 1, namely connected to the external fluid transfer component of an embodiment that was not pre-assembled, could not be derived directly and unambiguously from the application as originally filed.

Therefore, claim 1 introduced subject-matter that extends beyond the content of the application as originally filed.

*Sufficiency of disclosure (Article 83 EPC)*

The patent provided no direction as to how the external fluid transfer component was "adapted for transferring fluid from the closed wound or incision". Therefore, the invention was not disclosed sufficiently to be carried out by the skilled person. Although the patent disclosed that a foam piece may be used for the external fluid transfer component, the selection of the type of foam, e.g. choosing the appropriate porosity, represented an undue burden for the skilled person.

*Novelty (Article 54 EPC)*

The subject-matter of claim 1 lacked novelty over the disclosure of D2. In particular, D2 disclosed an envelope (38) of plastic film enclosing a foam, the envelope having a flange extending beyond the perimeter of the foam (page 5, lines 8 to 13, Figure 1). This flange,

which was formed of a pair of drapes (30 and 28) fused together on either side of the wound, represented a pair of side drapes located along a respective side of the wound as defined in claim 1.

The phrase "a pair of side drapes each located along a respective side of the said wound" did not imply that two separate side drapes had to be provided. The skilled person would have understood this phrase to mean that each pair of drapes (forming the flange) was located on both sides of the wound.

*Inventive step (Article 56 EPC)*

The subject-matter of claim 1 lacked inventive step over D2 in combination with the common general knowledge of the skilled person.

Starting from D2, the distinguishing feature of claim 1 was "a pair of side drapes each located along a respective side of the wound or incision between said external fluid transfer component and the patient's skin". If any technical effect at all was provided by this feature, it would be to prevent contact between the foam and the wound. Thus, the problem to be solved was to protect the wound area in general.

It was shown by the teaching of D7 (page 305, column 1) that this problem was common general knowledge. Furthermore, D7 taught the prevention of contact between the sponge and the wound edge to solve this problem (page 308, column 3).

Moreover, the problem of protecting the wound area was already solved by the provision of the film of D2 (page 7, lines 24 to 26). Thus, the provision of a pair of



drapes was merely an alternative solution to the same problem, which was obvious to the skilled person. Furthermore, D2 disclosed that the flanges of the envelope contacted the skin surrounding the wound (page 8, lines 2 to 5).

Pairs of drapes for the purpose of protecting the skin area adjacent to a wound were disclosed in D6 (column 1, lines 15 to 20; column 1, lines 56 to 59; column 4, lines 58 to 61; column 5, lines 61 to 64). D6 also stated that minimal damage was caused to the tissue surrounding the incision (column 7, line 68 to column 8, line 5; column 8, lines 33 to 38). Thus, the skilled person would have been aware of the use of pairs of drapes in wound dressings. It would have been simple for the skilled person to provide a pair of separate side drapes in the system of D2.

Furthermore, the subject-matter of claim 1 lacked inventive step in view of D2 alone, since providing a pair of separate side drapes instead of the single drape unit of D2 would increase the complexity of the system and would therefore represent a disadvantage. A disadvantageous modification of the prior art could not involve an inventive step.

Accordingly, the subject-matter of claim 1 lacked inventive step over D2 alone and over D2 in combination with the common general knowledge of D7 or D6.

*Request to include a statement in the minutes of the oral proceedings*

The respondent's statement that claim 1 required a pair of side drapes, i.e. two separate drapes each located along a respective side of the wound, should be included

in the minutes of the oral proceedings.

- X. The respondent's arguments, in so far as relevant to the present decision, can be summarised as follows:

*Claim 1 - added subject-matter (Article 123(2) EPC)*

Claim 1 included a combination of claims 1, 3, 4 and 9 of the application as originally filed, and related to embodiment VII of the application, as shown in Figures 17 to 22. Although that embodiment did not include a pressure source, it could be derived from the application as filed (page 1, lines 11 to 15; page 5, lines 4 to 14; and page 12, lines 1 to 13) that the invention was concerned with the use of pressure from a pressure source to treat a wound. Hence, it was clear from the structure of the application, starting from the general description of the invention, that all dressings were meant to be used with a pressure source. Furthermore, various components for coupling the dressing to the pressure source were disclosed (page 16, lines 14 to 21, Figures 12a to 12d), which could be used with dressings such as those claimed.

The connection to the external fluid transfer component mentioned in claim 1 has to be interpreted as a fluidic connection. Thus, in the embodiment of Figure 10, the pressure source was also connected to the external fluid transfer component. It was not necessary for the pressure source to be directly connected to the external fluid transfer component.

The application as filed therefore provided a direct and unambiguous basis for combining the pressure source of claim 9 with the features of claims 3 and 4.

*Sufficiency of disclosure (Article 83 EPC)*

The invention was sufficiently disclosed since the patent suggested the use of foam for the external fluid transfer component. The selection of an appropriate foam for the transfer of fluid was straightforward for the skilled person, particularly as the claim did not require the optimum foam to be selected.

*Novelty (Article 54 EPC)*

Claim 1 required a pair of side drapes, i.e. two separate drapes, each of which was located along a respective side of the wound. D2 did not disclose those drapes.

The single flange around the edge of the device of D2 could not be regarded as a pair of drapes as defined in claim 1. It was rather a continuous part of the upper and lower drapes forming the envelope. According to the appellant's interpretation, in D2, both drapes lay on both sides of the wound, whereas claim 1 required each drape to lie on one side of the wound.

Hence, the subject-matter of claim 1 was novel over D2.

*Inventive step (Article 56 EPC)*

Claim 1 defined a system for the treatment of closed wounds or incisions, whereas D2 related to the treatment of open wounds. Therefore, the skilled person would not have considered D2 to be a reasonable starting point for arriving at the invention.

The claimed invention solved the problem of protecting the edges of a closed wound or incision by using the pair of side drapes. Since D2 related to open wounds, this

problem was not referred to in this document.

The appellant's assertion that from a combination of D2 and common general knowledge the use of a pair of drapes was obvious for the skilled person, was based on hindsight. In fact, there was nothing in the prior art to suggest utilising a pair of drapes as defined in claim 1.

Although the pair of drapes would have rendered the dressing assembly more complex than the device of D2, the skilled person would not have recognised this as a disadvantage but as a solution to the technical problem of how to provide a more individualised dressing that can be customised to the wound. Hence, the subject-matter of claim 1 was not obvious when starting from D2.

### **Reasons for the Decision**

1. The appeal is admissible.
2. The invention

The invention as defined in claim 1 of the patent as granted relates to a dressing assembly for a wound or incision comprising an external patient interface including an external fluid transfer component and an over-drape placed over the external fluid transfer component. A re-closeable seal strip is connected to the over-drape for providing access to the external fluid transfer component. The assembly further comprises a pair of side drapes located between the external fluid transfer component and the patient's skin, a pressure source connected to the external fluid transfer component and an internal fluid transfer component for placing in the wound or incision.

An embodiment according to the invention is shown in Figures 17-22 and described as embodiment VII in the description (page 24, line 18 to page 25, line 14).

According to the description, the claimed system is adapted for closing a wound with an undermined area (page 24, lines 20 to 22). Due to the re-closeable seal strip, the fluid transfer components (foam pieces) can be changed and the wound healing process can be visually monitored (page 25, lines 6 to 13; Figure 22).

3. Added subject-matter

3.1 Claim 1 of the main request corresponds to a combination of claims 1, 3, 4 and 9 as originally filed. However, claim 9 was not dependent on claims 3 or 4. The appellant therefore argued that the application as originally filed disclosed two separate embodiments, one defined in claim 1 with claims 3 and 4, and having a pair of side drapes, and the other one in claim 1 with claim 9, and having a pressure source connected to the external fluid transfer component. The combination of these two embodiments as defined in claim 1 of the patent as granted was not disclosed in the original application.

3.2 The Board notes that according to page 1, lines 11 to 15, of the application as originally filed, the invention relates to "medical devices for treating closed wounds and incisions (...) with ambient air pressure created by an external patient interface and a vacuum source". Furthermore, on page 5, lines 12 to 14, it is mentioned under the heading "Summary of the Invention" that the patient interface is connected to a negative pressure source. In connection with embodiment VII, to which claim 1 is principally related, the transfer of fluid to and

from the internal foam piece is mentioned (page 25, lines 4 to 5). This fluid transfer requires a pressure source to draw fluid from the wound or to irrigate it. Hence, although embodiment VII (Figures 17 to 22) does not explicitly disclose a pressure source or a fluid port for connection to a pressure source, it can be derived directly and unambiguously from the overall disclosure of the application that all embodiments of the invention are intended for use with a pressure source, and thus also the embodiment VII.

- 3.3 The appellant also presented the argument that the embodiment VII was technically incompatible with embodiments IX, X, and XI, since it did not comprise a pre-assembled outer dressing. Therefore, the skilled person would not think of providing the device of embodiment VII with a pressure source.

The Board does not concur with this view. Figure 30, relating to embodiment X, shows an embodiment with a reclosable seal strip (622) which is described as being similar to the one in embodiment VII (page 29, lines 4 to 5) on an outer sheath (608). The outer sheath is also provided with fluid ports (624, 626) for connecting the foam piece (604) to a pressure source. The fact that embodiment VII does not disclose a sheath enclosing the foam piece, but rather a separate over-drape (316) to be placed over the external fluid transfer component (314), would not preclude the skilled person from providing that outer drape with a fluid port in order to connect the external fluid transfer component to a pressure source. Thus, although the embodiments exhibit certain differences they are not technically incompatible in the sense that it would not be possible to provide embodiment VII with a pressure source.

3.4 The Board also does not agree with the appellant's argument that the specific arrangement of the pressure source connected to the external fluid transfer component could not be derived from the application as originally filed. The connection to the external fluid transfer component mentioned in claim 1 has to be interpreted as a fluidic connection, such that fluid is drawn by the negative pressure from the external fluid transfer component. To achieve this, the pressure source does not have to be directly connected to the external fluid transfer component. In fact, all embodiments with a pressure source for providing fluid transfer from the wound (as shown e.g. in Figures 10, 15, 23, 24 and 28) disclose a fluidic connection of the pressure source via a fluid port in the outer sheath (e.g. coupling 417 in Figure 23) or a fluid transfer component (e.g. FTC3 in Figure 10). Hence, the connection of a pressure source as defined in claim 1 can be derived from the application as originally filed.

3.5 It follows that the ground for opposition under Article 100(c) EPC raised by the appellant does not prejudice the maintenance of the patent on the basis of the main request.

#### 4. Sufficiency of disclosure

4.1 The appellant argued that the claimed invention is not sufficiently disclosed since there is no instruction on how the external fluid transfer component was "adapted for transferring fluid from the closed wound or incision".

4.2 The Board notes that the patent suggests the use of a foam piece for the external fluid transfer component. The skilled person is well aware that a foam is adapted to

transfer fluid drained from the wound.

4.3 Contrary to the appellant's view, the Board does not consider it necessary to define the specific type of foam in the claim. Since the claim merely requires that the foam transfers fluid, it is straightforward for the skilled person to select an appropriate foam.

4.4 Hence, the ground for opposition under Article 100(b) EPC raised by the appellant does not prejudice the maintenance of the patent on the basis of the main request.

#### 5. Novelty

The appellant has contested the novelty of the subject-matter of claim 1 over D2.

D2 relates to a wound dressing that serves as a temporary covering for a wound and permits the application of negative pressure for the removal of fluids from the wound. It is common ground that the dressing assembly of D2 comprises an external patient interface including an external fluid transfer component (12) and an over-drape (14), a re-closeable seal strip (22), a pressure source and an internal fluid transfer component (36) as defined in claim 1 (page 7, lines 17 to 26, Figure 1).

However, the dressing assembly of D2 does not comprise "a pair of side drapes each located along a respective side of said wound or incision between said external fluid transfer component and the patient's skin".

The Board observes that in D2 the lower foam layer (36) is enveloped within two sheets of elastomeric material (38) which are sealed on their periphery (page 7, 3rd



paragraph). From Figure 1 it can be derived that a flange is built by the peripheral portion of the envelope. If the shape of the dressing is rectangular or square (page 8, lines 8 to 11), there are two parts of the flange on opposite sides of the envelope.

However, the Board does not concur with the appellant that these opposite parts of the flange can be regarded as a pair of side drapes as specified in claim 1. In this respect, the Board agrees with the respondent that the meaning of the term "pair" is that there are two separate and distinguishable side drapes, and not two parts of a single item.

The appellant also argued that the upper and the lower surfaces (30, 28) of the envelope (38) in D2 could be considered to be a pair of drapes fused together to form one pair of drapes on either side of the wound and that therefore each pair was located on both sides of the wound.

However, according to the appellant's interpretation, both drapes would lie on **both** sides of the wound, whereas claim 1 requires that each side drape is located on **one** respective side of the wound. Hence, also according to this interpretation, D2 does not anticipate the subject-matter of claim 1.

Consequently, the subject-matter of claim 1 of the main request is novel (Article 54(1) and (2) EPC) over D2 by virtue of the feature "a pair of side drapes each located along a respective side of said wound or incision between said external fluid transfer component and the patient's skin".

6. Inventive step

6.1 The appellant considered the subject-matter of claim 1 lacked inventive step over D2 alone or in combination with the common general knowledge of D6 or D7.

6.2 Although D2 specifically relates to the treatment of open wound, it can be considered to represent the closest prior art for the subject-matter of claim 1, since it discloses a wound dressing which is at least suitable for treating closed wounds or incisions.

6.3 As explained above, D2 does not disclose "a pair of side drapes each located along a respective side of said wound or incision between said external fluid transfer component and the patient's skin".

Due to this distinguishing feature it is possible to position the side drapes individually on the skin to protect the edges of a closed wound or incision. Hence, this feature addresses the problem of enhancing the flexibility of the dressing assembly in that it can be customized to the individual wound.

6.4 In this respect, the Board does not agree with the appellant's view that the provision of two side drapes did not solve any new or different technical problem compared to that of D2. D2 relates to the treatment of open wounds that generally do not have a defined wound edge as an incision. Hence, the problem of protecting the edges of a closed wound or incision is not addressed in D2.

It follows that the provision of two side drapes cannot be regarded as an alternative solution to a known

problem, as the appellant put it.

6.5 Moreover, the provision of a pair of side drapes between the external fluid transfer component and the patient's skin is not obvious over D2 alone. Although the device of claim 1 might be more complex than the device of D2, the distinguishing feature solves a technical problem in a non-obvious way, as demonstrated above.

6.6 Furthermore, the provision of a pair of side drapes between the external fluid transfer component and the patient's skin is not obvious in view of the common general knowledge disclosed in D6 or D7.

D7 teaches the alleviation of a possible rash on the skin surrounding an open wound by avoiding the overlap of foam on the skin or by selecting appropriate negative pressure (page 308, right-hand column). However, D7 does not suggest placing a pair of side drapes between the foam and the skin.

D6 does not relate to vacuum-assisted wound treatment, but to a dressing structure for use during a surgical procedure. The drape portions 16 and the towels 78 are not placed over the edges of the incision, but on the tissue surrounding the surgical site. The problem of protecting the edges of the incision is not mentioned in D6.

Thus, neither the disclosure of D6 nor that of D7 would motivate the skilled person to provide a pair of side drapes.

6.7 Consequently, the subject-matter of claim 1 involves an inventive step.

- 6.8 It follows that the ground for opposition under Article 100(a) EPC raised by the appellant does not prejudice the maintenance of the patent on the basis of the main request.
7. The description was adapted to the amended claims.
8. Request to include a statement in the minutes of the oral proceedings

During the oral proceedings, the opponent requested that the respondent's statement that claim 1 required a pair of side drapes, i.e. two separate drapes each of which was located along a respective side of the wound, should be included in the minutes of the oral proceedings.

Pursuant to Rule 124(1) EPC, the minutes of oral proceedings must contain the essentials of these proceedings and the relevant statements made by the parties. As is common practice in the Boards of Appeal, it is not the function of the minutes to record statements which a party considers to be possibly relevant. Instead, it is left to the discretion of the Board to decide what it considered essential or relevant in this respect. In the present case, the Board does not consider it necessary to include the statement in question in the minutes since it is included in the reasoning given above (point 5).

The appellant's request to include the statement in the minutes is therefore refused.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:
  - claims 1 to 3 of the main request filed with letter dated 6 September 2019;
  - description, adapted columns 3 and 4 filed during oral proceedings and columns 1, 2 and 5 to 24 of the patent as granted; and
  - Figures 1 to 46 of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated