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Datasheet for the decision of 12 July 2016

Case Number: T 0799/12 - 3.2.02

Application Number: 07001838.7

Publication Number: 1772160

IPC: A61M1/00, A61M27/00

Language of the proceedings: EN

Title of invention:
Cleansing dressing for wounds for vacuum therapy

Patent Proprietor:
KCI Medical Resources

Opponent:
Smith and Nephew, Inc.

Headword:

Relevant legal provisions:
EPC Art. 84, 123(2), 123(3), 76(1), 56, 111(1), 114

Keyword:
Clarity (yes)
Added subject-matter (no)
Extension of protection (no)
Inventive step (yes)

Decisions cited:
G 0009/91, T 0156/84

Catchword:

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Case Number: T 0799/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 July 2016

Appellant: (Opponent)	Smith and Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 (US)
Representative:	Appleyard Lees IP LLP 15 Clare Road Halifax HX1 2HY (GB)
Respondent: (Patent Proprietor)	KCI Medical Resources Zephyr House 122 Mary Street Grand Cayman (KY)
Representative:	Cordina, Kevin John Olswang LLP 90 High Holborn London WC1V 6XX (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 31 January 2012 concerning the maintenance of European patent No. 1772160 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	P. L. P. Weber

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision posted on 31 January 2012 concerning the maintenance of European patent No. 1 772 160. In the decision under appeal, the Opposition Division held that the patent as amended according to the main request then on file satisfied the requirements of the EPC, in particular those of Articles 123(2) and (3) and 56 EPC.

II. Notice of appeal was filed on 30 March 2012 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 29 May 2012.

III. The following documents are relevant for the present decision:

P2: US-A-5 549 584
P3: US-A-5 437 651
P4: WO-A-01/37 922.

IV. Oral proceedings were held on 12 July 2016.

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 filed during oral proceedings on 12 July 2016 and the first to fourth auxiliary requests filed on 8 October 2012.

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

"1. A vacuum bandage (10) for connection to a vacuum source and for use with a wound (16) having a wound surface (18), comprising

a wound dressing member (919) comprising a wound contacting surface (84) adapted to face toward the wound surface (18), a plurality of discrete holes (36) formed in the wound contacting surface, a port (51) configured to communicate with the vacuum source (12) and with each hole, characterised by a plurality of interconnected non-adhesive ridges (942, 944) provided on the wound contacting surface (84) to form multiple encompassed regions, one or more of the discrete holes being located in each of said multiple encompassed regions, and

a sealing film (62) for placement over the wound dressing member (919) to seal around the perimeter of the wound (16) to provide an enclosed space above the wound dressing member (919) in which a vacuum is formed by suction on the port (51)."

Claims 2 to 14 are dependent claims.

VI. The arguments of the appellant-opponent relevant for the present decision are summarised as follows:

(i) Article 84 EPC

The clarity objection was admissible. It concerned features of the claim which had been taken from the description. Since the Opposition Division allowed the claims, it implicitly made a decision under Article 84 EPC. Moreover, the objection had been raised with the statement of grounds of appeal and was hence part of the appellant's case.

It was completely unclear how a sealing film for placement over the wound dressing member to seal around the perimeter of the wound could "provide an enclosed space above the wound dressing member in which a vacuum is formed by suction on the port" because the film would be sucked onto the dressing member when vacuum was applied. Such an enclosed space could be provided only if there were additional features that prevented the film from contacting the dressing member, such as a spacing foam, packing material or bosses on the dressing member as described in the patent. These were essential features of the invention which had been omitted from the claim, so that the requirements of Article 84 EPC were not fulfilled.

(ii) Articles 123 and 76 EPC

If Figures 42 to 44, in particular page 28, lines 7-9 of the original application, were to be seen as a basis for the claimed interconnected ridges, then the claimed subject-matter was an unallowable generalisation of this disclosure. According to this passage, the ridges were part of a "stand-off" and included radial arms, a circle portion and arc portions concentric with the circle portion. Moreover, the embodiment of Figure 43 did not comprise a vacuum port. Therefore, the claimed subject-matter extended beyond the content of the original application and that of the entirely analogous original parent application (Articles 123(2), 76(1) EPC).

Claim 1 of the patent referred to a wound dressing member for use in a vacuum bandage connected to a vacuum source. Instead, claim 1 of the main request referred to a vacuum bandage for connection to a vacuum source. There was no longer any positive recitation of

the connection between the vacuum bandage and the vacuum source. Therefore, claim 1 of the main request was broader than the claims as granted, thereby contravening Article 123(3) EPC.

(iii) Inventive step

Even if document P4 was considered "late filed", its admission into the proceedings was requested because it was prima facie relevant to the maintenance of the patent. It disclosed almost all of the features of claim 1 and should therefore be considered to form the closest prior art. P4 had been cited as a novelty-destroying document during the examination proceedings, in the granted patent and also at the earliest possible moment in the appeal proceedings. Hence, the citation of P4 could not be seen by the proprietor to be surprising.

Document P4 disclosed in Figure 9 a bandage member whose regions between the channels 608 on the wound facing surface were depicted as ridges. It was not disclosed that the ridges were non-adhesive and interconnected to form multiple encompassed regions in which the holes were located. However, the skilled person would clearly expect such ridges not to stick onto the wound and would hence consider them to be non-adhesive. It appeared, moreover, that devising the ridges to be interconnected to form multiple encompassed regions had no technical effect over and above the provision of ridges alone. Even if the interconnection could be considered to further improve the distribution of negative pressure, and therefore contribute to the solution of the objective technical problem of providing more uniform negative pressure across the dressing member, the solution would be

obvious from P3. Figures 4 and 7-11 of P3 clearly taught the interconnection of ridges to form four multiple encompassed regions. Hence, the skilled person would incorporate this solution from P3 into the bandage of P4.

Document P2 disclosed a dressing member which lacked, however, the interconnected non-adhesive ridges on the wound facing surface. The technical effect of these ridges was, as explained in paragraph [0078] of the patent, to help establish a uniformly distributed negative pressure across the wound contacting surface of the dressing member. Also document P3 related to the application of suction to enable drainage from a wound. P3 disclosed a plurality of ridges on a surface that faced the wound which were expressly provided to distribute suction force evenly across that surface, regardless of whether the teaching related to the wound contact surface or not. P3 in its description of ridges offered an alternative method of forming dams or barriers inhibiting lateral diffusion of the wound exudate disclosed in P2, whereby it would be apparent to the skilled person that the adhesive areas of P2 could be substituted by the ridges of P3.

VII. The arguments of the respondent-patent proprietor relevant for the present decision are summarised as follows:

(i) Article 84 EPC

The clarity objection should not be admitted since, although it concerned a feature which had already been added to claim 1 during opposition proceedings, the objection had not been raised before the Opposition Division and, accordingly, no first-instance decision

had been given on this matter. The primary purpose of an appeal should be to review the correctness of the appealed decision.

The claimed enclosed space above the wound dressing member when vacuum was formed was a clear, unambiguous feature. The raised objection appeared to relate to the sufficiency of the disclosure, rather than to clarity. The features which the appellant alleged to be missing were disclosed as optional alternatives, certainly not as essential features.

(ii) Articles 123 and 76 EPC

The wound dressing member of Figures 42 to 44 (page 28, lines 5 to 9) provided a basis for the claimed interconnected non-adhesive ridges. Since a ridge was a narrow, raised strip on a surface, it was inherent in this definition that the ridge provided a stand-off which kept the wound dressing member away from contacting the wound. Page 28, lines 13 to 15 made it clear that the specific pattern of ridges shown in Figure 43 was just one example among others. A port for communication with the vacuum source was explicitly disclosed in the last paragraph of page 27. Hence, the requirements of Articles 123(2) and 76(1) EPC were fulfilled.

At oral proceedings the respondent clarified that it had no objection to the admittance of the objection under Article 123(3) EPC. The claim as granted did not require a vacuum bandage, but merely a wound dressing member suitable for use in a vacuum bandage. Claim 1 of the main request was therefore of narrower scope since it required a vacuum bandage comprising the wound dressing member.

(iii) Inventive step

The objections based on P4 should not be admitted since they were raised for the first time in appeal proceedings. The opponent had listed P4 in its notice of opposition, but chose not to raise any objections starting from P4 during the opposition proceedings. Consequently, the decision by the Opposition Division made no reference to that document. If the Board considered admitting P4 into the proceedings, the case should be remitted to the Opposition Division, as in T 156/84, in order not to deprive the parties of a full examination of the opposition before two instances. In case of remittal, apportionment of costs caused by additional proceedings before the Opposition Division were requested. At oral proceedings it was clarified that a referral to the Enlarged Board of Appeal as mentioned on page 10 of the respondent's reply dated 8 October 2012 was no longer requested.

In any case, P4 by itself or in combination with P3, or the combination of P2 with P3, did not render obvious the claimed bandage. The arguments were essentially those given in the reasons below.

Reasons for the Decision

1. The appeal is admissible.

2. The patent relates to a vacuum bandage comprising, in essence, a wound dressing member (919 in Figure 42) with holes (36) on its wound contacting surface and a port (51) for communication of a vacuum source with the holes, interconnected non-adhesive ridges (942, 944 in

Figure 43) provided on the wound contacting surface, and a sealing film (62 in Figure 3) placed over the wound dressing member providing an enclosed space above the wound dressing member in which vacuum is formed.

As explained in paragraph [0078] of the patent specification, the ridges are provided on the wound contacting surface so as to position the wound dressing member away from the wound surface and to allow the vacuum source to establish a generally uniformly distributed negative pressure to draw exudate from the wound through the holes.

3. Article 84 EPC

3.1 Admissibility

3.1.1 The respondent considered that the objection under Article 84 EPC was inadmissible. It argued that although the objection concerned a feature which had already been added to claim 1 during opposition proceedings, the objection had not been raised before the Opposition Division. Accordingly, no first-instance decision had been given on this matter.

3.1.2 The respondent is right in observing that the primary purpose of an appeal is to provide the adversely affected party with the opportunity to challenge the decision on its merits and to obtain a judicial ruling as to whether the first-instance decision was correct (G 9/91; OJ 1993, 408). However, according to established jurisprudence (G 9/91, point 19 of the Reasons), if amendments are made to the claims in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC. Whilst

it is true that in principle the appellant could have raised the clarity objection during the opposition proceedings, he did so for the first time in the statement of grounds of appeal, whereby the respondent and the Board had ample time to consider it. The Board is therefore of the view that the lack of a first-instance ruling on the clarity objection is not sufficient reason to disregard the objection in the appeal proceedings.

3.1.3 The objection under Article 84 EPC is hence admissible.

3.2 The feature objected to as lacking clarity is defined at the end of claim 1 as a sealing film for placement over the wound dressing member to seal around the perimeter of the wound to "provide an enclosed space above the wound dressing member in which a vacuum is formed by suction on the port".

The appellant argued that the sealing film would be sucked onto the dressing member when vacuum was applied, thereby eliminating any "enclosed space", unless the bandage had additional features which prevented this, such as a packing material or bosses (90) placed between the wound dressing member and the sealing film as mentioned in the patent specification (column 3, lines 21 to 25; column 15, lines 8 to 18; Figures 17 to 19).

3.3 The Board notes that the patent specification makes it clear that any of these features is an optional alternative. It is even explicitly said that some bandages function quite well without the packing material (column 3, lines 25 to 30). Moreover, the skilled person will immediately recognise that in order to achieve the claimed effect of providing "an enclosed

space above the wound dressing member in which a vacuum is formed by suction on the port", a number of other technical options may be implemented, such as devising the sealing film with the appropriate stiffness and/or form. There is hence no need for any of the constructional features which the appellant alleged to be missing.

The Board finds therefore that no essential features of the invention have been omitted from claim 1.

3.4 It is thus concluded that claim 1 of the main request satisfies the requirements of Article 84 EPC.

4. Article 123(2) and (3), 76(1) EPC

4.1 The definition of the vacuum bandage given in claim 1 is directly and unambiguously disclosed in the application as filed. A vacuum bandage for connection to a vacuum source is described throughout the entire application as filed, starting with the first sentence of the description. The features of the wound dressing member are generally based on the paragraph bridging pages 2 and 3 in combination with page 12, lines 9 to 11 and page 28, lines 5 to 9 disclosing the feature of the interconnected non-adhesive ridges (942, 944 in Figures 42 to 44) provided on the wound contacting surface. The sealing film as defined in the last paragraph of claim 1 is based on page 4, lines 7 to 10.

4.2 The appellant argued that if the embodiment of Figures 42 to 44, in particular page 28, lines 7-9, were to be seen as a basis for the interconnected ridges, then the definition of claim 1 constituted an unallowable generalisation of this disclosure. It argued that, according to this disclosure, the ridges

were part of a "stand-off" which included radial arms, a circle portion and arc portions concentric with the circle portion.

The Board disagrees. The notion of a "ridge" on a wound contacting surface carries the meaning of a narrow, raised strip on the surface. Therefore, the ridges necessarily allow the surface to stand off or away from the wound. Moreover, page 28, lines 13 to 15 indicates that the pattern of ridges may also be different from the one disclosed on page 28, lines 7 to 9 and shown in Figure 43, which includes radial arms, a circle portion and arc portions concentric with the circle portion. Hence, omitting these features from the definition of claim 1 does not lead to an unallowable generalisation of the original disclosure.

4.3 Contrary to a further submission from the appellant, the embodiment of Figures 42 to 44 does in fact comprise a port for communication with the vacuum source (51 in Figure 42; last paragraph of page 27).

4.4 Hence, the Board concludes that claim 1 of the main request satisfies the requirements of Article 123(2) EPC.

4.5 Since the aforementioned passages of the description and the figures of the application as filed are identical to the corresponding passages and figures of the parent application as filed, claim 1 of the main request satisfies the requirements of Article 76(1) EPC too.

4.6 Claim 1 of the granted patent defines "**a wound dressing member** for use in a vacuum bandage connected to a vacuum source", whereas claim 1 of the main request

defines **"a vacuum bandage** for connection to a vacuum source **comprising a wound dressing member"**, the latter having all the limitations of the wound dressing member of claim 1 of the granted patent. In particular, since in claim 1 of the main request the wound dressing member forms part of a vacuum bandage for connection to a vacuum source, the wound dressing member is certainly also suitable "for use in a vacuum bandage connected to a vacuum source", just as the wound dressing member of claim 1 of the granted patent. Moreover, the scope of protection of the claim of the main request defining the wound dressing member as part of a vacuum bandage is narrower than the scope of the claim of the granted patent defining the wound dressing member per se.

The appellant's argument that claim 1 of the main request no longer positively recited the connection between the vacuum bandage and the vacuum source is not relevant for the question of enlarging the protection, since the dressing member of claim 1 of the granted patent does not contain this connection either. In fact, in claim 1 of the granted patent, the wound dressing member is defined as being merely *suitable for use* in a vacuum bandage connected to a vacuum source. The wound dressing member according to claim 1 of the main request is also required to possess this suitability. Moreover, the appellant did not indicate which embodiment was supposed to be encompassed by the scope of the present main request which does not fall under the scope of the granted patent.

Consequently, the Board concludes that the scope of protection of claim 1 of the main request is narrower than that of claim 1 of the granted patent, whereby the requirements of Article 123(3) EPC are fulfilled.

5. Inventive step

5.1 Admissibility of objections based on P4 and remittal

5.1.1 The respondent requested that the objections concerning lack of inventive step starting from P4 as closest prior art should not be admitted into the appeal proceedings. The respondent correctly pointed out that P4 had merely been listed in the notice of opposition, but that no objections based on this document had been raised during the entire opposition proceedings. Accordingly, the decision by the Opposition Division did not make any reference to that document either. The respondent requested, moreover, that if the Board admitted P4 into the proceedings, the case should be remitted to the Opposition Division in order not to deprive the parties of a full examination of the opposition before two instances.

5.1.2 It is conceded that in principle the appellant could have raised the inventive-step objections starting from P4 in the opposition proceedings, rather than waiting to present them in the statement of grounds of appeal. However, P4 discloses a vacuum bandage for connection to a vacuum source for drawing exudate from a wound which appears, prima facie, to come closer to the claimed subject-matter than P2. It hence appears to the Board that P4 is indeed a relevant document which needs to be considered in order to establish with certainty whether the requirements of inventive step are fulfilled. As explained in T 156/84 (point 3.4 of the Reasons), which was cited by the respondent, the principle of examination by the Office of its own motion enshrined in Article 114(1) EPC takes precedence over the possibility of disregarding facts or evidence not submitted in due time provided for in

Article 114(2) EPC. Hence, the prima facie relevance of the objections starting from P4 is reason for the Board not to disregard them merely because they had not already been presented during the opposition proceedings.

5.1.3 Article 111(1) EPC leaves it to the discretion of the Board whether to exercise any power within the competence of the department of first instance or to remit the case to that department. Hence, a party has no absolute right to have each individual issue considered by two instances (established jurisprudence as cited in Case Law of the Boards of Appeal of the EPO, 7th edition 2013, IV.E.7.6.1). It is consequently of no relevance that in T 156/84, cited by the respondent, the deciding Board, after considering the specific circumstance of that case, ordered its remittal. As far as the present case is concerned, the Board notes that P4 is an earlier application by two of the inventors of the patent in suit which was cited in the patent specification (paragraph [0007]). Also its complexity is not such that it would justify a remittal of the case to the first instance. Moreover, since the objections had already been presented in the statement of grounds of appeal, the respondent and the Board were given ample time for their consideration.

In view of these circumstances and taking into consideration the imperative of procedural efficiency, the Board considers it appropriate to decide on the raised objections itself rather than to remit the case to the Opposition Division.

5.2 P4 as starting point

5.2.1 Document P4 discloses in Figure 9 and page 15, lines 7 to 29 a vacuum bandage for connection to a vacuum source comprising a cover film (602) and a wound dressing member (604) with lower channels (608) on the wound contacting surface and upper channels (606) on the upper side of the wound dressing member, the lower and upper channels being in communication with each other via apertures (614) to draw exudate from the wound.

Whilst the description of P4 is silent regarding any further details of the arrangement of the channels, the appellant appears to extract from the sketchy drawing of Figure 9 the additional information that the channels depicted on the wound contacting surface are so closely spaced that their separations form narrow, raised strips or ridges. Given the schematic nature of the drawing, this conclusion is not permissible.

Consequently, there is no direct and unambiguous disclosure in P4 that the wound contacting surface is provided with ridges.

5.2.2 Thus, the bandage of claim 1 differs from that of P4 in that a plurality of interconnected non-adhesive ridges are provided on the wound contacting surface to form multiple encompassed regions, one or more of the discrete holes being located in each of said multiple encompassed regions.

5.2.3 The Board considers that the technical effect of these differentiating features is to position the wound dressing member away from the wound surface, as indicated in paragraph [0078] of the patent (see also

point 2 above). The objective technical problem derivable from this effect is to establish a generally uniformly distributed negative pressure to draw exudate from the wound through the holes.

5.2.4 There is, moreover, no suggestion in P4 to specifically devise the separations between the channels on the wound contacting surface as ridges, i.e. as narrow raised strips. A fortiori, it would have not been obvious to devise such ridges as interconnected to form multiple encompassed regions in which the holes are located in order to solve the aforementioned objective technical problem.

Hence, the bandage of claim 1 of the main request is not rendered obvious by the disclosure of P4 by itself.

5.2.5 As an alternative, the appellant argued that the skilled person would have turned to P3 in search of a solution to the problem of improving the suction of wound fluids of the vacuum bandage of P4, since this problem was addressed in P3, for example, in column 2, lines 28 to 32 and column 3, lines 15 to 19.

5.2.6 Document P3 discloses a suction device for absorbing and collecting blood and other fluids which accumulate during a surgical procedure (column 2, lines 28 to 32). The device comprises a flexible backing plate (16) having ridges (22) on its bottom surface, the ridges being in contact with a fluid absorbing foam pad (12) which is placed on the surgical site (column 4, lines 57 to 67; column 6, lines 1 to 4; Figures 2 and 3). The ridges are placed in contact with the foam pad (12) and are provided so as to more evenly distribute the suction force across the surface of the fluid absorbing foam pad (column 5, lines 53 to 57). Hence, it is the

fluid absorbing foam pad, not the ridges, which may contact the wound during surgery.

It is thus clear that the backing plate with its ridges and the fluid absorbing foam pad are key parts of the surgical fluid absorbing device of P3. The device would not accomplish its purpose if, for example, the fluid absorbing foam pad was left out. However, when combining P4 with P3, as suggested by the appellant, the solution to the problem presented in P3 would have to be further modified by leaving out the fluid absorbing foam pad in order to arrive at the claimed bandage having ridges on the wound contacting surface.

Hence, the combination of P4 with P3 would not allow the skilled person to readily arrive at the claimed subject-matter.

5.3 P2 as starting point

5.3.1 Document P2 discloses (Figure 4) a wound dressing member (sheet 42) with holes (slits 48) on its wound contacting surface and a port (opening 56) for communication of a vacuum source with the holes, and a sealing film (outer sheet 54 with permeable sheet 58) placed over the wound dressing member providing an enclosed space above the wound dressing member (42) in which vacuum is formed (column 6, lines 27 to 46). The wound dressing member (42) also comprises an adhesive layer (44) provided with areas (46) where the adhesive layer is interrupted (Figures 4 and 5; column 5, lines 19 to 25). The appellant views portions of interrupted adhesive layer in Figures 4 and 5 as forming "ridges". Similar to the discussion of the schematic drawing in P4 above, it is not permissible to extract from the schematic drawings in P2 the

information that between different non-adhesive areas 46, the adhesive layer 44 forms narrow, elevated strips or "ridges". Moreover, the adhesive layer is certainly not "non-adhesive", as required by claim 1.

5.3.2 The bandage of claim 1 differs from that of P2 (at least) in that a plurality of interconnected non-adhesive ridges are provided on the wound contacting surface to form multiple encompassed regions, one or more of the discrete holes being located in each of said multiple encompassed regions.

5.3.3 Hence, as mentioned under point 5.2.3 above in relation to P4, regarding these differentiating features, the objective technical problem here is, as above, to establish a generally uniformly distributed negative pressure to draw exudate from the wound through the holes.

5.3.4 Thus, for analogous reasons as those given above, the skilled person would not readily arrive at the claimed bandage by applying the technical solution to the problem disclosed for the surgical device of P3 to the wound dressing of P2. Furthermore, it is particularly non-obvious to depart from the bandage of P2 with an adhesive wound contacting surface (column 5, lines 19 to 23) and replace this adhesive surface with, or even add to it, the non-adhesive ridges known from P3.

It follows that the combination of P2 with P3 does not render obvious the bandage of claim 1 of the main request.

5.4 As a consequence, the subject-matter of claim 1 of the main request satisfies the requirements of an inventive step under Article 56 EPC. A fortiori, the preferred

embodiments of dependent claims 2 to 14 are likewise patentable.

6. Since the objections raised do not prejudice the maintenance of the patent amended according to the main request, the Board does not need to consider the auxiliary requests.

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 14 of the main request filed during oral proceedings on 12 July 2016;

   - description: columns 1 and 2 filed during the oral proceedings on 12 July 2016; columns 3, 4, 7, 8, 21 and 22 filed during oral proceedings on 16 December 2011 and columns 5, 6, 9 to 20, 23 and 24 of the patent specification; and

   - figure sheets 1/20 to 20/20 of the patent specification.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated