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Datasheet for the decision of 15 September 2023

Case Number: T 1524/20 - 3.2.02

Application Number: 10010687.1

Publication Number: 2305341

IPC: A61M27/00, A61M1/00, A61F13/02

Language of the proceedings: EN

Title of invention:
Apparatus for aspirating, irrigating and cleansing wounds

Patent Proprietor:
Smith & Nephew PLC

Opponent:
KCI Licensing Inc.

Headword:

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - added subject-matter (yes)

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It can be changed at any time and without notice

Decisions cited:

Catchword:

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Case Number: T 1524/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 September 2023

Appellant: (Opponent)	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: (Patent Proprietor)	Smith & Nephew PLC 15 Adam Street London WC2N 6LA (GB)
Representative:	HGF HGF Limited 1 City Walk Leeds LS11 9DX (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 8 May 2020 concerning the maintenance of European Patent No. 2305341 in amended form**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	Y. Podbielski

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed against the Opposition Division's decision that, account being taken of the amendments according to the fourth auxiliary request made by the patent proprietor during the opposition proceedings, the European patent and the invention to which it relates met the requirements of the EPC.

The patent was opposed on the ground of added subject-matter.

II. The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted or on the basis of one of the first to fourth auxiliary requests, all filed with the statement of grounds of appeal on 18 September 2020.

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

III. The Board summoned the parties to oral proceedings and, in a communication accompanying the summons, expressed its preliminary view that none of the proprietor's requests appeared to be allowable, due to added subject-matter. In response, the proprietor withdrew its appeal and announced that it would not be attending the oral proceedings.

IV. The Board cancelled the oral proceedings.

V. **Claim 1 of the patent as granted (main request)** reads as follows:

"A dressing for treating a wound, comprising

a backing layer (42) for forming a relatively fluid tight seal or closure over a wound; an inlet pipe (46) and an outlet pipe (47);
a first hemispherical membrane (92) attached to the backing layer (42) to form a hemispherical chamber (94) with the backing layer (42);
a second hemispherical membrane (93) within the first hemispherical membrane (92) attached to the backing layer to form a hemispherical pouch (95);
wherein
the pouch (95) communicates with the inlet pipe (46) forming an inlet manifold, from which pipes (97) radiate hemispherically and run to the wound bed; wherein the chamber (94) communicates with the outlet pipe (47) forming an outlet manifold from which tubules (99) radiate hemispherically and run to the wound bed."

Claim 1 of the first auxiliary request reads as follows:

"A dressing for treating a wound, comprising
a backing layer (42) for forming a relatively fluid tight seal or closure over a wound; an inlet pipe (46) and an outlet pipe (47);
a first hemispherical membrane (92) attached to the backing layer (42) to form a hemispherical chamber (94) with the backing layer (42);
a second hemispherical membrane (93) within the first hemispherical membrane (92) attached to the

backing layer to form a hemispherical pouch (95); wherein

the pouch (95) communicates with the inlet pipe (46) forming an inlet manifold, from which pipes (97) radiate hemispherically and run to the wound bed, wherein the pipes (97) end in apertures (98) for delivering circulating fluid directly to the wound bed; wherein the chamber (94) communicates with the outlet pipe (47) forming an outlet manifold from which tubules (99) radiate hemispherically and run to the wound bed, wherein the tubules (99) end in openings (100) for collecting fluid directly from the wound."

Claim 1 of the second auxiliary request reads as follows:

"A dressing for treating a wound, comprising

a backing layer (42) for forming a relatively fluid tight seal or closure over a wound; an inlet pipe (46) and an outlet pipe (47);

a first hemispherical membrane (92) attached to the backing layer (42) to form a hemispherical chamber (94) with the backing layer (42);

a second hemispherical membrane (93) concentric with and within the first hemispherical membrane (92) attached to the backing layer to form a hemispherical pouch (95); wherein

the pouch (95) communicates with the inlet pipe (46) forming an inlet manifold, from which pipes (97) radiate hemispherically and run to the wound bed, wherein the pipes (97) end in apertures (98) for delivering circulating fluid directly to the wound bed; wherein the chamber (94) communicates with the outlet pipe (47) forming an outlet manifold from which tubules (99) radiate hemispherically and run to the wound bed, wherein the tubules (99) end in openings (100) for

collecting fluid directly from the wound."

Claim 1 of the third auxiliary request reads as follows:

"A dressing for treating a wound, comprising

a backing layer (42) for forming a relatively fluid tight seal or closure over a wound; an inlet pipe (46) and an outlet pipe (47);

a first hemispherical membrane (92) permanently attached to the backing layer (42) to form a hemispherical chamber (94) with the backing layer (42);

a second hemispherical membrane (93) within the first hemispherical membrane (92), the second hemispherical membrane permanently attached to the backing layer to form a hemispherical pouch (95); wherein

the pouch (95) communicates with the inlet pipe (46) forming an inlet manifold, from which pipes (97) radiate hemispherically and run to the wound bed, wherein the pipes (97) end in apertures (98) for delivering circulating fluid directly to the wound bed; wherein the chamber (94) communicates with the outlet pipe (47) forming an outlet manifold from which tubules (99) radiate hemispherically and run to the wound bed, wherein the tubules (99) end in openings (100) for collecting fluid directly from the wound."

Claim 1 of the fourth auxiliary request reads as follows:

"A dressing for treating a wound, comprising

a backing layer (42) for forming a relatively fluid tight seal or closure over a wound; an inlet pipe (46) and an outlet pipe (47);

a first hemispherical membrane (92) permanently attached to the backing layer (42) to form a hemispherical chamber (94) with the backing layer (42);

a second hemispherical membrane (93) concentric with and within the first hemispherical membrane (92), the second hemispherical membrane permanently attached to the backing layer to form a hemispherical pouch (95); wherein

the pouch (95) communicates with the inlet pipe (46) forming an inlet manifold, from which pipes (97) radiate hemispherically and run to the wound bed, wherein the pipes (97) end in apertures (98) for delivering circulating fluid directly to the wound bed; wherein the chamber (94) communicates with the outlet pipe (47) forming an outlet manifold from which tubules (99) radiate hemispherically and run to the wound bed, wherein the tubules (99) end in openings (100) for collecting fluid directly from the wound."

VI. The opponent's arguments, where relevant to the present decision, may be summarised as follows:

The independent claims of all of the proprietor's requests sought a basis in the embodiment described in relation to Figures 7a and 7b of application WO 2004/037334 A1 ("the grandparent application") as filed. However, they were all an unallowable intermediate generalisation of this embodiment because they did not comprise all of the following features:

a) that the backing layer was circular;

b) that both hemispherical membranes were attached centrally to the backing layer;

c) that both hemispherical membranes were permanently

attached to the backing layer;

d) that the second hemispherical membrane was concentric with the first hemispherical membrane.

These features in combination were necessary to obtain the advantages of the embodiment of Figures 7a and 7b as disclosed on page 16, lines 15 to 33 of the grandparent application as filed.

VII. The proprietor's arguments, where relevant to the present decision, may be summarised as follows:

Page 10, lines 15 to 17 and page 15, lines 1 to 3 of the grandparent application as filed provided a basis for omitting feature a), i.e. that the backing layer was circular.

Regarding feature b), the position of the hemispherical membranes was not functionally connected to the working of the claimed irrigation and aspirating system. Page 16, lines 30 and 31 of the grandparent application as filed disclosed that pipes could radiate regularly or irregularly (from the membranes) through the wound in use, from the inlet or outlet manifold respectively. This meant that the hemispherical membranes did not have to be centrally located.

Regarding feature c), in the grandparent application as filed the embodiment of Figures 7a and 7b included a wound filler. This was evidenced for example on page 21, lines 10 to 16 and 21 to 25, which described a wound filler forming inlet and outlet manifolds such as that described on page 58, lines 14 to 28 in relation to Figures 7a and 7b. Page 22, lines 7 to 29 further supported that the system in Figures 7a and 7b included

a wound filler. The passage on page 19, lines 19 to 21 disclosing the option of the wound filler being releasably attached to the backing layer applied to all the embodiments which included a wound filler, and thus also to that of Figures 7a and 7b. An adhesive film was merely one example of a releasable attachment, and the skilled person would be aware of other releasable adhesives or attachments that would be suitable for the embodiment of Figures 7a and 7b. The skilled person would have recognised that the permanent attachment described in relation to Figures 7a and 7b was not related or inextricably linked to the remaining features of the claimed embodiment.

Regarding feature d), page 16, lines 15 to 21 of the grandparent application as filed discussed the desire for wound irrigant and/or wound exudate to be distributed "more evenly, or pass in a more convoluted path under the wound dressing." This statement referred to the arrangement previously described in which there was no integer under the backing layer in the wound in use (page 16, lines 12 to 13). Thus it was only necessary for the claimed wound dressing to distribute fluid more evenly than a wound dressing with no integer under the backing layer. There was no requirement for the distribution of fluid to be completely even across the entire dressing, and therefore the membranes did not need to be concentric. The disclosure of irregular radiation of pipes (page 16, lines 30 to 32) confirmed that the irrigation and aspiration did not need to be completely evenly distributed in all embodiments. It followed that the hemispherical membranes did not have to be concentric in order for the desired irrigation and aspiration properties to be achieved.

Reasons for the Decision

1. The patent

The patent is derived from a divisional application of earlier European application 08 014 124.5 ("the parent application"), which is itself a divisional application of earlier European application 03 809 377.9 published under the PCT as WO 2004/037334 A1 ("the grandparent application").

The patent relates to a dressing for treating a wound. The claims of all the requests are directed specifically to the embodiment of Figures 7a and 7b reproduced below and described in paragraphs [0302] to [0304] of the patent as granted.

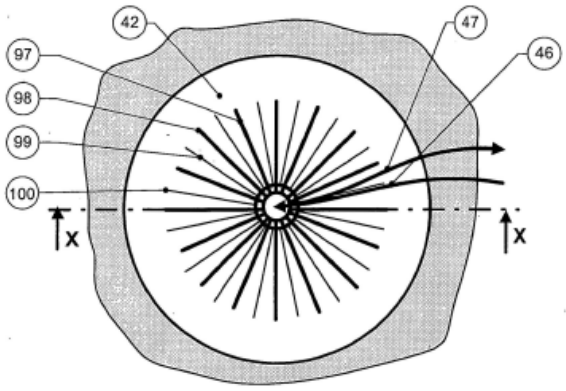

Figure 7a

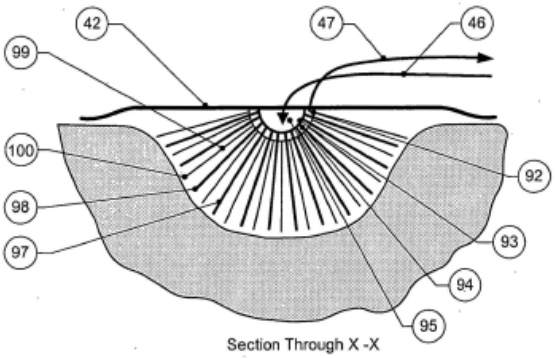

Figure 7b

The dressing comprises a backing layer (42) for forming a relatively fluid tight seal or closure over the wound, an inlet pipe (46) and an outlet pipe (47), a first hemispherical membrane (92) attached to the backing layer to form a hemispherical chamber (94) with the backing layer, and a second hemispherical membrane (93) within the first hemispherical membrane attached to the backing layer to form a hemispherical pouch (95).

The pouch communicates with the inlet pipe and forms an inlet manifold, from which pipes radiate hemispherically and run to the wound bed.

The chamber communicates with the outlet pipe and forms an outlet manifold from which tubules radiate hemispherically and run to the wound bed.

2. Added subject-matter

2.1 The independent claims of all the proprietor's requests are not based on any claims of the grandparent application as filed. They seek a basis in the embodiment described in relation to Figures 7a and 7b.

The description of the embodiment of Figures 7a and 7b (page 58, lines 14 to 28) discloses a dressing for treating a wound including, in combination, all of the features a) to d) mentioned by the opponent.

2.2 As the opponent pointed out, some advantages of the invention in relation to a configuration of the kind shown in Figures 7a and 7b are explained on page 16, lines 15 to 33 of the grandparent application as filed.

It is disclosed that for chronic wound dialysis it may be advantageous to provide a system "where wound irrigant and/or wound exudate may be distributed more evenly [...] over the wound bed", with the objective of distributing "irrigant over a sufficient functional surface area to irrigate the wound at a practical rate". A dressing "with a 'tree' form of pipes", radiating from an outlet and an inlet manifold would provide this more even distribution.

According to page 16, lines 30 to 34, although pipes may preferably radiate regularly but also irregularly through the wound, a "more suitable layout for deeper wounds" is disclosed "in which the pipes, etc. radiate hemispherically and concentrically, to the wound bed".

The embodiment of Figures 7a and 7b corresponds to this more suitable layout for deeper wounds.

Other layouts, for example for shallower wounds (page 17), exemplified in other embodiments in the description, may comprise other patterns of the pipes. It remains, however, that for the specific embodiment of Figures 7a and 7b the person skilled in the art is taught by page 16, lines 15 to 33 of the grandparent application as filed that the hemispherical and concentric distributions of pipes are equally important.

The description of Figures 7a and 7b, on page 58, lines 14 to 28 of the grandparent application as filed, discloses a specific configuration of the pipes and the manifolds, in which the features of the pipes and tubules extending concentrically and hemispherically from a circular backing layer are presented as equally important.

Hence the person skilled in the art receives the teaching that the embodiment of Figures 7a and 7b provides the advantages for treating deeper wounds because of the symmetrical distribution of the pipes and tubules as disclosed on page 58, lines 14 to 28. This means that the pipes and tubules must radiate hemispherically from concentric hemispherical manifolds attached centrally to a circular backing layer. The attachment must also be permanent, as disclosed in the same passage, because if it could be modified the symmetrical distribution would not be ensured.

2.3 The proprietor's arguments are based on passages of the grandparent application as filed which are general, but not applicable to the specific embodiment of Figures 7a to 7b. The general shape of the backing layer as disclosed on page 10, lines 15 to 17 and on page 14, line 35 to page 15, line 3 may well be applicable to several other embodiments, for example for treating shallower wounds. As regards the presence or not of a wound filler or of an integer in the embodiment of Figures 7a and 7b, this is equally irrelevant. As explained above, according to that embodiment the symmetrical distribution is important, independently of whether the hemispherical chamber and pouch act as wound fillers or not, or of whether there is a reinforcing member or any other element under the backing layer or not.

2.4 Since in none of the independent claims of the proprietor's requests is the dressing for treating a wound defined as comprising the combination of a backing layer which is circular and a first and a second hemispherical membrane which are concentric and permanently attached centrally to the backing layer,

none of the proprietor's requests can be allowed due to added subject-matter over the grandparent application as filed (Article 76(1) EPC).

3. Hence the patent has to be revoked for this reason alone (Article 101(2) and (3)(b) EPC), irrespective of whether the main request and the first to third auxiliary requests would not be allowable in view of the principle of the prohibition of *reformatio in peius* either, due to the withdrawal of the appeal by the proprietor.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated