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Datasheet for the decision of 16 November 2023

Case Number: T 0482/20 - 3.2.02

Application Number: 08858332.3

Publication Number: 2231218

IPC: A61M27/00, A61M1/00

Language of the proceedings: EN

Title of invention:
APPARATUS FOR TOPICAL NEGATIVE PRESSURE THERAPY

Patent Proprietor:
Smith & Nephew PLC

Opponent:
KCI Licensing Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - 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 0482/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 16 November 2023

Appellant: (Opponent)	KCI Licensing Inc. 12930 IH 10 West San Antonio , TX 78249 (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 3 January 2020 concerning maintenance of the European Patent No. 2231218 in amended form.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	N. Obrovski

Summary of Facts and Submissions

I. The appeal was filed by the opponent against the opposition division's interlocutory decision finding that European patent 2231218 as amended met the requirements of the EPC.

II. Oral proceedings before the Board took place on 16 November 2023.

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

The respondent (patent proprietor) withdrew its appeal during the oral proceedings, as well as the main request and auxiliary request 1. It requested that the patent be maintained on the basis of one of auxiliary requests 2 to 5 filed by letter of 13 May 2020.

III. Claim 1 of **auxiliary request 2** reads as follows:

"Apparatus (12) for the provision of topical negative pressure therapy to a wound, the apparatus comprising: a sealing membrane (14, 102, 212, 214, 504, 718) for covering a wound to form a wound cavity (17, 716); an aspirant conduit (18, 522, 714) having one end thereof capable of being operably associated, in use, with the wound cavity; vacuum means (26, 524) provided at a distal end of the aspirant conduit for applying a vacuum to the wound cavity when in use; wherein the apparatus further comprises air bleed means (30, 104, 200, 308, 528, 620, 710) in fluid communication with the wound cavity when in use, where the air bleed

means comprises an air bleed port (510, 600) comprising a socket portion (520, 606) having an air bleed hole (528, 620), a filter element (532) having predetermined pore size for preventing ingress of harmful bacteria and a recessed portion (530, 622) to receive said filter element (532),
wherein the socket portion is configured to receive the aspirant conduit,
wherein the filter element is retained in the recess in the air bleed port member,
wherein the recess comprises said air bleed hole therein which is covered by the filter element, and
wherein the air bleed port member is adhered to the sealing membrane and in use is capable of communicating with the wound cavity through an aperture in the membrane."

IV. Compared with claim 1 of auxiliary request 2, in claim 1 of **auxiliary requests 3 and 4** the part of the claim starting with "and a recessed portion" has been replaced with the following wording:
"and a recess (530, 622) to receive said filter element (532),
wherein the recess surrounds said air bleed hole,
wherein the socket portion is configured to receive the aspirant conduit."

V. Compared with claim 1 of auxiliary requests 3 and 4, claim 1 of **auxiliary request 5** further includes the following feature added to the end of the claim:

", and wherein the air bleed port has a domed shape having an aperture in a flanged base portion."

VI. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

All claim requests - added subject-matter

Claim 1 of each of the requests contained added subject-matter.

One of the amendments to claim 1 was the inclusion of the feature that the socket portion had an air bleed hole. Neither the claims as originally filed nor the embodiment in Figure 8 disclosed a socket portion having an air bleed hole. The air bleed hole in the embodiment in Figure 8 was provided in the wall portion 704. The wall portion could not be part of the socket portion because otherwise Figures 8A to 8D would only show a socket portion. The application as filed (page 12, lines 22 to 25) demonstrated that it was instead the neck portion 706 which served as the socket portion in that embodiment.

Hence, only the embodiments in Figures 5 to 7 could provide a basis for the feature of the socket portion having an air bleed hole; however, an important feature of the embodiments in Figures 5 to 7 was that the socket portion was configured to receive, in use, an end of the aspirant conduit only to the extent that the air bleed hole was left uncovered. By omitting this feature, claim 1 defined an unallowable intermediate generalisation.

VII. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

All requests - added subject-matter

Claim 1 of each of the requests did not contain added subject-matter.

Claim 1 recited that the socket portion was configured to receive the aspirant conduit and that the air bleed means were in fluid communication with the wound cavity when in use. Claim 1 thus would not be construed as encompassing an arrangement in which the air bleed hole was blocked by the aspirant conduit.

The feature that the socket portion received an end of the aspirant conduit was not inextricably linked to the socket portion having an air bleed hole. Instead, the application as filed disclosed that the socket portion could receive either an end of the aspirant conduit (Figures 5 to 7 and claim 24) or that the aspirant conduit could extend the whole way through the socket portion (Figure 8 and claim 23).

In the embodiment in Figure 8, the neck portion 706, the bellows portion 708 and the wall portion 704 were integrally formed as part of the port 700. All three portions had to be construed as being part of the socket portion because the aspirant conduit extended through the entirety of the wall portion. By way of example, a plug socket not only included the portions that received the electrical connection pins. Hence, in the embodiment in Figure 8 the socket portion comprised an air bleed hole. This was also evident from claims 21 and 23, which described a socket portion in which the aspirant conduit completely passed through the socket portion.

Claims 23 and 24 as originally filed as well as claim 1 of the requests were directed to a kit of parts. The claimed socket portion was adapted to receive the aspirant conduit, but how far the aspirant conduit was to be inserted was not a feature of the claimed

elements, i.e. there were no structural features of the socket portion that would prevent the air bleed hole from being blocked. Instead, how far the aspirant conduit was inserted related only to how the different parts of the claimed system could be used. The description on page 11, lines 32 to 33 simply instructed the user to insert the aspirant conduit up to the air bleed hole.

Hence, the feature of claim 1 of the socket portion having an air bleed hole had a basis in the application as filed without requiring any further feature relating to how the aspirant conduit was inserted into the socket portion.

Reasons for the Decision

1. The patent

Topical negative pressure (TNP) therapy uses a closed wound cavity covering a wound. A vacuum, i.e. a pressure lower than the surrounding ambient atmospheric pressure, is applied to the wound cavity. This has beneficial therapeutic effects such as increased blood flow to the wound and faster granulation of tissue, leading to faster wound healing.

While TNP therapy may be applied to hospitalised patients having large, serious wounds, there is also a need for portable apparatuses for the treatment of relatively small wounds where the patient may otherwise be fit and mobile and require treatment outside of a clinical setting.

In small wounds, good sealing is achieved with a relatively small area of sealing membrane around the wound. The membrane is typically semi-permeable, allowing the passage of gas such as air and water vapour to an extent. Due to the good sealing achieved with a small area of sealing membrane, it is easy to create a vacuum which does not decay due to leaks; however, the small amount of gas permitted into the wound results in very little flow through the aspirant conduit. It may thus occur that the wound exudate is not transported away and stagnates at the wound, causing an increased risk of infection.

The patent deals with a TNP therapy apparatus which promotes the reliable flow of wound exudate away from the wound. It comprises air bleed means which allow air to be admitted from the surroundings to the wound cavity, thus avoiding the disadvantages associated with the small amount of gas which would otherwise enter the wound cavity.

Reproduced below is Figure 5 of the patent specification, which shows an embodiment of a TNP therapy apparatus with a sealing membrane 514, an aspirant conduit 522, vacuum means 524 and air bleed means comprising an air bleed port 510 with a socket portion 520 having an air bleed hole 528.

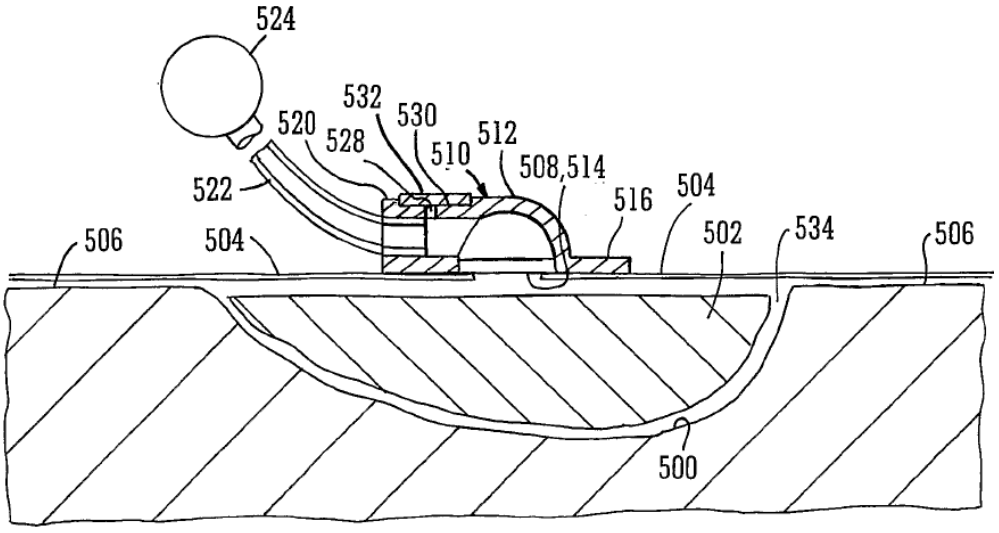

FIG. 5

2. Auxiliary request 2 - added subject-matter (Article 123(2) EPC)

2.1 Claim 1 has been amended to add the feature of the socket portion having a bleed hole. This feature is not disclosed in the claims as originally filed. The respondent submits that if claim 1 was read with a mind willing to understand, it would not be construed as encompassing an arrangement in which the air bleed hole was blocked by the aspirant conduit. Considering that the claim recites that the air bleed means comprising the air bleed port are in fluid communication with the wound cavity when in use, the Board shares this interpretation.

2.2 However, claim 1 still does not mention anything regarding how the air bleed hole is prevented from being blocked by the aspirant conduit. It must thus be determined whether the application as filed provides a basis for the claimed apparatus without specifying how this blockage is prevented.

2.3 The application as filed teaches two alternative ways of receiving the aspirant conduit at the socket portion while preventing the air bleed hole from being blocked.

2.4 The first way is disclosed in the embodiments in Figures 5-7. In these embodiments, the socket portion has an air bleed hole. The air bleed hole is prevented from being blocked by the aspirant conduit by receiving only an end of the aspirant conduit in the socket portion to an extent which leaves the air bleed hole uncovered (see Figure 5 reproduced above, page 10, lines 1-3 and page 11, lines 32-33). The application does not indicate whether there is any structural feature in these embodiments that physically prevents the aspirant conduit from being inserted further and covering the air bleed hole or whether it is up to the user to pay attention to this when inserting the aspirant conduit.

2.5 The second way is disclosed in connection with the air bleed port 700 shown in Figures 8A to 8E. In that embodiment, the neck portion 706 receives and holds the aspirant conduit 714 (see Figure 8E and page 12, lines 22 to 24). The aspirant conduit 714 passes completely through the air bleed port 700 and extends into the wound cavity 716 (see Figure 8E and page 12, lines 29-30). The air bleed hole 710 is provided at the wall portion 704, and the air bleed hole 710 is prevented from being blocked by a flexible bellows portion 708, which connects the neck portion 706 to the wall portion 704 and keeps the aspirant conduit 714 at a distance from the air bleed hole 710 (see page 13, lines 7 to 9).

2.6 The term "socket portion" is not used in the part of the application describing the embodiment in Figures 8A

to 8E. It is disputed by the parties which parts of the embodiment are to be regarded as a "socket portion" within the meaning of claim 1, and in particular whether the wall portion 704 is also part of the socket portion. This is relevant for establishing whether the socket portion has an air bleed hole in the embodiment in Figures 8A to 8E.

2.7 The Board is not convinced by the respondent's arguments that the wall portion 704 was part of the socket portion in the embodiment in Figures 8A to 8E. The fact that the aspirant conduit in the embodiment in Figures 8A to 8E passes through several elements, i.e. the neck portion 706, the wall portion 704 and the wound cavity 716, does not mean that these elements are to be regarded as part of the socket portion, in particular because they do not serve to hold the aspirant conduit, unlike the neck portion 706. This is irrespective of whether or not these further elements are integrally formed with the neck portion 706. Moreover, how the term "plug socket" may commonly be used has no bearing on how the term "socket portion" is to be construed in a patent application relating to an apparatus for providing topical negative pressure therapy. The respondent likewise refers to claims 21 and 23 as originally filed, with claim 23 indicating that the aspirant conduit passes completely through the socket portion; however, neither of these claims specifies that the socket portion has an air bleed hole, and, in the embodiment in Figures 8A to 8E, the aspirant conduit would pass completely through the socket portion irrespective of whether the socket portion is regarded as being only the neck portion 706 or as also comprising the wall portion 704. Hence, claims 21 and 23 have no impact on which part(s) of the

air bleed port 700 in Figures 8A to 8E constitute(s) the socket portion.

2.8 In view of the disclosure in the patent specification that it is the neck portion 706 which receives and holds the aspirant conduit (see Figure 8E and page 12, lines 22 to 24), the Board holds that in the embodiment in Figures 8A to 8E it is only the neck portion 706 which defines a socket portion within the meaning of claim 1.

2.9 It follows that the embodiment in Figures 8A to 8E does not comprise "a socket portion having an air bleed hole" as defined in claim 1. Hence, the application as filed only discloses a socket portion having an air bleed hole together with the specific way of receiving the aspirant conduit used in Figures 5 to 7 to prevent the air bleed hole from being blocked.

2.10 As submitted by the respondent, claim 1 is not restricted to the assembled apparatus, but instead relates to a kit of parts. In particular, claim 1 does not require the aspirant conduit to already be inserted in the socket portion. The respondent derives from this, and from the absence of any disclosure in the embodiment in Figures 5 to 7 of a structural feature to permit insertion of the aspirant conduit only up to the air bleed hole, that the feature that was allegedly omitted in claim 1 did not relate to the apparatus itself, but only to how it would be used and assembled by the user.

2.11 The Board is not convinced by this argument. The socket portion in Figures 5 to 7 is disclosed in the application as filed as a socket portion which, in use, receives an end of the aspirant conduit only to an

extent which leaves the air bleed hole uncovered. In particular, the geometry of the elements involved (i.e. the socket portion, the air bleed hole and the aspirant conduit in Figures 5 to 7) is such that the socket portion would not be suitable for receiving the aspirant conduit so as to pass completely through it without covering the air bleed hole. This is in contrast to the embodiment in Figures 8A to 8E, in which the air bleed hole remains uncovered regardless of how far the aspirant conduit has been inserted. Therefore, what claim 1 omits from the embodiments in Figures 5 to 7 relates not only to how the apparatus is used or assembled, but also to structural features of the components of the apparatus. These features relate to the geometry and function of the socket portion and of the air bleed hole and are thus in a close functional and structural relationship with the feature from these embodiments added to claim 1 of the socket portion having an air bleed hole.

2.12 It follows that the intermediate generalisation from the embodiments in Figures 5 to 7 defined by claim 1 is not allowable. Hence, auxiliary request 2 does not comply with Article 123(2) EPC.

3. Auxiliary requests 3 to 5

3.1 Auxiliary requests 3 to 5 were filed to address objections of lack of clarity and lack of inventive step. The amendments to claim 1 in these requests do not address the reasons why claim 1 of auxiliary request 2 contains added subject-matter, and the respondent has not provided any arguments in this regard, either.

3.2 It follows that auxiliary requests 3 to 5 do not comply with Article 123(2) EPC either, for the same reasons as set out above with regard to auxiliary request 2.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated