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Datasheet for the decision of 15 May 2025

Case Number: T 2557/22 - 3.3.10

Application Number: 17203441.5

Publication Number: 3326656

IPC: A61L2/00, A61M1/00

Language of the proceedings: EN

Title of invention:
REDUCED PRESSURE THERAPY APPARATUSES

Patent Proprietor:
Smith & Nephew plc

Opponent:
Mölnlycke Health Care AB

Headword:

Relevant legal provisions:
EPC Art. 76(1), 123(2)
RPBA 2020 Art. 13(2)

Keyword:
Divisional application - added subject-matter (yes)
Amendments - extension beyond the content of the application as filed (yes)
Amendment after summons - taken into account (no) - exceptional circumstances (no)

Decisions cited:
G 0002/10

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 2557/22 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 15 May 2025

Appellant: (Patent Proprietor)	Smith & Nephew plc Building 5, Croxley Park Hatters Lane Watford, Hertfordshire WD18 8YE (GB)
Representative:	Appleyard Lees IP LLP 15 Clare Road Halifax HX1 2HY (GB)
Respondent: (Opponent)	Mölnlycke Health Care AB Box 6 431 21 Mölndal (SE)
Representative:	Wallinger Ricker Schlotter Tostmann Patent- und Rechtsanwälte mbB Zweibrückenstraße 5-7 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 6 October 2022 revoking European patent No. 3326656 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	M. Kollmannsberger
	F. Blumer

Summary of Facts and Submissions

I. The patent proprietor appealed the Opposition Division's decision to revoke the patent under Article 101(3)(b) EPC.

II. The patent relates to a pump assembly useful in negative pressure wound therapy.

III. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(c) EPC for unallowable amendments. In opposition proceedings, the patent proprietor defended the patent in an amended form, a main request (MR) and seven auxiliary requests (AR1-AR7).

IV. The Opposition Division concluded that the patent proprietor's main request was not allowable because independent claims 1 and 24 extended beyond the original disclosure, Article 76(1)/123(2) EPC. Auxiliary requests 1-7 were admitted into the opposition procedure but were not held allowable for the same reason.

V. The independent claims 1 and 24 of the main request underlying the Opposition Division's decision, which was as well the appellant's main request in appeal proceedings, read as shown below. The numbering of the features is made for ease of reference. For claim 1, additions with respect to claim 1 of the parent application as filed are indicated by underlining.

Claim 1:

"*[1.1] A miniaturized, disposable, portable, battery powered canisterless pump assembly (104, 1000) for use in a negative pressure therapy kit for reduced pressure wound therapy, comprising*

[1.2] a housing (120);
[1.3] a sterile pump (232) supported within or by the housing, the pump comprising:

[1.4] a motor;
[1.5] an inlet and an outlet;
[1.6] a first valve configured to control a flow of a fluid through the inlet;
[1.7] a second valve configured to control a flow of a fluid through the outlet;
[1.8] a flow pathway through the pump assembly;
[1.9] a controller supported within or by the housing, the controller being configured to control an operation of the pump; and
[1.10] a single control button or switch (122, 1002) supported by the housing;
[1.11] one or more indicator lights (132, 1062, 1064, 1066) configured to alert a user to operating and/or failure conditions of the pump assembly;
[1.12] wherein the pump assembly is configured to transition to an end of life state when a duration of time has been reached or exceeded and indicate to a user that the pump assembly is to be disposed of;
and
[1.13] a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a

flow of gas through the flow pathway in a direction away from the pump;
[1.14] wherein the pump assembly further comprises a connector (128, 1150) for connecting a conduit (106) wherein said conduit is configured to be connected to a wound dressing; and
[1.16] wherein the pump is sterile in that the entire pump is sterile, including internal spaces or chambers of the pump, and the pump is configured such that a sterilisation gas can penetrate into the internal spaces or chambers.

Claim 24:
"*[24.1] A topical negative pressure wound therapy system comprising:*
[24.2] a miniaturized, disposable, portable, battery powered canisterless pump assembly (104,1000) comprising:
[24.3] a housing (120);
[24.3] a sterile pump (232) supported within or by the housing, the pump comprising:
[24.4] a motor;
[24.5] an inlet and an outlet;
[24.6] a first valve configured to control a flow of a fluid through the inlet;
[24.7] a second valve configured to control a flow of a fluid through the outlet;
[24.8] a flow pathway through the pump assembly;
[24.9] a controller supported within or by the housing, the controller being configured to control an operation of the pump; and
[24.10] a single control button or switch (122, 1002) supported by the housing;

[24.11] one or more indicator lights (132, 1062, 1064, 1066) configured to alert a user to operating and/or failure conditions of the pump assembly;
[24.12] wherein the pump assembly is configured to transition to an end of life state when a duration of time has been reached or exceeded and indicate to a user that the pump assembly is to be disposed of and
[24.13] a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow pathway in a direction away from the pump;
[24.14] wherein the pump assembly further comprises a connector (128, 1150) for connecting a conduit (106); and
[24.15] a wound dressing;
wherein the wound dressing is configured to be connected to the pump assembly via the conduit and wherein the pump assembly is configured to supply reduced pressure to the wound dressing; and
[24.16] wherein the pump is sterile in that the entire pump is sterile, including internal spaces or chambers of the pump, and the pump is configured such that a sterilisation gas can penetrate into the internal spaces or chambers."

VI. In its statement setting out the grounds for appeal and in the further course of the appeal proceedings the appellant submitted that, in contrast to the finding of the Opposition Division, all the features of claims 1 and 24 were disclosed individually and in combination in the original application as filed, as well as in the

parent application as filed. No subject-matter had been added, so the requirements of Articles 76(1) and 123(2) EPC were fulfilled. The same held for the claims of all auxiliary requests on file.

VII. The respondent (opponent) submitted that none of the claim sets sets submitted by the appellant complied with the provisions of Articles 76(1) and 123(2) EPC.

VIII. In a communication under Article 15(1) RPBA issued on 10 January 2025 the Board informed the parties about the points to be discussed during oral proceedings. The Board doubted that the requirements of Articles 76(1) and 123(2) EPC were fulfilled.

IX. Oral proceedings were held on 15 May 2025.

X. The final requests of the parties were the following:

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained based on its main request, or any of auxiliary requests 1 to 16, the main request and auxiliary requests 1 to 15 as filed with the statement of grounds of appeal, auxiliary request 16 as filed during the oral proceedings before the Board.

The respondent (opponent) requested that the appeal be dismissed. The respondent furthermore requested that all of the appellant's auxiliary requests not be admitted into the appeal proceedings.

XI. The wording of the independent claims of the appellant's main request has been given above. The exact claim wording of auxiliary requests 1-15 is not decisive. Auxiliary request 16 introduces the word "sterile" into features 1.1 and 24.2 so that these features read as follows (additions with respect to claim 1 of the parent application as filed are indicated by underlining):

"*[1.1] A miniaturized, disposable, portable, battery powered canisterless sterile pump assembly (104, 1000) for use in a negative pressure therapy kit for reduced pressure wound therapy, comprising (...)*"

"*[24.2] a miniaturized, disposable, portable, battery powered canisterless sterile pump assembly (104,1000) comprising (...)*"

XII. The decision was announced at the end of the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments (Article 76(1) EPC), Main request

2.1 The original application documents of the divisional application that gave rise to the patent under dispute include the disclosure of the parent application as filed. Thus, the PCT publication of the parent

application, WO 2013/064852, is referred to as the original disclosure for the purpose of assessing unallowable amendments under Article 76(1) and 123(2) EPC.

2.2 According to the impugned decision the individual amendments in claim 1 with respect to the original disclosure are originally disclosed, except the amendment in features [1.10] and [1.12]. Also, the Opposition Division considered feature [1.16] not to be disclosed in combination with some other features of the claim, in particular [1.11] and [1.12]. The respondent considers already the amendments in the individual features not to be disclosed in the original application documents, in particular the amendments in features [1.1], [1.10]-[1.14] and [1.16]. The respondent submits that the combination of these features was then even less derivable from the original application documents.

2.3 The appellant, in contrast, submitted that all features of the amended claims 1 and 24 were disclosed individually as well as in combination in the original application documents. The appellant stressed that according to the gold standard as defined in G 2/10 the original disclosure had to be read from a skilled person's point of view and should include the teaching that a skilled person obtains from the whole disclosure of the original application documents. In particular, the possible combination of features from different embodiments was disclosed in paragraph [0007] of the original description. Specifically, paragraph [0149] stated that features shown in figures 21/22 (pump assembly 1000) may be readily combined with the features shown in figures 1-6B (pump assembly 104).

2.4 General remarks

2.4.1 Under Article 76(1) and 123(2) EPC the European patent application or patent may not be amended in such a way that it contains subject-matter which extends beyond the application as originally filed. Regarding claim amendments, according to the so-called "gold standard" as set out in G 2/10 and now being established jurisprudence of the Boards of Appeal (see Case Law, II.E.1.3.1) amendments are allowed if the claimed subject-matter is disclosed, implicitly or explicitly, but directly and unambiguously to the skilled person, taking account of its common general knowledge.

2.4.2 In the present case it was undisputed that the combination of features defined in amended claim 1 is not disclosed in combination in any single embodiment of the original description. The drafting style of the application with its multitude of "embodiments", having themselves a multitude of optional features, renders it difficult to find disclosure for the feature combination of amended claim 1. With respect to the embodiment depicted in figure 21, to which the appellant specifically referred, paragraph [0149] states:

"Any of the embodiments of the pump assembly 1000 disclosed herein can have any of the same or similar components, features, materials, sizes, configurations, and other details of any other pump assembly embodiments disclosed or incorporated by reference herein, including the embodiment of the pump assembly 104 described above."

A skilled person is thus left without any guidance as to which features could be taken from which embodiments

("*disclosed or incorporated by reference*"), or even only from the pump assembly 104, in the same or in a similar way, to modify what is specifically disclosed in figure 21.

2.4.3 Such a disclosure is far from being direct and unambiguous, and, in the absence of any pointer, a skilled person cannot directly and unambiguously derive any specific combination of features therefrom. The Board fully agrees to the corresponding remarks in point 4.1.2 of the decision under appeal.

2.5 Specific objections

2.5.1 "Sterile"

According to amended claim 1 the pump assembly contains a sterile pump, features [1.3] and [1.16]. Only the pump is sterile, the pump assembly needs not to be sterile. The same is true for the negative pressure wound therapy system defined in claim 24, see features [24.3] and [24.16].

According to the appellant the individual feature [1.16] "*wherein the pump is sterile in that the entire pump is sterile, including internal spaces or chambers of the pump, and the pump is configured such that a sterilisation gas can penetrate into the internal spaces or chambers*" is disclosed in paragraph [0102]. It is correct that this, or at least a similar wording can be found there. However, firstly, the disclosure of paragraph [0102] is an explanation of figures 4A/4B which show many details and features which are not defined in the claim. Secondly, this paragraph refers to the *sterilisation process* of the pump. It does not disclose that in the end product, be it a pump assembly

or a wound therapy system, only the pump should be sterile.

During oral proceedings the appellant additionally referred to paragraphs [0002] and [0008]. However, paragraph [0002] refers to a sterile *pump kit*, not to a sterile pump, and paragraph [0008] contains a similar disclosure, see last sentence. Paragraph [0008] does state that the pump is not required to be sterilized, but that it may be sterilized in order to be used in a sterile environment, e. g. an operating room. However, especially in such a case it is clear to a skilled person that not only the pump needs to be sterilized, but also the other components of the assembly or system.

There is no disclosure anywhere in the original application documents of a pump assembly or a wound therapy system in which only the pump is sterile, as defined in amended claims 1 and 24. Such an embodiment is neither explicitly described nor can it be implicitly derived in a direct and unambiguous way, using common general knowledge. On the contrary, a skilled person would rather derive from the application's teaching as a whole that if the claimed devices are used under sterile conditions, not only the pump should be sterile.

2.5.2 Feature [1.1]

Claim 1 is directed to a "*miniaturized, disposable, portable, battery powered canisterless pump assembly*". The system defined in claim 24 likewise contains this combination of features, see [24.2]. Neither the original claims, nor the passages referred to by the Opposition Division in its decision, paragraphs [0073],

[0149], or [0061], disclose these attributes in combination with a "*pump assembly*". Nor do the passages to which the appellant additionally referred during oral proceedings, namely paragraphs [0081]-[0083], [0076], [0065], [0166], [0010], [0007] or claim 2.

It is correct that these passages individually disclose one or more of these attributes for a pump assembly. However, none of the passages combines all of them, and many of the passages disclose at the same time the contrary. According to paragraph [0073], the pump assembly 104 may be optionally miniaturized and portable in some embodiments, but also larger pumps may be used. According to paragraph [0071] the pump assembly of figure 1 may be canisterless, however, it may also be configured to include or support a canister. According to paragraph [0149], already addressed above, "*the pump assembly 1000 can be miniaturized and portable, although larger conventional portable or non-portable (e. g. wall suction) pumps can also be used*".

The original application documents do not disclose a "*miniaturized, disposable, portable, battery powered canisterless pump assembly*" in a direct and unambiguous way.

2.5.3 Combination of features [1.16], [1.12] and [1.11]

This is discussed in point 4.1.11 of the decision under appeal.

Feature [1.16] (sterilisation of the pump) is described in paragraph [0102]. This paragraph relates to the embodiment depicted in figures 4A and 4B. These figures neither show feature [1.11] (indicating lights for the

operating conditions) nor [1.12] (pump assembly configured to transit to an end-of-life state after a certain time). These two features are taken from paragraphs [0087]/[0150] and [0166] of the description. Paragraph [0087] relates to figures 2A-3C. Paragraph [00150] relates to figure 21 and requires *three* indicator lights, a feature not present in claim 1. Paragraph [0166] relates to figures 25 and 27 in which an end-of-life state is reached, but the text mentions a time threshold for deactivation which is not reproduced in claim 1. Thus, already the basis for the individual features as such is debatable.

For combining these features the appellant relied on the disclosure in paragraph [0149] and, more generally, in paragraph [0007], already discussed above in the general remarks. In the appellant's view individual features disclosed for separate "embodiments" in the original description may be readily combined, and a skilled person, taking into account the structure of the disclosure, would have considered such combinations to be disclosed. In particular, a skilled person would have realized that the description first disclosed features relating to the sterilization (paragraphs [0002], [0102]), followed by electrical system features necessary for the control of the pump. A skilled person would have considered these disclosures to be connected.

However, picking features described for different embodiments and combining them in a specific way does not correspond to a direct and unambiguous disclosure. As outlined above, the disclosure in paragraph [0149] at most tells a skilled person that features from different embodiments may be combined, but a skilled person has no information about which features from

which embodiments should be combined in which way. Without any pointer to such any such combination no specific combination is directly and unambiguously disclosed. A skilled person may have realized that different parts of the description relate to different themes, such as sterilisation or electronic control, but this is no pointer to combine specific disclosures taken from the different themes as it has been done in amended claims 1 and 24.

2.5.4 The Opposition Division additionally considered features [1.10] and [1.12] to extend beyond the original disclosure (points 4.1.7 and 4.1.9 of the decision under appeal). The respondent furthermore objected to features [1.11], [1.13] and [1.14].

In view of the above findings these issues need not be decided upon.

2.6 The amendments in independent claims 1 and 24 extend beyond the originally filed application documents. The patent cannot be maintained in amended form based on the appellant's main request, Article 101(3) EPC.

3. Amendments (Article 76(1) EPC), Auxiliary requests 1-15

The findings for the main request apply equally to the claims of auxiliary requests 1-15, independent of the question of whether these requests are admitted into appeal proceedings or not. In particular, the deficiencies as set out under points 2.5.1, 2.5.2 and 2.5.3 above are likewise present in the independent claims of auxiliary requests 1-15.

During oral proceedings the appellant did not defend these requests separately from the main request.

Thus, auxiliary requests 1-15 are not allowable for the same reasons than the main request. The respondent's request not to admit them into appeal proceedings is moot.

4. Auxiliary request 16

Auxiliary request 16 was filed during oral proceedings before the Board. It's admission into appeal proceedings is thus subject to the provisions of Article 13(2) RPBA. The respondent requested its non-admittance.

Article 13(2) RPBA requires exceptional circumstances, justified by cogent reasons, in order to admit an amendment of the appellant's appeal case at this stage of the proceedings.

The appellant submitted that the independent claims of auxiliary request 16 addressed the objection regarding the "sterile pump", the importance of which had emerged only in the course of the oral proceedings.

However, this objection was already on file at least since the respondent's reply to the statement of grounds for the appeal, see page 21 and following. Addressing this objection only at the day of oral proceedings has no justification under Article 13(2) RPBA. No exceptional circumstances are apparent. That an objection which was raised in the written procedure is discussed at oral proceedings is by no means exceptional. This holds in particular since the Board

had informed the appellant in its preparative communication under Article 15(1) RPBA that they might be asked to explain how claim 1 can be derived from the original application documents in a direct and unambiguous way, see point 8.5.4 there.

Thus, auxiliary request 16 is not admitted to appeal proceedings under Article 13(2) RPBA.

5. None of the appellant's requests on file fulfils the requirements of the EPC, Article 101(3)(b) EPC. Thus, the Board confirms the Opposition Division's decision to revoke the patent.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated