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14706464.6 Application Number:

Publication Number: 2968012

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A61M27/00

Language of the proceedings: ΕN

Title of invention:

ABSORBENT DRESSING WITH HYBRID DRAPE

Patent Proprietor:

KCI Licensing, Inc.

Opponent:

Smith & Nephew, Inc.

Headword:

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

Amendments - added subject-matter (yes)

Decisions cited:

G 0009/91, T 0263/05, T 1362/15, T 0895/18

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 2155/19 - 3.2.06

DECISION
of Technical Board of Appeal 3.2.06
of 21 March 2023

Appellant: Smith & Nephew, Inc. 1450 Brooks Road (Opponent)

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on

21 May 2019 concerning maintenance of the European Patent No. 2968012 in amended form.

Composition of the Board:

Chairman M. Harrison
Members: M. Hannam

J. Hoppe

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Summary of Facts and Submissions

- I. An appeal was filed by the appellant (opponent) against the interlocutory decision of the opposition division in which it found that European patent No. 2 968 012 in an amended form met the requirements of the EPC.
- II. The appellant requested that the decision under appeal be set aside and the patent be revoked.
- III. In its reply to the appeal, the respondent (patent proprietor) requested that the appeal be dismissed or, as an auxiliary measure, that the patent be maintained in amended form based on one of auxiliary requests 1 to 7, filed with the reply to the appeal.
- IV. The Board issued a summons to oral proceedings and a subsequent communication containing its provisional opinion, in which it indicated *inter alia* that the subject-matter of claim 1 of the main request seemed not to meet the requirement of Article 123(2) EPC. It further indicated that none of the auxiliary requests appeared to overcome this objection.
- V. Oral proceedings were held before the Board on 21 March 2023, during which the appellant withdrew auxiliary requests 1 and 3 to 7. At the close of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and the European patent be revoked.

The respondent requested that the appeal be dismissed (main request) or, as an auxiliary measure, that the

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patent be maintained in amended form based on auxiliary request 2, filed with the reply to the appeal.

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

"A dressing (124) for treating a tissue site (104), comprising: a base layer (132) having a periphery (152) surrounding a central portion (156) and a plurality of apertures (160) disposed through the periphery (152) and the central portion (156), wherein the base layer (132) is to cover the tissue site (104) and tissue surrounding the tissue site (104); a sealing member (140) having a periphery (164) and a central portion (168), the periphery (164) of the sealing member (140) positioned proximate the periphery (152) of the base layer (132), wherein the central portion (168) of the sealing member (140) and the central portion (156) of the base layer (132) define an enclosure (172);

an adhesive (136) positioned between the periphery (164) of the sealing member (140) and the periphery (152) of the base layer (132), wherein the adhesive (136) is in fluid communication with the apertures (160) in the base layer (132) so that, in use, the adhesive (136) extends through the plurality of apertures (160) in fluid communication with, and in contact with, the tissue surrounding the tissue site (104) through the apertures (160) in the base layer (132) for securing the dressing (124) to the tissue surrounding the tissue site (104);

a first wicking layer (176) disposed in the enclosure (172):

a second wicking layer (180) disposed in the enclosure (172);

an absorbent layer (184) positioned in fluid communication between the first wicking layer (176) and

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the second wicking layer (180), wherein a peripheral portion (186) of the first wicking layer (176) is coupled to a peripheral portion (187) of the second wicking layer (180) providing a wicking layer enclosure (188) surrounding the absorbent layer (184) between the first and the second wicking layer (176, 180); and a conduit interface (148) positioned proximate to the sealing member (140) and in fluid communication with the enclosure (172)."

Claim 1 of auxiliary request 2 reads as follows, with changes relative to claim 1 of the main request underlined:

"A system for treating a tissue site, comprising: an interface manifold adapted to be positioned proximate the tissue site;

- a dressing (124) for treating the tissue site (104), comprising:
- a base layer (132) having a periphery (152) surrounding a central portion (156) and a plurality of apertures (160) disposed through the periphery (152) and the central portion (156), wherein the base layer (132) is to cover the tissue site (104) and tissue surrounding the tissue site (104);
- a sealing member (140) having a periphery (164) and a central portion (168), the periphery (164) of the sealing member (140) positioned proximate the periphery (152) of the base layer (132), wherein the central portion (168) of the sealing member (140) and the central portion (156) of the base layer (132) define an enclosure (172);
- an adhesive (136) positioned between the periphery (164) of the sealing member (140) and the periphery
- (152) of the base layer (132), wherein the adhesive
- (136) is in fluid communication with the apertures

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(160) in the base layer (132) so that, in use, the adhesive (136) extends through the plurality of apertures (160) in fluid communication with, and in contact with, the tissue surrounding the tissue site (104) through the apertures (160) in the base layer (132) for securing the dressing (124) to the tissue surrounding the tissue site (104);

- a first wicking layer (176) disposed in the enclosure (172);
- a second wicking layer (180) disposed in the enclosure (172);

an absorbent layer (184) positioned in fluid communication between the first wicking layer (176) and the second wicking layer (180), wherein a peripheral portion (186) of the first wicking layer (176) is coupled to a peripheral portion (187) of the second wicking layer (180) providing a wicking layer enclosure (188) surrounding the absorbent layer (184) between the first and the second wicking layer (176, 180); and a conduit interface (148) positioned proximate to the scaling member (140) and in fluid communication with the enclosure (172); and

a reduced-pressure source adapted to be coupled in fluid communication with the conduit interface to provide reduced pressure to the dressing."

VII. The appellant's arguments may be summarised as follows:

Main request

The subject-matter of claim 1 extended beyond the content of the application as filed. The feature 'an adhesive positioned between the periphery of the sealing member and the periphery of the base layer' was originally disclosed only in relation to the system comprising the dressing, not the dressing in isolation,

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and had further features. Paragraph [0031] as filed included a multitude of optionally included features of the invention. Not including the disclosed 'sealed space' and 'fluid seal' from paragraph [0031] in claim 1, when including the feature relating to the adhesive being positioned between the peripheries therein, could not be seen as a direct and unambiguous disclosure of the claimed subject-matter. As regards the definition of the peripheries in claim 1, these were simply 'proximate' each other and not co-extensive. Claim 1 thus included embodiments in which e.g. the base layer extended beyond the sealing member, such embodiments not being originally disclosed, and thus further supported the contention that the subject-matter of claim 1 extended beyond the content of the application as filed.

VIII. The respondent's arguments may be summarised as follows:

Main request

The subject-matter of claim 1 met the requirement of Article 123(2) EPC. The feature 'an adhesive positioned between the periphery of the sealing member and the periphery of the base layer' in combination with the remaining features of claim 1 was directly and unambiguously disclosed in the application as filed. Whilst a combination of claims 25 and 30 as filed did not explicitly disclose this feature, it provided a strong pointer to this since claim 30 defined the adhesive being in fluid communication with the tissue surrounding the tissue site. In the entire description the sole location of the adhesive was disclosed to be between the peripheries of the sealing member and base layer; no alternative location was disclosed. Even if

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paragraph [0031] of the description were required to provide basis for the feature in question, claim 1 included all technically relevant features disclosed in this paragraph. The reference to Figures 1 to 3 at the start of the paragraph was also not problematic since these all disclosed the adhesive in precisely the claimed location i.e. between the periphery of the sealing member and the periphery of the base layer. The skilled person would interpret both the extent of the central portion and the dimension of the periphery of each of the base layer and sealing member in the same way, such that the periphery of the sealing member being 'proximate' the periphery of the base layer necessarily implied that the respective peripheries were co-extensive. The example presented by the appellant was not a technically reasonable interpretation of the claim wording and did thus not fall under the claim when considered by a skilled person; an exposed region of adhesive on the top of the peripheral surface of the base layer, for example, would undesirably adhere to anything placed in the vicinity of the dressing.

Auxiliary request 2

The appellant had raised no objections to claim 1 of this request in any submission such that the Board had no power to question the allowability of the request.

As regards compliance with Article 123(2) EPC, claim 1 found basis in a combination of claims 1, 8 and 17 as filed. The skilled person would understand that the combination of the features in these claims was reflected in the sole embodiment of the description. All technically linked and relevant features in

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paragraph [0031] as filed were also included in claim 1 such that a clear basis was evident.

Reasons for the Decision

1. Main request

Article 123(2) EPC

- 1.1 The subject-matter of claim 1 fails to meet the requirement of Article 123(2) EPC.
- 1.2 According to the appellant, at least the following feature of claim 1 lacked basis in the application as filed:

'an adhesive positioned between the periphery of the sealing member and the periphery of the base layer'.

It argued that this feature was disclosed in the application as filed solely in relation to the dressing when part of a system for treating a tissue site, and moreover in combination with additional features not included in claim 1; the feature in question was not disclosed in relation to the dressing alone, to which claim 1 was directed.

1.3 The respondent's argument that the skilled person received a strong pointer from claims 25 and 30 as filed that the adhesive was to be applied at the periphery of the sealing member and the periphery of the base layer can, in favour of the respondent, to some extent be accepted. However, due to the word "proximate" when referring to the location of the peripheral edges of the respective layers, the position

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of the adhesive in the manner defined cannot be unambiguously concluded. Claim 25 defines the central portions of each of the sealing member and base layer to form an enclosure with wicking and absorbent layers disposed therein, such that the central portions can implicitly be understood to at least partially cover the tissue site to be treated. Since adhering a dressing to the tissue site to be treated can be accepted to be undesirable, it follows that adhesive would preferably not be present on the central portions. This is underlined by claim 30 as filed defining the adhesive to be in fluid communication with the tissue surrounding the tissue site. This supports the respondent's contention that the skilled person is thus directed towards applying the adhesive to the periphery of the sealing member and the periphery of the base layer.

- 1.4 Nonetheless, as the respondent itself accepts, this 'pointer' does not itself provide a direct and unambiguous disclosure of the specifically defined location of the adhesive in claim 1. For the unambiguous disclosure of this, the respondent refers to paragraph [0031] as filed. This paragraph indeed explicitly discloses that 'the adhesive may be positioned at least between the periphery of the sealing member and the periphery of the base layer'.
- 1.5 This paragraph however commences with the words
 "Continuing with FIGS. 1-3,...". The Board thus finds
 that this feature in paragraph [0031] as filed is
 disclosed at least in combination with further features
 of the specific embodiment disclosed in Figure 1
 (relating to the system) and that disclosed in Figure 2
 (relating to the dressing). Such further features
 include the fluid seal formed between the sealing

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member and the tissue site and the sealed space 174. The omission of at least these further features from claim 1 presents an unallowable intermediate generalisation of the application as filed.

- 1.6 As to the respondent's contention that the repeated use of the word 'may' in relation to the disclosure of a plurality of features in paragraph [0031] implied these all being optional, the Board disagrees. The detailed description as filed discloses nearly every feature therein as possibly being included in the inventive system or dressing with wording such as 'may be', 'may provide', 'may include' etc. The result is a reservoir of features in the description which may or may not be part of the invention. The selection of just one of these optionally disclosed features for inclusion with the other features in claim 1 in isolation from related features described with similar emphasis, and even in the same paragraph as the feature taken-up into the claim, is thus not seen to meet the requirement of a direct and unambiguous disclosure of the claimed subject-matter in the application as filed.
- 1.7 The respondent's argument that the reference to Figures 1 to 3 at the start of paragraph [0031] was not problematic, since these figures all disclosed the adhesive in just the claimed location between the periphery of the sealing member and the periphery of the base layer, does not persuade the Board that the requirement of Article 123(2) EPC is met. The fact that the figures are consistent with the wording of the claim is not the standard to be met for this provision to be satisfied. As is clear from Figures 1 and 2, these depict an abundance of features relating to the specific embodiments of the claimed system / dressing. It is in this context that Figures 1 and 2 disclose the

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'adhesive positioned between the periphery of the sealing member and the periphery of the base layer'. Therefore, absent these additional features of Figures 1 and 2 disclosed in a structural combination with that taken up into claim 1, the present claim 1 lacks basis.

- 1.8 The respondent's contention that claim 1 included all technically relevant features disclosed in this paragraph is not accepted. Even disregarding the reference to Figures 1 to 3, paragraph [0031] explicitly discloses a 'fluid seal' being formed between the sealing member and the tissue site and 'a sealed space 174' (see also point 1.5 above). Both these features are functionally and structurally related to the sealing member, the periphery of which has been defined along with the periphery of the base layer to sandwich the adhesive in the feature taken up into claim 1. The omission of at least these further features from claim 1 also results in its subjectmatter not meeting the requirement of Article 123(2) EPC.
- The respondent's argument that the presence of a 'fluid seal' in claim 1 was implicit since the claimed invention concerned a low pressure wound heal system, is also not accepted. Whilst the patent disclosure as a whole is directed to such low pressure systems, claim 1 of the main request is not limited to such systems, this being directed simply to a 'dressing for treating a tissue site' absent any requirement for this dressing to be part of a low pressure system. There is consequently no need for the dressing of claim 1 to comprise a fluid seal such that this feature cannot be seen as implicitly included in the claimed subjectmatter.

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- 1.10 The respondent's argument that the entire description consistently disclosed the sole location of the adhesive to be between the peripheries of the sealing member and base layer may be correct, but this even so does not provide a direct and unambiguous basis for the feature in question to be taken in isolation. Wherever the feature 'an adhesive positioned between the periphery of the sealing member and the periphery of the base layer' is disclosed in the description, this is in a very specific context, not in the generality resulting from just extracting this feature for inclusion in claim 1 and omitting those features disclosed in combination with it in the specific embodiments.
- 1.11 As an example of the subject-matter of claim 1 extending beyond the content of the application as filed, the appellant outlined an embodiment falling under the scope of claim 1 which was not originally disclosed. This related to the base layer and sealing member not being co-extensive, the periphery of the base layer extending beyond the periphery of the sealing member. This would meet the definition of both the base layer and sealing member in claim 1 yet was not disclosed in the application as filed.
- 1.11.1 The respondent argued relative to this example that the skilled person would interpret both the extent of the central portion and the dimension of the periphery of each of the base layer and sealing member in the same way, such that the periphery of the sealing member being 'proximate' the periphery of the base layer necessarily implied that the respective peripheries were co-extensive. This is not accepted. Nothing in claim 1 defines that the peripheries of the base layer and sealing member must be co-extensive, it solely

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being defined that 'the periphery of the sealing member [was] positioned proximate the periphery of the base layer'. Such proximity does not imply that the peripheries must be co-extensive, nor indeed is this necessary from a technical point of view. The sole restriction in this regard is that the adhesive must be 'positioned between the periphery of the sealing member and the periphery of the base layer' which can be satisfied for example if just a portion of one periphery overlaps with the other periphery; no complete overlap of the two peripheries to enable these to be co-extensive is necessary to satisfy the definition of the peripheries in claim 1.

- 1.11.2 The respondent's argument that the appellant's example was not a technically reasonable interpretation of the claim wording, and did thus not fall under the claim, is also not accepted. Whilst the exposed region of adhesive on the top of the peripheral surface of the base layer could undesirably adhere to anything placed in the vicinity of the dressing, this disadvantage could reasonably be overcome with some type of 'release paper' or other material covering the otherwise exposed adhesive. Alternatively any exposed adhesive could beneficially allow further elements to be secured to the dressing such as, for example, the conduit 196 leading to the reduced-pressure source 128.

 Consequently, the appellant's example is a technically reasonable realisation of claim 1.
- 1.12 In writing, the respondent argued that claim 1 found basis in a combination of claims 1 and 8 as filed.

 Irrespective of these claims as filed being directed to a system for treating a tissue site rather than the claimed dressing for treating a tissue site, the present claim 1 defines details of the peripheral

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portions of the first and second wicking layers which are not to be found in claim 1 or 8 as filed. The respondent's argument is thus not persuasive.

- 1.13 In summary, therefore, the subject-matter of claim 1 lacks basis in the application as filed contrary to the requirement of Article 123(2) EPC.
- 1.14 The main request is thus not allowable.
- 2. Auxiliary request 2
- 2.1 This request was filed in reply to the appellant's grounds of appeal and also corresponds to auxiliary request 2 on file before the opposition division. No objections in writing were presented by the appellant in respect of this request.
- 2.1.1 As to the respondent's contention that the Board had no power to consider the allowability of this request since no objections had been raised by the appellant, this is not accepted. As stated in G9/91 (see Reasons 19), in case of amendments of the claims of a patent, such amendments are to be fully examined as to their compatibility with the requirements of the EPC (e.g. with regard to the provisions of Article 123 EPC).
- 2.1.2 Being directed to a system for treating a tissue site, all the claims of the patent as granted being directed to a dressing for treating a tissue site, claim 1 of auxiliary request 2 is an amendment to the claims as granted. The Board thus has an ex officio duty according to G9/91 to examine the amended claims as to their compliance with the EPC. As also stated in T 263/05, in the absence of any objections to such claims in inter partes proceedings, the Board should

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anyway consider at least *prima facie* whether such objections exist. This is indeed the case here, since *prima facie* the subject-matter claimed is for example not a combination of granted or filed claims which are dependent on each other.

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2.2 Article 123(2) EPC

- 2.2.1 As regards the basis for the subject-matter of claim 1, the appellant's reliance solely on claims 1, 8 and 17 as filed is not persuasive. Claims 8 and 17 as filed are each individually solely dependent on 'the system of claim 1'. There is thus no basis solely in claims 1, 8 and 17 for the claimed subject-matter, since a direct and unambiguous disclosure of the amalgamation of features in these claims in combination is absent. This conclusion is also consistent with established case law of the Boards of Appeal (see for example T 1362/15, Reasons 4; T 0895/18, Reasons 3.1.3)
- 2.2.2 The appellant's argument that, irrespective of the claim dependencies, the sole embodiment of the description supported the skilled person seeing the features from claims 1, 8 and 17 being disclosed in combination, is not accepted. The embodiment of the system for treating a tissue site relates to Figure 1 of the application as filed. This figure discloses a multitude of physical features in combination, not least the co-extensive peripheries of the base layer and the sealing member. The Board thus finds that the embodiment directed to the system for treating a tissue site fails to unambiguously support (merely) the features of claims 1, 8 and 17 as filed being disclosed in combination.

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- 2.2.3 The appellant's further argument that claim 1 included all technically linked and relevant features of the invention in paragraph [0031] as filed, such that a clear basis for the subject-matter of claim 1 was given, is also not accepted. As identified in point 2.2.2 above, at least the base layer and the sealing member being co-extensive was derivable as an integral structural feature of the system described in paragraph [0031] when seen in the context of Figures 1 and 2 as filed, which this paragraph concerns. The omission of at least this feature from claim 1 thus results in its subject-matter extending beyond the content of the application as filed.
- 2.2.4 The subject-matter of claim 1 of auxiliary request 2 thus fails to meet the requirement of Article 123(2) EPC. Auxiliary request 2 is therefore not allowable.

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:



D. Grundner M. Harrison

Decision electronically authenticated