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Datasheet for the decision of 25 April 2022

Case Number: T 1858/16 - 3.2.06

03003916.8 Application Number:

Publication Number: 1314410

IPC: A61F13/02

Language of the proceedings: EN

Title of invention:

Multi layered wound dressing

Patent Proprietor:

ConvaTec Technologies Inc.

Opponent:

Paul Hartmann Aktiengesellschaft

Headword:

Relevant legal provisions:

EPC Art. 84 RPBA 2020 Art. 13(1)

Keyword:

Claims - clarity - main request (no) - clarity - auxiliary requests 1 to 5 (no)
Late-filed auxiliary requests 6 to 8 - request clearly allowable (no)

Decisions cited:

G 0003/14, T 0378/02, T 1041/98

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 1858/16 - 3.2.06

D E C I S I O N

of Technical Board of Appeal 3.2.06

of 25 April 2022

Appellant: Paul Hartmann Aktiengesellschaft

(Opponent) Paul-Hartmann-Strasse D-89522 Heidenheim (DE)

Representative: DREISS Patentanwälte PartG mbB

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Respondent: ConvaTec Technologies Inc.
(Patent Proprietor) 6100 Neil Road, Suite 500

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Representative: D Young & Co LLP

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on

9 June 2016 concerning maintenance of the European Patent No. 1314410 in amended form.

Composition of the Board:

Chairman M. Harrison
Members: P. Cipriano

W. Ungler

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Summary of Facts and Submissions

- I. In its interlocutory decision the opposition division found that European patent No. 1 314 410 in an amended form met the requirements of the EPC.
- II. The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.
- III. The respondent (patent proprietor) requested, with its reply to the opponent's appeal, that the appeal be dismissed or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 5.
- IV. In preparation for oral proceedings, the Board issued a communication under Article 15(1) RPBA 2020 containing inter alia its provisional opinion that claim 1 of the main request and of auxiliary requests 2 to 5 lacked clarity contrary to Article 84 EPC.
- V. With letter dated 16 November 2020 the respondent filed further auxiliary requests 6 to 8.
- VI. In its letter dated 14 January 2022 the appellant requested *inter alia* that auxiliary requests 6 to 8 not be admitted into the proceedings.
- VII. With a further letter dated 3 February 2022 the respondent declared that it would not be attending the oral proceedings and that it maintained all its requests and written submissions.
- VIII. The oral proceedings were duly cancelled.

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IX. Claim 1 of the main request and of auxiliary request 6 reads as follows:

"A multi layered wound dressing which comprises an absorbent layer (2), a transmission layer (6) and a spreading layer (4), the spreading layer (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:

the spreading layer (4) is positioned between the transmission (6) and absorbent (2) layers:

the absorbent layer (2) has high absorbency but low lateral wicking:

the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4); the spreading layer (4) has high lateral wicking: the transmission layer has a high moisture vapour transmission rate;

and the lateral spread of exudate is limited in the absorbent layer (2) and maximised in the transmission layer (6);

so that the passage of exudate through the dressing follows a "T" shape."

The claims 1 of auxiliary requests 1 to 9 are annexed at the end of the decision.

X. The arguments of the appellant relevant for the decision are as follows:

Main request and auxiliary request 1 - Article 84 EPC

The feature "the spreading layer (4) has high lateral wicking" was not clear. Paragraph [0008] described only low lateral wicking. Paragraph [0016] of the patent did not give a definition either, since it was limited to a layer in the form of a net and only gave examples of

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possible values (i.e. "such as") that the lateral wicking might preferably have.

Auxiliary requests 2 to 5 - Article 84 EPC

Claim 1 lacked clarity, since it was not clear how high the lateral wicking had to be in order for it to "aid" the spread of exudate.

Auxiliary requests 6 to 8 - Article 13(1) RPBA 2020

Auxiliary requests 6 to 8 should not be admitted into the proceedings, since they were late-filed and not prima facie allowable.

XI. The arguments of the respondent relevant for the present decision are as follows:

Main request and auxiliary request 1 - Article 84 EPC

Following the decision G 3/14, the feature "the spreading layer (4) has high lateral wicking" could not be objected to for lack of clarity since the amendment to introduce this feature did not introduce a lack of clarity which was not already present in the granted claims.

In addition, the feature "the spreading layer (4) has high lateral wicking" was clear, since it had a well-recognised meaning in the context of the whole disclosure. As T 378/02 and T 1041/98 confirmed, relative terms such as "high" must be interpreted in the context of the whole disclosure of the patent.

Auxiliary requests 2 to 5 - Article 84 EPC

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The feature "the spreading layer (4) is a high lateral wicking layer... which aids the spread of exudate across a greater area of the dressing but away from the wound" was supported by the patent and would be readily understood by a person skilled in the art with a mind willing to understand.

Auxiliary requests 6 to 8 - Article 13(1) RPBA 2020

Auxiliary requests 6 to 8 should be admitted into the proceedings.

Auxiliary request 6 was filed in response to the Board's preliminary opinion that claim 2 contravened the requirements of Articles 123(2) and 76(1) EPC, which represented a "change of focus" to claim 2.

Auxiliary requests 7 and 8 were a direct response to the Board's preliminary opinion on clarity and novelty, which differed from the one of the opposition division. They addressed the clarity objections by defining the MVTR (moisture vapour transmission rate) of the transmission layer.

Reasons for the Decision

- 1. Main request Article 84 EPC
- 1.1 The respondent argued that the feature "the spreading layer (4) has high lateral wicking" could not be objected to for lack of clarity since the amendment to introduce this feature did not introduce a lack of clarity which was not already present in the granted claims (see G 3/14).

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According to the respondent, claim 1 as granted required the lateral wicking of exudate in the absorbent layer to be "less than that in the spreading layer" and to be "limited". Accordingly the granted claims already defined the lateral wicking of exudate in both the absorbent layer and the spreading layer, with the spreading layer wicking being higher than the absorbent layer and the absorbent layer having a "limited" lateral wicking.

The respondent further considered that the feature "the spreading layer (4) has high lateral wicking" in claim 1 of the main request (in particular when read in combination with "the absorbent layer has... low lateral wicking" and "the lateral wicking of exudate in the absorbent layer is less than that in the spreading layer") stated the same thing but merely in other words, did not introduce any further ambiguity and therefore did not introduce any additional non-compliance with Article 84 EPC.

"the spreading layer (4) has high lateral wicking" and "the absorbent layer has... low lateral wicking" imply not only that the lateral wicking in the spreading layer is higher than in the absorbent layer, as the respondent argued, but also that the lateral wicking in the spreading layer is high in absolute terms. For example, a lateral wicking rate could be higher than a low wicking rate in the absorbent layer but still be considered "low" in absolute terms.

The amendment therefore does not state the same as the granted claims and instead defines a more specific lateral wicking of the spreading layer than the one defined in claim 1 as granted such that an objection of

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non-compliance with Article 84 EPC as foreseen in ${\rm G}$ 3/14 can indeed be introduced.

1.2 The respondent argued that the feature "the spreading layer (4) has high lateral wicking" in claim 1 was clear, since "high lateral wicking" had a well-recognised meaning in the context of the whole disclosure. As T 378/02 and T 1041/98 confirmed, relative terms needed to be interpreted in the context of the whole disclosure of the patent.

Further, according to the respondent, paragraph [0008] of the patent defined "low lateral wicking" as being less than 20mm/60s. Thus, it followed that all the values above 20mm/60s were considered a "high lateral wicking rate". The teaching in paragraph [0016] that 30mm/60s was a high lateral wicking rate supported this.

1.2.1 The Board does not find these arguments persuasive.

Even if paragraph [0008] discloses that "low lateral wicking is meant as a lateral wicking rate of less than 20mm/60s" this does not necessarily imply conversely that all the values above that are to be understood as "high lateral wicking rate". Other relative terms could be used to refer to values above 20mm/60s (for example, medium, average, moderate...) before arriving at a lateral wicking considered "high".

Further, paragraph [0016] only discloses examples of possible values that the lateral wicking may preferably have. Since the respondent did not provide any further passages to support its contention and the Board cannot find any, the whole disclosure of the patent does not provide a definition for what the skilled person should understand as a "high lateral wicking rate".

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In the absence of such a definition and unlike in the decisions T 1041/98 (see Reasons 2) and T 378/02 (see Reasons 5), the Board finds that in the context of the disclosure of the patent in suit as a whole, the expression "high lateral wicking" does not represent a clear definition of any values that the lateral wicking must have and introduces a lack of clarity.

- 1.3 The clarity requirement of Article 84 EPC is thus not fulfilled. The main request is hence not allowable.
- 2. Auxiliary request 1 Article 84 EPC
- 2.1 In item 65 of its letter dated 16 November 2020 the respondent noted "that the reasons above for the Main Request apply mutatis mutandis to AR1 to 5". These reasons include items 22 to 34 which related to the clarity of the feature "the spreading layer (4) has high lateral wicking", in the main request.
- 2.2 The wording of claim 1 of auxiliary request 1 has been amended to include the feature that the transmission layer "overlies the side of said absorbent layer furthest from the wound" but does not contain any further substantive amendments. The wording of claim 1 therefore still contains the feature "the spreading layer (4) has high lateral wicking", the clarity of which is not affected by the introduced wording.
- 2.3 Therefore, for the same reasons as apply to the main request, the clarity requirement of Article 84 EPC is not fulfilled and auxiliary request 1 is therefore also not allowable.

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- 3. Auxiliary requests 2 to 5 Article 84 EPC
- 3.1 Relative to claim 1 of the main request, claim 1 of auxiliary request 2, 3 and 5 define *inter alia* not only that "the spreading layer (4) is a high lateral wicking layer" but also that the spreading layer (4) is a layer which "aids the spread of exudate across a greater area of the dressing but away from the wound".
- 3.2 The respondent argued (see paragraph 69 of its letter dated 16 November 2020) that this feature was supported by the patent and would be readily understood by a person skilled in the art with a mind willing to understand.

The Board does not find this argument persuasive. As long as the spreading layer allows (lateral) wicking, there is a spreading of exudate such that it is unclear for the skilled person how high such lateral wicking needs to be in order to "aid" the spread.

In a similar way as explained above in item 1.2, there is also nothing in paragraphs [0008] or [0016] of the patent that discusses specifically how high such a wicking rate must be in order to be considered to "aid" the spread.

- 3.3 As already stated in item 7.6 of its preliminary opinion, the Board now confirms that this feature introduces a lack of clarity, contrary to Article 84 EPC.
- 3.4 Relative to claim 1 of the main request, claim 1 of auxiliary request 4 defines *inter alia* that the spreading layer not only "has high lateral wicking" but "is a net".

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Defining the spreading layer as a net, however, does not change the fact that, as explained above under item 1.2, the expression "high lateral wicking" does not provide a clear definition of any values that the lateral wicking must have and thus introduces a lack of clarity.

- 3.5 Therefore, the clarity requirement of Article 84 EPC is not fulfilled for any of the claims 1 of auxiliary requests 1 to 5, whereby auxiliary requests 1 to 5 are not allowable.
- 4. Auxiliary requests 6 to 8 Article 13(1) RPBA 2020
- 4.1 Auxiliary requests 6 to 8 were filed with letter dated 16 November 2020 in an amendment to the party's appeal case.
- Article 13(1) RPBA 2020 stipulates that any amendment to a party's appeal case may be admitted only at the Board's discretion. This discretion is to be exercised in view of, inter alia, the current state of the proceedings, whether the amendment is detrimental to procedural economy, the suitability of the amendment to resolve the issues which were admissibly raised and whether the party has demonstrated that any such amendment, prima facie, overcomes the issues raised by another party in the appeal proceedings or by the Board and does not give rise to new objections.
- 4.3 Although the deletion of claim 2 rendered the respective objections which had been made against that claim's subject-matter under Articles 76(1) and 123(2) EPC moot, the wording of claim 1 of auxiliary request 6 corresponds verbatim to the wording of claim 1 of the

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main request. Thus, and regardless of whether there has been a change of focus or not (as was the respondent's argument), claim 1 of auxiliary request 6 is *prima* facie not suitable to overcome the clarity objections to claim 1 of the main request discussed above under item 1.

- 4.4 Claim 1 of auxiliary requests 7 and 8 have the same wording and differ from claim 1 of the main request in that they further define that:
 - the absorbent layer "is a fibrous layer, the fibrous layer comprising gel-forming fibres", and
 - the transmission layer has a moisture vapour transmission rate "of at least 1000 $\rm g/m^2/24$ hrs and overlies the side of said absorbent layer furthest from the wound" instead of a "high moisture vapour transmission rate".
- 4.5 The respondent argued that these amendments were a response to the Board's preliminary opinion on clarity and on novelty and that they addressed the clarity objections by defining the MVTR (moisture vapour transmission rate) of the transmission layer.

The Board does not accept these arguments, since defining the MVTR of the transmission layer does not address the clarity issue regarding the spreading layer that has been discussed above under item 1. The amendments to claim 1 of auxiliary requests 7 and 8 concern the absorbent layer and the transmission layer and are not linked to the spreading layer nor its wicking rate such that they are prima facie not suitable to overcome the clarity objections to claim 1 of the main request discussed above under item 1.

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- 4.6 In view of the above, the Board exercised its discretion under Article 13(1) RPBA 2020 not to admit auxiliary requests 6 to 8 into the proceedings.
- 5. Absent any request which meets the requirements of the EPC, the patent must be revoked (Article 101(3)(b) EPC).

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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

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Claim 1 of Auxiliary Request 1

AUXILIARY REQUEST 1

- 1. A multi layered wound dressing which comprises an absorbent layer (2), a transmission layer (6) and a spreading layer (4), the spreading layer (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:
- the spreading layer (4) is positioned between the transmission (6) and absorbent (2) layers; the absorbent layer (2) has high absorbency but low lateral wicking; the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4);
- the spreading layer (4) has high lateral wicking; the transmission layer has a high moisture vapour transmission rate and overlies the side of said absorbent layer furthest from the wound; nd the lateral spread is limited in the absorbent layer (2) and maximised in the transmission layer (6);
- 20 so that the passage of exudate through the dressing follows a "T" shape.

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Claim 1 of auxiliary request 2

AUXILIARY REQUEST 2

- 1. A multi layered wound dressing which comprises an absorbent layer (2), a transmission layer (6) and a spreading layer (4), the spreading layer (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:
- the spreading layer (4) is a high lateral wicking layer positioned between the transmission (6) and absorbent (2) layers which aids the spread of exudate across a greater area of the dressing but away from the wound; the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4);
- the absorbent layer comprises gel-forming fibres that are able to gel block which resists the lateral spread of exudate; the spreading layer (4) is a net; the transmission layer has a moisture vapour transmission rate of at least 1000g/m²/24hrs and overlies said absorbent layer;
- and the lateral spread is limited in the absorbent layer (2) and maximised in the transmission layer (6); so that the passage of exudate through the dressing follows a "T" shape.

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Claim 1 of auxiliary request 3

AUXILIARY REQUEST 3

- 1. A multi layered wound dressing which comprises an absorbent layer (2), a transmission layer (6) and a spreading layer (4), the spreading layer (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:
- the spreading layer (4) is a high lateral wicking layer positioned between the transmission (6) and absorbent (2) layers which aids the spread of exudate across a greater area of the dressing but away from the wound; the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4);
- the absorbent layer (2) comprises gel-forming fibres which are able to gel block which resists the lateral spread of exudate; the spreading layer (4) is a net; the transmission layer has a moisture vapour transmission rate of at least 1000g/m²/24hrs and overlies the absorbent layer;
- and the lateral spread is limited in the absorbent layer (2) and maximised in the transmission layer (6); so that the passage of exudate through the dressing follows a "T" shape, the dressing for the prevention or treatment of maceration of skin surrounding the wound.

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Claim of auxiliary request 4

AUXILIARY REQUEST 4

- 1. A multi layered wound dressing which comprises an absorbent layer
- (2), a transmission layer (6) and a spreading layer (4), the spreading layer (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:
- the spreading layer (4) is positioned between the transmission (6) and absorbent (2) layers;
 - the absorbent layer (2) has high absorbency but low lateral wicking and comprises gel-forming fibres which are able to gel block which resists the lateral spread of exudate;
- the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4);
 - the spreading layer (4) is a net that has high lateral wicking;
 - the transmission layer has a moisture vapour transmission rate of at least 1000g/m2/24hrs;
- and the lateral spread is limited in the absorbent layer (2) and maximised in the transmission layer (6);
 - so that the passage of exudate through the dressing follows a "T" shape.

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Claim 1 of auxiliary request 5

AUXILIARY REQUEST 5

- 1. A multi layered wound dressing which comprises an absorbent layer (2), a transmission layer (6) and a spreading layer (4), the spreading layer (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:
- the spreading layer (4) is a high lateral wicking layer positioned between the transmission (6) and absorbent (2) layers which aids the spread of exudate across a greater area of the dressing but away from the wound; the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4);
- the absorbent layer (2) comprises gel-forming fibres which are able to gel block which resists the lateral spread of exudate; the spreading layer (4) is a net; the transmission layer has a moisture vapour transmission rate of at least 1000g/m²/24hrs;
- and the lateral spread is limited in the absorbent layer (2) and maximised in the transmission layer (6); so that the passage of exudate through the dressing follows a "T" shape.

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Claim 1 of auxiliary request 6

AUXILIARY REQUEST 6

- 1. A multi layered wound dressing which comprises an absorbent layer
- 5 (2), a transmission layer (6) and a spreading layer (4), the spreading layer
 - (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:
 - the spreading layer (4) is positioned between the transmission (6) and absorbent (2) layers;
- the absorbent layer (2) has high absorbency but low lateral wicking; the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4);
 - the spreading layer (4) has high lateral wicking;
 - the transmission layer has a high moisture vapour transmission rate;
- and the lateral spread is limited in the absorbent layer (2) and maximised in the transmission layer (6);
 - so that the passage of exudate through the dressing follows a "T" shape.

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Claim 1 of auxiliary requests 7 and 8

- A multi layered wound dressing which comprises an absorbent layer
- 5 (2), a transmission layer (6) and a spreading layer (4), the spreading layer (4) overlying the side of the absorbent layer (2) furthest from the wound, wherein:
 - the spreading layer (4) is positioned between the transmission and absorbent layers;
- the absorbent layer (2) has high absorbency but low lateral wicking and is a fibrous layer, the fibrous layer comprising gel-forming fibres; the lateral wicking of exudate in the absorbent layer (2) is less than that in the spreading layer (4);
 - the spreading layer (4) has high lateral wicking;
- the transmission layer has a moisture vapour transmission rate of at least $1000 \text{ g/m}^2/24 \text{ hrs}$ and overlies the side of said absorbent layer furthest from the wound;
 - and the lateral spread is limited in the absorbent layer (2) and maximised in the transmission layer (6);
- 20 so that the passage of exudate through the dressing follows a "T" shape.