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**Datasheet for the decision
of 1 October 2015**

Case Number: T 0924/11 - 3.3.10

Application Number: 00959228.8

Publication Number: 1255575

IPC: A61L15/22, A61L15/42, A61L15/58

Language of the proceedings: EN

Title of invention:
FOAM/FILM COMPOSITE MEDICAL ARTICLES

Patent Proprietor:
3M Innovative Properties Company

Opponents:
Procter & Gamble, Inc.
Corpura BV

Headword:
Medical article /3M Innovative Properties Company

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2), 123(3)

Keyword:

Main request: Novelty - (no)

Auxiliary Request 1: amendments allowable (yes) -
insufficiency of disclosure (no) - novelty (yes) - inventive
step (yes)

Decisions cited:

Catchword:



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Boards of Appeal
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Case Number: T 0924/11 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 1 October 2015

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Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
16 February 2011 concerning maintenance of the
European Patent No. 1255575 in amended form.

Composition of the Board:

Chairman P. Gryczka
Members: C. Komenda
 D. Rogers

Summary of Facts and Submissions

I. The Appellants I (patent proprietor) and II (opponent 1) filed an appeal against the decision of the Opposition Division, which maintained the European patent No. 1 255 575 in amended form.

II. Notice of Opposition had been filed by the opponents 1 and 2 requesting revocation of the patent in suit in its entirety. They argued that based on Article 100(a) the claimed subject-matter was not novel (Article 54 EPC) and did not involve an inventive step (Article 56 EPC). Further, they raised an objection based on Articles 100(b) on the ground of insufficient disclosure of the invention pursuant to Article 100(b) EPC. The wording of claim 1 as granted was as follows:

"1. A medical article comprising a backing, an absorbent foam, and a fibrous adhesive disposed between the backing and the absorbent foam."

III. In the decision under appeal the Opposition Division referred inter alia to the following documents:

- (1) US-A-5 451 452,
- (2) US-A-5 873 869,
- (3) US-A-5 560 878 and
- (7) WO-A-96/08223.

In its argumentation the Opposition Division held that the patent in suit disclosed the invention as defined in the claims as granted and according to the claims of the then pending auxiliary requests in a manner sufficiently clear and complete for it to be carried out by a skilled person. However, the subject-matter according to claim 1 as granted was anticipated by either of documents (1),

(2) or (3). The then pending auxiliary request 1 was regarded as being not clear in the sense of Article 84 EPC. The subject-matter of the claims of the then pending auxiliary request 2 was regarded as being novel. Starting from document (7) as closest state of the art the Opposition Division held that it was not obvious to replace the continuous layer of adhesive between the backing and the absorbent foam by a fibrous adhesive as defined in claim 1 of auxiliary request 2 and to select particular dry and wet MVTR values in order to provide a medical article having improved wound treatment characteristics.

- IV. With its letter dated 27 June 2011 the Appellant I filed new auxiliary requests 1 to 7 and with letter of 7 January 2015 it filed auxiliary requests 8 to 15. Claim 1 of auxiliary request 1 read as follows:

"1. A medical article comprising a backing, an absorbent foam, and a fibrous adhesive disposed between the backing and the absorbent foam, wherein the fibrous adhesive is a coherent breathable fibrous adhesive nonwoven web formed from intimately entangled coherent pressure sensitive adhesive fibers."

- V. The Appellant I argued that the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person, because it was routine work for a skilled person to determine the degree of swelling of a medical article. Further, dependent claims 16, 17 and 31 defined the acceptable degree of swelling for substantially nonswellable foams or medical articles. It further argued that the subject-matter of the claims as granted was novel over documents (1), (2) or (3), because in order to arrive at the medical article according to claim 1 multiple selections would

have to be made within the specific disclosure of these documents. Starting from document (7) as closest state of the art the problem was to provide a medical article which was capable of keeping a moist wound environment for a broad range of wounds producing different amounts of exudate, while avoiding the pooling of excessive amounts of exudate. The examples of the patent in suit demonstrated that this problem has been successfully solved by using a fibrous adhesive instead of a continuous adhesive layer. Since none of the other cited documents suggested that the absorption characteristics of the medical article could be improved by using a fibrous adhesive the subject-matter of the claims was based on an inventive step.

- VI. The Appellant II reconfirmed its objection under Article 83 EPC with regard to the claimed subject-matter as defined in dependent claims 3, 16, 17 and 32. In particular it argued that the requirement of the foam being "substantially nonswellable" was not defined in the patent in suit. The only passage, which stated that there was little or no increase in volume of the foam upon absorption of water or saline was unclear and gave no guidance to the skilled person on how to select the suitable foams. The examples of the patent in suit used only one particular foam material, which however was swellable to a substantial degree. Therefore, a skilled person could not carry out the invention, since he would not know whether a product falls within the definition of "substantially nonswellable" or not. It further argued that the subject-matter of the claims as granted were anticipated by either of documents (1), (2) or (3), since these documents disclosed all technical features of the medical article according to claim 1 of the patent in suit. The combination of all features was obtainable by only one selection within one list.

Starting from document (7) it denied the presence of an inventive step, since the use of a fibrous adhesive instead of a continuous layer of adhesive was without inventive merit.

- VII. The party as of right, former Opponent 2, did neither file any observations, nor any requests.
- VIII. Appellant I requested that the decision under appeal be set aside and, as a main request, that the patent be maintained as granted, or alternatively, that the patent be maintained upon the basis of any one of Auxiliary Requests 1 to 15, Auxiliary Requests 1 to 7 being filed under cover of a letter dated 27 June 2011 and Auxiliary Requests 8 to 15 being filed under cover of a letter dated 7 January 2015.

Appellant II requested that the decision under appeal be set aside and the patent be revoked in its entirety.

- IX. At the end of the oral proceedings held before the Board on 1 October 2015 the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main Request

2. *Insufficiency of disclosure (Article 83 EPC)*

- 2.1 The Appellant II has objected to the subject-matter of granted claims 3, 16, 17 and 32 as having not been disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person. In

particular, it stated that the requirement of claim 3 that the medical article had to be "substantially nonswellable" had no clear definition and stood in clear contradiction to claims 15, 16 and 32, which allowed an increase in volume of 5% in claim 17, or 10% in claims 15 and 32. Further the application as filed did not contain any detailed test method how to determine the volume increase, nor any other information enabling the skilled person to identify suitable foam components, since in the examples of the patent in suit only one single foam component was used, which did swell to a significant extent. Therefore, the skilled person did not have the necessary information that allowed him to decide whether he worked within or outside the scope of the claims.

- 2.2 According to Article 100(b) EPC, the European patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person.
- 2.3 With respect to sufficiency of disclosure, the relevant question is whether the patent in suit provides sufficient information which enables the skilled person, when taking into account common general technical knowledge, to reproduce the claimed medical articles.
- 2.4 The swelling of an article is a property conventional in the art. There exist standardized methods to measure the degree of swelling, which also is indicated in the patent specification paragraph [0041]. Accordingly the skilled person has no difficulty to determine the degree of swelling referred to in dependent claims 15, 16, 17 and 32.

2.5 Furthermore the objection of Appellant II rather refers to determining the limits of the subject-matter claimed. Accordingly, that objection is thus related to the question whether the claims clearly define the matter for which protection is sought, which is a matter of Article 84 EPC.

The Board observes that Article 84 EPC is not a ground for opposition within the sense of Article 100 EPC. For these reasons the Appellant's objection cannot be taken into consideration.

2.6 Consequently, the Appellant's challenge to the sufficiency of the disclosure of the patent in suit under Article 100(b) EPC is rejected.

3. *Novelty (Article 54 EPC)*

3.1 The Appellant II cited inter alia document (1) as anticipating the subject-matter of granted claim 1.

3.2 Document (1) discloses an absorbent article comprising a backsheet and an absorbent foam (column 37. line 55 to column 39, line 7; Fig. 3). The backsheet is joined to the absorbent foam by various means, either by direct foaming of the absorbent foam onto the back sheet or by securing the foam to the backsheet by a uniform layer of adhesive or by a patterned layer or an array of separate lines, spirals or spots of adhesive (column 37, lines 56 to 65).

3.3 The Appellant I argued that the subject-matter of claim 1 as granted was novel, since it could only result from a selection out of two lists of features disclosed in document (1). First it had to be selected whether an adhesive is used or not, then the specific geometrical

arrangement of the adhesive layer had to be selected from the possibilities disclosed in document (1) in this respect.

However, the disclosure of document (1) is clear on the fact that the two elements of the medical article, which is the backsheet and the absorbent foam, have to be joined together. The means of how to join the backsheet to the absorbent foam, therefore, represent only one list of possibilities. The selection within this list of the embodiment relating to the separate lines or spirals of adhesive represent therefore only one single choice. This argument of the Appellant I is therefore not convincing.

3.4 For these reasons the Board concludes that the subject-matter of claim 1 of the main request is anticipated by document (1) (Article 54 EPC).

3.5 Since the subject-matter of claim 1 of the main request is anticipated by the disclosure of document (1), it needs not to be decided, whether there are other documents anticipating the subject-matter of claim 1.

Auxiliary Request 1

4. Amendments (Article 123 EPC)

4.1 Claim 1 of auxiliary request 1 differs from claim 1 as granted in that the medical article was further restricted by the addition of the passage "wherein the fibrous adhesive is a coherent breathable fibrous adhesive nonwoven web formed from intimately entangled coherent pressure sensitive adhesive fibers" (see paragraph IV *supra*).Basis for this amendment is to be

found on page 6, lines 4 to 6 of the original application documents.

4.2 Therefore, the Board is of the opinion that the requirements of Article 123(2) and (3) EPC are met.

5. *Insufficiency of disclosure (Article 83 EPC)*

With regard to insufficiency of disclosure the Appellant II brought forward the same arguments for the subject-matter of claims 3, 16, 17 and 32 of the auxiliary request I, as for the main request. Therefore, the same arguments and conclusions apply also to the subject-matter of the auxiliary request I (see point 2. above). Thus, the subject-matter of claims 3, 16, 17 and 32 is regarded as being disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person.

6. *Novelty (Article 54 EPC)*

Novelty of the subject-matter of auxiliary request was not objected to be the Appellant II. Since none of the cited documents discloses all technical features of the subject-matter of claim 1 of auxiliary request 1, the Board will not investigate further into this issue.

7. *Inventive step (Article 56 EPC)*

7.1 The patent in suit is directed to a medical article comprising a backing, an absorbent foam, and a fibrous adhesive disposed between the backing and the absorbent foam. A similar medical article is already disclosed in document (7). During the oral proceedings before the Board both Appellants accepted document (7) as representing the closest state of the art.

- 7.2 Document (7) discloses a spynosorbent wound dressing, which provides a consistent moist wound healing environment on the wound surface while coping with different amounts of wound exudate through their ability to adjust their moisture vapor transport rate in response to the level of exudate (page 12, lines 3 to 21). The article disclosed in document (7) comprises a film layer and an exudate transport layer (page 12, line 22). The minimum dry MVTR of the article is greater than 2000 g/m²/24 hours (page 11, line 21-23, page 17, lines 5, 10). In the particular embodiment of Example 5 the spynosorbent wound dressing comprises a polymeric polyurethane film joined to a layer of hydrophilic absorbent foam. The two layers are either joined together via direct lamination by the application of heat and pressure, or by applying an adhesive/polymeric film laminate structure to the absorbent foam and affixing the adhesive face of the polymeric film to the absorbent foam (Example 3). The resulting product exhibits a wet MVTR of about 4045 g/m²/24 hours and a dry MVTR of about 2120 g/m²/24 hours (page 33, lines 18 to 22).
- 7.3 According to the Appellant I the problem to be solved by the invention was to provide a medical article which prevents the wound from drying and avoids at the same time the pooling of excessive amounts of exudate.
- 7.4 As a solution the patent in suit proposes the medical article according to claim 1, which is characterized in that the backsheet and the absorbent foam are joined together via a fibrous adhesive, which is a coherent breathable fibrous adhesive nonwoven web formed from intimately entangled coherent pressure sensitive adhesive fibers.

7.5 In order to demonstrate that this problem is solved the Appellant I referred to the examples comprised within the patent in suit.

Examples 1 to 17, which contain a fibrous adhesive according to claim 1 of the Auxiliary Request 1 show low swell values, low dry MVTR, i.e. they do not dry out the wound surface, and show a high wet MVTR, i.e. they avoid the pooling of exudate as they allow excessive humidity to pass through the backsheet. In Examples 18 and 19 the backsheet and the absorbent foam were joined together via a continuous film of adhesive. The resulting wound dressing had, however, a very low wet MVTR, which led to the pooling of excessive exudate and to the maceration of the wound surface.

Therefore, the Board is satisfied that the above mentioned technical problem is successfully solved.

7.6 However, none of the cited documents gives the skilled person any incentive to solve the above mentioned technical problem by specifically selecting a fibrous adhesive, which is a coherent breathable fibrous adhesive nonwoven web formed from intimately entangled coherent pressure sensitive adhesive fibers.

7.7 For these reasons, the Board concludes that the subject-matter of claim 1, and by the same token that of dependent claims 2 to 32, according to Auxiliary Request 1 involves an inventive step within the meaning of Articles 52(1) and 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent with the following claims and a description to be adapted:

Claims:

No: 1 to 32 of Auxiliary Request 1 filed under cover of a letter dated 27 June 2011.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated