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**Datasheet for the decision  
of 10 September 2019**

**Case Number:** T 0999/17 - 3.3.10

**Application Number:** 06791423.4

**Publication Number:** 1931289

**IPC:** A61L26/00, A61L15/42, A61F13/00

**Language of the proceedings:** EN

**Title of invention:**  
BEVELLED FOAM

**Patent Proprietor:**  
Coloplast A/S

**Opponents:**  
Hollister Incorporated  
Paul Hartmann AG

**Headword:**  
BEVELLED FOAM / Coloplast

**Relevant legal provisions:**  
EPC Art. 56, 100(b)

**Keyword:**

Inventive step - main request (no) - auxiliary request A-4  
(yes) -non obvious alternatives  
Grounds for opposition - insufficiency of disclosure (no)

**Decisions cited:**

**Catchword:**



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Case Number: T 0999/17 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 10 September 2019**

**Appellant:** Coloplast A/S  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 14 February  
2017 revoking European patent No. 1931289  
pursuant to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairwoman**            R. Pérez Carlón  
**Members:**             J.-C. Schmid  
                              W. Van der Eijk

## Summary of Facts and Submissions

I. The appellant (proprietor of the patent) lodged an appeal against the decision of the opposition division revoking European patent No. 1 931 289, independent claim 1 thereof reading as follows:

"1. Non-adhesive foam dressing having an edge portion (1) and a central portion (2), wherein the edge portion (1) is a bevelled edge portion (1), where the density of the foam material is higher at the edge portion (1) of the dressing than it is at the central portion (2) of the dressing characterised in that the central portion (2) of the foam dressing has a density of more than 100 kg/m<sup>3</sup>."

II. Respondents I and II (opponents (1) and (2), respectively) requested in their notice of opposition the revocation of the patent-in-suit in its entirety on the grounds of lack of novelty and inventive step (article 100(a) EPC), and insufficient disclosure of the invention (article 100(b) EPC). Inter alia the following documents were cited in the opposition proceedings:

- (4) US-A-4 055 388,
- (7) WO-A-99/52569,
- (8) US-A-5 154 928,
- (12) EP-B-0 457 977,
- (13) WO-A-2004/039421,
- (14) GB-B-718 040 and
- (19) EP-B-0 691 113.

According to the opposition division, the patent-in-suit provided sufficient disclosure to produce a foam

dressing with a central portion with a density of more than  $100 \text{ kg/m}^3$  and to increase the density of the edge portion. The absence of an upper limit for the density value did not lead to insufficiency of disclosure. Claims 1 to 3, 14 and 15 of the patent as granted met the requirements of article 83 EPC. Dependent claims 4 to 6 and 13 specified foam dressings in terms of density values of foam portions having zones larger than 2 mm. However, the skilled person could not determine the volume of a foam sample having a length smaller than 2 mm, or a length substantially larger than 2 mm and the shape depicted in figures 3C to 3G of the patent. Dependent claim 7 specified an average density of the entire edge portion. Dependent claims 8 to 12 specified density ratio of edge and central portions. Since the patent failed to indicate which part of the edge portion should be considered for measuring density, dependent claims 4 to 12 of the main request did not meet the requirements of article 83 EPC.

With regard to inventive step, document (19) represented the closest prior art. This document disclosed a non-adhesive wound foam dressing comprising a central portion and bevelled edge portions. The wound foam dressing further contained a hydrophilic wound contacting layer (3) and a backing layer (2) besides foam body (1). Layers (2) and (3) could be attached to body (1) either in a separate operation or simultaneously. The treatment of the edge portion with heated platen under pressure produced a non-adhesive wound foam dressing with a central portion and bevelled compressed edge portions with higher densities than the central portion. The subject-matter of claim 1 therefore differed from the disclosure of document (19) only in that the central portion of the dressing had a

density of more than  $100 \text{ kg/m}^3$ . The technical problem was to provide a non-adhesive wound foam dressing having improved absorption and transportation capacity. Document (13) disclosed polyurethane foam wound dressings having the claimed density range for the same technical effects. Hence, the subject-matter of claim 1 of the patent as granted lacked an inventive step over document (19) combined with document (13).

III. During the oral proceedings held on 10 September 2019 before the board, the appellant defended the maintenance of the patent as granted, and on the basis of auxiliary requests A-1 to A-5, B-1 to B-6 and C-1 to C-6.

Claim 1 of auxiliary request A-1 differs from claim 1 of the main request by further requiring the density of the foam dressing of the central portion to be less than  $400 \text{ kg/m}^3$ .

Claim 1 of auxiliary request A-2 differs from claim 1 of auxiliary request A-1 in that the foam dressing has a wound-contacting surface for providing direct contact between said foam dressing and a wound.

Claim 1 of auxiliary request A-3 differs from claim 1 of auxiliary request A-1 in that the foam is a hydrophilic polyether based polyurethane.

Claim 1 of auxiliary request A-4 differs from claim 1 of the main request in that the average density of a first zone defined by the outermost 2 mm's of the dressing is between  $600 \text{ kg/m}^3$  and  $900 \text{ kg/m}^3$  and the density of the foam material of the central portion is between  $150 \text{ kg/m}^3$  and  $200 \text{ kg/m}^3$ .

IV. According to the appellant there was no serious difficulty for the skilled person to define a zone being the outermost 2 mm of the edge portion of a dressing and to measure its density. The volume of the outermost 2 mm of the dressing could be calculated without any difficulty according to its geometry. The arguments of the respondents against the sufficiency of disclosure of the claimed subject-matter were rather arguments dealing with clarity. Hence, all claims of the patent as granted met the requirements of Article 83 EPC.

With respect to inventive step, document (19) represented the closest prior art to the invention.

The dressing of claim 1 of the main request differed from that disclosed in document (19) in that the density of the central portion was greater than  $100\text{kg}/\text{m}^3$  and in that the edge portion has a higher density than the central portion. These structural differences addressed the problem of fluid absorption properties and leakage of foam dressings, while avoiding excess pressure on the patient's skin at the edge of the dressing. None of the cited documents taught that reduced leakage with simultaneous improvement of skincare properties could be achieved with a bevelled edge having a higher density at the edge portion than at the central portion. Document (13) addressed the problem of moisture vapour transmission, while the invention addressed the problem of absorption and transport of liquid. Accordingly, claim 1 of the main request was inventive over documents (19) and (13). The subject-matter of claim 1 of auxiliary requests A-1 to A-3 involved an inventive step for the same reasons as for the subject-matter of claim 1 of the main request.



The dressing of claim 1 of auxiliary request A-4 was characterized by having an average density of the outermost 2 mm of the dressing from  $600 \text{ kg/m}^3$  to  $900 \text{ kg/m}^3$  and a density of the central portion from  $150 \text{ kg/m}^3$  to  $200 \text{ kg/m}^3$ . According to document (19), the density of the foam dressing should preferably lie below  $100 \text{ kg/m}^3$ . Furthermore, the density of the outermost 2 mm of the claimed dressing was far away from that disclosed in document (19). There was no hint in the cited prior art to arrive at the claimed dressing. The subject-matter of claim 1 or auxiliary request A-4 involved therefore an inventive step.

- V. According to respondent I, the patent did not provide any teaching from which the skilled person could derive how to determine the density of the edge portions of the claimed dressing. The main request and the auxiliary requests failed to meet the requirements of Article 83 EPC.

The heated platen used in the preparation of the dressing disclosed in document (19) created bevelled edges with higher densities than the central portion. The subject-matter of claim 1, therefore, differed from the dressing disclosed in this document only by the density of the central portion of the foam dressing being above  $100 \text{ kg/m}^3$ . The effect thereof was improved absorption and transportation capacity. The problem to be solved could therefore be seen as the provision of a non-adhesive foam dressing having improved absorption and transportation capacity. A solution to this problem was provided in document (13), which related to polyurethane foam wound dressings having density ranges above  $100 \text{ kg/m}^3$  for improved moisture vapour transmission rate. A person of skill in the art would therefore have found an incentive to combine documents

(19) and (13) and arrive at the subject-matter of claim 1 of the patent as granted. The subject-matter of claim 1 of the main request lacked therefore an inventive step.

The subject-matter of claim 1 of the patent-in-suit lacked also an inventive step starting from document (4) or document (7) as the closest prior art.

With regard to auxiliary request A-4, the additional feature with respect to claim 1 of the main request was that the density of the edge portion, defined by the outermost 2 mm of the dressing, was between  $600 \text{ kg/m}^3$  and  $900 \text{ kg/m}^3$ . The technical effect of the edge portion having a high density was that the foam could tend to cause a barrier effect of the edge portion of the dressing, such that the leakage was markedly reduced. Thus, the problem was the provision of a dressing with a reduced tendency to leak. This problem was addressed in document (13), which disclosed that the moisture vapour transmission rate was poor for foam dressings with a density above  $400 \text{ kg/m}^3$ . The skilled person trying to reduce leakage from a wound dressing, would have found in document (13) that an increased density would prevent transmission of moisture. Claim 1 of auxiliary request A-4 therefore lacked inventive step.

VI. According to respondent II, the patent specification did not sufficiently disclose the test procedure for determining the density of foam portions. The instructions given in sections [0005] and [009] of the patent-in-suit did not allow to obtain reproducible values of densities. Foams were compressible materials. It was therefore not possible to precisely measure small volumes of foam material, and therefore to accurately determine the density. This applied more

particularly to the outermost 2 mm of the dressing shapes as depicted in figures 3C to 3E. Furthermore, the method of determining the density was destructive; with the consequence that it was not possible to form the claimed dressings.

With respect to inventive step, document (19) represented the closest prior art to the invention. The dressing of claim 1 of the main request differed from the dressing disclosed in figure 6C only due to the choice of the density of the foam in the central portion, which was higher than  $100\text{kg/m}^3$ . However, document (19) contemplated this density. The subject-matter of claim 1 of the main request lacked an inventive step in the light of document (19) alone. Auxiliary request A-4 should not be admitted to the appeal proceedings since it was not convergent with the higher ranked auxiliary requests. The limitations of the densities to particular values in claim 1 of auxiliary request A-4 were arbitrary, and therefore could not contribute to inventive step. Hence, the subject-matter of claim 1 of auxiliary request A-4 also lacked an inventive step.

VII. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted, or, subsidiarily, on the basis of auxiliary requests A-1 to A-5, B-1 to B-6 and C-1 to C-6, all auxiliary requests being filed with the letter dated 15 June 2017.

The respondents requested that the appeal be dismissed.

VIII. At the end of the oral proceedings held on 10 September 2019, the decision of the board was announced.

## **Reasons for the Decision**

1. The appeal is admissible.

*Inventive step*

*Main request: claim 1 of the patent as granted*

2. *Closest prior art*

The patent-in-suit relates to a non-adhesive foam dressing having a bevelled edge which is able to handle the exudation of a wound and which is in compliance with the compression therapy (see paragraph [0002]). It is useful in connection with the treatment of venous ulcers.

Document (19) relates to a wound foam dressing which permits comfortable application of pressure to a wound whilst absorbing significant quantities of moisture from the wound -see [0011]. The foam dressing is made of three foam layers, named body layer (1), backing (or barrier) layer (2) and wound-contacting layer (3) -see figure 1. The body layer is united with the wound-contacting layer and the barrier layer on opposite faces using a heated press (see paragraph [0043]). The wound-contacting layer has a thickness of 3 to 7 mm (see paragraph [0039]), which is reduced to about 1 mm by the lamination process (see page 5, lines 28 and 29). It is made of polyurethane foam having a density of 12 to 75 kg/m<sup>3</sup> (see paragraph [0039]), typically 15-19 kg/m<sup>3</sup> (see paragraph [0042]). The body layer has a thickness from 3 to 20 mm (see paragraph [0013]) and is made of polyurethane foam having a density of 27-31 kg/m<sup>3</sup>, typically 30 kg/m<sup>3</sup> (see paragraph [0035]). It is

typically made of polyether polyurethane foam and has a thickness of 11 mm in its relaxed uncompressed state (see paragraph [0033]) and of about 10 mm after the lamination process (see page 5, line 29). The backing layer has a thickness of 0.2 to 0.8 mm, preferably 0.4 mm (see paragraph [0018]) and is made of high density polyurethane foam (see paragraph [0017]), for instance a high density polyether polyurethane foam having a density of 325-435 kg/m<sup>3</sup> (see paragraph [0038]). The edge of the dressing may be straight or may be shaped (see paragraph [0049] and figures 3 to 8).

The backing and wound-contacting layers may be terminated independently at the edge (see paragraph [0049]) or secured together (figures 6 to 8). The foam dressings represented in figures 3 to 8 have bevelled edges.

The board considers, in agreement with the parties and the opposition division, that document (19) represents the closest state of the art to the invention, and hence takes it as the starting point in the assessment of inventive step.

According to the respondents, documents (4), (7), (8), (12) and (14) may also be suitable starting points for the assessment of inventive step.

According to the problem-solution approach to assess inventive step, it is necessary to establish the closest state of the art to the invention, to establish the differentiating features of the claimed invention, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art. This

"problem-solution approach" ensures that inventive step is assessed on an objective basis and avoids an ex post facto analysis.

The closest prior art to the invention is represented by a prior art document disclosing subject-matter conceived for the same purpose as the claimed invention and additionally having the most relevant technical features in common.

Document (4) relates to a protective pad adapted to be positioned on an elbow or heel of a patient (see claim 1). Documents (8) and (12) disclose adhesive foam dressings. However such dressings cannot be used in connection with a compression therapy, since it would damage the skin surrounding the wound which may be extremely fragile (see [0006] of the patent-in-suit). Hence, the pads/dressings disclosed in documents (4), (8) and (12) are not conceived for the same purpose as those of the present invention.

Document (7) primarily relates to a method of forming high density polyurethane foams. This foam may be used as a wound contacting layer of a dressing (see claims 1 and 16). The dressing also comprises a backing layer (see page 9, lines 11 to 14) and may also comprise a wicking layer between the wound contacting layer and the backing layer to draw moisture from the wound facing layer (see page 10, lines 26 to 37). Suitable materials for the wicking layer include non-woven viscose fabrics or cellulosic fabrics. Document (14) discloses a foam dressing having a bevelled edge, but without any indication of the density of the foam material. Accordingly, the dressings disclosed in documents (7) and (14) are not structurally closer to

the claimed dressings than those disclosed in document (19).

Consequently, the lines of arguments of the respondents starting from documents (4), (7), (8), (12) and (14) as the closest prior art document to the invention do not need to be considered.

3. *Technical problem*

During the oral proceedings before the board, the appellant defined the problem underlying the patent-in-suit as to provide alternative foam dressings that address the problem of leakage and excess pressure.

4. *Solution*

The solution proposed is the dressing of claim 1 characterized by a central portion of the foam dressing having a density of more than  $100\text{kg/m}^3$ .

According to the appellant, document (19) did not allow the density of the dressing edges to be calculated. There was no evidence that the density of the foam material was higher at the edge portion of the dressing depicted in figure 6 of document (19). Hence, the solution was also characterized in that the density of the foam material was higher at the edge portion (1) of the dressing than it was at the central portion (2) of the dressing.

However, it is not necessary to calculate the density of the edge portion of the dressing to conclude that it is necessarily higher at the edge portion than it is in the central portion of the dressing. Indeed, the dressing depicted in figure 6 of document (19) consists

of three layers. After shaping the dressing, i.e. after compression, the body layer has the lowest density. The thickness of this layer decreases at the edge portion, while that of the two other layers of higher densities remains unchanged until the end of the edge of the dressing. Hence, the density of the foam dressing is inevitably higher at the edge portion than it is in the central portion. This additional differentiating feature can thus not be accepted.

Consequently, the solution is characterized by the sole distinguishing feature with respect to the dressing disclosed in figure 6 of document (19), namely that the central portion of the foam dressing has a density of more than  $100 \text{ kg/m}^3$ .

5. *Success*

Having regard to the results of the tests of leakage and indentation as shown in examples 2 and 3 of the patent-in-suit, the board is satisfied that the claimed dressing is a solution of the technical problem as defined in point 3 above.

6. *Obviousness*

The dressing disclosed in document (19) addresses the problem of excess pressure -see paragraph [0011]. It also addresses the problem of leakage - see paragraph 20. As acknowledged by the appellant, the central part of the dressing described in document (19) may have a density greater than  $100 \text{ kg/m}^3$ , namely up to  $126 \text{ kg/m}^3$  (see appellant's letter dated 4 July 2019, second half of page 3).



The skilled person would therefore contemplate a dressing wherein the central portion has a density greater than  $100 \text{ kg/m}^3$  as an obvious solution to the problem of providing an alternative dressing addressing the problem of leakage and excess pressure and would thus arrive at the subject-matter of claim 1 without the exercise of inventive skill.

Accordingly, the subject-matter of claim 1 of the main request lacks an inventive step in the light of document (19).

*Auxiliary requests A-1 to A-3*

7. According to the appellant the situation re inventive step of the subject-matter of claim 1 of these auxiliary requests did not differ from that of the main request.

Consequently, since the subject-matter of claim 1 of the main request lacks an inventive step, this conclusion also applies for the subject-matter of claim 1 of these auxiliary requests.

*Auxiliary request A-4*

8. *Admissibility*

Respondent II objected the admissibility of auxiliary request A-4 into the appeal proceedings, since this request was not convergent with the previous ones.

Auxiliary request A-4 corresponds to auxiliary request D' filed on 16 November 2016 pending before the opposition division (renumbered as auxiliary request 4 in the contested decision) -see annex 5; point VII of

the summary of facts and submissions of the contested decision. This request was rejected for insufficiency of disclosure -see point 3 of the reasons. Auxiliary request A-4 was filed again with the statement setting out the grounds of appeal.

With respect to the issue of convergence, the board notes that auxiliary requests A-1 to A-3 had not been filed to address the issue of inventive step starting from document (19) as the closest prior art (see point 7 above). The appellant was furthermore ready to withdraw the previous auxiliary requests if there would be a problem of convergence.

Under these circumstances, the board sees no reasons not to admit auxiliary request A-4 into the appeal proceedings.

9. *Amendments*

Claim 1 of auxiliary request A-4 differs from claim 1 as granted in that the average density of a first zone defined by the outermost 2 mm of the dressing is between  $600 \text{ kg/m}^3$  and  $900 \text{ kg/m}^3$  and the density of the central portion is between  $150 \text{ kg/m}^3$  and  $200 \text{ kg/m}^3$ . These modifications are based on dependent claim 13 of the application as filed, and also on dependent claim 13 of the patent as granted.

Dependent claims 2, 7, 12 and 13 of the patent as granted have been deleted and the remaining dependent claims have been renumbered.

Accordingly, the claims of auxiliary request A-4 meet the requirements of Article 123 (2) and (3) EPC.

10. *Sufficiency of disclosure*

According to the patent specification, measuring density of foam is common practice. Density should be measured under conditions of typical use that is at a temperature of 20°C, air pressure of 1013 hPa and relative humidity of 40%. Under these conditions, a sample of the foam material is measured to determine the volume V and weighed to determine the mass m and the density d is then calculated as  $d = m/V$ . In example 1 of the patent-in-suit the density of portions of three dressings was measured. The foam dressings were cut. The length, width and thickness of the test pieces were measured, and subsequently the pieces were weighed. The densities were calculated as mass divided by volume. All of the test pieces were 2 mm in the length direction and 20 mm wide.

As regards its objection of sufficiency of disclosure, respondent II focused on the difficulties in determining the volume of very small foam samples. Thus, it was not possible for the skilled person to carry out the invention in its essential aspects. It was the respondent II's point that owing to this ambiguity, the skilled person could not assess whether a dressing fell within or outside the scope of the claim.

This objection rather relates to the scope of the claims. However, Article 84 EPC is in itself not a ground of opposition. For an insufficiency objection arising out of an ambiguity, it is necessary to show that the ambiguity deprives the skilled person of the possibility to carry out the invention. The respondents failed to show that.

In the present case, in the absence of any evidence to the contrary the information given in the specification is deemed to be sufficient for the skilled person to be in a position to arrive at the dressings as claimed.

Respondent II furthermore objected that measurements of the density of the different portion of the dressing were destructive, and thus it was not possible to form a dressing as claimed.

However, the measurements of densities serve to determine whether a manufactured dressing falls within the scope of the claim. These measurements are only necessary to set out the manufacturing process. The patent-in-suit indicates different ways to modify the density of the foam dressing, if necessary. For example, the edge part can be compressed, which gives a highest density to the edge part compared to the central part of the foam. Once a process with suitable parameters has been finalised, dressings with the appropriate densities can be produced without their destruction. Hence, respondent II's argument must be rejected.

The board comes therefore to the conclusion that the dressings as defined in claims 1 and 10 of auxiliary request A-4 can be prepared by a person skilled in the art without undue burden, using common general knowledge and having regard to further information given in the patent in suit, such that the opposition ground pursuant to Article 100(b) EPC fails.

11. *Novelty*

Although raised as ground for opposition against claim 1 as granted, this issue was no longer in dispute

before the board in view of the amendments made to claim 1 of auxiliary request A-4. The board is also satisfied that the subject-matter of claim 1 of auxiliary request A-4 is novel over the cited documents.

12. *Inventive step*

The closest prior art and the technical problem to be solved remain the same as for the main request -see points 2 and 3 above.

The proposed solution is the dressing of claim 1 of auxiliary request A-4 characterized by an average density of a first zone defined by the outermost 2 mm of the dressing of  $600 \text{ kg/m}^3$  to  $900 \text{ kg/m}^3$  and a density of the central portion of  $150 \text{ kg/m}^3$  to  $200 \text{ kg/m}^3$ .

It remains to be decided whether or not the proposed solution to this technical problem is obvious in view of the cited state of the art, i.e. whether is it obvious for the skilled person to provide an alternative dressing with an average density of a first zone defined by the outermost 2 mm of the dressing of  $600 \text{ kg/m}^3$  to  $900 \text{ kg/m}^3$  and a density of the central portion of  $150 \text{ kg/m}^3$  to  $200 \text{ kg/m}^3$ .

According to respondent II, the claimed solution was merely an arbitrary choice and therefore did not involve an inventive step.

However, document (19) does not disclose dressings having the claimed specifications. The claimed solution therefore does not represent a choice within the ambit of document (19). Furthermore, the characterizing features are not arbitrary since they address the

problem of leakage and excess pressure. Therefore, respondent II's argument must be rejected.

According to respondent I, the solution was obvious in the light of document (13), which disclosed that the moisture vapour transmission rate was poor for foam dressings with a density above  $400 \text{ kg/m}^3$ . A person of skilled in the art trying to solve the problem of wound dressing leakage, would appreciate on the basis of document (13) that an increased density would prevent transmission of moisture.

However, the foam of the dressing of document (13) should preferably have a density of  $100 \text{ kg/m}^3$  to  $400 \text{ kg/m}^3$  (see page 6, lines 15-16). Document (13) does not disclose dressings with higher densities at the edges, let alone dressings having an average density of the outermost 2 mm of  $600 \text{ kg/m}^3$  to  $900 \text{ kg/m}^3$ , while maintaining the density of the central portion between  $150 \text{ kg/m}^3$  to  $200 \text{ kg/m}^3$ . The skilled person would not have arrived at the subject-matter of claim 1 by combining the teaching of document (13) with that of document (19).

To summarize, document (19) alone, or in combination with document (13), does not render the dressing of claim 1 of auxiliary request A-4 obvious.

For these reasons, the board concludes that the subject-matter of claim 1, and by the same token that of dependent claims 2 to 11, of auxiliary request 4 involves an inventive step.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of claims 1-11 of auxiliary request A-4, filed with the grounds of appeal, dated 15 June 2017, and a description yet to be adapted.

The Registrar:

The Chairwoman:



C. Rodríguez Rodríguez

R. Pérez Carlón

Decision electronically authenticated