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D E C I S I O N
of 10 December 2001

Case Number: T 0680/99 - 3.2.6

Application Number: 91916779.1

Publication Number: 0503029

IPC: A61F 13/00

Language of the proceedings: EN

Title of invention:
WOUND DRESSING HAVING A COUNTOURED ADHESIVE LAYER

Patentee:
Hollister Incorporated

Opponent:
Coloplast A/S

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0680/99 - 3.2.6

D E C I S I O N
of the Technical Board of Appeal 3.2.6
of 10 December 2001

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 3 May 1999 revoking European patent No. 0 503 029 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: P. Alting van Geusau
Members: G. Pricolo
M. J. Vogel

Summary of Facts and Submissions

I. The mention of the grant of European patent No. 0 503 029 in respect of European patent application No. 91 916 779.1 filed on 16 September 1991 was published on 12 February 1997.

II. Notice of opposition was filed against the patent as a whole by the respondent (opponent) under Article 100(a) EPC on the grounds that the subject-matter of the claims lacked novelty and inventive step.

III. By decision posted on 3 May 1999 the Opposition Division revoked the patent. The Opposition Division held that the subject-matter of claim 1 did not involve an inventive step over the prior art as disclosed in documents

D1: US-A-4 867 748;

D7: US-A-4 952 618;

D8: Brochure "Tegasorb ulcer dressing", 3M Co., January 1989.

IV. The appellant (patentee) lodged an appeal, received at the EPO on 30 June 1999, against this decision. The appeal fee was paid simultaneously with the filing of the appeal. The statement setting out the grounds of appeal was filed on 8 September 1999. With letter dated 10 August 2001 the appellant filed an auxiliary request to maintain the patent in amended form.

V. Oral proceedings took place on 10 December 2001.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted. The auxiliary request was no longer maintained.

The respondent (opponent) requested that the appeal be dismissed.

VI. Claim 1 as granted reads as follows:

"1. A wound dressing comprising an adhesive layer (26) which in use contacts a wound and surrounding normal skin; and a flexible water-impervious, polymeric backing layer (22) covering one side of said adhesive layer; said adhesive layer consisting essentially of from about 50 to 70% by weight of a water soluble or swellable hydrocolloid, or a mixture of such hydrocolloids, selected from the group consisting of sodium carboxymethylcellulose, calcium carboxymethylcellulose, pectin, gelatin, high molecular weight carbowax, carboxypolymethylene, and polyvinyl alcohol, with said hydrocolloid or mixtures of hydrocolloids being dispersed in from about 30 to 50% by weight of a water-insoluble, viscous elastomer selected from the group consisting of polyisobutylene, natural rubber, silicone rubber, acrylonitrile rubber, and polyurethane rubber; said dressing including a body portion in which the thickness of adhesive layer exceeds 0.5 mm; characterised in that said dressing includes a wide peripheral flange (38) of reduced thickness extending outwardly beyond said body portion a distance of at least 10 mm and in which the thickness of said adhesive layer of said flange does not exceed

about 0.5 mm, the flange being of substantially uniform thickness throughout its full extent."

VII. In support of its requests the appellant relied essentially on the following submissions:

Claim 1 of the patent in suit related to a wound dressing comprising a wide peripheral flange. Since the embodiment shown in Figure 7 was not provided with such a flange, it did not fall within the scope of claim 1.

Document D1, which represented the closest prior art, disclosed a wound dressing comprising a flange of uniform thickness with a hydrocolloid adhesive layer having a thickness of less than 0.5 mm. D1, however, neither disclosed nor suggested that the flange extended outwardly beyond the body portion a distance of at least 10 mm. D1 gave no indication either about the width or about the function of the flange. Essentially, D1 only taught the provision of a bevelled edge portion for preventing adhesive material from flowing outside the wound dressing, and was not concerned with the problem of avoiding the channeling effect referred to in the patent in suit. It was true that D1 disclosed, in an embodiment relating to an ostomy ring, that the area of reduced thickness adjacent the opening should have a radial width of more than 10 mm. This, however, was only for the purpose of cutting an aperture to fit a stoma having a diameter greater than the opening, and was not meant to prevent adhesive material from flowing outside the dressing.

Documents D7 and D8, relating to the same product, namely the Tegasorb dressing, disclosed a wound dressing having a backing film entirely coated with a

pressure-sensitive acrylic adhesive layer and a smaller sheet of hydrocolloid adhesive material secured to the acrylic adhesive layer. Accordingly, if the skilled person found that there was hydrocolloid adhesive material flowing outside the dressing of D1 despite the provision of bevelled edge portions, he would have provided a backing film with an acrylic adhesive as taught by D7 and D8, thereby providing a peripheral flange with an acrylic adhesive, rather than an hydrocolloid adhesive as required by claim 1 of the patent in suit.

Moreover, it was not within the general knowledge of the skilled person, nor was it known from the cited prior art, that wrinkling and channeling could be avoided by the provision of a wider flange.

Therefore, the prior art did not give the skilled person any incentive to focus on the flange for solving the problem of wrinkling and channeling so that the subject-matter of claim 1 involved an inventive step.

VIII. The arguments of the respondent can be summarized as follows:

The only feature distinguishing the subject-matter of claim 1 from the wound dressing of D1 was that the flange extended beyond the body portion a distance of at least 10 mm. D1 taught that the flow of adhesive from the dressing could be restricted by the provision of a bevelled edge portion. The skilled person confronted with the problem of further restricting the flow of adhesive would try to improve the sealing ability at the bevelled edge portions. For doing this, the skilled person would obviously consider making

longer the bevelled edge portions of the dressing according to D1, this being the only possibility of intervention. He would also perform simple experiments to determine a suitable outward extension for the flange, thereby arriving in an obvious manner at an extension of more than 10 mm.

The problem associated with the wrinkling effect or channeling referred to in the patent in suit was also solved with the improvement in the sealing ability. Indeed, since the provision of a good seal avoided any outflow and inflow of liquid, it also directly avoided flow of adhesive from the dressing due to channeling.

Furthermore, D1 specifically disclosed an ostomy ring with an inner edge having a radial width of 1.5 cm. Considering that D1 also disclosed that what applied to the outer edges of ostomy sealing rings also applied to their inner edges, and that both the inner and outer edge provided a sealing function, the skilled person would select the radial width of 1.5 cm also for the outer edge, thereby directly arriving at a peripheral outer flange longer than 10 mm.

D1 also disclosed that it was usual to place a pressure sensitive tape extending a suitable length, e.g. 1-2 cm from the edge, on the outer edges of dressings in order to avoid flow of hydrocolloid material from the dressing. It was clear from this disclosure that an improved sealing was obtained if a sufficiently large edge portion was provided, and that this applied not only to the specific case in which a tape was used but also to the case where the outwardly extending flange was provided with a hydrocolloid adhesive layer.

Therefore, the subject-matter of claim 1 was obvious in view of the disclosure of document D1 alone.

Reasons for the Decision

1. The appeal is admissible.

2. *The subject-matter of claim 1*

The dressing shown in figure 7 of the patent in suit does not have a peripheral flange, but two distinct end portions (62). Since claim 1 clearly and unambiguously requires the presence of a peripheral flange, this embodiment does not fall within the scope of claim 1, as was admitted by the appellant. This inconsistency does not fall under any of the grounds of opposition and therefore does not affect the validity of the patent.

3. *State of the art - Novelty*

3.1 Using the wording of claim 1, document D1 discloses (see Fig.1) a wound dressing comprising an adhesive layer (4) which in use contacts a wound and surrounding normal skin; and a flexible water-impervious, polymeric backing layer (3) covering one side of said adhesive layer; said adhesive layer consisting essentially of (see column 3, lines 54 to 66) a water soluble or swellable hydrocolloid, or a mixture of such hydrocolloids, selected from the group consisting of carboxymethylcellulose (sodium carboxymethylcellulose is explicitly disclosed in US-A-3 339 546 referred to on column 3, line 56 of D1), pectin, gelatin, high molecular weight carbowax, carboxypolymethylene, and

polyvinyl alcohol, with said hydrocolloid or mixtures of hydrocolloids being dispersed in a water-insoluble, viscous elastomer selected from the group consisting of polyisobutylene, natural rubber, silicone rubber, acrylonitrile rubber, and polyurethane rubber; said dressing including a body portion in which the thickness of adhesive layer exceeds 0.5 mm (see column 4, lines 56 to 58), the dressing including a wide peripheral flange (13) of reduced thickness extending outwardly beyond said body portion and in which the thickness of said adhesive layer of said flange does not exceed about 0.5 mm (see column 4, lines 63, 64), the flange being of substantially uniform thickness throughout its full extent.

In the Board's judgment, in agreement with the opinion expressed by the parties, the only feature distinguishing the subject-matter of claim 1 from the dressing according to D1 is that said flange extends outwardly beyond said body portion to a distance of at least 10 mm.

3.2 Document D7 discloses (see Figures 1 and 2) a wound dressing comprising a hydrocolloid adhesive layer (12) which in use contacts a wound and surrounding normal skin; and a flexible water-impervious, polymeric backing film (14) covering one side of said adhesive layer; said dressing including a body portion in which the thickness of the adhesive layer exceeds 0.5 mm (see column 5, lines 53 to 55), and a wide peripheral flange of reduced thickness extending outwardly beyond said body portion, the flange being of substantially uniform thickness throughout its full extent. This peripheral flange is provided in that portion of the dressing where the hydrocolloid adhesive layer (12) is absent

(see Figure 2), and consists of the peripheral portions of removable delivery sheet (20), removable release liner (18), backing film (14) and adhesive layer (16). Adhesive layer 16 consists of a conventional pressure-sensitive skin adhesive (column 4, lines 55 to 57).

Therefore, document D7 fails to meet the requirement of claim 1 that the flange has "said adhesive layer", i.e. the hydrocolloid adhesive layer. Moreover, there is no indication to be found in D7 about the width of the flange.

3.3 It was undisputed by the parties that D7 and D8 relate to the same product. D8 discloses the feature, not shown in D7, that the peripheral flange extends outwardly beyond the body portion to a distance of at least 10 mm. However, as D7, it does not disclose that the flange has a hydrocolloid adhesive layer.

3.4 The other cited prior art fails to disclose a peripheral flange with a hydrocolloid adhesive layer.

Therefore, the subject-matter of claim 1 is novel.

4. *Inventive step*

4.1 There is agreement among the parties, and this was also the position of the Opposition Division, that document D1 represents the closest prior art. The Board shares this view as D1 discloses a wound dressing which is the most suitable for the desired purpose of the invention, which generally consists in providing a wound dressing attached to the body by means of a water-absorbent hydrocolloid adhesive layer only (see column 1, lines 5 to 16, of the patent).

4.2 Starting from the closest prior art, the problem to be solved is to effectively restrict the flow of adhesive from the dressing, and to avoid a wrinkling effect or channeling in the peripheral edge which may allow contaminants into the wound or may allow fluids from the wound and/or adhesive to exit the border of the dressing (column 1, line 52 - column 2, line 2; column 1, lines 32 to 37).

4.3 The solution proposed is that the flange extends outwardly beyond the body portion to a distance of at least 10 mm.

4.4 Document D1 teaches that flow of sealing pad material from under the cover layer can be avoided if the sealing pad at least along all outer edges is bevelled so that its thickness adjacent the edge does not exceed 1/4 of the thickness of the sealing pad in its non-bevelled portions (column 1, lines 54 to 57; column 2, lines 40 to 50). In one embodiment (figure 1) the bevelled outer portion of the dressing "has an area of a constant thickness as the lesser thickness of the bevel" (column 4, lines 22 to 25). However, D1 is silent about the function of this area of constant thickness in this embodiment, and certainly does not suggest that it contributes in preventing flow of sealing pad material from under the cover layer because this function is attributed to the bevelling of the edges. Therefore, there is no reason for a skilled person to carry out investigations aimed at finding whether the flow of sealing pad material (hydrocolloid adhesive) could be further prevented, or the wrinkling effect avoided, by the selection of appropriate dimensions for said area of constant thickness (corresponding to the flange of claim 1 of the patent

in suit), in particular by the selection of its width to be at least 10 mm.

4.5 The other cited prior art does not disclose a peripheral flange with a *hydrocolloid* adhesive. Hence, it also does not suggest that the selection of appropriate dimensions for such a flange may have any technical effects.

4.6 The assumption of the Opposition Division that it is common general knowledge that wrinkling and channeling can be avoided by an extended flange (page 5 of the decision), has been contested by the appellant.

This assumption is not substantiated by any evidence. The available prior art relating to the type of wound dressing with an hydrocolloid adhesive contacting the wound merely discloses that flow of hydrocolloid adhesive is avoided either by the provision of bevelled edges (in accordance with the teaching of D1), or by the provision of a tape (see D1, lines 54 to 62) or flange (see eg D7) on which a *pressure sensitive* adhesive is applied.

Furthermore, the Board is not aware of any general knowledge that an extended flange with a *hydrocolloid* adhesive has an effect either on wrinkling and channeling or on the sealing ability of the dressing.

Therefore, the mentioned assumption cannot be followed by the Board.

4.7 The Board cannot agree with the respondent's view that the skilled person seeking to improve the sealing ability at the bevelled edge portions of the dressing

of D1 could only make them longer, because D1 already discloses an explicit solution to this problem, consisting in the provision of a pressure sensitive tape on the outer edges of the dressing (column 1, lines 54 to 62).

Neither can the Board follow the view of the Opposition Division that the skilled person is "in a one way street situation and has only one technical possibility to overcome the wrinkling and channeling of the dressing and this possibility is the extension of the flange". Indeed, the prior art neither discloses nor suggests that the obvious solution to the wrinkling and channeling is a wider flange with a hydrocolloid adhesive. Furthermore, the disclosure in D1 of pressure sensitive tape for avoiding flow of adhesive is a clear suggestion towards the provision of such a tape, rather than an extended flange, in case flow of adhesive due to channeling takes place in use.

4.8 The respondent further argued that it would have been obvious for a skilled person to select the radial width of 1.5 cm, disclosed in D1 for the inner flange of an ostomy ring, also for the outer edge thereof.

D1 discloses that sealing rings for ostomy equipment are manufactured with a smaller diameter of the central aperture than the normal outer diameter of stomas, so that the aperture can be cut before attachment to exactly fit the stoma it is intended for (column 5, lines 3 to 11). Accordingly, the inner flange has a radial width corresponding to the area around the aperture expected to be removed when used for a stoma having a maximum width within the normal range (column 5, lines 11 to 17). Since the maximum stoma

diameter is approximately 4 cm, and the aperture is typically 1 cm, the radial width of the inner flange is consequently 1.5 cm. Therefore, the inner flange has a radial width of 1.5 cm only for the purpose of providing enough material so that an aperture can be cut which exactly fits the stoma it is intended for. D1 does not disclose that the provision of an inner flange improves the sealing ability of the sealing ring. Indeed, the inner flange may even be dispensed with if the sealing ring is applied to a stoma having the maximum diameter of 4 cm, as the whole inner flange would have to be cut in such a case. Consequently, the skilled person would have no reason to apply a radial width of 1.5 cm also to the outer flange.

Even the passage of D1 referred to by the respondent (column 2, lines 50 to 52): "this applies to the outer edges of dressings as well as ostomy sealing rings, and to a certain degree also to the inner edge" would not lead the skilled person to modify the outer flange to have a radial width of 1.5 cm. Indeed the mentioned passage merely states that a bevelled portion provides the same advantages on both the inner and outer edges (see column 2, lines 40 to 56), and does not disclose or suggest that the inner and outer flanges should have same radial width.

4.9 D1 further discloses that it is usual to place a pressure sensitive tape extending a suitable length, e.g. 1-2 cm from the edge, on the outer edges of dressings in order to avoid flow of hydrocolloid material from the dressing.

However, a pressure sensitive tape is provided with a conventional adhesive that does not have, as a

hydrocolloid adhesive, a tendency to flow along the edges of the dressing. For this reason, a pressure sensitive tape provides a barrier against flow of hydrocolloid material from the dressing. Yet there is no suggestion in the prior art that a tape having a hydrocolloid adhesive would likewise provide a suitable barrier, and therefore the skilled person would have no reason to extend the flange of the dressing of D1 to have a width equal to that of the pressure sensitive tape.

4.10 It follows that the subject-matter of claim 1 cannot be derived in an obvious manner from the relevant prior art and therefore involves an inventive step.

Dependent claims 2 to 21 define further embodiments. Their subject-matter is likewise deemed to be novel and inventive.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained unamended.

The Registrar: The Chairman:

M. Patin P. Alting van Geusau