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Application No.: 83 304 155.1
Publication No.: 0 099 748
Title of invention: Adhesive wound dressing

Classification: A61F13/02

D E C I S I O N
of 4 February 1992

Proprietor of the patent: Smith and Nephew Associated Companies p.l.c.

Opponent: Johnson & Johnson

Headword:

EPC Article 56

Keyword: "Inventive step (no)"

Headnote



Case Number : T 108/90 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 4 February 1992

Appellant :
(Proprietor of the patent)

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(Opponent)

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Decision under appeal :

Decision of Opposition Division of the European
Patent Office dated 11 December 1989 revoking
European patent No. 0 099 748 pursuant to
Article 102(1) EPC.

Composition of the Board :

Chairman : G. Szabo
Members : M. Noel
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 099 748 was revoked by decision of the Opposition Division on the ground that its subject-matter did not involve an inventive step having regard to the documents

- (5) EP-A-0 050 514,
- (2) US-A-3 927 669, and
- (1) GB-A-1 280 631

II. The Appellant (Proprietor of the patent) lodged an appeal against this decision on 29 January 1990, paying the fee for appeal and submitting a Statement of Grounds in due time.

One month before the date set for oral proceedings which was held on 4 February 1992, he submitted a new set of amended Claims 1 to 12, the Claim 1 of which reads as follows:

"A moisture vapour transmitting wound dressing comprising (a) a conformable backing layer which has an adhesive layer on one surface thereof and (b) a low wound adherency absorbent pad on the adhesive side of the backing layer which absorbent pad comprises an absorbent foam layer and a low adherency wound facing layer characterised in that the dressing allows the wound under the dressing to heal under moist conditions without causing the skin surrounding the wound to macerate, that at least one of said backing layer and said adhesive layers is continuous to provide a barrier to bacteria and liquid water, that the absorbent pad, having an area which is less than that of the backing layer, is located in a central region of the backing layer inset from the edges of the backing layer and comprises a conformable open cell foam of a

hydrophilic polyurethane and a low adherency wound facing layer of an elastomer net consisting of strands and junctures and that the wound dressing has a moisture vapour transmission rate of from 300 to 5000 grams/square metre/24 hours at 37.5°C at 100% to 10% relative humidity difference".

III. In his written submissions and in the oral proceedings the Appellant has argued substantially that while the document (1) might be considered as being the closest prior art as it describes a suitable upper backing layer and an absorbent pad, nothing is said therein, however, about the very nature and the structure of the lower absorbent pad. On the other hand, the document (2) describes an absorbent pad made of cell foam of hydrophilic polyurethane. However, the disclosed arrangement ensures that the wound is kept dry, which is contrary to the basic requirement, of the patent in suit that the dressing is designed to allow the wound to heal under moist conditions.

The Respondent (Opponent) has submitted that with respect to the dressing disclosed in document (1) according to which a pad is provided on the adhesive face of a backing layer, the invention is confined to the provision of a suitable absorbent pad capable of absorbing large amounts of wound exudate such as disclosed in document (2). It is within the normal competence of the skilled person to select from those materials which are suitable to solve his problem, the most appropriate one.

IV. The Appellant requests that the decision under appeal be set aside and that the patent be maintained on the basis of the claims in the version submitted on 9 January 1992.

The Respondent requests that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Formal aspects.

The amendments made to the claims and to the description as requested in the Appellant's letter of 9 January 1992 are not open to formal objection under Article 123 EPC.

3. Closest prior art.

The Board considers the document (1) as the state of the art closest to the invention, as it was also admitted by the parties during oral proceedings.

The document (1) describes more particularly the upper layers of the dressing, that is a moisture vapour transmitting wound dressing comprising a conformable backing layer which has an adhesive layer on one surface thereof and a low absorbent pad on the adhesive side of the backing layer. Further, at least one of the said backing and adhesive layers is continuous to provide a barrier to bacteria and liquid water and the absorbent pad, having an area which is less than that of the backing layer, is located in a central region of the backing layer inset from the edges of the backing layer.

4. Novelty

The subject-matter of Claim 1 differs from that of document (1) in respect of the following features:

- the absorbent pad comprises a conformable open cell foam of a hydrophilic polyurethane, and

- a low adherency wound facing layer of an elastomer net consisting of strands and junctures;
- the dressing allows the wounds to heal under moist conditions without causing the skin surrounding the wound to macerate.

The adhesive dressing according to document (1) also has a moisture vapour transmission rate of at least 300 grams/square meter/24 hours at 40°C at 100% to 20% relative humidity difference. This last feature differs from the wordings of Claim 1 in that respect that there are slight differences in the values of the parameters (temperature, relative humidity) used for defining the vapour transmission rate. During oral proceedings the Appellant admitted, however, that such minor discrepancies were not significant for the assessment of the validity of Claim 1 and could be overlooked.

Since no other document comes closer to the subject-matter of Claim 1 than document (1), the former must be regarded as novel.

5. Problem and solution

The differences listed above form the solution of the objective technical problem underlying the present patent of providing an adhesive wound dressing having a low adherency to wounds and being capable of absorbing rapidly large amounts of wound exudate, while maintaining the wound in a moist condition.

6. Inventive step

6.1 The document (2) describes a moisture vapour transmitting wound dressing comprising a conformable backing layer 13 (as seen on Figure 4), and an absorbent pad 11 on the adhesive side of the backing layer. As in the patent, the dressing according to document (2) uses an absorbent pad made of open cells foam of a hydrophilic polyurethane. The use of such material is regarded in the patent as essential, since it ensures a rapid absorption of large amounts of wound exudate while allowing the wound to be maintained in a moist condition (cf. page 4, lines 17-28).

Furthermore, the adherency wound facing layer 12 in document (2), consists of a "thin sheet of plastic having a number of openings there through, the plastic being any one of such materials that adheres poorly (or not at all) to the skin or portions of the wound" (cf. Column 2, lines 44-48, emphasis added). The wound facing layer according to Claim 1 is therefore distinguished from that in document (2) in that the claimed elastomer (plastic) layer is made of a net consisting of strands and junctures. The facing layer which is given by way of an example in document (2) and has a plurality of openings, is regarded by the Board as purely equivalent to the claimed structure since it represents also a kind of layer with openings like a net and offers the same properties for the same purpose as those requested in the patent (cf. page 3, lines 52 to 54). Any distinction between the two variants offers no recognisable or surprising advantage.

6.2 The skilled person starting from document (1) and looking for means capable of resolving the problem set in point 5 above will immediately turn to document (2) which describes on the one hand the superposition of a low adherency wound facing layer covering an absorbent layer and, on the other hand, a material perfectly suitable for

the absorbent layer. Therefore, the modification of the conventional pad generally disclosed in document (1) by a pad made of the material described in details in document (2) in order to make use of the known properties and advantageous effects of the hydrophilic polyurethane foam must be regarded as obvious for the person skilled in the art.

- 6.3 The Appellant submitted (cf. Section III above) that there was no obvious reason to assume that a material which is suitable in the known dressing for keeping the wound dry will be also suitable in the present case, where the wound has to be kept in a moist condition, which is completely opposite to what the skilled person can derive from document (2).

This line of argument cannot be accepted by the Board which considers that in document (2) the wordings according to which "the wound is kept dry" must be seen in its context as meaning only that maceration is to be avoided. By providing in the wound area a sufficient supply of air, a high evaporation or dessication rate is obtained. Despite the fact that, as explained in document (2), the cellular hydrophilic polyurethane foam absorbs and retains large amounts of liquids within the polymer material, the absorption capacity of the dressing is obviously limited, so that the final dessication stand of the wound depends primarily on the quantity of wound exudate produced and already retained, regardless of the vapour transmission rate of the pad and/or of the whole dressing.

While amounts of liquid are partially lost by evaporation as moisture vapour, it remains that large volumes of exudate accumulate beneath the dressing and cannot be resorbed in totality so that in document (2) the wound

under the dressing will be maintained in a substantially moist condition as well. Be this as it may, the materials used for the absorbent pad are exactly the same in document (2) and in the patent, and the same results are therefore also to be expected.

6.4 Further, the Board observes that the moisture level at the wound surface can be controlled by the backing layer as well. The supply of air to the wound and hence the evaporation rate may be higher in document (2) than it is in the patent, because in document (2) the backing layer 13 does not protrude beyond the edges of the absorbent pad 11, as the dressing is applied to the skin (cf. Figure 3). However, the skilled person is starting from document (1) in which the absorbent pad is, as in the patent, placed already centrally and completely surrounded by the backing layer when the dressing is adhered to the skin. Thus, by providing the backing layer of document (1) with a pad corresponding to that of document (2) the evaporation rate might somewhat be reduced as compared to that of document (2) but within the same very broad range. In the Board's view, any consequent difference in effects could be readily expected by the skilled person.

6.5 For the foregoing reasons, the Board is satisfied that the subject-matter of Claim 1 lacks an inventive step as required by Article 56 EPC.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



S. Fabiani



G. Szabo

R. Naf. 18.02.92

JM 21-2-92