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File Number: T 577/89 - 3.2.2

Application No.: 82 300 715.8

Publication No.: 0 059 048

Title of invention: Wound dressing

Classification: A61F 13/00

DECISION
of 1 December 1992

Applicant: Smith and Nephew Associated Companies PLC

Opponent: Johnson & Johnson

Headword:

EPC Articles 56, 83, 84, 102(3)
Rules 27(1)(e), 29(1)

Keyword: "Sufficiency of disclosure (confirmed)" - "Claims clear defining the matter to be protected (yes)" - "Inventive step (yes, after amendment)"



Case Number : T 577/89 - 3.2.2

DECISION
of the Technical Board of Appeal 3.2.2
of 1 December 1992

Appellant : Johnson & Johnson
(Opponent) One Johnson & Johnson Plaza
New Brunswick, New Jersey 08903 (US)

Representative : Fisher, Adrian John
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GB-London WC1A 2RA (GB)

Respondent : Smith and Nephew
(Proprietor of the patent) Associated Companies PLC
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Representative : McCall, John Douglas
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Decision under appeal : Interlocutory decision of the Opposition Division
of the European Patent Office dated 9 August 1989
concerning maintenance of European patent
No. 0 059 048 in amended form.

Composition of the Board :

Chairman : P. Dropmann
Members : J.B.F. Kollár
G. Davies

Summary of Facts and Submissions

- I. European patent No. 0 059 048 comprising eleven claims was granted on 31 July 1985 in response to European patent application No. 82 300 715.8 filed on 12 February 1982.
- II. A notice of opposition was filed by the Appellant (Opponent) requesting revocation of the patent on the grounds that the subject-matter thereof was not patentable within the terms of Articles 52 to 57 EPC and/or that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- III. By an interlocutory decision pursuant to Article 106(3) EPC, dispatched on 9 August 1989, the Opposition Division decided to maintain the patent in amended form as specified in a communication pursuant to Rule 58(4) EPC dated 4 April 1989.

The Opposition Division considered that the patent as amended disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and was of the opinion that the subject-matter of Claim 1 involved an inventive step.
- IV. On 5 September 1989 the Appellant lodged an appeal against this decision and paid the appropriate fee. The statement of grounds was received on 4 December 1989.
- V. On 11 April 1990 the Respondent filed observations on the grounds of appeal.
- VI. Thirteen prior art documents were cited in the course of the opposition proceedings of which the following were referred to during this appeal:

- D3: GB-A-1 142 323
- D4: GB-A-1 417 962
- D5: GB-A-1 450 201
- D6: GB-A-1 398 011
- D7: GB-A-2 002 288
- D8: GB-A-1 562 244
- D10: US-A-3 927 669
- D11: US-A-3 543 750
- D12: BE-A-831 023.

VII. In preparation for the oral proceedings, the Board issued a communication on 17 June 1992 in which it particularly pointed out that the expression "approximately circular" in the description could cause ambiguity when interpreting the term "net" and that certain properties of the layers of the dressing appeared to form essential features of the invention.

VIII. Oral proceedings were held on 1 December 1992. At these proceedings the Respondent submitted an amended set of claims and description. Amended Claim 1 reads as follows:

"A low adherency wound dressing which consists essentially of a conformable, apertured wound facing layer and an absorbent layer capable of absorbing wound exudate and comprising a conformable open-cell hydrophilic foam, characterised in that the dressing is a laminate of the absorbent layer and the wound facing layer, in that the foam of the absorbent layer is a flexible foam having a thickness of 0.5 mm to 20 mm, the cells having a cell size of from 30 micrometres to 700 micrometres and in which 20% to 70% of the total membrane area of the cells consists of membrane openings, and in that the wound facing layer comprises a conformable net of elastomeric

polymer in which the strands and junctures of the net are formed integrally, which net at its wound face has a void area which is 35% to 65% of the area of the net."

IX. The arguments of the Appellant both in the written procedure and at the oral proceedings, insofar as these are still relevant to the present claims, may be summarised as follows:

- (a) The patent in suit did not satisfy the requirements of Rule 27(1)(e) EPC in that it did not describe in detail at least one way of carrying out the invention claimed.
- (b) In view of the widely differing sizes of cells normally included in the kind of foam under discussion it was not clear if the range introduced in Claim 1 identified the average cell size and it was stressed that, in view of the irregular size and shape of the cells of the foam, the percentage of the membrane openings of the cells introduced in Claim 1 would be difficult to determine.
- (c) The term "net" used in Claim 1 was allegedly obscure since no physical features characterising the net were included in the claim so the reader was unable to determine what was to be understood by the net, especially in view of the expression "approximately circular" originally contained in column 3, line 52 of the description. As to the void area of the net it was submitted, in support of a drawing introduced during the oral proceedings, that Claim 1 did not clearly exclude round tops of the net at its wound face, which shape of the tops would result in a void area of almost 100% of the net. Concerning the term

"net", it was finally argued that the expression "formed integrally" did not clearly delimit the net itself and that the determination of the scope of Claim 1 was thus difficult.

- (d) Considering document D10 as the closest prior art and taking into account that the net specified in the claim could not, in the Appellant's opinion, be distinguished from the apertured film described in D10, the subject-matter of the claim differed from D10 only by the use of the term "elastomeric", by the limitation of the void area and by the dimensional features of the foam comprised in the absorbent layer. It was further argued that D6 showed a dressing wherein the wound-facing layer was of elastomeric polymer and that the skilled man, taught by D10 (column 2, lines 44 to 48) to construct the wound-facing layer of a relatively thin sheet of plastic having a number of openings therein, which plastic adheres poorly or not at all to the wound, would adopt as a matter of routine the elastomeric polymer material known from D6 for construction of the wound-facing layer according to D10.

- (e) Regarding the two remaining features in Claim 1 concerning the void area and the dimensional features of the foam, the Appellant submitted that neither could support the patentability of Claim 1. The first only signified an arbitrary selection from D10 and the alleged advantages of the second, inter alia to keep the wound in a moist condition, had neither been credibly solved nor supported by the patent in suit; in this context the Appellant criticised tests filed on 10 March 1988 in response to the statement of opposition.

X. In his written submissions and at the oral proceedings the Respondent substantially argued as follows:

- (a) The description and drawings of the patent in suit comprised detailed examples of the processes and material properties appropriate for the claimed dressing; thus the patent instructed the skilled man in how to carry out the invention. The requirements of Article 83 and Rule 27(1)(e) EPC were thus satisfied.
- (b) As to the cell size of the foam, it was stressed that the range, which was not intended to be an average, identified said size clearly in Claim 1. Concerning the percentage of the membrane openings, it was believed that the skilled man had access to means which enabled him to determine whether or not a product fell within the claimed scale.
- (c) It was pointed out that Claim 1 characterised the net by features of specific material, strands and junctures, all being physical features and that the said net moreover was defined by limiting the void area.

In order to avoid any ambiguity, however, the expression "approximately circular" had been deleted from the specification in which thus remained arrangements of strands and areas of holes in polygonal form.

A void area of almost 100% was not claimed in the patent. Consequently, the nets were, in a sectional view, flat-topped, not round-topped as shown in the drawing submitted by the Appellant. The flat tops of the strands of the net did not cause any difficulty

when determining the void area at the wound face of the claimed net.

The expression "integrally" in Claim 1 should be interpreted in the light of the description, which, however, did not preclude manufacturing the net by methods other than the casting method exemplified in the patent; as an example, a biaxial stretching of films was mentioned. All nets, in which the strands and junctures of the net were formed integrally during manufacture and having void areas within the claimed range and the material properties as claimed fell within the subject-matter of Claim 1. Thus, foils having square holes punched therein and nets having circular or elliptical apertures were excluded.

- (d) For the purpose of assessing the inventive step of Claim 1, document D10 was considered by the Respondent to be the closest prior art. A delimitation of the claim with respect to the disclosure of D10 pursuant to Rule 29(1) EPC, together with insertion of further limiting features in the characterising features had been made as well as corresponding amendments to the description.

It was submitted that the present invention lay in the specific and particular combination of an absorbent layer and a wound-facing layer as set out in detail in Claim 1. The claimed combination provided startling advantages of which the most important was ensuring that the wound did not dry out fully. It was submitted that neither D10 nor D6 recognised the requirement to maintain the wound surface moist but directed the reader away from the present invention by requiring that the wound be kept

dry. The skilled person would thus not have been led to the present invention by said documents. It was further stressed that replacing one of the claimed layers would result in loss of their advantageous mutual interaction and reference was made in this context to the tests presented on 10 March 1988 in response to the statement of opposition.

- XI. The Appellant requested that the decision of the Opposition Division be set aside and the patent revoked.

The Respondent requested that the appeal be dismissed and the patent maintained on the basis of Claims 1 to 11 and the description submitted during the oral proceedings together with the figures as granted.

Reasons for the Decision

1. The appeal is admissible.
2. Formal aspects

The amendments made to the claims and to the description by the Respondent during the oral proceedings on 1 December 1992 are not open to formal objection under Article 123 EPC.

3. Clarity

As has been stated in a number of previous decisions of the Boards of Appeal, Article 84 EPC is not a ground of opposition under Article 100 EPC.

In the Board's judgment, when amendments are made to patents during opposition proceedings, Article 102(3) EPC

requires consideration by both instances as to whether the amendments contravene any requirement of the Convention, including Article 84 EPC; however Article 102(3) EPC does not allow objections to be based upon Article 84 EPC, if such objections do not arise out of the amendments made (cf. T 301/87, OJ EPO 1990, 335, points 3.3 - 3.8). Thus, the objection to Claim 1 on the ground of lack of clarity raised by the Appellant in this case, alleging that the meaning of the term "net" in the characterising portion of said claim is not clear, is not admissible as a matter of principle because the objection does not arise out of the amendments made.

However, since the Appellant in his written submissions and during the oral proceedings placed considerable emphasis on the word "net" used in the patent in suit, arguing that the net is not characterised by physical features, the Board wishes to make it clear that it is unable to accept the Appellant's arguments. The Board accepts the explanation given by the Respondent at the oral proceedings that Claim 1 characterises the net by features of specific material, certain void areas and integrally-formed strands and junctures, all of said features being physical ones. When interpreting the term "integrally" on the basis of information given in the description of the patent in suit (cf. especially column 3, lines 23 to 26), the Board takes the view that, by further limiting the void area to 35% to 65%, Claim 1 clearly defines whether a particular void area arrangement would be included in the scope of Claim 1. The opinion of the Board is supported by the fact that the expression "approximately circular" has been deleted from the patent and that, because of the claimed "strands", only arrangements of hole areas having polygonal shape are thus included in the claimed net.

4. Disclosure of the invention

In the general part of the description, in the description of the preferred embodiment referring to the drawings as well as in the examples, detailed technical information is given about the claimed dressing, its layers and their embodiments and dimensions as well as about suitable materials and advantageous effects which the invention is considered to have in relation to the prior art.

Furthermore, examples of processing the layers and bringing them together to form the dressing are given in the description. The description and drawings thus have a technical character and the Board does not find any well-founded reasons for believing that the skilled man would be unable, on the basis of the information given in the patent documents, to extend the particular teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis. The Appellant stressed at the oral proceedings that no information was included in the patent about how to determine the claimed scales of the percentage of the membrane openings of the cells and of the cell size of the foam of the absorbent layer. Since the reader is presumed to have the general background and technical knowledge appropriate to the art, the Board accepts, in absence of disagreement from the Appellant, the Respondent's opinion that the skilled man has access to means which enable him to determine whether or not a product falls within the claimed scale.

As to the allegation of the Appellant that it is difficult to determine the void area of the net, in support of which he submitted a drawing during the oral proceedings showing, in a sectional view, the net with round tops, which would permit a void area of almost 100%, the Board

takes the view that round-topped nets are excluded for the reason that a void area of almost 100% is excluded from Claim 1.

The Board is thus satisfied that the disclosure of the invention is sufficiently clear and complete to satisfy the requirements of Article 83 and Rule 27(1)(e) EPC.

5. Novelty

The Board is satisfied that none of the documents cited during the proceedings discloses a wound dressing having all the features defined in Claim 1.

Since this has never been disputed, there is no need for further detailed substantiation of this matter.

Therefore, the subject-matter as set forth in Claim 1 is to be considered novel within the meaning of Article 54 EPC.

6. Closest prior art

The Board considers document D10 to be the state of the art closest to the invention, as admitted by the parties during the oral proceedings. This document relates to a product comprising all features of the preamble of Claim 1 of the patent in suit.

7. Problem and solution

Claim 1 is distinguished from the closest prior art known from D10 in that

- the dressing is a laminate of the absorbent layer and the wound facing layer,

- the foam of the absorbent layer is a flexible foam having a thickness of 0.5 mm to 20 mm,
- the cells have a cell size of from 30 micrometres to 700 micrometres,
- 20% to 70% of the total membrane area of the cells consists of membrane openings,
- the wound facing layer comprises a conformable net of elastomeric polymer,
- the strands and junctures of the net are formed integrally,
- the net at its wound face has a void area which is 35% to 65% of the area of the net.

The differences listed above form the solution to the objective, technical problem underlying the present patent, that is, providing a wound dressing having lower adherency to the wound and being less painful to remove than previous such dressings and thus promoting the healing process of the wound.

8. Inventive step

8.1 The Appellant has stressed throughout the opposition and appeal procedure that it would be obvious to the skilled person to supplement the incomplete teaching of D10 as set out in the foregoing feature analysis with the teaching of D6. Taking into account that D6 indeed teaches the use of a conformable, perforated, wound-facing layer of elastomeric polymer in order to reduce adhesion, the Board nevertheless cannot accept the Appellant's line of argument. The reason is that D6 specifically teaches circular perforations of a void area of preferably about 20% (which figure follows from D6, page 1, lines 61-64). Thus, the Board considers that, in order to arrive at the subject-matter of Claim 1, the skilled person, after combining the teaching of D10 with that of D6, would then

have to make further changes in order to alter the shape of the perforations and move away from the preferred void area. In addition, he would have to determine the properties of the foam in the absorbent layer as far as its thickness, cell size and percentage of the membrane openings are concerned. There is no hint in the prior art as to these features.

8.2 The Respondent, during the previous proceedings, repeatedly emphasised that an important advantageous effect of the invention lay in the fact that the claimed combination allowed the wound to be maintained in a moist condition, so preventing the dressing from adhering to the wound. The Appellant has not proved the contrary. The Board, therefore, is of the opinion that there is no logical chain of reasoning to explain why the skilled man would have taken the steps of combining known features from D10 and D6. In both said documents, the intention is to maintain the area of the skin covered by the dressing "dry". In this context, reference is made especially to the passage in D10 at column 1, line 66 to column 2, line 3, wherein it is stated that the facing surface of the wound is kept dry and provided with a continuous supply of air, as well as to the passage at column 2, lines 62 and 63 which indicates that the pad maintains the area of the skin covered by the pad dry. Attention is also drawn to D6, page 2, lines 25 to 29, where it is stated that a scab is formed on the wound. Consequently, neither D10 nor D6 recognises the requirement for maintaining moisture at the wound surface. These documents rather direct the reader away from the present invention by requiring that the wound be kept dry. Thus, the skilled man would not have been led to the present invention by either or both of these documents.

8.3 The Board takes the view, in the absence of any proof presented by the Appellant to the contrary, that the wound surface is kept moist by the use, in accordance with the present invention, of a combination of an absorbent layer and a wound-facing layer having the properties as set out in Claim 1 of the patent in suit. Moreover, keeping in mind the problem to be solved by the invention (see point 7 above) and considering that the formation of a scab and consequent drying will lead to a relatively high adherency level of the dressing, the Board finds an indication of inventiveness in the surprisingly advantageous effect of the claimed combination. This, by allowing the wound to be maintained in a moist condition, assists not only in preventing the dressing from adhering to the wound, but also in preventing the wound being reopened on removal of the dressing, a feature which also promotes the wound-healing process.

8.4 The Board has examined the remaining documents cited during the procedure which concern developments in the field of wound dressings and represent a number of teachings which in theory could be combined. However, in the absence of a reason for doing so, they remain separate teachings the relevance of which, in the Board's opinion, is less than the teachings known from the more relevant, above-discussed documents D10 and D6.

8.5 It follows from the preceding paragraphs that the subject-matter of Claim 1 is not foreseen by the documents cited by the Appellant. Consequently, it involves an inventive step. The same applies to Claims 2 to 11 which relate to preferred features of the dressing according to Claim 1.

Order

For these reasons, it is decided that:

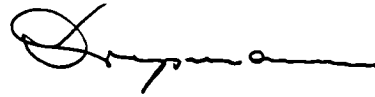
1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of Claims 1 to 11 and the description submitted during the oral proceedings, together with the figures as granted.

The Registrar:



S. Fabiani

The Chairman:



P. Dropmann



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