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File Number: T 583/89 - 3.2.2

Application No.: 82 300 716.6

Publication No.: 0 059 049

Title of invention: Wound dressing

Classification: A61F 13/00

D E C I S I O N
of 2 December 1992

Applicant: Smith and Nephew Associated Companies PLC

Opponent: Johnson & Johnson

Headword:

EPC Articles 56, 84, 102(3) and 112(1)(a)

Keyword: "Request to refer a point of law concerning basis for interpretation of a claim to the Enlarged Board of Appeal (rejected, irrelevant)" - "Claims clear defining the matter to be protected (yes)" - "Inventive step (yes, after amendment)"



Case Number : T 583/89 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 2 December 1992

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

Representative : Fisher, Adrian John
CARPMAELS & RANSFORD
43 Bloomsbury Square
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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. 0 059 049 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. 0 059 049, comprising sixteen claims, was granted on 6 November 1985 in response to European patent application No. 82 300 716.6 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:

- D1: GB-A-1 280 631
- 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.

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, exemplified in the communication, of the layers of the dressing appeared to form essential features of the invention. It further raised an objection under Article 123(2) EPC.

VIII. Oral proceedings were held on 2 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 comprises a conformable, apertured wound facing layer, an intermediate absorbent layer capable of absorbing wound exudate and comprising a conformable open-cell hydrophilic foam and an outer layer, which wound dressing is characterised in that the wound facing layer comprises a conformable net of an elastomeric polymer in which the strands and junctures of the net are formed integrally, and which net has a void area

at its wound face which is 35% to 65% of the area of the net, the intermediate 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 the outer layer comprises a bacterial barrier which is a continuous, conformable, moisture vapour transmitting polymeric film having a moisture vapour transmission rate of 300 to 5,000 grams/square metre/24 hours at 37.5°C and at 100% to 10% relative humidity difference."

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

- (a) It was submitted that the term "net" used in Claim 1 was obscure.
- (b) The Appellant, making use of Article 112(1)(a) EPC, requested that in view of the alleged obscurity of the term "net" the following point of law be referred to the Enlarged Board of Appeal:

"Is a claim clear according to Article 84 EPC if its meaning cannot be determined without reference to the minutes of the oral proceedings or the decision?"

- (c) As to the presence of an inventive step in Claim 1 of the patent in suit, it was submitted that the impugned decision improperly considered the allowability of said claim starting from D10. Document D6 disclosed the use of an elastomeric polymer as material for the wound-facing layer, the

use of an absorbent pad and the use of an adhesive backing layer, which could be formed from a plastic film; the dressing of the present Claim 1 was alleged to be distinguished from D6 by:

- (i) the use of a "net", as distinguished from an apertured film,
- (ii) the use of a hydrophilic foam pad, rather than the absorbent pads disclosed on page 1, lines 84 to 88 of D6, and
- (iii) the provision of an outer layer having the properties specified in Claim 1.

In view of the alleged obscurity of the term "net", distinction (i) could not, in the Appellant's opinion, be relied upon and it was accordingly submitted that the problem which the claimed invention solved was the provision of an alternative absorbent pad material in the dressing in D6; it was further stressed that the choice of a hydrophilic foam as suitable absorbent material and the choice of a moisture/vapour-transmitting, adhesive backing material were both obvious in view of the common general knowledge of those skilled in the art - reference being made especially to D10 and to Example 14 of D1 specifying MVP (= moisture vapour permeability) values corresponding to the one of the film claimed in the discussed patent. Concerning the MVP values, the Appellant, referring to Decision T 108/90 of 4 February 1992 (unpublished) (relating to a wound dressing), stressed that the claimed range of the MVP value of the outer layer was not surprising since MVP values under 500 would lead to

maceration of the wound and MVP values over 5000 to desiccation of the wound.

It was finally submitted that the invention relied on a simple combination of features disclosed in documents D6, D10 and D1, from which combination no surprising result followed because the individual parts produced no non-obvious interaction.

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

(a) In order to avoid ambiguity as to the shape of the apertures in the net, the expression "approximately circular" had been deleted from the specification in which thus remained arrangements of strands and areas of holes in polygonal form.

As to the percentage of the void area of the net, said area had been restricted to 35% to 65% of the area of the net.

It was pointed out that the passages concerning the thin, perforated, flexible films forming the wound-facing layer had already been deleted from the specification during previous proceedings.

(b) The Respondent stressed that the point of law that the Appellant requested be referred to the Enlarged Board of Appeal was irrelevant to the present case since no reference needed to be made to the minutes of the oral proceedings or the decision to determine the clarity of Claim 1, which characterised the "net" by features of specific material, strands and junctures, and limited void area, all of these being physical features. It was further stressed in this

context that 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.

- (c) 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 and corresponding amendments to the description, were presented during the oral proceedings.

It was submitted that the present invention lay in the specific and particular combination of a wound-facing layer, an absorbent layer and an outer 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 fully dry out. It was submitted that neither D10 nor D6 recognised the need to maintain moisture at the wound surface but directed the reader away from the present invention by requiring that the wound be kept dry. Thus, the skilled person would not have been led to the present invention by the said documents, irrespective of whether he started from D6

or D10. Moreover, the skilled person would not find either the net or the properties of the layers in D6 or D10. Neither gave D1 a hint about the properties of the outer layer, since Example 14 in said document referred to the MVP value of the dressing and not of the outer layer; moreover, concerning the alleged obviousness of the claimed range of the MVP value of the outer layer, regarding which the Appellant relied on Decision T 108/90 (unpublished), the Respondent denied the relevance of the Appellant's argument on this point stating that the wound itself did not macerate but only the surrounding area thereof did.

The Respondent finally stressed that the claimed combination ensuring a promoted regulation of the moist wound healing could not, for the above reasons, be considered an arbitrary mosaic of the teachings of the prior art and pointed out that replacing one of the claimed layers would result in loss of their advantageous mutual interaction; reference was made in this context to the tests presented on 7 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. He also requested that the point of law formulated in point IX(b) above be referred to the Enlarged Board of Appeal.

The Respondent requested that the appeal be dismissed and the patent maintained on the basis of Claims 1 to 16 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 the description by the Respondent during the oral proceedings on 2 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 24 to 27), 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.

The Board is also satisfied that the passages concerning thin, flexible films which have been perforated were deleted from the specification and takes the view that, when interpreting the expression "integrally" in Claim 1 in the light of the description, column 3, lines 24 to 27, the skilled reader is unambiguously instructed by the patent in suit that all nets in which the strands and junctures are formed integrally during manufacture and having void areas within the claimed range and the material properties as claimed fall within the subject-matter of Claim 1. Thus foils having square holes punched therein and nets having circular or elliptical apertures are excluded.

4. 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.

5. Inventive step

5.1 The Appellant has stressed throughout the opposition and appeal proceedings that it would be obvious to the skilled person starting from D6 to supplement the incomplete teaching of D6 with the teaching of D10. Taking into account that D6 indeed teaches the use of a conformable, perforated, wound-facing layer of elastomeric polymer, an intermediate absorbent layer and an outer layer, the Board nevertheless cannot accept the Appellant's line of argument. D6 forms a less suitable basis for Claim 1 than D10, which latter document not only relates to a similar dressing comprising the three afore-mentioned layers but also uses a conformable open-cell hydrophilic foam pad as against the absorbent pads disclosed on page 1, lines 84 to 86 of D6. Therefore, the Board considers D10 to represent the state of the art closest to the invention and is satisfied that Claim 1 has been correctly delimited with regard to the disclosure of this document.

5.2 The differences listed in the characterising portion of Claim 1 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.

5.3 Keeping in mind the problem to be solved by the invention, it is observed that D6 specifically teaches circular perforations of a void area of preferably about 20%, which figure follows from D6, page 1, lines 61 to 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 D6 with that of D10, would first 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 and the properties of the film forming the bacterial barrier in the outer layer. There is no hint in the prior art as to these features.

5.4 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 person would have taken the steps of combining known features from D6 and D10. 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 person would not have been led to the present invention by either or both of these documents in which, moreover, neither the net nor the properties of the outer layer are to be found.

5.5 The Board is of the opinion that D1 also gives no hint about the properties of the outer layer since Example 14 of said document, to which the Appellant referred in this context, relates to the MVP value of the dressing and not of the outer layer. According to column 4, lines 6 to 12 of the patent specification, the outer layer of the wound dressing serves to regulate the moisture loss from the wound area under the dressing and also to act as a barrier to bacteria.

5.6 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 the three layers having the properties as set out in Claim 1 of the patent in suit. Moreover, regarding the problem to be solved by the invention 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. The Board takes the

view that said indication of inventiveness is supported by interaction between the individual features of the claimed combination which cannot be considered as a simple combination of teachings disclosed in D6, D10 and D1 since these documents, in the absence of any hint to such interaction, lack relevance to the present invention for the reasons put forward above.

- 5.7 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, D6 and D1.
- 5.8 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 16 which relate to preferred features of the dressing according to Claim 1.
6. As mentioned in paragraph IX(b) above, the Appellant requested a referral to the Enlarged Board of the question whether a claim may be considered clear, according to Article 84 EPC, if its meaning cannot be determined without reference to the minutes of the oral proceedings or the decision. The Board holds that this question is irrelevant to the present case since it finds that the claim in question, Claim 1, is clear and no reference to the minutes of the oral proceedings or this decision is required to determine the meaning of the claim. A referral of the question posed to the Enlarged Board, therefore, is not justified.

Order

For these reasons, it is decided that:

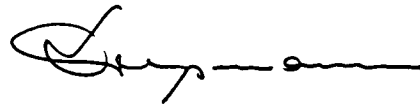
1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of Claims 1 to 16 and the description submitted during the oral proceedings, together with the figures as granted.
3. The request to refer a point of law to the Enlarged Board of Appeal is refused.

The Registrar:

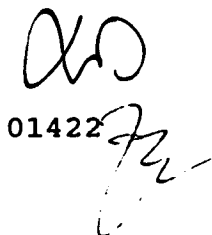


S. Fabiani

The Chairman:



P. Dropmann



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