BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal ~~Yes~~ / No

File Number: T 324/89 - 3.3.2

Application No.: 81 304 884.0

Publication No.: 0 050 514

Title of invention: Wound dressings and processes for their preparation

Classification: A61L 15/01

D E C I S I O N
of 13 June 1991

Proprietor of the patent: Smith and Nephew Associated Companies plc.

Opponent: Johnson and Johnson

Headword: Wound dressing/SMITH & NEPHEW

EPC Article 56

Keyword: "Inventive step (yes) - Reassessment of the state of the art - non-obvious alternative"

Headnote

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 324/89 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 13 June 1991

Appellant : (Opponent)	Johnson & Johnson 501 George Street New Brunswick, New Jersey 08903 (US)
Representative :	Fisher, Adrian John Carpmaels & Ransford 43 Bloomsbury Square London WC1A 2RA (GB)
Respondent : (Proprietor of the patent)	Smith and Nephew Associated Companies plc 2, Temple Place Victoria Embankment London WC2R 3PB (GB)
Representative :	McCall, John Douglas W.P. Thompson & Co. Coopers Building Church Street Liverpool L1 3AB (GB)
Decision under appeal :	**Decision of Opposition Division of the European Patent Office dated 25 November 1988, posted on 19 April 1989 rejecting the opposition filed against European patent No. 0 050 514 pursuant to Article 102(2) EPC.**

Composition of the Board :

Chairman : P.A.M. Lançon
Members : I.A. Holliday
R.L.J. Schulte

Summary of Facts and Submissions

I. European patent No. 0 050 514 concerning wound dressings and processes for their preparation was granted on the basis of 15 claims contained in European patent application No. 81 304 884.0.

Independent Claims 1 and 10 read as follows:

"1. A sterile wound dressing which is contained within a bacteria-proof package and which comprises a wound facing layer and optionally an absorbent layer which wound facing layer comprises a sterile net comprising intersecting strands in which the strands and junctures are formed integrally, characterised in that the net comprises elastomeric polyurethane and has about 4 to 40 intersections per cm of strand which strands define openings having a minimum dimension of 0.05 mm and a maximum dimension of 2 mm.

10. A method of making a sterile net suitable fur use in a sterile wound dressing as claimed in any of claims 1 to 9 which method comprises casting an elastomeric polyurethane as a solution, dispersion, hot melt or powder onto a surface having a pattern of discrete raised areas and interconnected recessed areas which correspond to the openings and strands of a sterile net as defined in Claim 1 and heating, drying or cooling the cast net as appropriate to form a solid net.

II. The Appellant filed a notice of opposition against the European patent requesting revocation on the grounds that the subject-matter of the patent lacked inventive step. Twenty prior art documents were cited in the course of the opposition proceedings of which the following remain relevant in this appeal:

(2) GB-A-1 398 011
(3) US-A-3 292 619
(12) GB-A-1 417 962
(16) US-A-3 483 018
(17) GB-A-1 280 631

III. The Opposition Division rejected the opposition being of the opinion that although the Opponent had demonstrated firstly that perforated films had long been in use as wound dressings and secondly that polyurethane, especially as foam was also known for this purpose, it would not have been obvious to combine these teachings. In particular, the Opposition Division took the view that document (2), which was considered by the Opponent to be close prior art, did not relate to an "integral net" within the definition of Claim 1 of the patent in suit, but was a punched film. It was, accordingly, not a suitable starting point from which to consider replacement of the materials actually mentioned therein by polyurethane elastomer.

IV. The Appellant lodged an appeal against the said decision. The arguments of the Appellant both in the written procedure and at the oral proceedings on 13 June 1991 may be summarised as follows.

It was submitted firstly that the term "net" used in Claim 1 of the patent in suit was obscure. The Appellant referred to the Oxford English Dictionary definition of "net", together with that of "strand" and "juncture". The essential feature of a "net" according to the said definition was that it possessed a large proportion of open areas. This did not seem to be the case with the products of the patent in suit. It was also argued that a net consisting of strands could not have circular openings

as envisaged in column 2, line 44 of the patent. The Appellant drew attention to diagrams filed on 7 June 1986 during the opposition procedure illustrating a twenty times enlargement of the "net" of Example 1 of the patent together with a similar structure having the same size and number of circular holes; in both cases the open area was considerably less than the solid surrounding area. In the Appellant's view such structures could not be considered to consist of "strands" and "junctures" within the commonly understood meanings of these terms.

It was consequently the Appellant's view that the perforated elastomeric films disclosed in the wound dressings of document (2) were equivalent to the "nets" of the disputed patent and accordingly, it would have been obvious to replace the elastomers actually disclosed in (2) with a polyurethane.

The Appellant also advanced a general argument that, from the considerable number of documents cited, it was first of all apparent that perforated films had been in use in wound dressings since at least 1935. Secondly polyurethanes were also well known for this purpose. It was thus the Appellant's view that the subject-matter of Claim 1 of the patent was merely a collocation of integers all of which were within the common general knowledge of those skilled in the art.

The Appellant also criticised the comparative experiments filed in response to the statement of opposition.

V. The Respondent (Proprietor of the patent), in refuting the Appellant's arguments drew the Board's attention to the configuration of the "holes" in the network illustrated in Figures 3 to 5 of the patent. A diagram showing a larger area of "net" was also supplied at the oral proceedings.

Having regard to the truncated pyramid shape of the holes, the Appellant's plan view of the network would indicate a larger solid area than the perspective view supplied by the Respondent. The side of the net in contact with the wound would have larger open areas than the opposite side which preferably is joined to an absorbent pad. The Respondent confirmed that document (6), considered by the Board to be particularly relevant, did indeed consist of a "net", although obtained by embossing a plastics film/absorbent pad laminate in contrast to the casting process of the patent in suit. The Respondent also believed that the Kendall product "TELFA", used in the comparative tests filed in response to the opposition, was prepared in accordance with document (6).

In respect of document (12), the Respondent denied that the polyurethane in contact with the wound was an elastomer. The foam used in (12) has at least one side consisting of partially collapsed cells. Although the surface is compacted, it remains highly absorbent when contacted with a wound. It accordingly represented a highly specialised type of foam and was the basis of the "LYOFOAM" dressings used in the above-mentioned comparative tests. During the oral proceedings, the Respondent challenged the Appellant to produce evidence that it was common general knowledge at the priority date of the patent to use polyurethane elastomers in contact with wounds.

The Respondent offered to make certain amendments to the description to remove the reference to networks having circular holes and to make clear in column 2, line 5 that the strands and junctures were formed during manufacture.

VI. The Appellant requests that the decision of the Opposition Division be set aside and that the patent be revoked.

The Respondent requests the dismissal of the appeal.

Reasons for the Decision

1. The appeal is admissible.

2. The Appellant has placed considerable emphasis on the word "net" used in the patent in suit, arguing that it is not used in its normally understood meaning. The Board can, however, accept the explanation offered by the Respondent at the oral proceedings. Taking, on one hand, a plan view of the "net" according to Example 1 of the patent, as illustrated in Figure B, filed by the Appellant on 7 June 1986 during the opposition procedure, the open areas of the "net" appear to be considerably less than the solid portions. On the other hand, when the actual configuration of the "net" is taken into consideration, it is apparent that the "holes" of the net have a truncated pyramid form having a solid angle of 60°. Thus, the "open" side of the net, which is intended to face the wound, has four 1 mm squares per 5 mm of length. Clearly on this side, the open area well exceeds the area of the intervening strands and junctures. Since the net is approximately 0.5 mm thick, the square holes on the opposite side have dimensions of only ca. 0.42 mm. Such a configuration is not only evident from the drawing submitted by the Respondent during the oral proceedings but also from Figures 4 and 5 of the patent and from the actual sample of net which appears in the examination file (filed 10 December 1982). The plan view submitted by the Appellant accordingly gives a misleading impression of the configuration of the net. The Board is thus satisfied that the disclosure is sufficiently clear and complete to satisfy the requirements of Article 83 EPC.

2.1 If the purpose of the Appellant were merely to raise an objection of lack of clarity of the claim per se, the Board can only point out that the above is an objection which falls within the terms of Article 84 EPC and is not one of the grounds of opposition in terms of Article 100 EPC.

2.1.1 Accordingly, the requests for amendment of the description submitted by the Respondent cannot be considered as being in response to the opposition. Amendments to the specification which are merely cosmetic and not made in response to a valid ground of opposition cannot be considered during opposition procedure. As emphasised by decisions of the Boards of Appeal, opposition procedure is not to be misused as an extension of examination (cf. T 127/85, OJ EPO 1989, 271 and G 1/84, OJ EPO 1985, 299, Reasons point 9). The requests are therefore refused.

3. The patent in suit relates to wound dressings and methods for their preparation.

3.1 In the opinion of the Board, the closest state of the art is document (6). According to (6) wound dressings are prepared from a laminate of a thermoplastics film (e.g. polyethylene) and a pad of absorbent material (e.g. cotton fibres). The said laminate is embossed by means of a pattern roll containing four sided bosses, which according to an example make ca. 375 depressions per square inch of film surface. The said depressions slope inwardly into the body of the said pad from the raised portions bordering the depressions in analogous manner to the nets of the patent in suit. Each depression is punctured by several holes which enables exudate from the wound to pass through the film to the absorbent pad. Thus, the thermoplastics film surface which is placed in contact with the wound has

the configuration of a "net" in accordance with Claim 1 of the patent in suit. This is apparent from Figs. 1 and 2 of (6) and was also accepted by the Respondent during the oral proceedings. The exemplified net would have in the region of eight depressions per linear cm, i.e. within the range specified by Claim 1 of the patent in suit.

3.2 In relation to the above prior art, the problem to be solved by the disputed patent is to provide an alternative wound dressing which has the desired properties of sterility, conformability and low adhesion to the wound.

Having regard to description of the patent in suit and the comparative examples filed during the opposition procedure, the Board is satisfied that the problem has been solved by the sterile wound dressing according to the present Claim 1.

4. None of the documents cited in the opposition proceedings disclose the specific wound dressing defined by Claim 1; the dressing claimed can thus be regarded as new. In any event, novelty is not in dispute.

5. It remains to consider whether the subject-matter of Claim 1 satisfies the requirements of Article 56 EPC in respect of inventive step.

5.1 The dressing of Claim 1 differs from that known from (6) in that instead of a net of thermoplastics film being used as the wound facing layer, the patent in suit employs a net of polyurethane elastomer. The Appellant has asserted throughout the opposition and appeal procedure that the use of polyurethane elastomers in wound facing layers was common general knowledge at the priority date of the patent in suit. However, when challenged at the oral proceedings to support this assertion with documentary

evidence, was unable to do so. Considerable weight was attached to document (12). However, as correctly pointed out by the Respondent, the polyurethane foam employed in the dressings of (12) is not described as an elastomer and furthermore the surface which is brought into contact with the wound has been subjected to a treatment in which the foam cells are irreversibly collapsed. In other words, even if the foam according to (12) were elastomeric, the problem, concerning modification of the polyurethane, was entirely different and no teaching could be desired from it that polyurethane elastomers in general are suitable for wound facing layers. Polyurethane elastomers are mentioned in documents (16) and (17); in fact the same series of commercially available "Estane" polymers as employed in the examples of the patent in suit are utilised. However, in accordance with (16) and (17), the polymers are used as backing layers which are not in contact with the wound. There is nothing in the remaining prior art suggesting the use of polyurethane elastomers in wound facing layers. Accordingly, the Appellant has not established that such use belonged to the state of the art let alone the common general knowledge of the person skilled therein. In any event, it is to be noted that in accordance with the jurisprudence of the Boards, patent specifications in general are not regarded as forming part of the common general knowledge (cf. T 206/83, OJ EPO 1987, 5, Reasons points 5 and 6; T 171/84, OJ EPO 1986, 95, Reasons, point 5). Accordingly there would have been no incentive from the prior art cited by the Appellant which would have induced the skilled man to replace the thermoplastics net known from the dressing according to (6) with the polyurethane net presently claimed.

5.2 In relation to the desired properties of low adhesim, which are part of the problem to be solved, the Appellant has criticised the comparative tests filed by the

Respondent citing decisions T 20/81 (OJ EPO 1982, 217) and T 164/83 (OJ EPO 1982, 149). The Respondent assured the Board that the commercial dressing "TELFA" used in the said tests is a product according to document (6) and that "LYOFOAM" is manufactured according to document (12). Accordingly, the tests have been carried out in comparison with highly pertinent prior art and the criteria laid down in the cited decisions are satisfied. The Appellant also referred to decision T 93/83 of 25 November 1986 (not published in the OJ EPO) in which it was maintained that certain comparative tests were not valid, since the margin of error had not been stated. Such margins or error can only be important where the test values recorded are quite close together but are irrelevant in the present case where the force required to remove the "TELFA" dressing was 441 gcm^{-2}, that for "LYOFOAM" 228 gcm^{-2} and that for the product of Example 1 of the patent in suit only 87 gcm^{-2}.

5.3 Starting from document (12), which the Respondent during the opposition procedure regarded as close prior art, must lead to an analogous conclusion. In this case the problem could be seen in obtaining a dressing having lower adhesion to the wound than that obtained with the products known from (12), e.g. "LYOFOAM". It might seem prima facie obvious than a dressing having less physical contact with the would would have a lower adhesion thereto than one in which the surface of the treated foams according to (12) were in contact with the wound. However, were the skilled man to compare the "network" dressing according to (6), i.e. "TELFA", with the product of (12), he would find that the former had the higher adhesion to the wound. Accordingly, there would be no incentive to replace the specially treated foam known from (12) with the polyurethane net presently claimed.

5.4 Document (2) can be considered as more remote prior art. Having regard to the explanations offered by the Respondent, the Board is satisfied that the perforated elastomeric film used therein is not a "net" in accordance with Claim 1 of the patent in suit. There is thus no incentive from the cited prior art to replace the said perforated film with the elastomeric polyurethane net presently claimed.

5.5 In the written procedure, the Appellant has also advanced a general argument that since each and every feature of Claim 1 belongs to the common general knowledge of one skilled in the art, the subject-matter thereof must lack inventive step. The Board cannot accept that this is the case. It is the arrangement of the said features and their relationship one with another which determine the presence or absence of inventive step. The argument must, in any event, fail in the present case since, as indicated above, the Appellant was unable to show that the use of polyurethane elastomers in wound contacting layers was common general knowledge at the priority date of the patent in suit.

5.6 It follows from the preceding paragraphs that the subject-matter of Claim 1 is not foreshadowed by the documents cited by the Appellant. Consequently, it involves an inventive step. The same applies to Claims 2-9 which involve particular embodiments of the dressing according to Claim 1.

6. The above findings also show that the methods according to Claim 10 and sub-claims 11-15 are in no way rendered obvious by the documents cited by the Appellant. Consequently, these claims also involve an inventive step, especially since the Appellant has made no specific attack on the method claims during the appeal proceedings.

7. Accordingly, there are no grounds which prejudice the maintenance of the patent in the form as granted.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Martorana P.A.M. Lançon