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**D E C I S I O N**  
**of 10 November 2000**

**Case Number:** T 0432/97 - 3.3.2

**Application Number:** 87305900.0

**Publication Number:** 0251810

**IPC:** A61L 15/16

**Language of the proceedings:** EN

**Title of invention:**

Wound dressing

**Patentee:**

JOHNSON & JOHNSON

**Opponent:**

Mölnlycke AB

Paul Hartmann Aktiengesellschaft

**Headword:**

Wound dressing/JOHNSON

**Relevant legal provisions:**

EPC Art. 83, 84, 123, 54(3)(4), 158

**Keyword:**

"Main and first auxiliary request - novelty: no"

"Implicit disclosure"

"Second auxiliary request - novelty: yes"

"Prior art embodiments do not fall inevitably within the claimed range"

**Decisions cited:**

G 0010/91

**Catchword:**

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Case Number: T 0432/97 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 10 November 2000

**Appellant:** JOHNSON & JOHNSON  
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**Appellant:** Mölnlycke AB  
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**Respondent:** Paul Hartmann Aktiengesellschaft  
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**Decision under appeal:** Interlocutory decision of the Opposition Division  
of the European Patent Office posted 21 February  
1997 concerning maintenance of the European  
patent No. 0 251 810 in amended form.

**Composition of the Board:**

**Chairman:** P. A. M. Lançon

**Members:** J. Riolo

C. Rennie-Smith

## Summary of Facts and Submissions

- I. European Patent No. 0 251 810 based on application No. 87 305 900 was granted on the basis of 10 claims.

The independent claims 1 and 10 as granted read as follows:

1. A liquid permeable dressing comprising one or more sheets of apertured material coated with a sufficient amount of a crosslinked silicone to encapsulate the apertured material, said dressing being sterile and contained within a bacteria-proof envelope.

10. A dressing comprising one or more layers of support material, having a tacky silicone gel coating on one surface thereof and a non-tacky silicone elastomer coating on the other surface.

- II. Notices of opposition were filed against the granted patent by the appellant opponent (opponent 01) and the respondent (opponent 02).

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step.

The following document was inter alia cited during the proceedings.

(1) WO-A-8705206.

- III. The interlocutory decision of the Opposition Division established that the patent could be maintained in an amended form under Article 106(3) EPC on the basis of the text as submitted during the oral proceedings.

The amended independent claims 1 and 9 read as follows:

1. A liquid permeable dressing comprising one or more sheets of apertured material coated with from 20 to 700 g of a non-tacky crosslinked silicone per square metre or from 70 to 700 g of a tacky crosslinked silicone gel per square metre, so as to encapsulate the apertured material, said dressing being sterile and contained within a bacteria-proof envelope.

9. A dressing comprising one or more layers of support material, having from 60 to 350 g/m<sup>2</sup> of a tacky silicone gel coating on one surface thereof and from 20 to 150 g/m<sup>2</sup> of a non-tacky silicone elastomer coating on the other surface.

Compliance of the amended subject-matter of the patent in suit with Article 54(3) and (4) EPC in relation with Article 158 EPC over the international application (1) was acknowledged by the Opposition Division.

The Opposition Division found that the indication of the specific amounts of non-tacky and tacky crosslinked silicone gel coatings used in the dressing of independent claims 1 and 9 rendered novel the claimed subject-matter over document (1) which did not disclose any particular amounts for the coating.

It also considered that the amended subject-matter was inventive over the most relevant prior art documents (2) DE-A-2007449, (3) US-A-4034751 and (5) EP-A-92999.

The opponent O1 raised no objection of lack inventive step in the subject-matter of the patent in suit.

- IV. The appellant opponent and the appellant patentee both lodged appeals against the said decision.
- V. A main request and four auxiliary requests were submitted by the appellant patentee. The set of claims of the first and second auxiliary requests were filed on 24 August 2000 with its letter dated 23 August 2000 and the set of claims of the third and fourth auxiliary requests filed on 16 October 2000 with its letter of the same date.

The set of claims of the main request corresponds to the set of claims as granted.

The set of claims of the first auxiliary request corresponds to claims 1 to 9 as granted with claim 10 being identical to claim 9 of the set of claims on the basis of which the patent has been maintained in the interlocutory decision of the Opposition Division (see above under III).

The set of claims of the second auxiliary request is identical to set of claims on the basis of which the patent has been maintained in the interlocutory decision of the Opposition Division (see above under III).

In the third and fourth auxiliary requests preferred ranges of silicone have been defined in claim 1, the other claims being identical to claims 2 to 9 of the second auxiliary request.

- VI. Oral proceedings were held before the Board on 10 November 2000.

VII. The submissions of the appellant opponent, in the written procedure and oral proceedings, can be summarized as follows:

It maintained the grounds of opposition under Article 100(a) EPC as to the lack of novelty of the patent in suit.

Although it agreed that, contrary to the requirements of the dressing of the patent in suit, document (1) did not disclose *expressis verbis* either that the dressing must be sterilized and put into a bacteria-proof envelope or that the dressing must be coated with the specific amount of 20-700 g/m<sup>2</sup> of the crosslinked silicone gel, it contended that these features were to the skilled person implicitly disclosed in (1).

As evidence, the appellant opponent filed three declarations from surgeons with its letter dated 18 November 1997 stating that it was clear from the intended use of the dressing of document (1), ie "open wound healing", that this dressing must be sterile.

It also filed experimental data, with its grounds of appeal and with its subsequent letter of 26 January 2000, to show that a skilled man, manufacturing a wound dressing according to the teaching of document (1), would inevitably apply a crosslinked silicone gel to the carrier in an amount within the range given in the contested patent.

In addition, it raised further objections pursuant to Articles 123, 100(b) and 84 EPC against the subject-matter of claim 1 of the third and fourth auxiliary requests. During the oral proceedings it accepted that



these new grounds were too late to be raised against the subject-matter of the set of claims of the second auxiliary request as this set of claims was the one on which the interlocutory decision of the Opposition Division was based and as these objections were only raised six weeks before the oral proceedings (ie almost three years after the date of the interlocutory decision).

The appellant opponent made no objection as to inventive step.

The opponent O2 took no part in the appeal proceedings.

VIII. The arguments of the appellant patentee submitted in the written procedure and oral proceedings can be summarized as follows:

As regards the "sterility" feature, it was of the opinion that, since it was not **literally inevitable** that the skilled reader of document (1) would take the steps of sterilising the dressing and putting it into a bacteria-proof envelope, this document did not anticipate the subject-matter of the patent in suit.

In addition, it maintained that the specific weight of crosslinked silicone used for coating the dressing was also novel over document (1). In that respect, it disputed the reliability of the appellant opponent's experimental evidence to the effect that this amount of silicone was an inevitably implicit feature of the dressings of document (1) because, in its opinion, the dressings used in the tests were chosen arbitrarily.

The appellant patentee, referring to the decision of

the Enlarged Board of Appeal G 10/91 (OJ 1993, 420, point 18), did not give its approval to consideration in the appeal proceedings of the fresh ground of opposition under Article 100(b) EPC raised by the appellant opponent.

- IX. The appellant opponent requested that the decision of the Opposition Division be set aside and that the patent be revoked.

The appellant patentee requested that the patent be maintained as granted or with the set of claims of the first or second auxiliary requests filed with its letter dated 23 August 2000 or with the set of claims of the third or fourth auxiliary requests filed with its letter dated 16 October 2000.

## **Reasons for the Decision**

1. The appeals are admissible.
2. *Main request*
  - 2.1 Articles 123(2) and (3) and 84 EPC.

The set of claims of the main request corresponds to the set of claims as granted.

No objection under Articles 123(2) and (3) and 84 EPC was raised with respect to this set of claims and the Board sees no reason to differ.

- 2.2 Novelty

2.2.1 Document (1) has been cited under Article 54(3) EPC as prejudicial to the novelty of the subject-matter of the patent in suit.

Document (1) describes a liquid permeable wound dressing comprising one or more sheets of apertured material coated with a sufficient amount of a crosslinked silicone to encapsulate the apertured material (claim 1, Figures 1 and 2, page 3, lines 16 to 18, page 4, lines 9,10 and 18 to 22, page 5, paragraph 2).

Document (1) does not mention *expressis verbis* that the wound dressing is sterile and contained within a bacteria-proof envelope.

It must therefore be decided whether the skilled person would nevertheless consider these features implicitly contained in the document.

In that respect the Board notes that document (1) does not deal with dressings in general but with a particular type of dressing ie an open wound dressing (see eg page 1, lines 25 to 32; page 4, line 36 to page 5, line 8)).

Not just only the skilled person but the general reader knows that an open wound must, before dressing, be clean and free from bacterial germs and then preserved in that state by applying a dressing.

It is accordingly essential that the dressing to be applied to the cleaned wound should also be free of bacterial germs.

It is also common general knowledge that a germ free dressing will not remain so if it not protected before use from other sources of bacterial contamination. Placing the germ-free wound dressing in a bacteria-proof envelope is therefore the inevitable step to take in order to preserve it from such contamination.

Accordingly, the skilled person would implicitly read into document (1) that the wound dressing must be sterile and contained within a bacteria-proof envelope.

In conclusion, the subject-matter of claim 1 of the main request lacks novelty under Article 54(3) and (4) EPC.

2.2.2 The appellant patentee emphasized that it was not literally inevitable that the skilled reader of document (1) would take the step of sterilising the wound dressing as both sterile and non-sterile dressings for open wounds are available.

The Board accepts that there are dressings which can be purchased in a non-sterile state. This does not however remove the therapeutical requirement for such dressings to be germ-free when placed on an open wound. In other words, a non-sterile dressing only qualifies as open wound dressing once it has been made germ-free ie once it is sterile. Accordingly, non-sterile dressings are merely precursors or intermediates of actual wound dressings and the Board is satisfied that the words "wound dressing" necessarily imply dressings which, because of the use to which they are put, must be sterile.

The Board does not accept the argument of the appellant

patentee that a wound dressing according to document (1) could be either sterilised or just disinfected so that claim 1 of the main request should be regarded as novel since it requires a sterile rather than a disinfected wound dressing.

In that respect, the Board notes that the claims and the description of the patent in suit are completely silent as to any definitions of sterilisation and disinfection which would enable a clear technical distinction to be drawn between the results obtained from either of those processes. Both processes being aimed primarily at killing germs, the Board can not recognise any novelty arising from the choice of a sterile dressing rather than a disinfected dressing.

The Board does not dispute the fact that, as put forward by the appellant patentee, germ removal must reach a certain minimum level in order for a dressing to be described as "sterile" on its packaging. However, this is a commercial or regulatory requirement which, moreover, depends on national regulations which may vary according to country and time. It would therefore be unsound to allow this consideration to determine the assessment of novelty of the contested subject-matter.

3. *First auxiliary request*

3.1 Articles 123(2) and (3) and 84 EPC.

No objection under Articles 123(2) and (3) and 84 EPC was raised with respect to this set of claims and the Board sees no reason to differ.

3.2 Novelty

As claim 1 of this set of claims is identical to claim 1 of the main request, the conclusions under 2.2 hold also good for this auxiliary request.

4. Second auxiliary request

4.1 Articles 123(2) and (3) and 84 EPC

The set of claims of the second auxiliary request is identical to the set of claims on the basis of which the patent was maintained in the interlocutory decision of the Opposition Division.

No objection under Articles 123(2) and (3) and 84 EPC was maintained by the appellant opponent during oral proceedings with respect to this set of claims. As this set of claims is distinguished from the set of claims as granted merely by the deletion of claim 6 and the restriction of claim 1 and claim 9 to the numerical ranges disclosed in terms on, respectively, page 7 line 29 and on page 9 lines 4 to 11 of the application as originally filed, the Board sees no reason to object.

4.2 Novelty

4.2.1 The appellant opponent submitted that the introduction of specific ranges of amounts of non-tacky crosslinked silicone or tacky crosslinked silicone gel in the subject-matter of claim 1 of the second auxiliary request did not render it novel. Indeed, it contended that the functional definition of the amount of silicone gel applied in document (1), which required enough gel to encapsulate the carrier but not so much so that the apertures would be obstructed, would

inevitably lead to an amount of gel coating within the range of crosslinked silicone gel of claim 1 as shown by the experimental data filed with its grounds of appeal and with its subsequent letter filed on the 26 January 2000.

- 4.2.2 As document (1) is completely silent about any specific amounts of non-tacky crosslinked silicone or tacky crosslinked silicone gel, the relevant question as regards novelty is indeed whether the functional definition of the amount of silicone gel given in this document **inevitably** leads to an amount of gel coating within the range of crosslinked silicone gel of claim 1.

In that respect, the Board notes that the tests provided by the appellant opponent were conducted on a very narrow range of carrier materials, whereas document (1) is not at all limited as to the nature of the carrier material; and notes moreover that the materials tested had a hole size in the range 1,2 to 2,3 mm<sup>2</sup> whereas document (1) contemplates carriers having hole sizes as small as 0.25 mm<sup>2</sup> and as large as 4 mm<sup>2</sup> (claim 6).

These experiments are therefore not representative of the whole disclosure of (1), in particular because the nature of the fibrous network (ie the carrier) and the hole size precisely influence the weight of silicone gel needed to achieve encapsulation, as stated by the expert who carried out the experiments filed on the 21 January 2000 (annex 1, page 1, last paragraph to page 2, first paragraph).

It is moreover clear from the conclusions relating to

this study that it would not be any encapsulated dressings according to document (1) which would require an amount of crosslinked silicone gel automatically and inevitably falling within the claimed range (annex 1, page 2, paragraphs 2 and 5).

Indeed, in the passages of his report headed "Conclusions" and "Concluding remarks", the expert only expressed the opinion that "from the experimental results obtained it can be concluded that the technical information given (in (1))... will **most probably** lead an expert in the field to develop a wound dressing ... where the gel weight per m<sup>2</sup> would be in the range mentioned (in (1))" and that "it should be **quite obvious and self-evident** for an expert in the field to **develop** wound dressings where the gel weight per m<sup>2</sup> would easily fall within the weight interval mentioned (in (1))" (emphasis added).

Therefore, as the point at issue is not inventive step but novelty, novelty under Article 54(3) EPC of the claimed range over the disclosure in document (1) has to be acknowledged under the present circumstances even though the claimed range could appear to be extremely obvious and self evident to the skilled person.

In view of the above, the Board concludes that the subject-matter of claim 1 of the second auxiliary request fulfills the requirements of novelty under Article 54 EPC.

Accordingly the subject-matter of its dependent claims 2 to 7 and the subject-matter of claim 8 relating to a method of forming a dressing according to claim 1 are also novel.



Novelty of the subject-matter of the independent claim 9 has not been questioned by the appellant opponent and the Board sees no reason to differ.

4.3 Inventive step

No inventive step objection was raised by the appellant opponent in its grounds of appeal. Moreover, during the oral proceedings, it confirmed that it had no objection to the patent in suit as regards inventive step.

As the Board sees no reason to differ, inventive step is not at issue.

**Order**

**For these reasons it is decided that:**

The appeals are dismissed.

The Registrar:

The Chairman:

A. Townend

P. A. M. Lançon