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D E C I S I O N
of 4 December 2002

Case Number: T 0775/99 - 3.3.7

Application Number: 94921838.2

Publication Number: 0663235

IPC: B01D 71/54

Language of the proceedings: EN

Title of invention:
Phase Separated Membrane

Applicant:
TAKIRON CO. LTD.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 111(1)

Keyword:
"Amendments - added subject-matter (no)"
"Decision re appeals - remittal (yes)"

Decisions cited:
-

Catchword:
-



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Boards of Appeal

Chambres de recours

Case Number: T 0775/99 - 3.3.7

D E C I S I O N
of the Technical Board of Appeal 3.3.7
of 4 December 2002

Appellant: TAKIRON CO. LTD.
3-13, Azuchimachi 2-chome
Chuo-ku
Osaka-shi
Osaka 541 (JP)

Representative: Hansen, Bernd, Dr. Dipl.-Chem.
Hoffmann Eitle
Patent- und Rechtsanwälte
Arabellastrasse 4
D-81925 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 March 1999
refusing European patent application
No. 94 921 838.2 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: R. E. Teschemacher
Members: G. Santavicca
B. L. ter Laan

Summary of Facts of Submissions

- I. European patent application 94 921 838.2 is based on international patent application PCT/JP94/01254, filed on 29 July 1994, claiming a priority in Japan of 30 July 1993 (JP 208 831/93) and published on 9 February 1995 under No. WO 95/03879.

The application as originally filed comprised 5 claims, claim 1 reading as follows:

"1. A phase-separated membrane in which a crosslinked gelatin phase and an uncrosslinked segmented polyurethane phase are present as a mixture."

Dependent claims 2 to 5 concerned preferred embodiments of the membrane according to claim 1.

- II. By a decision of the Examining Division, posted on 11 March 1999, the above application was refused. That decision was based on the claims as originally filed.

- III. Having regard to documents D1 (US-A-4 997 656) and D2 (DE-A-1 569 231), the Examining Division held that:

(a) Novelty of the subject-matter of claim 1 could be acknowledged, albeit with some doubts in view of the analogous structure obtained in D1 when the drug-containing polyurethane layer melted and flowed into the pores of the gelatin membrane.

(b) As to inventive step, the closest prior art document was D1.

The claimed membrane was distinguished from the product of D1 in that it contained both the gelatin and the polyurethane as a mixture of separated phases.

Since there was no evidence for any technical effect which could be attributed to these distinguishing features, the technical problem had to be formulated as providing an alternative structure within the general teaching of D1.

However, it would have been obvious to provide a structure which presumably resulted anyway when using the system of D1, ie to combine the drug-containing base layer of polyurethane of D1 with a gelatin membrane, the pores of which were already filled with polyurethane. Such an arrangement was also contemplated in the application in suit.

Also, since D2 disclosed a plaster structure optionally containing medicaments, whereby gelatin and polyurethane had been incorporated in a single layer, there was no technical prejudice against the incorporation of polyurethane and gelatine in a single layer.

- (c) The additional features of claims 2 to 5 were all known from D1 and had not been shown to contribute to any unexpected technical effect.
- (d) Therefore, the application was refused.

IV. On 30 April 1999, the applicant lodged an appeal against that decision and paid the prescribed fee on the same day. With the statement of grounds of appeal, received on 8 July 1999, the appellant enclosed a set of four claims substituting the claims as originally filed, as the sole request.

V. In a communication in preparation for oral proceedings, the Board detailed the points to be dealt with, *inter alia* the requirements of Articles 123(2), 84, 54 and 56 EPC.

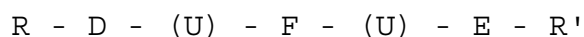
VI. Oral proceedings were held on 4 December 2002.

During the discussion, the appellant explained the gist of the invention underlying the application in suit and how the invention was to be seen in the light of the prior art documents, represented by D1 and D2.

The Board elucidated its objections, doubts and questions, in particular regarding product claim 1, in view of the prior art represented by D1, in particular the result inevitably obtained during the use of the product disclosed in D1.

As a result of that discussion, the appellant submitted a set of 14 claims as the new sole request, replacing the request then on file, independent claims 1 and 7 reading as follows:

"1. A phase-separated membrane for a plaster preparation for transdermal administration in which a crosslinked waterinsoluble desalted alkali gelatine phase and an uncrosslinked segmented amphipathic polyurethane phase which is in a solid state at temperatures of not lower than 0°C and lower than 30°C and is molten to a liquid state at from 30 to 40°C are present as a mixture wherein a number average molecular weight of said segmented polyurethane is from about 1000 to about 13000, and a number average molecular weight of each of the segments is from about 200 to about 3000, wherein the segmented amphipathic polyurethane of the following formula is used:



wherein D and E each represents a polymer of ethylene oxide, propylene oxide, tetramethylene oxide or 1,2-butylene oxide, or a random or block copolymer thereof, R and R' each represents a terminal H, CH₃, C₂H₅, C₃H₇ or C₄H₉ thereof, D=E or D≠E, R=R' or R≠R', F represents a constituting structure which is the moiety of a diisocyanate compound excluding two isocyanate groups, (U) represents a urethane bond, and at least one of D and E is hydrophilic and at the same time at least one of D and E has a characteristic such that it melts near the temperature of the human skin, wherein the gelatine phase forms a skeleton of the membrane and is present at a proportion of at least 40% based on the total weight of the membrane, and forms a three-dimensionally continued phase, wherein the segmented amphipathic polyurethane is present at a proportion of 60% or less based on the total weight of the membrane and forms a continuous phase at least in the thickness direction of the membrane."

"7. A method for preparing a phase-separated membrane for a plaster preparation for transdermal administration, in which an uncrosslinked segmented amphipathic polyurethane is heat-melted and the heat-melted segmented amphipathic polyurethane is mixed, while stirring, with an aqueous solution of desalted alkali gelatin and a crosslinking agent and, after defoaming, the mixture is spread on a base film having a good peeling property, and dried for about 2 days at an ordinary temperature to obtain the phase-separated membrane, wherein the crosslinked water insoluble gelatin and the uncrosslinked segmented amphipathic polyurethane which is in a solid state at temperatures of not lower than 0°C and lower than 30°C and is molten to a liquid state

at from 30 to 40°C are present as a mixture wherein a number average molecular weight of said segmented polyurethane is from about 1000 to about 13000, and a number average molecular weight of each of the segments is from about 200 to about 3000, wherein the gelatine forms a skeleton of the membrane and is present at a proportion of at least 40% based on the total weight of the membrane, and forms a three-dimensionally continued phase, wherein the polyurethane is present at a proportion of 60% or less based on the total weight of the membrane and forms a continuous phase at least in the thickness direction of the membrane."

Dependent claims 2 to 6 and 8 to 14 concern preferred embodiments of the product of claim 1 and the process of claim 7, respectively.

VII. The arguments of the appellant in support of the claimed subject-matter can be summarised as follows:

- (a) Claim 1 concerned a phase-separated membrane that was based on the features of original claims 1 to 4, the novel segmented polyurethane of formula (II) and further features, that had been considered essential in the communication of the Board.

New independent process claim 7 was necessary for protecting the process of preparation of the membrane disclosed in the original application and, via Article 64(2) EPC, the membrane directly obtained thereby. Also, new dependent claims had been drawn up for protecting preferred aspects of the invention underlying the application in suit.

The basis of all of the amendments in the original application were specified.

- (b) The product disclosed in D1 was composed of a multi-layer structure, consisting of different layers, *inter alia* a drug-containing layer (3) and a release controlling layer (4).

This release controlling layer was a membrane made of crosslinked gelatin, which was obtained by the removal of dextran. That structure had small pores and it did not include any segmented polyurethane. It was difficult for the segmented polyurethane to enter into those small pores. Even if it entered, it would contain the drug, so that the initial structure of the membrane according to the application in suit was not obtained.

Consequently, the rate and amount of drug release, which depended on the pore size and the presence of polyurethane, could not be properly controlled.

- (c) The phase-separated membrane underlying the application in suit was used as a drug-release controlling membrane by closely attaching it to a base (drug-storing layer) for a transdermal absorption preparation.

The segmented polyurethane that was present as a separated phase in the membrane according to claim 1 was not described in D1 or in any other document on file, which documents did not describe the process of preparation of the membrane defined in claim 7 either.

Due to its molecular weight, the segments used as well as their molecular weights, that polyurethane was suitable for controlling the release rate and amount of the drug to the skin much better than the polyurethane disclosed by D1.

- (d) Therefore, the new claims overcame all the objections raised in the impugned decision.

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 14 as filed during the oral proceedings as the sole request.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

2.1 Independent claim 1 is based on the features of original claims 1 to 4, with the inclusion of the following further limitations:

- (a) "for a plaster preparation for a transdermal administration", which is based on page 1, second sentence, as well as page 6, lines 2 to 3.
- (b) The definitions "water insoluble, desalted, alkali", as applicable to gelatin, which are based on original page 5, last paragraph, first sentence, as well as on page 9, first full paragraph, in particular the third line thereof.

(c) The definition of the melting characteristics of the segmented polyurethane, which is based on original claim 2 with the further limitations mentioned in the paragraph bridging pages 6 and 7.

(d) The definition of the segmented polyurethane of formula (II), which is based on the features mentioned in the paragraph bridging pages 12 and 13, as well as the features of page 18, last paragraph.

(e) The definition of the particular structure formed by gelatin and polyurethane, which is based on original page 5, first full paragraph.

2.2 The additional features of claim 2 correspond to those of original claim 5.

2.3 The additional features of claim 3 are based on the paragraph bridging original pages 8 and 9, in particular the last sentence thereof.

2.4 The additional features of claims 4 and 5 are based on original page 8, second full paragraph.

2.5 The additional features of claim 6 are based on original page 7, first full paragraph.

2.6 Independent method claim 7 is based on the paragraph bridging original pages 7 and 8 with the further limitations of the product to be prepared thereby as defined in claim 1, apart from the absence of the definition of the segmented polyurethane of formula (II). The basis for the further limitations is as given under point 2.1 above.

- 2.7 The additional features of claims 8 to 12 concern preferred embodiments of the method of preparation according to claim 7, which have their basis on original page 8, first full paragraph.
- 2.8 The additional features of claims 13 and 14 have a basis on page 8, penultimate paragraph, and the first sentence of the last paragraph, respectively.
- 2.9 As far as the combination of the features of original claims 1 to 4 with the further limitations is concerned, it is based on the specific description of the membrane starting on original page 5, first full paragraph.
- 2.10 Therefore, the amendments to the claims meet the requirements of Article 123(2) EPC.

3. *Further issues*

The new claims submitted during the oral proceedings overcome the grounds of refusal and do not raise the problems addressed in the Board's communication and in the discussion during the oral proceedings.

The amended claims are directed not only to a specific membrane comprising the segmented polyurethane of formula (II) but also to a method of preparation of a membrane comprising a polyurethane having a less restricted definition.

Thereby they shift the focus of the subject-matter under review, thus constituting a new case.

Therefore, in order to enable full consideration of the new case by the Examining Division, without depriving the appellant of the possibility to be heard by two instances, the Board does not consider it appropriate to deal with the matter any further.

Accordingly, the Board remits the case to the first instance for further prosecution pursuant to Article 111(1) EPC.

In this respect, the following points may be of relevance:

- (a) An independent claim directed to a method of preparation of the membrane according to the invention underlying the application in suit, ie claim 7, was not present originally and might need a further search.
- (b) Furthermore, the Board has become aware of document EP-A-0 671 176, the comparative examples of which might be considered as additional evidence in respect of the product of 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 department of first instance for further prosecution.

The Registrar:

The Chairman:

C. Eickhoff

R. Teschemacher