

Veröffentlichung im Amtsblatt	Ja/Nein
Publication in the Official Journal	Yes/No
Publication au Journal Officiel	Oui/Non

Aktenzeichen / Case Number / N<sup>o</sup> du recours : T 171/88 - 3.2.2

Anmeldenummer / Filing No / N<sup>o</sup> de la demande : 84 308 236.3

Veröffentlichungs-Nr. / Publication No / N<sup>o</sup> de la publication : 0 147 072

Bezeichnung der Erfindung: A process for making a polyurethane condom

Title of invention:

Titre de l'invention :

Klassifikation / Classification / Classement : A61F 5/43

### ENTSCHEIDUNG / DECISION

vom / of / du 7 May 1990

Anmelder / Applicant / Demandeur : Desert Medical, Inc.

Patentinhaber / Proprietor of the patent /  
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Article 56

Schlagwort / Keyword / Mot clé : "Inventive step - denied"

Leitsatz / Headnote / Sommaire



Case Number : T 171/88 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.2  
of 7 May 1990

**Appellant :** Desert Medical, Inc.  
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**Decision under appeal :** Decision of Examining Division 127  
of the European Patent Office dated  
2 December 1987 refusing European  
patent application No. 0 147 072  
pursuant to Article 97(1) EPC

**Composition of the Board :**

**Chairman :** G. Szabo  
**Members :** H. Seidenschwarz  
L. Mancini

## Summary of Facts and Submissions

- I. European patent application No. 84 308 236.3 filed on 28 November 1984 (publication No. 0 147 072) was refused by a decision of the Examining Division 127 dated 2 December 1987.
- II. The reason for the refusal was that the subject-matter of Claim 1 filed with the letter of 9 July 1987 did not involve an inventive step in the light of the teachings known from the documents GB-A-1 221 840 and the Chemical Abstracts, Vol. 71, 28 July 1969, page 52, abstract No. 13909u.
- III. On 14 January 1988, the Appellant lodged an appeal against the decision. The appeal fee was paid on 4 February 1988 and the statement of grounds was submitted on 11 April 1988.
- IV. Oral proceedings took place on 7 May 1990.

The Appellant filed a new set of Claims 1 to 10 as main request and three different Claims 1 as auxiliary requests. The arguments submitted by him may be summarised as follows:

- (i) GB-A-1 221 840 disclosed a method for preparing thin-walled polyurethane moulded articles such as condoms by a dipping cycle, which articles had good mechanical properties and no pinholes. According to this method the dipping was repeated any desired number of times. This clear teaching, therefore, led away from using a single dipping process for getting a pinhole-free condom.

- (ii) The Chemical Abstract No. 13909u described in very general terms a process for making so-called dipped articles from partially blocked urethane by applying at least one layer to a form. This layer could be cured by heating. Girdles were mentioned however as the only example of the dipped articles which would be very porous in comparison with thin articles like a condom. Therefore, there were no reasons for an attempt to make a simple dipping process.
  
  - (iii) Also the document US-A-3 846 378 cited on page 15 of the application in suit disclosed a "synchronous" process for thermally-curable blocked polyurethanes involving a single dipping step followed by curing the cast at an elevated temperature for producing an article like a film. There was no reference at all to condoms.
  
  - (iv) As far as the Claims 1 according to the auxiliary requests were concerned it was referred to the application in suit, page 8, line 8 to page 9, line 9 and to page 10, lines 19 to 24. From this it was quite clear that the selection of reaction parts should be such to get a certain percentage of hard and soft segments for obtaining a product having special characteristics. GB-A-1 221 840 did not contain any reference that such values should be achieved.
- V. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request and the auxiliary requests presented at the oral proceedings.
- VI. The Claims 1 of the requests read as follows:

**Main request:**

"A process for producing polyurethane condoms with walls of substantially uniform thickness of from 0.038 mm (0.0015 inch) to 0.102 mm (0.004 inch), utilizing a single dipping stage, which comprises the steps of:

(a) establishing a single dipping bath, said bath comprising a solvent solution of a polyurethane prepolymer blocked by a heat-reversible end-blocking agent, said prepolymer being the reaction product of a polyisocyanate and at least one long chain polyol, said polyol being amorphous and non-crystalline at room temperature and having an average molecular weight of from 500 to 5000 and an average hydroxy number of from about 225 to 22.4, and said polyisocyanate having an NCO/OH ratio of from about 0.95/1 to 1.1/1;

(b) dipping moulds on which condoms are to be formed in said single dipping bath for a period of time of from about 30 to 60 seconds for depositing a polyurethane film in the form of a condom on each of said moulds;

(c) withdrawing said moulds from said single dipping bath at the rate of from about 16 to 90 cm per minute;

(d) curing said deposited film in the form of a condom on each of said moulds by exposure to elevated temperature for a time sufficient to effect said cure;

(e) cooling the said cured film on said moulds to a temperature of from 50 to 60°C at which time an integral cuff is formed at the base of the said film on each of said moulds; and

(f) removing said deposited film in the form of a condom with an integral cuff from each of the said moulds."

As the Claims 1 according to the three auxiliary requests differ only from Claim 1 according to the main request by additional features in step (a), only these different steps (a) are cited.

**1. Auxiliary request:**

"(a) establishing a single dipping bath, said bath comprising a solvent solution of a polyurethane prepolymer blocked by a heat-reversible end-blocking agent, said prepolymer being the reaction product of a polyisocyanate and at least one long chain polyol, a chemical cross-linking agent and optionally an extender, said polyol being amorphous and non-crystalline at room temperature and having an average hydroxy number of from about 225 to 22.4, said polyisocyanate having an NCO/OH ratio of from about 0.95/1 to 1.1/1, and the proportions of said constituents being such that the polyurethane formed on curing is a segmented polyurethane in which the percent hard segment is in the range from 14 to 25% and the molecular weight per cross-link is from 5000 to 30000  $M_C$ ;"

**2. Auxiliary request:**

"(a) establishing a single dipping bath, said bath comprising a solvent solution of a polyurethane prepolymer blocked by a heat-reversible end-blocking agent, said prepolymer being the reaction product of a polyisocyanate and at least one long chain polyol, a chemical cross-linking agent and optionally an extender, said polyol being amorphous and non-crystalline at room temperature and having an average molecular weight of from 500 to 5000 and an average hydroxy number of from about 225 to 22.4, said polyisocyanate having an NCO/OH ratio of from about 0.95/1 to 1.1/1, and the proportions of said constituents being such that the polyurethane formed on curing is a segmented polyurethane in which the percent hard segment is in the range from 16 to 20% and the molecular weight per cross-link is from 8000 to 25000  $M_C$ ;"

**3. Auxiliary request:**

"(a) establishing a single dipping bath, said bath comprising a solvent solution of a blocked polyurethane prepolymer formed by the reaction of a heat-reversible end-blocking agent with a mixture of from 13 to 23% polyisocyanate, 70 to 84% long-chain diol, 0.75 to 6% polyfunctional alcohol as chemical cross-linking agent, and optionally 0.5 to 3.0% short-chain diol extender, said long-chain diol being amorphous and non-crystalline at room temperature and having an average molecular weight of from 500 to 5000 and an average hydroxy number of from about 225 to 22.4, said polyisocyanate having an NCO/OH ratio of from about 0.95/1 to 1.1/1, and the proportions of said constituents being such that the polyurethane formed on curing is a segmented polyurethane in which the percent hard segment is in the range from 14 to 25% and the molecular weight per cross-link is from 5000 to 30000  $M_C$ ;"

**Reasons for the Decision**

1. The appeal is admissible.
2. The question whether there are any formal objections to the current version of the claims according to the main request as well as to the auxiliary requests, needs not to be answered since all four Claims 1 are anyway unallowable on another ground.
3. After examination of all documents cited in the international search report as well as those referred to in the description of the application in suit, the Board is satisfied that none of them expressly disclosed a process for producing polyurethane condoms having in combination all the features as defined in the Claims 1.

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

Therefore, the subject-matter as set forth in the Claims 1 is novel in the sense of Article 54 EPC.

4. The subject-matter of the Claims 1 relates to a process for producing polyurethane condoms with walls of substantially uniform thickness. In the Board's view US-A-3 846 378 must be considered as the most relevant prior art and the starting point for the assessment of the inventive step of the claimed subject-matter. This document discloses a procedure which is useful in preparing the prepolymers used in the claimed process (cf. also EP-A-0 147 072, page 15, lines 1 to 38). In the known procedure a mixture of diols, the cross-linking agent, and an end blocking agent is prepared and the mixture is heated. To this mixture is added the diisocyanate followed by the polymerisation catalyst. The reaction thereafter proceeds under its own reaction heat. The solution coating compositions used in the procedure are prepared by dissolving the polyurethane prepolymer in a suitable solvent.

The products of this procedure are elastomers, films, textile finishes, adhesives and other forms in which polyurethanes are commonly employed. For example cross-linked elastomeric and film is obtained by casting the reaction mixture on a glass plate and curing it for 30 minutes at 160°C before the film is removed (cf. column 2, lines 10 to 20, 25 to 29; line 63 to column 3, line 10 in combination with Examples 4 and 5 in column 7).

The document US-A-3 846 378, therefore, reveals the general teaching, namely to produce a thin-walled product



by depositing in a single stage a film of a solvent solution of a polyurethane prepolymer on the surface of a mould and to heat the deposited film to effect curing of the film.

5. The technical problem in respect of this method was to apply the known technique to the manufacture of other articles, particularly of condoms. According to the Appellant, this means in relation to the subject-matter of Claim 1 according to the main request to provide an inexpensive, simple process for producing a pinhole-free condom of uniform thickness, or in relation to the subject-matter of the Claims 1 according to the auxiliary requests, a condom which has the appropriate elastomeric properties (cf. also EP-A-0 147 072, page 4, lines 14 to 21; page 6, lines 26 to 33; page 8, line 13 to page 9, line 32).

The solution of the problem was essentially to use a dip-moulding technique which requires only one dip of a condom form or mould into a polyurethane solution. This single dipping process permits close control of the condom thickness. Cure of the polyurethane film mould is effectuated by means of heat once the form is raised from the polyurethane solution.

6. None of the requests include claims to the condoms themselves which are obtainable by the processes in the case, either in structural terms or defined by a so-called produce-by-process claim. Such products, if claimable, should then be novel and inventive irrespective of the inventive character of the process of preparation (cf. T 150/82, Claim categories/IFF, OJ EPO 1984, 309). If so, the processes for preparing such entities would have also been rendered claimable, even in the case where the method in question is otherwise obvious per se in view

of their analogous character to known methodology (cf. T 119/82, Gelation/EXXON, OJ EPO 1984, 217). However, in the absence of such claimable product, the claimed process for making the article must be non-obvious itself and not a mere "analogy process" of the above character. Thus it is important to examine the origin and character of any differences which can be recognised in comparison with the standard technique shown in US-A-3 846 378.

7. The subject-matter of Claim 1 according to the main request differs from the known process in that

1. the polyol is amorphous and non-crystalline at room temperature and having an average molecular weight of from 500 to 5000 and an average hydroxy number of from about 225 to 22.4, and the polyisocyanate has an NCO/OH ratio of from about 0.95/1 to 1.1/1 (step (a));
2. the moulds are dipped in the single dipping bath for a period of time of from about 30 to 60 seconds for depositing the polyurethane film on each side of the moulds (step (b));
3. the moulds are withdrawn from the single dipping bath at the rate of from about 16 to 90 cm per minute (step (c)); and
4. the cured film on the moulds is cooled to a temperature of from 50 to 60°C at which time an integral cuff is formed at the base of the cured film on each side of the moulds (step (e)).

In addition to the above-mentioned differences, the subject-matter of the Claims 1 according to the auxiliary requests differs in step (a) also from the known process in that

5. the proportion of the constituents of the reaction product for performing the prepolymer are such that the polyurethane formed on curing is a segmented polyurethane in which the percent hard segment is in range from 14 to 25% and the molecular weight per cross-link from 5000 to 30000  $M_c$  (auxiliary requests 1 and 3), or from 16 to 20% and 8000 to 25000  $M_c$  (auxiliary request 1 and 2); and
  
6. the blocked polyurethane prepolymer is formed by the reaction of the heat-reversible end-blocking agent with a mixture of from 13 to 23% polyisocyanate, 70 to 84% long chain-diol and 0.75 to 6% polyfunctional alcohol as chemical cross-linking agent (auxiliary request 3).

The addition of an extender to the aforementioned mixture is only "optional" in all three Claims 1 according to the auxiliary requests. Therefore, this feature as being a non-distinctive characteristic has to be disregarded.

8. However, the skilled person concerned with the problem of further applications of the known polyurethane technique according to US-A-3 846 378, in particular to condoms, would also be necessarily aware of the document GB-A-1 221 840, which concerns a process for producing such condoms having a wall thickness of less than 0.050 mm, or even 0.020 to 0.030 mm in thickness. The document discloses the conditions which are necessary in such a process that the material being used meets the requirements of pinhole-freedom, high tensile strength and elongation of the produced condoms. These conditions are the following (cf. page 2, lines 8 and 9; 15 to 26, 38 to 60; Example 4):

- (i) In the dipping bath which comprises a solvent solution of an isocyanato-terminated polyurethane

prepolymer by reacting polyols, the polyol is amorphous and non-crystalline at room temperature and has an average molecular weight within the range of from 500 to 5000, a hydroxyl number of from 30 to 500 and a polyisocyanate compound in the NCO/OH ratio of more than 1/1.

(ii) The moulds are dipped in the dipping bath for a period of 30 seconds for depositing one layer of a polyurethane film in the form of a condom on each of the moulds, and withdrawn from the dipping bath at a speed of 40 cm per minute.

(iii) The deposit film on the moulds being cured in a curing bath is cooled at a temperature such as from 40 to 120°C.

It is clear that the integral cuff of the condoms is formed during the final cooling stage and before removing the condoms from the moulds, because only during the cooling stage the film can be rolled up on the moulds, starting from the base, to a desired position from the condom tip.

9. Apart from the fact that in the known process the dipping is conducted in any desired order and any desired number of times, the parameters of the known process correspond more or less to the parameters cited in Claim 1 according to the main request or lie in the near range of these parameters. Therefore, from the document GB-A-1 221 840 the person skilled in the art learns clearly which polyurethane prepolymer and polyol components can most advantageously be applied to preparation of condoms with the necessary elastomeric properties. Knowing this clear relationship between the properties of the basic material

being used in the process and the final product, said person skilled in the art realises that the teaching known from the document GB-A-1 221 840 can be combined with the general teaching disclosed by the document US-A-3 846 378 and that this combination results in a process for producing polyurethane condoms.

10. Thus it is no surprise that conditions (i) to (iii) correspond to 1 to 4 in Point 7 above. The replacement of the emulsion technique using several dips within the one dip heat curing method can maintain the other conditions of the earlier technique for making the same kind of condom without difficulty. There can be no invention based on selecting slightly different or even broader ranges for physical conditions which nevertheless fully cover or overlap with those disclosed in the cited documents. In the absence of non-obvious products, and thereby novel aspects in the effects of the processes, such variations in the conditions are either simple optimisations or necessary adaptations. This is because there is no disclosure as to any surprising effect in respect of the process itself which goes beyond what is expected from such kinds of adjustments and choices. None of these can render the process, which is otherwise fully analogous to what was already disclosed in US-A-3 846 378, non-obvious.
11. For the aforementioned reasons, the subject-matter of Claim 1 according to the main request lacks an inventive step as required by Article 56 EPC.
12. The added conditions in the auxiliary requests, i.e. those listed under 5 and 6 in Point 7 above, represent no unusual or unknown details either. The use of the particular reagents defined in step (a) of Claim 1 of the main request already covers the particular percentages,

cross-link distances, isocyanate polyfunctional alcohol properties in the resulting product. Clearly, a general methodology would necessarily be optimised in these respects to obtain the desired quality of products. The selected conditions are neither untypical in polyurethane chemistry, nor is it explained what advantages these choices represent for the process itself. Again in view of the known or obvious character of the products themselves, further limitations in otherwise known processes are technically meaningless without disclosure as to their particular technical relevance. Thus Claims 1 of the auxiliary requests also lack an inventive step.

13. The Board has also looked at the dependent Claims 2 to 10 filed with the main request and come to the conclusion that they contain no features which could have been considered as imparting patentability to the subject-matter of Claim 1.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar:

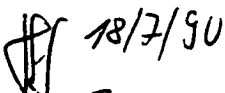



N. Maslin

The Chairman:



G. Szabo

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