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Datasheet for the decision of 15 February 2011

Case Number: T 0217/09 - 3.2.07

Application Number: 00908195.1

Publication Number: 1175355

IPC: B65D 85/24

Language of the proceedings: EN

Title of invention:
Storage package and a method for packaging

Patentee:
Astra Tech Aktiebolag

Opponent:
HOLLISTER INCORPORATED

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty (main request) - no"
"Inventive step (auxiliary requests I, V, VII to IX): no (remaining requests withdrawn)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0217/09 - 3.2.07

D E C I S I O N
of the Technical Board of Appeal 3.2.07
of 15 February 2011

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 November 2008 revoking European patent No. 1175355 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: H. Meinders
Members: K. Poalas
E. Dufrasne

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the Opposition Division revoking the European patent No. 1 175 355.

II. Opposition had been filed against the patent as a whole based on Article 100(a) EPC (lack of novelty and inventive step), on Article 100(b) EPC (insufficient disclosure) and on Article 100(c) EPC (unallowable amendments).

III. The Opposition Division found that the subject-matter of claim 1 according to each one of the main, first, second and third requests is not novel.

IV. The documents of the opposition proceedings referred to in the present decision are the following:

D2: English translation of the Japanese patent application 55-12265,
D6: WO 98 19729 A,
D7: WO 97 49437 A,
D9: EP 0 217 771 A,
D10: US 5 443 907 A.

Oral proceedings before the Board took place on 15 February 2011.

V.

(a) The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, as amended on the basis of one of the auxiliary requests I and V filed with letter dated 4 April

2009, or one of the auxiliary requests VII to IX filed with letter dated 14 January 2011.

(b) The respondent (opponent) requested that the appeal be dismissed.

VI. Independent claims 1 according to the above mentioned requests read as follows (amendments over claim 1 of the patent as granted are depicted in bold or struck through):

Main request

"A storage package (1) which contains a urinary catheter (7) having a coated surface (8) which exhibits a reduced friction when wetted with a wetting liquid and a supply of the wetting liquid (9) wherein during storage, the coated surface (8) of the urinary catheter (7) is constantly maintained in direct contact with said wetting liquid (9), characterized in that the surface coating (8) is provided on a substrate of a material having a melting temperature exceeding 100°C, and preferably exceeding 130°C".

Auxiliary request I

"A storage package (1) which contains a urinary catheter (7) having a coated surface (8) which exhibits a reduced friction when wetted with a wetting liquid and a supply of the wetting liquid (9) wherein during storage, the **whole of the urinary catheter (7), including the** coated surface (8) of the urinary catheter (7) is constantly maintained in direct contact with said wetting liquid (9), characterized in that the

surface coating (8) is provided on a substrate of a material having a melting temperature exceeding 100°C, and preferably exceeding 130°C".

Auxiliary request V

"A storage package (1) **comprising an inner container (3)** which contains a urinary catheter (7) having a coated surface (8) which exhibits a reduced friction when wetted with a wetting liquid and a supply of the wetting liquid (9) wherein during storage, the **whole of the urinary catheter (7), including the** coated surface (8) of the urinary catheter (7) is constantly maintained in direct contact with said wetting liquid (9), characterized in that the surface coating (8) is provided on a substrate of a material having a melting temperature exceeding 100°C, and preferably exceeding 130°C**, in that the wetting liquid comprises an anti-bacterial agent, and in that the storage package further comprises an outer container that encloses the inner container"**.

Auxiliary request VII

"A storage package (1) **comprising an inner container (3)** which **defines a cavity which encloses the whole** ~~contains~~ **of** a urinary catheter (7) having a coated surface (8) which exhibits a reduced friction when wetted with a wetting liquid and a supply of the wetting liquid (9) **in a volume sufficient for the coated surface (8) to remain constantly wetted thereby during storage,** wherein during storage, the **whole of the urinary catheter (7) including the** coated surface (8) of the urinary catheter (7) is constantly

maintained in direct contact with said wetting liquid (9), characterized in that the surface coating (8) is provided on a substrate of a material having a melting temperature exceeding 100°C and preferably exceeding 130°C**, and in that the storage package further comprises an outer container that encloses the inner container, and in that the wetting liquid comprises an anti-bacterial agent, which maintains the catheter and wetting liquid sterile during an extended storage period of 3-5 years**".

Auxiliary request VIII

"A storage package (1) which contains a urinary catheter (7) having a coated surface (8) which exhibits a reduced friction when wetted with a wetting liquid and a supply of the wetting liquid (9) **wherein the storage package (1) comprises a container (3) which defines a cavity (5) which houses the whole of the urinary catheter and the wetting liquid (9), wherein the wetting liquid is contained in the cavity (5) in a volume sufficient for the coated surface (8) to remain constantly wetted thereby during storage, and** wherein during storage, the coated surface (8) of the urinary catheter (7) is constantly maintained in direct contact with said wetting liquid (9), characterized in that the surface coating (8) is provided on a substrate of a material having a melting temperature exceeding ~~100°C and preferably exceeding~~ 130°C**, and in that the container is formed of a material having a melting temperature exceeding 130°C**.

Auxiliary request IX

"A storage package (1) **comprising an inner container (3)** which **defines a cavity which encloses the whole** ~~contains~~ **of** a urinary catheter (7) having a coated surface (8) which exhibits a reduced friction when wetted with a wetting liquid and a supply of the wetting liquid (9) **in a volume sufficient for the coated surface (8) to remain constantly wetted thereby during storage,** wherein during storage, the **whole of the urinary catheter (7), including the** coated surface (8) of the urinary catheter (7) is constantly maintained in direct contact with said wetting liquid (9), characterized in that the surface coating (8) is provided on a substrate of a material having a melting temperature exceeding ~~100°C, and preferably exceeding~~ 130°C**, in that the inner container is formed of a material having a melting temperature exceeding 130°C, in that the storage package further comprises an outer container that encloses the inner container, and in that the wetting liquid comprises an anti-bacterial agent, which maintains the catheter and wetting liquid sterile during an extended storage period of 3-5 years**".

VII. The appellant argued essentially and as far as it is relevant for the present decision as follows:

Main request - Claim 1 - Novelty, Article 54 EPC

There is no disclosure in D2 of a wetting liquid and a coating which confers a reduced friction of the coating when wetted with the wetting liquid. According to the passage bridging pages 2 and 3 it is the provision of large amounts of drugs retained in the hydrophilic

resin layer that prevent infection, patient pain and makes it possible to perform local therapy. Thus the drug is pain relieving after the catheter has been inserted. D2 does not disclose a catheter which reduces pain during insertion of the catheter by providing a low friction surface.

Further, there is no disclosure in D2 that the coated surface of the catheter is constantly maintained in direct contact with the wetting liquid during storage. The practical example 1 of D2 only discloses the use of a limited amount of drug solution, said amount decreasing significantly already during the final steps of the preparation of the catheter.

Finally, there is no explicit disclosure in D2 that the surface coating is provided on a substrate of a material having a melting temperature exceeding 100 °C. Even if the practical example 1 of D2 mentions air-drying in a clean box at 120°C for 1 hour, this is not an explicit teaching that the catheter substrate material should have a melting temperature exceeding 100 °C. The high temperature is in this case apparently used to contract and adhere a previously prepared coating tube to the catheter, and there is thus no need for the catheter in itself to be heated.

Auxiliary request I - Claim 1 - Inventive step, Article 56 EPC

The storage package according to claim 1 differs from the one known from D6 in that the catheter substrate has a melting temperature exceeding 100°C and in that

the whole of the urinary catheter is constantly maintained in direct contact with the wetting liquid.

According to page 3, line 30 of D6 the catheter is pretreated with the liquid swelling medium. According to the passages on page 4, lines 19 to 27 and on page 7, lines 8 to 14 the catheter is advantageously provided with means preventing the swelling medium from getting into contact with surface parts of the catheter not provided with the hydrophilic layer for an activation period during which the medium is applied to the surface part provided with said hydrophilic layer. On page 6, lines 8 to 17 is stated that the hydrophilic coating is either activated prior to arrangement of the catheter in the package or immediately following said arrangement before closing the package by treatment with a liquid swelling medium. There is no disclosure in D6 that the whole catheter is in contact with the swelling medium. Only the part of the catheter provided with the hydrophilic coating may be in contact with the swelling medium, the rest is covered by these means preventing contact.

One of the cheapest methods for sterilization is steam sterilization. A material to be steam sterilized has to be capable to withstand temperatures above 100°C. By providing such a material for the catheter a cheaper sterilization method for the whole package is provided.

D7 mentions several drawbacks of PVC catheters. It advises the skilled person to use instead of PVC a polyether block amide. Said last product is, however, very expensive, it is used for reducing shrinkage

otherwise occurring in the process of coating PVC and because the hydrophilic coatings adhere well to it.

Starting from the catheter of D6 and being confronted with the problem of lowering the overall production costs of the package the skilled person sees no reason to turn to D7. D7 refers to the specific problems generated by a specific coating process at high temperature. In such a case the use of an expensive material like polyether block amide is proposed and the person skilled in the art would not take into consideration such an expensive material when trying to solve the problem of lowering the overall production costs of the package.

Auxiliary request V - Claim 1 - Inventive step, Article 56 EPC

Due to the addition of an anti-bacterial agent to the wetting liquid the sterilization costs are reduced, an extended shelf-life is achieved and a cost-efficient product is accomplished. Since none of the state of the art documents available in the file proposes the addition of an anti-bacterial agent in order to achieve the above-mentioned objects, the addition of the anti-bacterial agent to the wetting liquid involves an inventive step.

Auxiliary request VII - Claim 1 - Inventive step, Article 56 EPC

Due to the addition of an anti-bacterial agent to the wetting liquid which is further capable for maintaining the catheter and the wetting liquid sterile during an

extended storage period of 3-5 years the sterilization costs are reduced, an extended shelf-life is achieved and a cost-efficient product is accomplished. Since none of the state of the art documents available in the file proposes the addition of an anti-bacterial agent in order to achieve the above-mentioned objects, the addition of the anti-bacterial agent to the wetting liquid as claimed in claim 1 involves an inventive step.

Auxiliary request VIII - Claim 1 - Inventive step, Article 56 EPC

The storage package according to claim 1 differs from the one known from D6 *inter alia* in that both the catheter substrate and the container are made of a material having a melting temperature exceeding 130°C. One of the cheapest methods for sterilization is steam sterilization requiring a material to be treated which withstands temperatures exceeding 130°C. By providing such a material a cheaper sterilization method for the whole package is provided.

None of the prior art documents available in the file provides a hint for the use of such material for both the catheter substrate and the container in order to provide a cheaper sterilization method for the whole storage package.

Auxiliary request IX - Claim 1 - Inventive step, Article 56 EPC

Claim 1 according to auxiliary request IX is a combination of claim 1 according to auxiliary request VII with claim 1 according to auxiliary request VIII.

Since the subject-matter of each one of the latter claims involves an inventive step then also the subject-matter of claim 1 according to auxiliary request IX involves an inventive step.

VIII. The respondent argued essentially and as far as it is relevant for the present decision as follows:

Main request - Claim 1 - Novelty, Article 54 EPC

It is clear from the second paragraph of page 2 of D2 that the hydrophilic resin coating on the catheter substrate is there for its low friction properties when wetted, facilitating thereby insertion into the human body.

The appellant contends that the coated surface of the catheter is not maintained in direct contact with the wetting liquid because of the limited amount of wetting liquid discussed in D2. First of all, there is no requirement in claim 1 that the entire surface be in direct contact with the liquid, and secondly a simple calculation based on the information given in the practical example 1 of D2 as to the interior diameter and the length of the tube and the exterior diameter of the catheter, see page 7, lines 23 to 32, as well as the amount of liquid introduced into the tube, see page 8, lines 5 to 9, shows that the tube has enough liquid in it to keep the coated surface in direct contact with the wetting liquid.

Auxiliary request I - Claim 1 - Inventive step, Article 56 EPC

D6 clearly discloses that the entire catheter is immersed in and in constant direct contact with the wetting liquid.

Polyether block amide used as catheter substrate is disclosed in D7 as being suitable for curing at temperatures between 50 and 130°C for a duration of between 5 and 300 minutes, see page 6, lines 14 and 15 and claim 6. It must be borne in mind that this capability of the material is not necessarily exclusively limited to heat sterilization; the latter purpose does not appear in the claim. However, even taking heat sterilization into account the following applies.

When starting from D6 as the closest prior art and having as the only distinguishing feature of the subject-matter of claim 1 over D6 that the material of the catheter substrate has a melting temperature exceeding 100°C, the objective problem to be solved is the provision of a catheter substrate made of a material which withstands a sterilization heat treatment.

The skilled person would immediately recognize that the materials mentioned in D7 as being suitable for manufacturing coated catheter substrates at curing temperatures of up to 130°C can also withstand such temperatures during heat sterilization and would then combine the teaching of D6 with the teaching of D7 to solve this problem and would arrive at the subject-

matter of claim 1 without exercising an inventive activity.

Auxiliary request V - Claim 1 - Inventive step, Article 56 EPC

The object of D6 is the provision of a ready-to-use storage package comprising a catheter which can be withdrawn from its package and which is prepared for direct insertion in the urethra in a substantially sterile condition. This means that bacteria development should be prevented so that the swelling liquid and the therein embedded catheter would keep their sterility during a long period of time. Adding an anti-bacterial agent into such a liquid is a method well-known to the person skilled in the art for preventing bacteria development within such a liquid and the addition of an anti-bacterial agent to the wetting liquid does not require from the person skilled in the art the exercise of inventive activity.

Auxiliary request VII - Claim 1 - Inventive step, Article 56 EPC

The arguments concerning the addition of the anti-bacterial agent to the wetting liquid presented for auxiliary request V are applicable *mutatis mutandis* also here, since the claimed shelf-life is also mentioned in D6, page 3, line 33 to page 4, line 4.

Auxiliary request VIII - Claim 1 - Inventive step, Article 56 EPC

Depending on the temperature to be applied to the different parts of the storage package during the manufacturing process, i.e. during the sterilization process, the skilled person would choose the appropriate materials for the catheter substrate and the container, in the present case a material having a melting temperature exceeding 130°C, without exercising an inventive activity.

Auxiliary request IX - Claim 1 - Inventive step, Article 56 EPC

Claim 1 according to auxiliary request IX is a combination of claim 1 according to auxiliary request VII with claim 1 according to auxiliary request VIII. Since the subject-matter of each of the latter claims does not involve an inventive step then also the subject-matter of claim 1 according to auxiliary request IX does not involve an inventive step.

Reasons for the Decision

1. *Main request - Claim 1 - Novelty, Article 54 EPC*

1.1 The appellant disputes that the following features of the subject-matter of claim 1 are known from D2:
a) the coating confers a reduced friction when wetted with a wetting liquid,

b) the coated surface of the catheter is constantly maintained in direct contact with the wetting liquid during storage,
c) the surface coating is provided on a substrate of a material having a melting temperature exceeding 100°C.

1.2 The Board cannot follow the appellant's arguments for the following reasons:

1.2.1 As regards features a):

In the field of catheter manufacturing it is common technical knowledge of the skilled person that they should have low friction properties in order to avoid or reduce pain and discomfort during insertion into the human body. It is also known that this feature of low friction is commonly achieved by a hydrophilic coating on the catheter which is wetted at the time of use or before, see D6, page 5, lines 20-32 or D7, page 7, line 25 to page 8, line 4.

The skilled person reads and interprets the disclosure of D2 in the light of this common technical knowledge. In particular, when reading the citation on page 2, lines 20 to 26 in combination with the citation on page 2, lines 3 to 6 the latter stating that the coating with a hydrophilic resin is advantageous because it enhances the compatibility with the human body and decreases the discomfort and pain due to insertion, the skilled person understands directly and unambiguously that the hydrophilic resin is used for its low friction properties, naturally when wetted, facilitating thereby insertion into the human body. It is apparent to the skilled reader of the passages on

page 2, two last paragraphs and on page 6, lines 3 to 5 of D2 that where said document discusses a catheter and its compatibility, this clearly deals with the compatibility of the catheter with body tissues due to its reduced friction surface when wetted. The containing of drugs in the coating is a separate issue. Furthermore, the Board concurs with point 3.1 (page 4, first complete paragraph) of the impugned decision, which establishes that the coating of the catheter according to the practical example 1 of D2 is made of hydroxyethyl methacrylate and that the skilled person knows that this material is a hydrophilic polymer which is preferably selected in the field of catheters for forming a hydrophilic coating having low friction properties when wetted, see eg. D10, column 1, lines 22 to 29, column 5, lines 44 to 54 and column 6, lines 16 to 24. The skilled person would therefore understand directly and unambiguously that in this example said coating has been selected exactly for that purpose.

Therefore, a coated surface which exhibits reduced friction when wetted with a wetting liquid is known from D2.

1.2.2 As regards features b):

At the end of the packaging process as described in the practical example 1 of D2, the glass tube containing the catheter is filled with an aqueous solution. The coating of the catheter is therefore in contact with a wetting liquid. Since the manufacturer would obviously not risk having parts of the coating drying out during storage and thus a catheter which is not constantly ready for immediate use, as mentioned on page 2, line 1

of D2, the skilled person derives directly and unambiguously therefrom that the coating of the catheter is constantly maintained in direct contact with the wetting liquid. Finally, the appellant did not provide any evidence for its allegation that in the practical example 1 of D2 such a small amount of liquid is present that not even a part of the coated part of the catheter is constantly in direct contact with it.

1.2.3 As regards features c):

According to lines 18 to 27 of page 7 of D2 "[a]fter the polymerization, **the hydrophilic resin tube** of external diameter 5 mm and internal diameter ca. 4 mm **was removed** from the glass tube, and unreacted monomers and the like were extracted by boiling in water for 3 days and nights. After air-drying in a clean box, **this tube** was cut to 27 cm, and after smoothing the edges, it was swelled by immersion in methanol for ca. 30 minutes, and applied onto on a 16 Fr Foley catheter onto which resin of the same composition as the tube had previously been coated by the immersion method. On air-drying in the clean box, **the tube** contracted and adhered to the catheter, and **on maintaining at 120°C for 1 hour**, it adhered more firmly to the catheter, and a Foley catheter having a thick hydrophilic resin covering layer was obtained"(emphasis added by the Board).

The Board, based on this information in D2, considers that it is clear to the skilled person not to expose a catheter substrate in combination with a previously prepared coating tube to air-drying within a clean box for 1 hour at 120°C, without having a catheter

substrate which is able to withstand a temperature of 120°C, i.e. by having a melting temperature exceeding 120°C.

Thus, feature c) is also known from D2.

1.3 All features therefore being directly and unambiguously derivable from D2, the subject-matter of claim 1 is not novel and the requirements of Article 54 EPC are not met.

2. *Auxiliary request I - Claim 1 - Inventive step, Article 56 EPC*

2.1 The appellant argued that the subject-matter of claim 1 differs from the catheter known from D6 in that

a) during storage, the whole of the urinary catheter is constantly maintained in direct contact with the wetting liquid, and in that

b) the catheter substrate has a melting temperature exceeding 100°C.

2.2 The Board is convinced that feature a) is known from D6 for the following reasons:

2.2.1 On page 6, lines 8 to 13 of D6 is stated that the hydrophilic surface coating of the catheter is prepared to activate its low friction character, prior to the arrangement of the catheter in the package or immediately following said arrangement before closing the package, by treatment with a liquid swelling medium.

According to the Board's understanding of the second alternative described in the above cited passage of D6, the swelling liquid is poured over the catheter and its coated parts when the catheter is already positioned in the package, said pouring being continued until the package is completely filled with said liquid and subsequently the package is closed. This understanding of the Board is also supported by the sentence on page 6, lines 13 to 17 stating that "[s]ince the welding seam is arranged to provide a narrow cavity around the catheter tube the amount of swelling liquid needed for preparation of the hydrophilic coating can be kept low". This can only mean that the whole cavity of the package is full of said liquid.

2.2.2 The passages on page 4, lines 19 to 27 and on page 7, lines 8 to 24 of D6 refer to the application of a film layer over the openings 4 and other parts of the catheter, so that internal and external surfaces not treated with the hydrophilic coating do not get into contact with the swelling liquid. This is not done to continuously protect these surfaces, but merely to limit the amount of liquid used to activate the low friction character of the coating (by not being present inside the catheter) to the time actually needed to perform this function, by being a material soluble by the swelling medium. The latter feature means, however, that when this required exposure time is over, the covering material will have disappeared and the entire catheter will be in direct contact with the wetting liquid, for the remainder of the shelf-life, with a sufficiently activated low friction capability.

2.2.3 Therefore, feature a) of claim 1 is also known from D6.

2.3 Concerning feature b) the Board notes that D6 does not refer to any specific material to be used for the catheter described therein. Thus, the feature of claim 1 that the substrate of the catheter has a melting temperature exceeding 100°C is not known from D6. This is then the only differentiating feature between the subject-matter of claim 1 and the storage package known from D6. The Board assumes, in favour of the appellant, that this feature allows that the catheter can be heat sterilized, even though the claim leaves it open which purpose this feature is meant to serve.

2.3.1 The objective technical problem to be solved may therefore be seen in the provision of an appropriate material for the catheter substrate coated with a reduced friction layer which withstands a heat sterilization treatment.

2.3.2 On page 1, lines 10 to 17 of D6 is mentioned that "urinary catheters of the kind to which the invention pertains are known, inter alia, from" several prior art documents. The appellant argued that the catheters disclosed in these documents were all PVC catheters, which did not resist temperatures over 100°C. Be that as it may, this merely confirms the above mentioned definition of the problem. The person skilled in the art seeking to find a catheter substrate able to withstand such temperatures has, however, more state of the art at his disposal, such as D7. D7 discusses the replacement of PVC by other materials **which can be sterilized by steam** (page 1, line 18) and which show less shrinkage than PVC (page 2, lines 18 - 20) as a

further advantage. D7, page 2, line 25 and page 6, lines 14 and 15 propose for that purpose polyether block amide. The Board notes that polyether block amide is explicitly mentioned in paragraph [0028] of the patent in suit as an appropriate material having a melting temperature exceeding 130°C.

2.3.3 Therefore, the Board comes to the conclusion that the skilled person seeking to solve the above mentioned problem, would find the solution in D7 and would apply that teaching to the catheter of D6, without exercising an inventive activity, thus arriving at the subject-matter of claim 1.

2.4 The appellant argued that the material selection for the catheter substrate according to claim 1 enables steam sterilization of the whole storage package and as a result thereof a cheaper production of said storage package, including the coated catheter. The problem to be solved was therefore finding a more economic way of producing the package with the coated catheter.

The Board cannot follow this argument because in order to apply steam sterilization, i.e. temperatures exceeding 100°C, to the whole storage package including the coated catheter not only the catheter substrate but also the hydrophilic coating and the package have to be made of a material withstanding such temperatures. Since neither for the coating nor for the package such threshold limits for their materials are present in claim 1 the problem of reducing costs as defined by the appellant cannot be considered solved by providing only the catheter substrate of a material withstanding temperatures exceeding 100°C. As these materials are

not defined and their costs are not known, the provision of said materials solely for the catheter substrate does not necessarily solve the problem defined by the appellant. In this respect said feature cannot be regarded as providing an inventive contribution to the storage package known from D6.

2.5 The appellant further argued that given the fact that catheter substrates are generally made of PVC the skilled person would not use a more expensive material like polyether block amide since this would increase the overall production costs.

This argument cannot be followed by the Board either since such considerations clearly did not exist for the persons mentioned as inventors in D7. Polyether block amide is mentioned in D7 for allowing steam sterilization and reducing shrinkage with a further advantage of a good adherence of the PVP coating on the catheter substrate (see D7, page 3, lines 19 to 23), which is one of the preferred coatings in the patent in suit, see paragraph [0020]. Apparently the higher price is offset not only by the further advantages but also by the lower sterilization costs.

2.6 For the above-mentioned reasons the subject-matter of claim 1 of auxiliary request I does not involve an inventive step.

3. *Auxiliary request V - Claim 1 - Inventive step, Article 56 EPC*

3.1 Claim 1 according to auxiliary request V differs from claim 1 according to auxiliary request I in that the

storage package comprises an outer container that encloses an inner container, the latter containing the urinary catheter, and in that the wetting liquid comprises an anti-bacterial agent.

3.2 The appellant stated during the oral proceedings that the provision of an additional outer container enclosing the container with the catheter was not a difference over D6. The Board sees this feature as a distinguishing feature over the package of D6, however not as one providing inventive step as such arrangements are well known in the art, such as D2 (page 8, lines 3 to 12), for sterilized catheters.

3.3 Given the fact that the subject-matter of claim 1 according to auxiliary request I does not involve an inventive step, see point 2.6 above, the question to be answered is whether the further provision of an anti-bacterial agent to the wetting liquid involves an inventive step.

The appellant argued that the effect of this feature is to keep the catheter sterile for a longer storage period. The Board in the following accepts this for the sake of argument, even though this purpose or effect is not claimed nor directly evident from the mere mention of such an agent.

3.4 The Board follows the respondent's argument that according to D6, page 3, lines 16 to 32 the object of D6 already is the provision of a ready-to-use storage package comprising a catheter which can be withdrawn at any time from its package and is prepared for direct insertion in the urethra in a substantially sterile

condition. Such sterile condition should be provided for a period of time up to 5 years, typically 36 months, see page 3, line 33 to page 4, line 4.

This already means that bacteria development should be prevented so that the swelling liquid and the therein embedded catheter will keep their sterility during such an extended storage period.

Adding an anti-bacterial agent into said liquid to guarantee the maintenance of sterility is a well-known method to the person skilled in the art for preventing bacteria development within such liquids. This does not require from the person skilled in the art to exercise an inventive activity.

3.5 The appellant argued that due to the addition of the anti-bacterial agent to the wetting liquid the sterilization costs are reduced, an extended shelf-life is achieved and thus a cost efficient product is accomplished. Since none of the state of the art documents proposes the addition of an anti-bacterial agent in order to achieve the above-mentioned objects the addition of the anti-bacterial agent to the wetting liquid as claimed in claim 1 involves an inventive step.

The Board cannot follow this argument. The reduction of the sterilization costs has already been discussed in point 2.5 above. The extended shelf-life, i.e. the extended storage period, has been discussed in point 3.4 above. The cost-efficiency is the simple result of both. The patent in suit, other than the mere mention of the "antibacterial agent" does not give any further information regarding this agent, nor its concentration,

which is evidence of an improvement in costs/quality over what is already achieved with the catheter of D6. Also, no relationship is established between lower sterilization costs and the anti-bacterial agent.

3.6 Accordingly, the subject-matter of claim 1 of auxiliary request V does not involve an inventive step.

4. *Auxiliary request VII - Claim 1 - Inventive step, Article 56 EPC*

4.1 Claim 1 of auxiliary request VII differs from claim 1 of auxiliary request V in that the inner container defines a cavity which encloses the whole of the urinary catheter, the supply of the wetting liquid is in a volume sufficient for the coated surface to remain constantly wetted thereby during storage and the anti-bacterial agent maintains the catheter and wetting liquid sterile during an extended storage period of 3-5 years.

4.2 According to figure 1 of D6 the cavity 11 of the package 7 encloses the whole of the urinary catheter 1 and the wetting liquid. Furthermore, according to point 2.2.1 above the supply of the wetting liquid is in a volume sufficient for the coated surface to remain constantly wetted thereby during storage. Thus, the first two features mentioned above are known from D6.

4.3 Given the fact that the subject-matter of claim 1 according to auxiliary request V does not involve an inventive step, see point 3.6 above, the issue at stake is whether the provision of the anti-bacterial agent to the wetting liquid is such that the catheter and

wetting liquid are maintained sterile during an extended storage period of 3-5 years involves an inventive step.

4.4 As it is stated on page 3, line 33 to page 4, line 4 of D6 the normally expected shelf-life is up to five years, typically 36 months, i.e. 3 years. In point 3.4 above the Board has already given its reasons why it is obvious for the person skilled in the art to add an anti-bacterial agent to the wetting liquid, to keep it sterile for this extended period. As the catheter of D6 is of the ready-to-use type, this addition is done not only to keep the wetting liquid sterile, but via that liquid also the catheter itself, during the same extended period. This means that also this feature cannot contribute to an inventive step.

4.5 Therefore, the subject-matter of claim 1 of auxiliary request VII does not involve an inventive step.

5. *Auxiliary request VIII - Claim 1 - Inventive step, Article 56 EPC*

5.1 The additional feature in the preamble of claim 1 that "the storage package comprises a container which defines a cavity which houses the whole of the urinary catheter and the wetting liquid, wherein the wetting liquid is contained in the cavity in a volume sufficient for the coated surface to remain constantly wetted thereby during storage" is known from D6, see figure 1 of D6 and point 2.2.1 above.

The storage package according to claim 1 differs therefore from the one known from D6 in that the

melting temperature for both the catheter substrate and the container exceeds 130°C. Due to said feature the catheter substrate and the container can together undergo a sterilization treatment which requires a temperature exceeding 130°C. As in point 2.3 above the Board assumes, in favour of the appellant, this to be the effect, even though this purpose is not evident from the claim.

5.1.1 The objective technical problem to be solved may be seen in the provision of a catheter substrate and a container which together can undergo a sterilization treatment at a temperature exceeding 130°C.

In points 2.3.2 and 2.5 above the Board has already given its reasons why the provision of polyether block amide as proposed in D7 for the catheter substrate in D6 solves this problem, when sterilizing the catheter. The patent in suit, paragraph [0028] states that this material has a melting temperature exceeding 130°C.

5.1.2 As mentioned in D6, page 1, line 18 to page 2, line 3 it is usual in the prior art to arrange the catheter in a corresponding container, where the container with the catheter is subsequently sterilized. The Board considers that the person skilled in the art applying the teaching of D7 to make the catheter substrate of D6 heat sterilizable will have to decide, in view of the prior art mentioned above, to make the corresponding container also of a material having a melting temperature exceeding 130°C. In fact, the container (package 7) of D6 is made of an impermeable laminated comprising aluminium foil and thermoplastic film, which is welded along a circumferential seam, see page 5,

line 33 to page 6, line 7. This is the same as what the patent in suit proposes, see paragraph [0029] and the choice of material thus reduces itself to the thermo-plastic film having a melting temperature over 130°C. Also the latter choice does not require the exercise of inventive activity.

5.2 The appellant further argued that the claimed choice of materials for the substrate of the catheter and the container, both having a melting temperature exceeding 130°C enables steam sterilization of the whole storage package and that accordingly, due to the fact that this is a cheap sterilization method, the production of said storage package in a cheaper way is enabled. Since none of the state of the art documents present on file proposes such a material selection for reducing production costs this selection as claimed in claim 1 involves an inventive step.

The Board cannot follow this argument for the same reasons as given in point 2.4 above. In order to apply steam sterilization (temperatures exceeding 100-125°C) the whole package, i.e. not only the catheter substrate and the container but also the hydrophilic coating has to be made of a material withstanding such temperatures. Since such material characteristics for the coating are not mentioned in claim 1 the problem of reducing production costs as defined by the appellant cannot be considered solved by providing only the catheter substrate and the container of a material having melting temperatures exceeding 130°C. The coating material not being defined, its costs are not known, and the provision of a material having melting temperatures exceeding 130°C solely for the catheter

substrate and the container does not necessarily solve the problem defined by the appellant. In this respect said features cannot be regarded as providing any inventive contribution to the storage package known from D6.

5.3 For the above-mentioned reasons the subject-matter of claim 1 of auxiliary request VIII does not involve an inventive step.

6. *Auxiliary request IX - Claim 1 - Inventive step, Article 56 EPC*

Claim 1 according to auxiliary request IX is a combination of claim 1 according to auxiliary request VII with features of claim 1 according to auxiliary request VIII. Since the subject-matter of each of the two latter claims has been found by the Board as not involving an inventive step, see points 4.5 and 5.3 above, also the subject-matter of claim 1 according to auxiliary request IX doesn't involve an inventive step. No combinatorial effect between the features of the claims 1 according to auxiliary requests VII and VIII was argued by the appellant and the Board finds that no such effect exists.

Therefore, the subject-matter of claim 1 of auxiliary request IX does not involve an inventive step.

7. None of the requests being allowable, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Nachtigall H. Meinders