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## Datasheet for the decision of 7 May 2014

Case Number: T 1155/13 - 3.2.02

Application Number: 05025319.4

Publication Number: 1642611

IPC: A61M25/00, A61M25/01

Language of the proceedings: ΕN

#### Title of invention:

A ready-to-use urinary catheter assembly

### Patent Proprietor:

Coloplast A/S

#### Opponents:

Hollister Incorporated Dansac A/S

#### Headword:

### Relevant legal provisions:

EPC Art. 56, 100(b), 100(c) EPC R. 80 RPBA Art. 13(1)

## Keyword:

New line of argument into the proceedings admissibility (yes) Amendments - added subject-matter (no, after amendment) Sufficiency of disclosure - auxiliary request (yes) Inventive step - auxiliary request (yes)

## Decisions cited:

T 0051/08, T 0468/09

## Catchword:



## Beschwerdekammern **Boards of Appeal** Chambres de recours

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Case Number: T 1155/13 - 3.2.02

DECISION of Technical Board of Appeal 3.2.02 of 7 May 2014

Appellant: Hollister Incorporated 2000 Hollister Drive (Opponent 1)

Libertyville, Illinois 60048-3781 (US)

Representative: Høiberg A/S

> St. Kongensgade 59 A 1264 Copenhagen K (DK)

Respondent: Coloplast A/S Holtedam 1 (Patent Proprietor)

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Party as of right: Dansac A/S

Lille Kongevej 304 (Opponent 2)

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Representative: Høiberg A/S

> St. Kongensgade 59 A 1264 Copenhagen K (DK)

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 7 March 2013 rejecting the opposition filed against European patent No. 1642611 pursuant to Article 101(2)

EPC.

#### Composition of the Board:

Chairman E. Dufrasne Members: P. L. P. Weber D. Ceccarelli

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## Summary of Facts and Submissions

The appeal of opponent 01 is against the decision of the Opposition Division posted on 7 March 2013 to reject the oppositions.

The notice of appeal was filed on 17 May 2013 and the appeal fee paid on the same day.

The statement setting out the grounds of appeal was filed on 17 July 2013.

II. The present appeal concerns European patent EP-B-1642611. The application on which it is based is a divisional application of EP-A-1145729 (parent), which itself is a divisional application of EP-A-0923398 (grandparent).

The originally filed application documents (description, claims, figures) being the same for all three applications, in the present decision the Board will refer to the application as published EP-A-1642611.

III. The claims relevant for the decision have the following wording:

Claim 1 of the patent as granted reads as follows:

"A ready to use urinary catheter assembly comprising a catheter (1) which can be withdrawn from its package (7,16) and is prepared for direct insertion in the urethra and in a substantially sterile condition, where the catheter (1) is a urinary catheter having on at least a part of its surface (2) a hydrophilic surface layer, characterized in that the package (7,16) as a

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whole is made of a gas impermeable material defining a compartment (12,19,23) and defining a cavity (11,18) for accommodating the catheter (1), said compartment (12,19,23) accommodating a liquid swelling medium, and that the swelling medium is confined in a storage body (14) of a spongy or gel-like material located in the compartment (12,19,23)."

The set of claims of the patent as granted further comprises dependent claims 2 to 12. Dependent claims 4 and 8 read as follows:

- "4. A ready to use urinary catheter assembly according to any of the previous claims, wherein the compartment (12,19,23) is entirely integrated with the cavity (11,18) for the catheter."
- "8. A ready to use urinary catheter assembly according to any of the previous claims, wherein the compartment (12,19,23) is separated from the cavity (11,18)."

In the set of claims according to auxiliary request E, claim 1 is identical to claim 1 of the main request but claims 4 and 8 have been deleted and the other dependent claims renumbered accordingly.

Claim 1 according to auxiliary request D reads as follows:

"A ready to use urinary catheter assembly comprising a catheter (1) which can be withdrawn from its package (7,16) and is prepared for direct insertion in the urethra and in a substantially sterile condition, where the catheter (1) is a urinary catheter having on at least a part of its surface (2) a hydrophilic surface layer, characterized in that the package (7,16) as a

whole is made of a gas impermeable material defining a compartment (12,19,23) and defining a cavity (11,18) for accommodating the catheter (1), said compartment (12,19,23) accommodating a liquid swelling medium, and that the swelling medium is confined in a storage body (14) of a spongy or gel-like material located in the compartment (12,19,23), wherein the compartment (12,19,23) for the liquid swelling medium is in liquid flow communication with the cavity (11,18) for accommodation of the catheter."

With respect to the main request, claims 4, 6 and 8 have been deleted and the other dependent claims renumbered accordingly.

IV. In appeal proceedings relating to the parent European patent EP-B-1114582 a first decision was taken by the present Board (T 0468/09). In that decision the Board dealt with an objection under Article 100(b) EPC and concluded that sufficiency of disclosure was given. The objecting party had submitted documents D7 and D29 (identical to D3 and D18 in the present appeal, point 4 of the statement setting out the grounds of appeal) in support of its objection.

Claim 1 of the main request in the proceedings leading to T 0468/09 reads as follows:

"A urinary catheter assembly comprising at least one urinary catheter (1) having on at least a part of its surface a hydrophilic surface layer (6) intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7,16,29,34,42,46,51,51') made of a gas impermeable material and having a cavity (11,18,39,48,53) for

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accommodation of the catheter (1,58,69), characterized in that the cavity accommodates said liquid swelling medium for provision of a ready-to-use catheter assembly."

V. Oral proceedings were held on 7 May 2014.

The final requests of the parties were the following:

The appellant (opponent 01) requested that the impugned decision be set aside and that the European patent No. 1642611 be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of auxiliary requests E and D, filed during the oral proceedings, and auxiliary requests A to C, filed with letter dated 29 November 2013, in that order.

No request was submitted by the other party (opponent 02).

VI. The following documents are cited in the present decision:

D7: US-A-5334166 D9: WO-A-96/30277

VII. The arguments of the appellant can be summarised as follows:

Main request - Added subject-matter

Claim 4 of the patent as granted required that the compartment be entirely integrated with the cavity for the catheter. This meant that claim 1 of the patent as granted was also intended to cover this particular embodiment and not only, as the wording might suggest, the embodiments in which a compartment and a cavity were defined. However, in the application as filed, when the compartment was integrated with the cavity there was no storage body. Already for this reason claim 1 contained subject-matter extending beyond the application as filed.

This line of argument was already present in the notice of opposition, so that the respondent could not be surprised. This line of argument had therefore to be admitted into the appeal proceedings.

Furthermore, the liquid swelling medium had to be transferred from the storage body to the cavity in order to activate the low friction surface. The application as filed, in the context of the embodiment according to figures 1 and 2 having a storage body for the liquid swelling medium (as defined in claim 1), required liquid flow communication between the compartment and the cavity. Liquid flow communication was needed to have the liquid flowing into the cavity around the catheter, so that this feature had to be considered an essential feature which could not be dispensed with. In claim 1 this feature of the liquid flow communication was not present, so that the subject-matter of claim 1 was an intermediate generalisation extending beyond the content of the application as filed.

Additionally, the present wording of claim 1 also covered the second series of embodiments in which the

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compartment was completely separated from the cavity with no liquid flow communication, as for instance confirmed by dependent claim 8 of the patent as granted which required the compartment to be separated from the cavity. However, these embodiments never included a storage body for the liquid swelling medium.

For the reasons above, claim 1 of the main request contained subject-matter extending beyond the content of the application as filed.

Auxiliary requests E and D - Admissibility

Auxiliary requests E and D should not be admitted into the proceedings. They did not fulfil the requirements of Rule 80 EPC, because the deletion of dependent claims 4 and 8 was not occasioned by a ground for opposition.

Auxiliary request E - Added subject-matter

The objection of the absence of fluid flow communication between the compartment and the cavity still applied to claim 1 of this request, so that this request also contained subject-matter extending beyond the content of the application as filed.

Auxiliary request D - Added subject-matter

No objection.

Auxiliary request D - Sufficiency of disclosure

The appellant agreed with the findings in decision T 0468/09.

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Auxiliary request D - Inventive step

The subject-matter of claim 1 was not inventive over a combination of document D9 with document D7. D9 represented a well-known state-of-the-art urinary catheter assembly in which water or another liquid swelling medium had to be poured into the cavity of the package in order to activate the hydrophilic surface coating of the catheter. Precisely for the wetting of hydrophilic coatings, document D7 suggested the use of a sponge through which the catheter would be drawn to activate the hydrophilic coating, and which could be stored in the package, as was explicitly mentioned in column 5 of D7. Hence, the person skilled in the art would arrive without any inventive step at the subject-matter of claim 1.

The other lines of argument relative to lack of inventive step presented in the appellant's written submissions were not maintained with respect to the subject-matter of claim 1 of auxiliary request D, as explicitly stated during the oral proceedings.

VIII. The arguments of the respondent can be summarised as follows:

Main request - Added subject-matter

The line of argument of the appellant considering the wording of claim 4 of the patent as granted should not be admitted into the proceedings because it was not in the statement of the grounds of appeal, and it was also not in the first-instance decision, so that this question could not be dealt with in an appeal.

Nothing in the wording of claim 1 suggested that the compartment and the cavity should be completely separated. Present claim 1 intended to cover the embodiments of the first series, including those in which the liquid swelling medium was anywhere in the package, as the package as a whole was made of gas impermeable material. This gas impermeability was present regardless of how the package was constructed, and if the gas impermeability was present the device would work in any case. This meant that an indication of the presence of liquid flow communication between the cavity and the compartment was not necessary and also not essential, so that it was not to be introduced into claim 1. Even if claim 1 were considered to also cover the second series of embodiments (according to claim 8 and figure 7), although there was no literal basis for a spongy storage material being used in all embodiments of this second series, the person skilled in the art would realise that such a storage medium could equally be used in all these embodiments, so that also in this case there would be no extension of subject-matter beyond the content of the application as filed.

Auxiliary requests E and D - Admissibility

Auxiliary requests E and D should be admitted into the proceedings because they dealt with precisely the objections of added subject-matter raised by the appellant shortly before the oral proceedings.

Auxiliary request E - Added subject-matter

The argumentation developed regarding the absence of the fluid flow communication feature in claim 1 of the - 9 - T 1155/13

main request still applied for claim 1 according to auxiliary request E.

Auxiliary request D - Added subject-matter

The feature of the fluid flow communication was explicitly added in claim 1 of auxiliary request D, so that in this request all objections of added subjectmatter had been dealt with.

Auxiliary request D - Sufficiency of disclosure

Decision T 0468/09 was res iudicata, so that this matter could not be discussed again.

Auxiliary request D - Inventive step

Starting from the state of the art according to document D9, the person skilled in the art had no reason to consider document D7 because it was not related to intermediate urinary catheterisation in any type of environment. And even if he considered document D7 he would not come to the solution claimed in claim 1, because the teaching of D7 was to use the sponge for transferring the wetting fluid to the catheter and not for storing the wetting fluid in the catheter assembly. Therefore the subject-matter of claim 1 was inventive over a combination of documents D9 and D7.

## Reasons for the Decision

- 1. The appeal is admissible.
- 2. Technical field of the invention and general content of the description as originally filed.

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Urinary catheters are essentially of two types: indwelling catheters which are meant to remain in the urethra for a longer period of time and which are in general inserted in hospital, and intermittent catheters which are meant for introduction into the urethra in particular by the patient for a single emptying of the bladder and then taken out again afterwards.

Intermittent catheters can further be subdivided into those lubricated with a gel or other lubricant and those with a hydrophilic surface which needs to be activated (by water or saline solution) to demonstrate its low friction properties.

With prior-art catheter assemblies of this latter type, as disclosed in D9, the patient needs water, has to pour the water into the package cavity accommodating the catheter and wait for the swelling of the hydrophilic coating in order to obtain a catheter ready for use. Depending on the quality of the water used as liquid swelling medium, risks of infection exist.

The invention as presented in the introductory part of the description [0008] aims at allowing users to prepare the catheter for use wherever they are, without the need to find water or to carry water with them in another receptacle, without the constraint of having to pour water into the package cavity containing the catheter, and without the associated risk of infection.

The general concept of the invention is to propose an assembly comprising a catheter package for accommodation of the catheter and the liquid swelling medium so that the liquid necessary to activate the low friction hydrophilic surface of the catheter is always available together with the catheter in that package.

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Of course the gas impermeability has to be adapted to the intended shelf life for such products [0010].

The original description presents two series of embodiments. In the general part of the description the first series of embodiments is described starting from paragraph [0011] and the second series of embodiments is described starting from paragraph [0022]. In the part of the description in which specific embodiments are described in more detail, embodiments of the first series are described starting from paragraph [0026] and figure 1, and embodiments of the second series are described starting from paragraph [0046] and figure 7.

The essential difference between the two series of embodiments is summarised e.g. in paragraph [0045] which reads as follows:

"Whereas, in the embodiments described so far, the compartment for the liquid swelling medium is in direct liquid flow communication with the cavity narrowly surrounding the catheter tube, which requires the package as a whole to be made of a gas-impermeable material, the compartment for the swelling liquid may alternatively be separated from the catheter cavity in such a way that the liquid flow communication there between is not established until preparation of the catheter is performed prior to the intended use. Thereby, only the swelling medium compartment itself needs to have walls of a gas-impermeable material preventing leakage of the swelling medium by diffusion, whereas the wall parts of the package surrounding the catheter may be made of a relatively cheaper liquid tight material."

## 3. Main request

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Main request - Added subject-matter

3.1 The respondent considered that the line of argument presented by the appellant and based on dependent claim 4 of the patent as granted should not be admitted into the proceedings because it was late-filed, not in the statement setting out the grounds of appeal in which the complete case should be presented, and not dealt with in the impugned decision.

According to Article 13(1) RPBA the Board has the discretionary power to admit an amendment to a party's case into the proceedings. In the present situation, considering that this argument had already been presented in the notice of opposition, that the nature of the matter does not present any complexity and that this new line of argument was filed in due time before the oral proceedings, the Board decided to admit it into the proceedings.

3.2 Dependent claim 4 of the patent as granted is directed to a urinary catheter assembly in which the compartment is entirely integrated with the cavity for the catheter. In the description of the application as filed only one embodiment is described in which the compartment is entirely integrated with the cavity for the catheter, namely the embodiment described in paragraph [0014] in which the hydrophilic surface layer of the catheter is activated immediately after completion of the production process, when the swelling medium has been introduced into the package. As already explained in point 4.4 of the reasons for decision T 0468/09, in this embodiment, not shown in the figures, the spongy body i.e. a storage body is not used, the coating or surface layer being prepared and

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activated immediately after completion of the production process. In fact in this embodiment there is no need for a storage body since the hydrophilic surface layer will be kept in its activated state in the package.

Hence, the presence in the claims of the patent as granted of dependent claim 4 depending on claim 1 necessarily means that claim 1 is also intended to extend to an embodiment in which the compartment is entirely integrated with the cavity, <u>and</u> comprising a spongy or storage body (as required by the wording of claim 1). Such an embodiment has, however, never been described in the description of the application as filed.

For this reason alone, claim 1 of the main request contains subject-matter which extends beyond the content of the application as filed.

3.3 The respondent explained that the intention was for claim 1 to cover only the urinary catheter assemblies according to the first series of embodiments described in the application as filed.

In the Board's view this cannot be inferred from the wording of the claim. The wording of the claim requires the presence of a compartment and the presence of a cavity and dependent claim 8 is specifically directed to embodiments in which the compartment is separated from the cavity. This is an indication that the subject-matter of claim 1 extends to assemblies in which the compartment is separated from the cavity, as in the assemblies according to the second series of embodiments. However, there is no general teaching in the application as filed as to the presence of a

storage body in the embodiments according to the second series.

For this reason as well, claim 1 of the main request contains subject-matter which extends beyond the content of the application as filed.

3.4 Even taking the view, as submitted by the respondent, that the present patent concentrates on embodiments requiring a cavity and a compartment, the fluid swelling medium being stored in a spongy or gel-like storage material in a compartment defined in the package, the following is observed:

Claim 1 requires "...that the package (7,16) as a whole is made of a gas impermeable material defining a compartment (12,19,23) and defining a cavity (11,18) for accommodating the catheter (1)...". In other words, not only must the package be made as a whole of gas impermeable material, but the package must also define a compartment and define a cavity. Moreover, the wording of the claim requires that the cavity accommodate the catheter and that the compartment accommodate the liquid swelling medium, this liquid swelling medium being confined in a storage body of a spongy or gel-like material located in the compartment.

In the application as filed, only two embodiments are described in which a spongy or gel-like material body is used for the storage of the liquid swelling medium, namely the embodiment according to figures 1 and 2 (and 3 to 6) and the embodiment according to figure 7. For the latter it is mentioned (in paragraph [0047]) that: "In the container 25 the swelling liquid may be confined in a spongy material in the same way as in the embodiments described above."). However, in this

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embodiment (paragraph [0046]) "...the compartment for the swelling liquid is formed by a pouch-like container 25 arranged around the proximal part 26 of the catheter tube 2 outside the hydrophilic coating 6" and "The catheter 1 and the pouch-like container 25 are arranged together in the package 29...". In other words, in the embodiment according to figure 7 the compartment is not defined by the package as required by claim 1 but is included in the package as a separate item. This embodiment, thus, does not fall under the wording of claim 1.

Hence, the only embodiments of the application as filed falling under the wording of claim 1 are those of figures 1 to 6, in which the compartment and the cavity are defined by the package and in which there is a storage body for the liquid swelling medium in the compartment. In all these embodiments there is a direct flow communication between the compartment and the cavity, so that when it is intended to prepare the catheter for use, the liquid swelling medium can be pressed out of the storage body and can flow into the catheter cavity to activate the surface layer (paragraph [0016]). This is confirmed for instance at the beginning of paragraph [0045] cited above: "...in the embodiments described so far the compartment for the liquid swelling medium is in direct liquid flow communication with the cavity ... ".

Since claim 1 does not recite such liquid flow communication between the compartment and the cavity, it extends as well to embodiments in which, although the package defines the compartment and the cavity, and a storage body is present in the compartment, the compartment and the cavity could be physically separated without forming a single space. Such

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embodiments have however not been described in the application as filed.

The respondent considered that it would be self-evident for the person skilled in the art that a storage body could be used in any of the embodiments described in the application as filed, and that the fluid flow communication feature would therefore not be necessary in claim 1.

The Board does not share this analysis. In all embodiments of the first series in which a storage body is present, the compartment and the cavity are permanently connected together to form a single space and the storage body is present to prevent the liquid swelling medium from flowing towards the cavity as long as it is not desired to activate the hydrophilic surface layer. Thus, the function of the storage body is clear. This function is technically not necessary when the compartment is completely dissociated from the cavity. In the embodiment according to figure 7, the function of the storage body possibly used (paragraph [0047]) may be related to the presence of holes on the container for sliding the latter along the catheter.

Therefore, the Board does not see why, for the person skilled in the art, it would be directly and unambiguously derivable from the application as filed that the storage body should or even only could be used in any of the embodiments disclosed, and in particular in the urinary catheter assemblies in which the compartment is completely separated from the cavity also falling under the wording of claim 1.

Also for the reasons above, the Board considers that claim 1 according to the main request contains subject-

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matter which extends beyond the content of the application as filed.

- 3.5 Hence, the ground for opposition pursuant to Article 100(c) EPC prejudices the maintenance of the patent on the basis of the main request.
- 4. Auxiliary requests E and D Admissibility

The appellant considered that auxiliary requests E and D should not be admitted into the proceedings because they did not fulfil the requirements of Rule 80 EPC in that the deletion of dependent claims 4 and 8 was not occasioned by a ground for opposition under Article 100 EPC.

The Board cannot agree with the appellant, all the more since the appellant itself has used these dependent claims to interpret the wording of claim 1 when formulating its objection under Article 100(c) EPC. These requests must therefore be considered a bona fide attempt to reply to the objections brought forward by the appellant.

Therefore the Board decides to admit these auxiliary requests into the proceedings.

5. Auxiliary request E - Added subject-matter

The set of claims according to auxiliary request E differs from the set of claims according to the main request in that dependent claims 4 and 8 have been deleted and the other dependent claims renumbered accordingly. Thus, the wording of claim 1 is identical in both requests.

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The objection related to the absence of the fluid flow communication feature raised against claim 1 of the main request is therefore still applicable to claim 1 of auxiliary request E.

For this reason, the subject-matter of claim 1 according to auxiliary request E still extends beyond the content of the application as filed, so that the patent cannot be maintained on the basis of this request. Hence, the ground for opposition pursuant to Article 100(c) prejudices the maintenance of the patent in that version.

- 6. Auxiliary request D
- 6.1 Auxiliary request D Added subject-matter

In claim 1 of this request the feature of the fluid flow communication has been added, so that the reason for the objection above is no longer present. Additional objections regarding added subject-matter have not been raised by the appellant and the Board does not see any either.

6.2 Auxiliary request D - Sufficiency of disclosure

In the present appeal an objection of lack of sufficiency has been raised by the appellant. However, decision T 0468/09 dealt with an insufficiency objection in relation to the patent granted on the basis of the parent application.

More specifically, although claim 1 of the patent granted on the basis of the parent application and claim 1 of the present patent granted on the basis of the divisional application have a different wording (as - 19 - T 1155/13

apparent above), in the decision cited above the Board considered that the embodiment of figures 1 and 2 falling under the wording of claim 1 of the present patent also fell under the wording of the claim at issue in that decision. Furthermore, documents D3 and D18 mentioned in connection with insufficiency of disclosure in the present appeal (point 4 of the statement setting out the grounds of appeal) are the same as documents D7 and D29 used by the same parties in the former appeal proceedings and mentioned in the earlier decision T 0468/09.

Hence, since decision T 0468/09 is res iudicata and dealt with insufficiency of disclosure in relation to the same embodiments, and the facts are the same, the present Board has no power to examine this objection again (T 0051/08).

## 6.3 Auxiliary request D - Inventive step

In the oral proceedings held before the Board, the appellant maintained its objection of lack of inventive step only on the basis of the combination of document D9 with D7.

The appellant started from D9 published on 3 October 1996 before the second priority date (1 November 1996), this second priority date being that valid for present claim 1 at least because of the presence of the spongy of gel-like storage material in the compartment, which was only disclosed in that second priority document. This was not disputed by the parties.

D9 discloses a urinary catheter kept in a package which has to be opened before use. Once opened, sterile water or tap water has to be poured into the assembly (page

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7, line 23 to page 8, line 10, figure 5), and the whole is left for 30 seconds so as to activate the low friction surface. The catheter is then ready for use.

Hence, in the terms of the present claim, D9 discloses a urinary catheter assembly comprising a catheter which can be withdrawn from its package and is prepared for direct insertion in the urethra and in a substantially sterile condition, where the catheter has on at least a part of its surface a hydrophilic surface layer.

The distinguishing features are the following features:

- the assembly is a ready-to-use catheter assembly;
- the package as a whole is made of a gas impermeable material;
- the package defines a compartment and defines a cavity for accommodating the catheter, said compartment accommodating a liquid swelling medium;
- the swelling medium is confined in a storage body of a spongy or gel-like material located in the compartment;
- the compartment for the liquid swelling medium is in liquid flow communication with the cavity for accommodation of the catheter.

The objective problem solved by these differentiating features can be seen as to improve and facilitate the performance of intermittent urinary catheterisation in any type of environment and in a substantially sterile condition (paragraph [0008] of the patent).

The appellant considered that document D7 would lead the person skilled in the art in an obvious manner to the claimed subject-matter. It considered that D7 suggested the use of a sponge to wet a hydrophilic coating and in column 5, lines 47 to 50, D7 even

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suggested that the wetting apparatus could be packaged together with the catheter. This would also bring the person skilled in the art to use the sponge disclosed in D7 for storing water inside of the assembly according to D9.

The Board does not share this opinion. D7 discloses a wetting device for wetting medical guide wires or catheters having an outer coating of hydrophilic material which provides a slippery surface when activated by a wetting fluid. This wetting device essentially consists of two tubular parts connected together, one having a larger diameter than the other. Inside the tubular part with the larger diameter an absorbent material is present. This larger diameter part also includes longitudinal slots, so that its cylindrical walls can be compressed onto the absorbent material. When it is desired to wet a catheter or a quidewire the wetting device is wetted by dipping it into the desired wetting fluid to allow the absorbent material to soak up the wetting fluid. The wetting device can then be put onto the guidewire or the catheter, and the quidewire or catheter can then be drawn through the absorbent material of the wetting device in order to wet the hydrophilic coating (e.g. column 6, lines 20 to 22, column 7, lines 60 to 64). It is further indicated in column 5, lines 47 to 52 that such a wetting device may be packaged together with various catheters or quidewires.

In the Board's opinion, it follows that even if the person skilled in the art looked at document D7, this would at most bring it to package together with the urinary catheter disclosed in document D9 a wetting device according to document D7. Document D7 still does not suggest to build the package as a whole from a gas

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impermeable material, to define a compartment and a cavity in this package, to have the wetting material wetted with the liquid swelling medium in this compartment, and to have the compartment and the cavity in liquid flow communication.

For the reasons above, the subject-matter of claim 1 is inventive within the meaning of Article 56 EPC.

## 7. Adaptation of the description

The appellant considered that the second sentence in paragraph [0009] of the description of the patent in suit should also be deleted, as it suggests the presence of a separate compartment having walls of gas impermeable material.

The Board does not share this opinion, because the second sentence of paragraph [0009] cannot be read in isolation from the first sentence of the same paragraph. This first sentence makes it clear to the reader that a urinary catheter assembly according to the invention is characterised in that it contains the features of claim 1. In other words, the second sentence of this paragraph must be read as a consequence of the first one, namely that, because the package as a whole is made of gas impermeable material, as required by claim 1, in particular the walls of the compartment are of gas impermeable material so that it can accommodate this liquid swelling medium.

Therefore the second sentence of paragraph [0009] does not have to be deleted.

8. For the reasons above, the claims according to auxiliary request D, together with the adapted

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description and the drawings filed during the oral proceedings, fulfil the requirements of the EPC.

#### 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 with the order to maintain the patent on the basis of:
- claims 1 to 9 of auxiliary request D;
- columns 1 to 7 of the adapted description; and
- figures 1 to 6,

all filed during oral proceedings.

The Registrar:

The Chairman:



D. Hampe E. Dufrasne

Decision electronically authenticated