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**Datasheet for the decision
of 23 March 2012**

Case Number: T 2125/10 - 3.2.02

Application Number: 97918923.0

Publication Number: 0923398

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:

A ready-to-use urinary catheter assembly

Patent Proprietor:

Coloplast A/S

Opponents:

Hollister Limited
Manfred Sauer GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes)"

Decisions cited:

T 1574/05, T 1917/06

Catchword:

-



Case Number: T 2125/10 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 23 March 2012

Appellant: Coloplast A/S
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 30 July 2010
revoking European patent No. 0923398 pursuant
to Article 101(3)(b) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal of the patent proprietor was filed against the decision of the Opposition Division posted on 30 July 2010 to revoke the patent.

The notice of appeal was filed on 7 October 2010 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 9 December 2010.

- II. Oral proceedings took place on 23 March 2012.

- III. The Appellant requested as main and only request that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 14 November 2005.

Respondent 3 (Opponent 3) requested that the appeal be dismissed.

Respondent 4 (Opponent 4) requested that the appeal be dismissed.

- IV. A first decision, T 1574/05, was taken on 18 December 2008 by the Board following a first appeal against a first decision of the Opposition Division in the opposition proceedings against the same patent.

In that decision the Board established that claim 1 of the main request (the same as in the present appeal) complied with Article 123(2) and (3) EPC, that both intermediate document D25 and document D11/D11A did not anticipate the subject-matter of claim 1 and that the

subject-matter of claim 1 was inventive over the combination of documents D12/D12A and D8 and over the combination of documents D8 and D12/D12A.

The Board then remitted the case to the first instance for further prosecution.

V. In the subsequent and impugned decision, the Opposition Division held that the subject-matter of claim 1 was not inventive in view of the combinations of documents D28 and D8 (with reference to D44 and D12) in a first line of argumentation and over the combination of documents (D8 or D10) and (D9 or D28) in a second line of argumentation.

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

D8: US-A-3967728
D9: WO-A-86/06284
D10: EP-A-0677299
D11: JP-A-55-12265
D11A: English translation of D11
D12: CN-A-1106744
D12A: English translation of D12
D25: WO-A-97/26937
D26: WO-A-96/30277
D28: Brochure "LoFric®"
D42: Expert report of Mrs A.M. Winder of
13 September 2005
D44: Expert report of Mr M.Svanum of 15 September 2005
D46: Witness statement of Mrs C.R. Hartkopp of
12 September 2005

D47: Witness statement of Mrs C.R. Hartkopp of
October 2005.

VII. Claim 1 according to the main request reads as follows:

A urinary catheter assembly comprising at least one urinary catheter (1, 58, 69, 77, 81, 102) 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 (16, 29, 34, 42, 46, 51, 51', 101) having a cavity (39, 53, 57, 74) for accommodation of the catheter (1, 58, 69, 77, 81, 102), characterized in that:

the package (16, 29, 34, 42, 46, 51, 51', 101) is closed, made of a liquid tight material, and includes a compartment (25, 31, 35, 40, 47, 54, 54', 56, 63, 64, 71, 78, 82, 89, 95, 105) having walls of a gas impermeable material,

the compartment (25, 31, 35, 40, 47, 54, 54', 56, 63, 64, 71, 78, 82, 89, 95, 105) is separated from the cavity (39, 53, 57, 74) for accommodation of the catheter (1, 58, 69, 77, 81, 102), and

the swelling medium is confined in said compartment (25, 31, 35, 40, 47, 54, 54', 56, 63, 64, 71, 78, 82, 89, 95, 105) in a liquid state until the intended use of the catheter for provision of a ready-to-use catheter assembly.

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

It was important to understand what kind of catheter the invention was concerned with. There were two main categories of catheters: indwelling catheters and intermittent catheters. Indwelling catheters were soft catheters which remained in the body for a longer period of time, e.g. about 2 months. They could not be too slippery in order to avoid the risk of them slipping out during use. Further, they needed to be inserted by trained medical staff in a hospital or controlled environment. With this kind of catheters the patients would never be faced with the problem of emptying their bladder, because the catheter was "permanent".

The second category of catheters were so-called intermittent catheters. They were considerably narrower and were used in response to the need of the patients to empty their bladder.

Intermittent catheters could be of two kinds: the so-called gel catheters and the hydrophilic catheters. In the first category of catheters a lubricant, in general a gel, was put on a surface of the catheter before introduction into the urethra. In the second category a hydrophilic surface needed to be activated to expose its low friction property before the catheter could be used.

It was clear from the description of the patent in suit that the invention was concerned with this second type of intermittent catheters. This could be seen for instance in paragraphs [0004], [0006], [0007] of the

patent. This kind of catheter could not be left in the body because after a while its surface became sticky. Although there was no explicit reference to intermittent catheters in the claim, when reading the claim in the light of the description the person skilled in the art would have no doubts that the claim concerned an assembly with an intermittent catheter with a hydrophilic surface. The claimed catheter clearly required a hydrophilic surface which had to be activated before use.

Such catheters with hydrophilic surfaces, as for instance disclosed in D28, had some drawbacks, as explained for instance in document D46: the water could be messy and pouring water into the assembly needed some dexterity. Paragraph [0007] of the patent explained these problems. It was to be noted that these problems were only encountered by the users themselves during self-catheterisation. In a hospital environment these problems did not exist.

The present case was very similar to the case T 1917/06 decided by the Board. As in that case, only an assembly with an intermittent catheter having a hydrophilic surface as for instance disclosed in D28 could be the closest prior art. This was in line with the established jurisprudence of the Boards of Appeals that the closest prior art should be as close as possible to the invention, mostly have the same or a very similar structure and exhibit the same or similar technical problems.

When using an assembly as disclosed in D28 the patient needed to have access to water and he/she had to have

the necessary dexterity to pour the water into the package.

With the present invention the handling was simplified, the risk of spillage was obviated, water quality could be guaranteed and the amount of water necessary for a swelling of the hydrophilic coating could be guaranteed.

Hence, the objective problem could be defined as one of facilitating safe and reliable activation of the hydrophilic coating in any environment.

The solution to this problem was not obvious because nothing in the cited prior art prompted the person skilled in the art to the solution. The problem was only associated with hydrophilic catheters as was also the case in decision T 1917/06. The combination with document D8 made by the Respondents was therefore a typical example of an ex-post analysis. D8 had nothing to do with intermittent catheters, on the contrary it was concerned with indwelling catheters. As already mentioned such catheters were placed by physicians or nurses in a controlled environment. Hence, the person skilled in the art had no reason to expect a solution to his problem in this document.

It was noteworthy that not a single document cited by the Respondents referred to both hydrophilic and gel catheters. This was a clear indication that for the person skilled in the art they were not perceived to be related to similar problems.

The commercial success of the catheter assembly according to the invention was an additional indication for its non-obviousness.

The submission of the Respondents that the objective problem would be the sterility of water was not realistic. Catheters coated with hydrophilic surfaces, such as LoFric of D28, had existed for more than 13 years and sterility of water had never been a problem.

The subject-matter of claim 1 therefore was inventive.

IX. The arguments of Respondent 3 can be summarised as follows:

There was neither a definition of the users nor was there any stiffness limitation in the claim.

Starting from D28 as the closest prior art it was accepted that the first part of the claim was known from the document. In addition the disclosed package was also necessarily liquid tight.

The objective problem solved by the provision of a separate compartment with the swelling medium was to guarantee sterility.

The preservation of sterility was a constant concern in the medical field as was discussed for instance in D8 col.1 lines 23 to 26 and lines 30 to 33. This was also the problem addressed in paragraphs [0007] and [0008] of the patent in suit. It was to be noted that D8 was among the documents listed in the introductory part of

the patent in suit, which demonstrated that even the Appellant associated the two technologies. As was mentioned in document D44 point 20, the same technicians develop gel catheters and hydrophilic catheters so that there was no reason for the person skilled in the art not to seek a solution in D8. D8 disclosed a separate compartment for the lubricant within the catheter assembly to guarantee access to sterile lubricant at any moment. This prompted the person skilled in the art to apply the same teaching to the assembly according to D28 and, hence, to put a pouch of water into the assembly shown in D28 to solve the problem of sterility. In addition the use of the verb "flow" in col.3 lines 32 to 35 of D8 was an additional indication that already in the device according to document D8 the lubrication was done with a liquid so that the step of putting water into the pouch rather than the lubricating liquid was even smaller.

Conversely, when starting from document D8 as the closest prior art, there could be nothing inventive in replacing the lubricated catheter by a hydrophilic catheter with the appropriate lubricant. This was a simple alternative the person skilled in the art would use if he wished to pack a hydrophilic surface catheter in an assembly.

Hence, the subject-matter of claim 1 was not inventive.

- X. The arguments of Respondent 4 can be summarised as follows:

The claim was not limited to intermittent catheters and, in any case, it was not sufficient to indicate an application of the device without defining the additional features which made the device suitable for this application. The line of argument of the Appellant was therefore not supported by the structural features of the claimed assembly.

The problem had to be seen in a much simpler way. Whether gel catheters or hydrophilic catheters, these catheters needed an additional element because they did not exhibit a low friction surface in their normal condition. Whether the additional element was water or gel was not decisive, it always had to be sterile. In this context it could not be argued that for each type of catheter there was a different person skilled in the art. The person skilled in the art was the same for both types of catheters.

In addition to what Respondent 3 already mentioned, it should be noted that when starting from D28 the person skilled in the art was already motivated to look for an improvement in sterility since the sterility of water was already mentioned on page 9 of D28. Therefore, he would refer to the associated pouch according to D8.

As to the line of argumentation starting with document D8 as closest prior art, it was to be noted that the teaching of this document was exactly the same as the present invention since document D8 taught using a separate pouch for the gel in order to always have a sterile gel at the disposal of the nurse or physician wishing to use a urinary gel catheter.

One obvious reason why the person skilled in the art would wish to replace the gel catheter with a hydrophilic catheter in the assembly disclosed in document D8 was the fact that the lubricant used with gel catheters was quite oily and easily stained the clothes of the nurses or physicians, which was an unpleasant situation in hospital in particular when the physician had to visit several patients. To avoid this staining the use of a catheter activated with water was self evident.

Hence the subject-matter of claim 1 was not inventive.

Reasons for the Decision

1. The appeal is admissible.

Technical field

2. 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 placed at hospital and intermittent catheters which are meant for introduction into the urethra by the patient for a single emptying of the bladder and then taken out again after the emptying. The intermittent catheters can further be subdivided into catheters being lubricated with a gel or another lubricant and catheters having a hydrophilic surface which needs to be activated (by water or saline solution) to demonstrate its low friction properties. With prior art catheter assemblies comprising this latter type of catheter, as for instance shown in D28,

the patient has to pour water into the package cavity accommodating the catheter and wait for the swelling of the hydrophilic coating in order to obtain a catheter ready to use.

The claimed assembly comprises both a urinary catheter with a hydrophilic surface and a separate compartment comprising the swelling medium. This assembly allows patients to prepare the catheter for use wherever they are without the need to find water or to carry water with them in another recipient, and without the constraint of having to pour water into the package cavity containing the catheter.

Inventive step

3. In their submissions in the present appeal proceedings the Respondents essentially presented two lines of argument, one line starting from the prior art according to D8 (or similar assemblies e.g. from D10) as closest prior art and one line starting from D28 (or similar assemblies e.g. from D26) as closest prior art.
4. As already indicated the invention concerns a urinary catheter assembly with an intermittent urinary catheter having a hydrophilic coating which requires activation before use.

This is clear from several passages of the description. Already in paragraph [0001] of the patent in suit it can be read: "*This invention relates to at least one urinary catheter assembly comprising a urinary catheter having on at least a part of its surface a hydrophilic surface layer intended to produce a low friction*

surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter...".

In the opinion of the Board the fact that the low friction surface should be produced prior to use is already a clear indication that the invention is concerned with intermittent catheters.

In the introductory part of the patent this is specifically repeated several times. In paragraph [0004]: *"An important feature of any urinary catheter used for intermittent catheterisation of the bladder ..."*; paragraph [0006]: *"When catheters of this kind are used directly by the users outside the medical environment of a hospital or a clinic..."* ; paragraph [0007]: *"In order to reduce the risk of infection inherent with the performance of intermittent catheterisation..."* ; paragraph [0008]: *"On this background, it is the object of the invention to improve and facilitate the performance of intermittent urinary catheterisation..."*. This is again repeated for instance in paragraph [0026] in which the embodiments shown on the figures are described: *"In the embodiment shown in figures 1 and 2 the urinary catheter assembly of the invention is intended for intermittent catheterisation..."*.

Claim 1 further recites in its preamble that the assembly comprises a *"catheter having on at least a part of its surface a hydrophilic surface layer 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 in the characterising portion that *"the swelling medium is confined in said compartment in a liquid state until the intended use of the catheter for provision of a ready-to-use catheter assembly"*.

Thus, in the opinion of the Board it is amply clear for the person skilled in the art reading the patent in suit that the claimed invention is concerned with an assembly comprising an intermittent catheter having a hydrophilic surface to be activated before use.

5. It is established jurisprudence of the Boards of Appeal that the closest prior art should be an object of the same type as that claimed, preferably exhibiting the same kind of technical problems as those solved by the invention (Case Law of the Boards of Appeal, 6th edition 2010, I.D.3).

Hence, in the opinion of the Board, only an assembly comprising an intermittent urinary catheter having a hydrophilic surface layer producing a low friction surface when activated can be the closest prior art. In this respect the Board concurs with the analysis made in T 1917/06 under point 6.1.

In particular, this means that an assembly comprising a urinary catheter with a low friction surface obtained with gel or lubricant as disclosed in D8 cannot be the closest prior art.

D28 discloses a catheter assembly of the type claimed. Although D28 does not have an exact publication date, the parties (in particular the patent proprietor) accept that D28 discloses a catheter assembly which was known before the priority date of the patent in suit.

D28 discloses a urinary catheter in a package which has to be opened before use. Once opened, sterile water or

tap water is poured into the assembly (Directions for use), the whole is left for 30 seconds so as to activate the coating. The catheter is then ready to use.

Hence, in the terms of the claim, D28 discloses a urinary catheter assembly comprising at least one urinary catheter having on at least a part of its surface a hydrophilic surface layer 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 having a cavity for accommodation of the catheter.

Thus, the preamble of claim 1 is known from D28. This was not disputed by the parties.

The package of D28 is also closed until used and it must be made of liquid tight material since it is meant to contain water when the coating is to be activated.

6. Consequently, the distinguishing features are the remaining features of the characterising portion:
 - the package includes a compartment having walls of a gas impermeable material,
 - the compartment is separated from the cavity for accommodation of the catheter, and
 - the swelling medium is confined in said compartment in a liquid state until the intended use of the catheter for provision of a ready-to-use catheter assembly.

The swelling medium is thus always present as a part of the claimed assembly and is separated from the cavity accommodating the catheter so that the latter is maintained dry before use. The swelling medium is kept in a separate compartment having walls of a gas impermeable material so that the swelling medium cannot evaporate or be contaminated by any gas in the environment of the package.

The effects of these distinguishing features are the following:

- the patient can use the catheter without having to find an appropriate source of swelling medium ;
- the whole set is potentially easier to use by patients with poor dexterity as there is no need to pour the swelling medium into the package cavity accommodating the catheter ; and
- the catheter is potentially more sterile when used as the swelling medium can be kept sterile in the compartment.

7. Thus, the problems arising during use of the prior art assemblies and mentioned in paragraphs [0006] and [0007] of the patent or in D46 are potentially solved by the claimed assembly: the problem of having to find water to activate the coating is solved as the necessary water is part of the assembly. The water in the separate compartment can be sterilised so that potential problems with sterility are avoided. Finally, since the compartment containing the water is part of the assembly, a direct flow of the water into the package cavity containing the catheter is allowed, so

that the difficulties of filling this cavity with water from the tap are eliminated.

Thus, the objective problem can be seen as one of how to improve the usability in any environment of an assembly comprising a hydrophilic urinary catheter, particularly as far as the activation of the hydrophilic surface is concerned.

8. In the opinion of the Board none of the cited documents suggests the specific features mentioned under point 6. above, amounting to creating a separate compartment in the assembly (already comprising an intermittent catheter with a hydrophilic surface coating) in which the necessary swelling medium is stored until the catheter is used.

The state of the art solution suggested to patients when availability or quality of water was a difficulty is mentioned in D42 or D47, namely for the patient to take along a small bottle of sterile or mineral water. However, this is far away from suggesting the provision of a separate compartment for the swelling medium in each single assembly.

Contrary to the opinion of the respondents, the solution to the objective problem can in any case not be found in the field of the urinary catheters using gel as lubricant already because with this type of catheter the problem of having to find the gel and pour it into the package cavity accommodating the catheter in order to activate a low friction surface is not present.

9. The Respondents considered that the objective problem was to improve the sterility of water and that this problem was also at the origin of the invention in D8, as mentioned in the introductory part of that document col.1, lines 30 to 34.

The Board cannot follow this line of argument. As already indicated, D28 concerns a hydrophilic catheter and specifically mentions that, when not at hospital, water can be taken at the tap: "*Fill the pack nearly to the top with, for example, sterile water or saline in hospital and mains tap water at home*" (Directions for use, step 2). This is a clear indication that the sterility of water was not considered a major problem for the use of the intermittent catheter disclosed in D28.

D8 discloses a catheter of another type, namely one with a surface to be lubricated with a lubricant prior to use instead of a hydrophilic surface to be activated with a swelling medium. D8 addresses a problem which is typical for hospital environments in which the sterility requirements are more important and more stringent than elsewhere. More care must be taken in hospital environments because the risks for operated and/or weak patients are much higher than for normal healthy persons. It is in this specific context that the sterility of the lubricant is addressed. Nowhere in D8 is the problem of sterility ever addressed in broad terms, let alone in association with water.

In the opinion of the Board there is no reason why the person skilled in the art would take this document into account in order to find a solution to a problem arising with an intermittent catheter having a

hydrophilic surface to be activated with a swelling medium, in particular water. Contrary to the lubricants used in order to lubricate the catheter according to D8, water is available almost everywhere. It is available in any toilet, more generally at the tap and if necessary it can easily be bought in bottles and transported together with the catheter.

Further there is no need to pour the lubricant into any package cavity accommodating the catheter in order to activate the low friction surface.

Hence, there is no reason why the person skilled in the art would envisage finding a way to improve the usability of an intermittent catheter with a hydrophilic surface in document D8.

In addition, the catheter disclosed in D8 is an indwelling catheter and not an intermittent catheter as it appears from several passages of that document.

In particular in col.1, lines 30 to 34, the example which is given is that of a physician giving emergency treatment which may require the use of a catheter.

However, in emergency situations when the patient is unconscious and/or is to be operated on it is not a single emptying of the bladder which is necessary, but a catheterisation for a certain length of time. Also in col.3, lines 20 to 25 it is mentioned that the nurse or physician would squeeze the pouch or roll the pouch containing the lubricant.

Accordingly there is no doubt that the catheter described in D8 is an indwelling catheter. This is a further reason why the Board does not think that the person skilled in the art would seek an improvement in the usability of a hydrophilic intermittent catheter in

a document dealing with indwelling catheters needing a lubricant.

10. The Respondents further considered that the sentence in D8, col.3, lines 33 to 35 that *a channel is formed adjacent to the catheter which promotes the flow of the lubricant there along* would support that a liquid lubricant would be used and would flow into the adjacent cavity housing the catheter and thus make the step of replacing the lubricant by water even more obvious.

In the assembly according to D8 the catheter 12 is positioned on a substrate 10 as paperboard before it is shrink wrapped in a transparent thermoplastic film (col.2, lines 8 to 12 and lines 29 to 32). The passage referred to by the Respondents relates to the way the catheter is packed. When a shrink-wrap is used as a protection shield around the catheter, in its shrunk state, it will come quite close to the exterior surface of the catheter and form a channel adjacent the catheter which will help the lubricant going close to the surface of the catheter to be lubricated when the lubricant is forced out of the pouch by the nurse or the physician, as explained col.3 lines 20 to 25. However, this does not mean that the lubricant will flow like a liquid along the catheter.

11. Respondent 3 further submitted that according to D44, point 20, the same department of the Appellant's firm developed intermittent catheters with gel lubrication as well as intermittent catheters with hydrophilic surfaces. This would be evidence that the person skilled in the art would automatically consider both

types of catheters or catheter assemblies for any development and seek a solution to the objective problem related to hydrophilic catheters in the field of gel catheters as disclosed in D8.

Apart from the reason given above as to why the person skilled in the art would not seek a solution in D8, such kind of arguments cannot lead to an objective assessment of inventive step. The presence or absence of inventive step would namely depend on the structure of a department or firm i.e. on whether or not several product lines are developed or not in the same department. The reason why a particular firm chooses to develop a product or another and in which internal department cannot play any role when it comes to an objective assessment of inventive step.

12. In the same context, and contrary to the opinion of the Respondents, the fact that document D8 is mentioned in the introductory part of the patent is not sufficient to establish that for the person skilled in the art gel catheters and hydrophilic catheters are equivalent and are developed by the same people and, hence, to combine the teaching of D8 with the assembly disclosed in D28 would be obvious.

In the introductory part of the patent in suit D8 is cited in a list of documents dealing with urinary catheter assemblies. If the Respondents were correct in their assumption then any combination of documents cited in any introductory part of the description of the patent would be obvious for the person skilled in the art just because the documents were cited by the then applicant.

The Board does not endorse this analysis, since such a way of assessing inventive step cannot be objective.

13. For the sake of completeness the Board wishes to reply to the argument of Respondent 4 that starting from D8 as closest prior art, it would be obvious for the person skilled in the art to change the type of catheter in the package since it is well known that the oily lubricant used in relation with the type of catheters disclosed in D8 would regularly stain physicians' and nurses' clothing. The person skilled in the art would therefore replace the catheter disclosed in D8 by a catheter having a hydrophilic surface with whose such problems do not arise because the activating medium is water.

As already explained above the Board is of the opinion that the catheter assembly disclosed in D8 cannot be the closest prior art.

In any case even if the person skilled in the art started from a catheter assembly as disclosed in D8 the Board does not accept that the concept of a gel catheter would be dropped when trying to improve or further develop such a catheter assembly. In the opinion of the Board this cannot be an obvious development. There are many things the person skilled in the art could do or try to do before abandoning the general concept of gel catheters such as improving the quality of the lubricant or the way it is put on the catheter, etc.

14. Hence, on the basis of the documents and arguments on file, the subject-matter of claim 1 according to the main request is inventive.
15. The Respondents had neither objections against the adapted set of sub-claims nor against the adapted description or figures.
The Board does not see any either.

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 22 of the main request filed on 14 November 2005;
 - Description, columns 1 to 12 filed on 6 October 2005; and
 - Figures 1 to 23 filed on 6 October 2005.

The Registrar:

The Chairman:

A. Counillon

E. Dufrasne