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**Datasheet for the decision
of 21 June 2017**

Case Number: T 0166/16 - 3.2.02

Application Number: 05027158.4

Publication Number: 1647298

IPC: A61M25/00, A61M25/01, A61L29/08

Language of the proceedings: EN

Title of invention:
A ready-to-use urinary catheter assembly

Patent Proprietor:
Coloplast A/S

Opponent:
Hollister Incorporated

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 87, 89

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

T 1504/05, T 1917/06, T 0468/09, T 2125/10, T 0801/13,
T 1155/13, T 1477/15

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 0166/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 June 2017

Appellant: Hollister Incorporated
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
16 November 2015 concerning maintenance of the
European Patent No. 1647298 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal of the opponent is against the decision of the opposition division posted on 16 November 2015, finding that, account being taken of the amendments made by the patent proprietor according to Auxiliary Request 1, the patent and the invention to which it related met the requirements of the EPC.

The notice of appeal was filed on 25 January 2016 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 23 March 2016.

- II. Oral proceedings were held on 21 June 2017.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of Request B filed with letter dated 21 April 2017.

The respondent's former main request to have the patent maintained in the amended form allowed by the Opposition Division, was withdrawn during oral proceedings.

- III. Documents cited in the present decision:

D1: WO-A-97/26937;

D1P: SE9600276-1;

D2: JP-B2-55-12265;

D2A: English translation of D2;

D3: WO-A-96/30277;
D4: US-A-3967728;
D5: DE-A-2317839.

- IV. The patent in suit is based on divisional application 05027158.4, filed on 13 December 2005, of divisional application 05025319.4 (EP-A-1642611), filed on 21 November 2005, of divisional application 01114582.8 (EP-A-1145729), filed on 18 June 2001, of parent application 97918923.0 (EP-A-0923398), filed on 18 September 1997.

The present Board has already taken a number of decisions in relation to several of the cases mentioned above:

on EP-B-0923398: T 1574/05 and T 2125/10;
on EP-B-1145729: T 0468/09, T 0801/13 and T 1477/15;
on EP-B-1642611: T 1155/13.

- V. Claim 1 according to request B reads as follows (amendments to the granted version underlined by the Board):

"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 closed catheter package (7, 16, 29, 34, 42, 46, 51, 51') made of a liquid tight film material having a cavity (11, 18, 39, 48, 53) for accommodation of the catheter (1, 58, 69), characterized in that the package (7, 16, 29, 34, 42, 46, 51, 51') includes a compartment (12, 19, 25, 30, 35, 40, 47, 54, 54', 56, 64, 71, 78, 82) having walls of a gas impermeable material, said compartment (12,

19, 25, 30, 35, 40, 47, 54, 54', 56, 64, 71, 78, 82) accommodating said liquid swelling medium for provision of a ready-to-use catheter assembly, where the compartment is in the form of a rupturable pouch (56) or an compressible ampoule (54) closed by a breakable closure device and arranged in the cavity (57) and the compartment is separated from the 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."

Dependent claim 6 of the request allowed by the Opposition Division has been deleted.

VI. The arguments of the appellant (opponent) can be summarised as follows :

Novelty in view of D1

D1 was prior art to be considered for the examination of novelty because its priority date was valid. For a priority to be valid, it was not necessary for all the features to be explicitly disclosed in the priority document. It had already been decided in T 1917/06, Reasons, 4, that the priority of D1 was valid and D1 anticipated the subject-matter of claim 1.

Novelty in view of D2

Since claim 1 of D2 included the option of the therapeutic drug being contained in a sealed cavity, it anticipated the feature of the "rupturable pouch" in claim 1 of the patent in suit. Since D2 also disclosed all the other features of claim 1, it anticipated the claim's subject-matter.

Inventive step

Starting from D3 the person skilled in the art wishing to improve sterility would take over the rupturable pouch disclosed for the same purpose in D4 or D5, and so the subject-matter of claim 1 was not inventive.

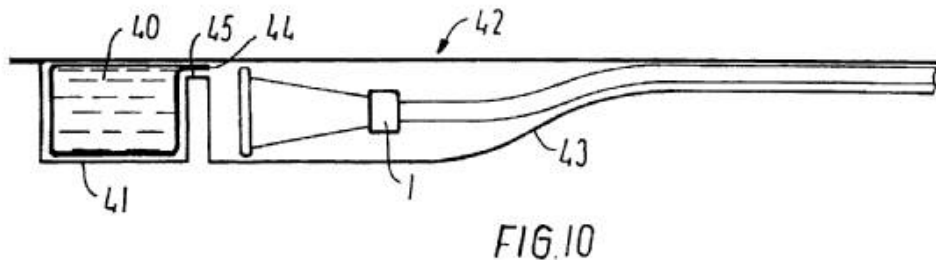
VII. The arguments of the respondent (patent proprietor) are essentially those underlying the reasons for this decision as set out below.

Reasons for the Decision

1. The appeal is admissible.
2. The invention

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 D3, 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 invention concerns an assembly which comprises both a urinary catheter with a hydrophilic surface to be activated and a separate compartment, more precisely an ampoule or a pouch, containing the liquid 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 receptacle, and without the constraint of having to pour water into the package cavity containing the catheter.



3. Novelty

It was common ground between the parties that the first priority of the patent in suit was not valid, and so the relevant date for examining the novelty of the subject-matter of claim 1 was the filing date of the second priority document, 1 November 1996.

3.1 Novelty in view of D1

Document D1 was filed on 22 January 1997 with a priority date of 25 January 1996. The priority date of the patent in suit being 1 November 1996, D1 can only belong to the prior art to be taken into consideration for examining novelty, if its own priority is valid.

As accepted by the parties, the key feature for determining whether the priority is valid is the

feature of the package being closed. This feature is in claim 1 of Request B, and explicitly in D1 (page 11, lines 26, 27), but not explicitly in D1P.

In this matter the Board agrees with the analysis under point 5.1 of decision T 1574/05 concerning a patent based on a divisional application of the same family and in which the main claim also contained the feature of the package being closed. In that decision D1 was numbered D25.

Point 5.1 of decision T 1574/05 reads as follows:

"5.1 D25 is an earlier European application published after the priority date of the contested patent. It is therefore prior art under Article 54(3) and (4) EPC, provided that its priority date is valid, i.e. that priority document D25P discloses the same invention as that described in D25 (Article 87(1) EPC).

D25 discloses a wetting apparatus for wetting a hydrophilic catheter having a water-containing sachet 6 incorporated in a urine collection bag 1 (see Figure 1). The collection bag is provided with an inlet 14 for introduction of the catheter 3 (see page 10, lines 6 to 7). Alternatively, the bag may be provided with a closed end in place of the inlet 14 (see page 11, lines 26 to 27).

Therefore, there is no doubt that D25 discloses a closed package as recited in Claim 1 in dispute.

Priority document D25P is much more succinct. In the one and only drawing, the "inlet" has no reference number. The side view does not enable to ascertain whether the inlet is open or closed. While the bag described in D25P is sterilised using the same sterilising gas (ethylene oxide) (see page 3, lines 19 to 21) as that used in D25, the sterilisation operation alone does not allow to conclude

with certainty whether the "bag" is open or closed, since it depends principally on the meaning of the term "sterilisation", which is not further defined in the document.

Under established case law, a claimed feature may be entitled to a priority date only if it is derivable directly and unambiguously from the priority document (G 2/98). A document should therefore not be interpreted on the basis of additional evidence or general knowledge going well beyond the scope of the document to be interpreted. This is particularly true with respect to the interpretation of the expression "sterile conditions" mentioned in D25P, from which it thus cannot be deduced that the bag is closed. As a consequence, D25 is not entitled to the priority date of D25P, and does not belong to the state of the art."

The appellant (opponent) further argued that the priority of D1 had been considered to be valid
T 1917/06.

However, the main claim in that decision did not contain the feature of the package being closed which is at stake in the present case, and so that decision has no relevance for the present decision.

As a consequence, D1 is not entitled to the priority of D1P, pursuant to Article 87 EPC, and so D1 is not to be taken into account when examining the novelty of the subject-matter of claim 1, pursuant to Article 89 EPC.

3.2 Novelty in view of D2

Example 1 of D2 (analysed on the basis of the English translation D2A), discloses a urinary catheter 1 enclosed in a polyethylene sterile plastic bag 9. The catheter has a hydrophilic resin coating 2. The part of the catheter with the coating is enclosed in a glass

tube 3 with rubber stoppers 4, 5 closing the tube, or in a polyvinyl chloride bag tube 3 (example 2). A small quantity of drug is present in the glass tube and this drug is meant to impregnate the coating to provide a low-friction surface and subsequent release of the drug in the urethra of the patient.

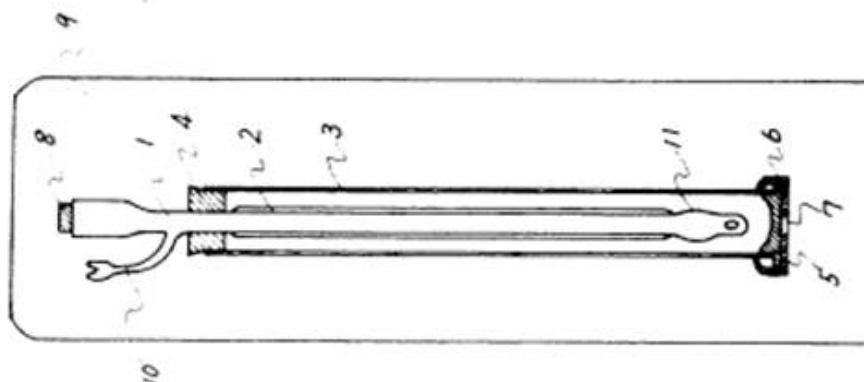


Figure 1 of D2

The appellant (opponent) argued that, since claim 1 of D2 included the option of the therapeutic drug being contained in a sealed cavity, it anticipated the feature of the "rupturable pouch" present in claim 1 of the patent in suit. The sealed cavity had to be considered rupturable because it was self-evident that, in order for the pouch or cavity to be emptied, it had to be opened, or ruptured.

The Board does not share this opinion. As mentioned above, in the embodiments disclosed in D2, the part of the catheter including the hydrophilic resin covering layer is either in a glass tube closed by rubber stoppers or a polyvinyl chloride bag tube, but in both cases together with the therapeutic drug. Hence, the sealed cavity meant in claim 1 of D2 can only be this cavity and not a compartment separate from the cavity in such a way that the liquid flow communication is not

established, until preparation of the catheter as required by claim 1. Moreover, there is no indication in D2 that the glass or the polyvinyl chloride bag tube is meant to be rupturable as also required by claim 1.

Hence, the subject-matter of claim 1 according to Request B is novel in view of D2 (Article 54 EPC).

4. Inventive step

The appellant (opponent) argued that the subject-matter of claim 1 was obvious starting from D3 in combination with D4 or D5. It would be obvious to integrate a separate compartment containing the liquid swelling medium in order to improve sterility, as suggested by D4 or D5. The fact that these documents disclosed indwelling catheters was not important in this context since the person skilled in the art wished to solve a sterility problem, the same problem as that addressed in D4, and the solution to which he would find in the sterile rupturable pouch 17.

The Board does not agree with the appellant (opponent) and concurs with the findings in T 2125/10, in particular points 5 to 9 of the Reasons, where D28 discloses an assembly similar to that of D3 in the present case, and D8 is the same document as D4 here. T 2125/10 concerned a patent based on a divisional application of the same family. Claim 1 of that patent was also directed to a urinary catheter assembly according to the pre-characterising part of present claim 1 and further comprising a separate compartment having walls of gas-impermeable material in which the liquid swelling medium was confined.

Hence, the Board considers that the reasoning developed in T 2125/10 concerning a more general claim is all the more applicable to the subject-matter of the more restricted claim of the patent in suit. This reasoning went as follows:

"5. (...)

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.

(...)

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."

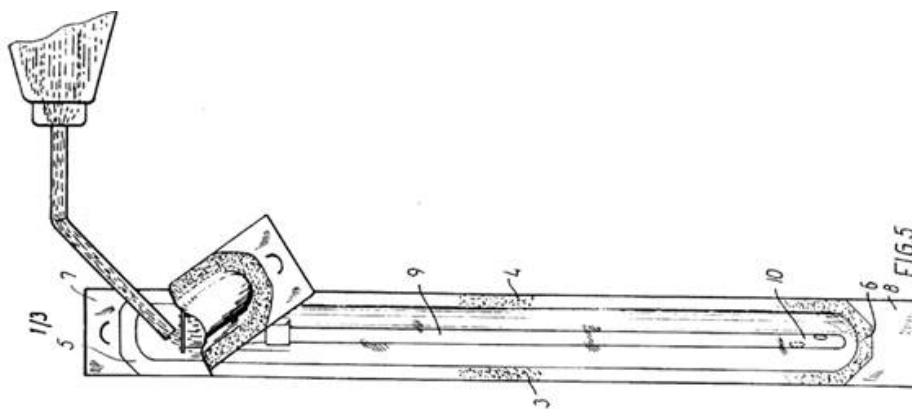


Figure 5 of D3 (D28 in T 2125/10)

"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 (...) 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.

(...)

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."

On the combination with D8 (D4 in the present case), the Board in T 2125/10 held:

"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.

(...)

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."

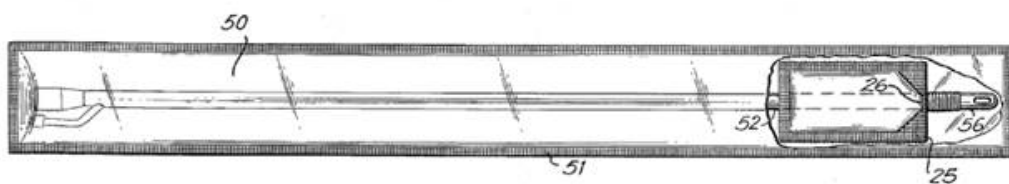


Figure 5 of D4 (D8 in T 2125/10)

"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."

For the same reasons the Board concludes that, in the present case, the subject-matter of claim 1 according to Request B is inventive starting from D3 in combination with D4.

D5 does not change the above reasoning since it also concerns an indwelling catheter to be lubricated with a lubricant as in D4. In order to facilitate the cumbersome lubrication of the catheter with gel (page

1, first paragraph) and to reduce the risk of infection (page 1, second paragraph), D5, just like D4, proposes putting the lubricant in a rupturable pouch 7 attached to the cavity housing the catheter, so that the user can press the lubricant into contact with the part of the catheter to be inserted into the patient's body. This is exactly the same kind of assembly as disclosed in D4.

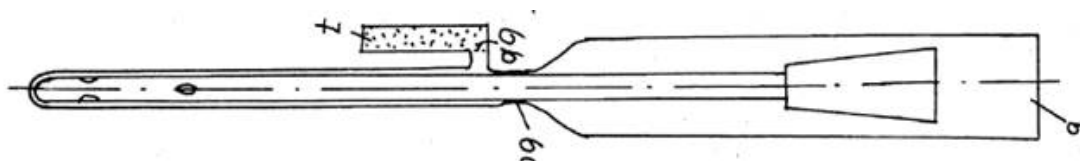


Figure 3 of D5

Therefore, the Board also concludes that the subject-matter of claim 1 according to Request B is inventive starting from D3 in combination with D5.

Hence, the subject-matter of claim 1 according to Request B involves an inventive step (Article 56 EPC).

5. It follows that the patent can be maintained on the basis of the claims according to Request B.

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 18 of Request B filed with letter dated 21 April 2017 ; and
 - description and figures of Auxiliary Request 1 as found to meet the requirements of the Convention in the decision under appeal.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated