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**Datasheet for the decision  
of 7 February 2022**

**Case Number:** T 0693/19 - 3.2.02

**Application Number:** 10840071.4

**Publication Number:** 2515988

**IPC:** A61M25/00, A61M25/16

**Language of the proceedings:** EN

**Title of invention:**

CATHETER ASSEMBLY/PACKAGE UTILIZING A HYDRATING/HYDROGEL  
SLEEVE AND METHOD OF MAKING AND USING THE SAME

**Patent Proprietor:**

C.R. Bard Inc.

**Opponent:**

Dentsply IH AB

**Relevant legal provisions:**

EPC Art. 54, 56, 83, 123(2)  
RPBA 2020 Art. 13(1), 13(2)

**Keyword:**

Amendment after summons - exercise of discretion - taken into account (yes)

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

**Decisions cited:**

T 0172/17



**Beschwerdekammern**

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Case Number: T 0693/19 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 7 February 2022**

**Appellant:** Dentsply IH AB  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
7 January 2019 concerning maintenance of the  
European Patent No. 2515988 in amended form.**

**Composition of the Board:**

**Chairman** M. Alvazzi Delfrate  
**Members:** S. Dennler  
N. Obrovski

## **Summary of Facts and Submissions**

- I. The appeal was filed by the opponent ("the appellant") against the opposition division's interlocutory decision to maintain the contested patent in amended form on the basis of auxiliary request 1.
- II. In this decision, the opposition division held that the subject-matter of claim 1 of auxiliary request 1 did not contain added subject-matter and that it was novel and involved an inventive step, especially in view of the following documents:

**D1:** JP 55-12265 B2  
**D1a:** English translation of D1  
**D2:** US 2009/0299334 A1  
**D3:** US 2007/0225687 A1  
**D5:** WO 98/11932 A1  
**D8:** US 7,380,658 B2

Moreover, the invention was considered to be sufficiently disclosed in the patent.

- III. In response to the Board's communication pursuant to Article 15(1) RPBA 2020, in which the Board had expressed its preliminary opinion, the patent proprietor ("the respondent") filed auxiliary request 2, which included an amendment to claim 1.
- IV. During the oral proceedings before the Board, held on 7 February 2022, the respondent filed auxiliary request 3, which differed from auxiliary request 2 in that claim 8 had been deleted, as well as amended pages of the description, which had been adapted to the claims.

V. At the end of the oral proceedings, the parties' requests were as follows.

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

The respondent requested that the patent be maintained in amended form on the basis of auxiliary request 3.

VI. Claim 1 of **auxiliary request 3**, which is identical to claim 1 of auxiliary request 2, reads as follows (amendments compared to claim 1 of auxiliary request 1 have been highlighted by the Board):

*"A catheter assembly (10; 110; 310) comprising:  
an elongate member (14; 114; 314) having a proximal end and a distal end;  
the distal end having at least one drainage opening (15; 115; 315; 415);  
a fluid containing member (20; 120; 320A) arranged on the elongate member, and  
a container (12; 112; 320B) containing the elongate member and the fluid containing member, wherein the fluid containing member comprises a material which swells when exposed to a fluid and which absorbs and retains fluid in a wall between an inner diameter (20B) and an outer diameter (20A), wherein the outer diameter of the fluid containing member is fluid impermeable so as not to wet the container when contacting the same; characterized in that the fluid containing member has a length that is substantially equal to a coated tube portion (C) of the elongate member, the coating of the coated tube portion is hydratable, and the inner diameter of the fluid containing member is fluid*

permeable and wets and hydrates the coating of the coated tube portion when contacting it."

VII. The **appellant's arguments**, as far as they are relevant for the present decision, can be summarised as follows.

*Admittance of auxiliary request 3*

Auxiliary request 3 was late-filed. The added subject-matter objection to claim 1 of auxiliary request 1, which the amendment made in claim 1 of auxiliary requests 2 and 3 addressed, had already been substantiated in the appellant's statement of grounds of appeal. In its communication pursuant to Article 15(1) RPBA 2020, the Board had merely refined this objection. Hence, this amendment could and should have been filed with the respondent's reply. There were no exceptional circumstances under Article 13(2) RPBA 2020 justifying the submission of auxiliary request 3 at this stage of the appeal proceedings.

Furthermore, claim 1 of auxiliary request 3 *prima facie* contained added subject-matter. Indeed, the application as filed consistently disclosed, especially in paragraph [0033] and claim 18, that the coating was specifically arranged on the outer surface of the distal end of the elongate member. As claim 1 of auxiliary request 3 did not specify where the coating was arranged, but encompassed, for example, a coating arranged on the catheter's inner surface, claim 1 was based on an unallowable intermediate generalisation of the embodiments originally disclosed.

For these reasons, auxiliary request 3 should not be admitted into the proceedings.

*Added subject-matter*

In addition to the particular arrangement of the coating mentioned above, several other features of the embodiments originally disclosed, also inextricably linked with the features defined in claim 1, had also been omitted, which gave rise to further unallowable intermediate generalisations. These objections had been initially raised in respect of auxiliary request 1 but still applied to auxiliary request 3.

Firstly, it followed from paragraph [0063] that the claimed feature according to which the outside diameter was fluid-impermeable could not be isolated from the further feature according to which the package was also fluid-impermeable and did not absorb fluid.

Secondly, the claimed feature according to which the fluid-containing member had a length that was substantially equal to a coated tube portion of the elongate member was disclosed in paragraph [0037] only in combination with an outer member comprised in the container. This outer member enclosed both the elongate member and the fluid-containing member and had a specific length.

*Sufficiency of disclosure*

The invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Indeed, the description only disclosed absorbent and swelling materials which were not fluid-impermeable, such as hydrogels and hydrophilic materials (paragraphs [0032] and [0079]). Known fluid-impermeable materials,

such as aluminium, were not easily bonded to this kind of material. Hence, the person skilled in the art would not be able to build a fluid-containing member with the claimed properties, even in the form of a layered structure as held in the decision under appeal.

Furthermore, at least some of the wetting fluid was necessarily contained in the wetted coating. Therefore, it was not feasible that, as defined in claim 9, the fluid-containing member be the only device containing fluid in the container. The description did not shed any light on this contradiction.

*Novelty over D1*

The subject-matter of claim 1 of auxiliary request 3 was not novel over D1. In particular, D1 (Figure 1) disclosed a catheter 1 comprising a hydrophilic resin coating (see D1a, page 7, last paragraph entitled "Practical Example 1"). The hydrophilic resin tube 2 applied onto the coated catheter and the glass tube 3 - which was clearly fluid-impermeable and contained an aqueous liquid - together formed, in combination, a fluid-containing member as defined in claim 1. This interpretation of D1 was not excluded by the wording of claim 1.

*Inventive step starting from D1*

If the subject-matter of claim 1 of auxiliary request 3 were to be regarded as novel over D1, it still could not be considered to involve an inventive step over this document. Indeed, distinguishing features of claim 1 over D1 could only be considered to be minor differences. The person skilled in the art would have arrived at the subject-matter of claim 1 via a mere



routine adaptation of the catheter assembly known from D1, without exercising any inventive skill.

*Inventive step starting from D2 or D3*

The subject-matter of claim 1 of auxiliary request 3 also lacked inventive step over D2 and over D3.

The subject-matter of claim 1 differed from the assemblies disclosed in D2 and D3 only in that the fluid-containing member comprised a material which swelled when exposed to a fluid and which absorbed and retained fluid, arranged in a wall between an inner diameter and an outer diameter of the fluid-containing member. This solved the objective technical problem of providing the wetting fluid in a more stable form.

Faced with this problem, the person skilled in the art would have considered either D5 or D8, which both related to easy-to-use coated catheter assemblies. D5 disclosed that a wetting liquid could be confined in a storage body such as a spongy material or an absorbing gel (page 4, lines 27-35; page 12, lines 6-27). D8 also disclosed that a wetting fluid could be arranged in a liquid-sequestering material (column 3, lines 30-45). D8 further disclosed a fluid-impermeable hydrogel sleeve 20 arranged on the catheter (column 5, lines 10-15, 49-53 and 61-64).

These teachings would have prompted the person skilled in the art to include such a material in the assemblies of D2 or D3 in order to solve the problem. Thus, the person skilled in the art would have arrived at the subject-matter of claim 1 in an obvious manner.

VIII. The **respondent's arguments**, as far as they are relevant for the present decision, can be summarised as follows.

*Admittance of auxiliary request 3*

Auxiliary request 3 was filed in reaction to a clarity objection to claim 8 of auxiliary request 2 that the appellant had raised for the first time in the oral proceedings before the Board. Auxiliary request 3 differed from auxiliary request 2 in that claim 8 had been deleted, which immediately resolved the issue.

Auxiliary request 2, which included an amended claim 1, had been filed to address the added subject-matter objection that the Board had raised in its communication under Article 15(1) RPBA 2020. This objection differed substantially from the objection raised by the appellant in its statement of grounds of appeal. Therefore, the respondent could not have filed auxiliary request 2 with its reply to the statement. Auxiliary request 3, which included the same amendment to claim 1, was thus not late-filed.

This amendment clearly overcame the Board's objection as the features added to claim 1 of auxiliary requests 2 and 3 were those pointed out by the Board in its communication. Moreover, this amendment did not give rise to any new issues. In particular, it did not introduce any added subject-matter. Admitting auxiliary request 3 was therefore not detrimental to procedural economy.

Auxiliary request 3 should therefore be admitted into the proceedings.

*Added subject-matter*

Claim 1 of auxiliary request 3 did not contain any added subject-matter. It was implicit from claim 1 that the coating of the coated portion was arranged on the outer surface of the elongate member. Moreover, the fact that claim 1 failed to define that the coating was arranged at the distal end of the elongate member, that the container was fluid-impermeable and non-absorbent, and that the container comprised an outer member, was not in breach of Article 123(2) EPC. Indeed, these features were not inextricably linked to the claimed features; rather, they were presented as being purely optional in the description as filed.

*Sufficiency of disclosure*

The invention was sufficiently disclosed. A person skilled in the art would have no difficulty in selecting appropriate materials to form a fluid-containing member as defined in claim 1.

In addition, there was no contradiction between claims 1 and 9. The feature that the fluid-containing member was the only device containing fluid in the container simply meant that the fluid-containing member was the only source of wetting fluid in the assembly.

*Novelty over D1*

The appellant's interpretation of D1 was incorrect. The hydrophilic resin tube 2 applied onto the catheter in fact formed a coating of the catheter as defined in claim 1. The thin layer of resin initially coated onto the catheter merely improved the adhesion of this resin tube to form a thick covering layer. Thus, only the glass tube 3, which contained the wetting fluid for

hydrating the hydrophilic resin covering layer, could correspond to the fluid-containing member of claim 1. This glass tube did not comprise a material which swelled when exposed to a fluid and which absorbed and retained fluid as required by claim 1. Therefore, the subject-matter of claim 1 was novel over D1.

*Inventive step starting from D1*

A material which swelled when exposed to a fluid and which absorbed and retained fluid as required by claim 1 was not a minor difference. Starting from D1, the person skilled in the art would not have arrived at the subject-matter of claim 1 in an obvious manner.

*Inventive step starting from D2 or D3*

The assemblies disclosed in D2 and D3 already included measures to prevent loss or leakage of the wetting fluid from the fluid-containing member, for example a sliding seal as mentioned in paragraph [0025] of D2. The person skilled in the art starting from these documents would thus have had no incentive to seek further ways of preventing fluid spillage.

Even if the person skilled in the art were to do so, they would not arrive at the subject-matter of claim 1 in an obvious manner.

Indeed, D5 consistently disclosed that the wetting liquid should be kept in a separate compartment during storage and should only be applied to the hydrophilic coating when needed for immediate use. Thus, the teaching of D5 led away from the invention of the contested patent and would not have led the person skilled in the art to the subject-matter of claim 1.

Moreover, while D8 was also concerned with the problem of avoiding fluid spillage during use, it taught a different solution, namely that the catheter coating was hydrated before use by vapour hydration instead of by direct contact with a wetting liquid. Starting from D2 or D3, the person skilled in the art would therefore not have considered D8.

Finally, introducing an absorbing material around the coated portion of the catheters of D2 or D3, within the fluid-containing members, would have made it almost impossible to retract the latter as required to use the catheters as intended. The person skilled in the art would therefore not have considered this modification.

## **Reasons for the Decision**

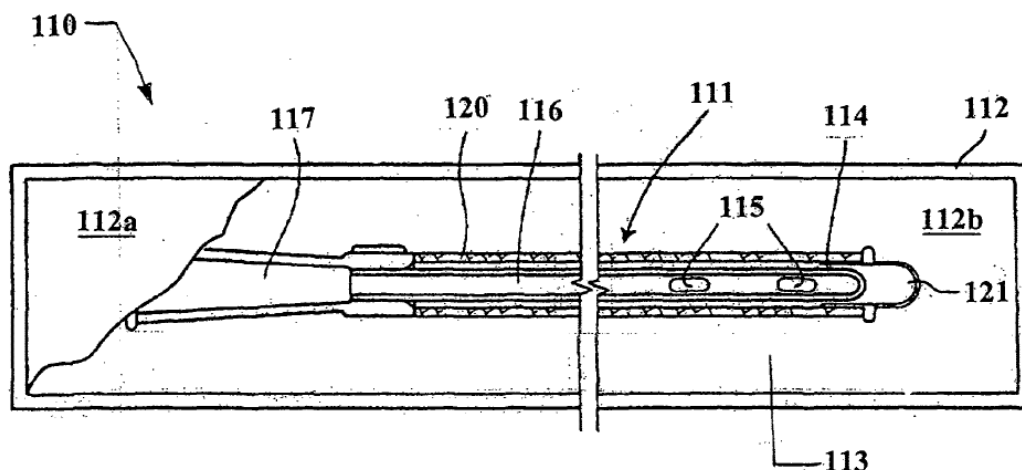
### **1. The subject-matter of the contested patent**

1.1 The contested patent relates to catheter assemblies for intermittent catheterisation of a patient, such as urinary catheters for insertion into the bladder for drainage of urine therefrom when normal draining is impossible or difficult (paragraph [0004]).

1.2 To facilitate insertion into the patient, the catheters may be provided with a coating which, when wetted, makes their surface slippery (paragraph [0008]). Known pre-wetted catheters are exposed to a wetting fluid loosely contained within the sealed catheter package, so that they are ready for insertion immediately upon opening the package. However, such catheter assemblies are prone to fluid spillage during use, once the package has been opened. They may also be difficult to

handle because of the catheter's slippery wetted surface (paragraphs [0012] and [0013]).

1.3 The patent provides for a pre-wetted catheter assembly that minimises these drawbacks. An example of a catheter assembly (110) as claimed is illustrated in Figure 8, reproduced below.



It comprises a fluid-containing member (120) which is arranged on the catheter (111) and has a length substantially equal to that of a coated portion (114) of the catheter. The fluid-containing member contains a material which swells when exposed to a fluid and which absorbs and retains fluid in a wall between an inner diameter and an outer diameter, said outer diameter being fluid-impermeable.

Thus, even prior to use the coated portion is maintained in a wetted state within the container (112) by the fluid-containing member, while the wetting fluid is confined and retained in contact with the coated portion only. This prevents fluid from spilling out of the container after opening and avoids unnecessarily wetting other portions of the catheter, which facilitates handling of the latter (paragraphs [0051] and [0058]).

## **2. Admittance of auxiliary request 3**

2.1 Auxiliary request 3 was filed during the oral proceedings before the Board in reaction to a clarity objection to dependent claim 8 of auxiliary request 2, which had been raised by the appellant for the first time in the oral proceedings before the Board.

Auxiliary request 3 differed from (the subsequently withdrawn) auxiliary request 2 in that dependent claim 8 had been deleted. Auxiliary request 2 had been filed after notification of the summons to oral proceedings. The amendment to claim 1 made in auxiliary request 2 (and thus in auxiliary request 3) addressed an added subject-matter objection which had been raised in the Board's communication under Article 15(1) RPBA 2020.

The admittance of auxiliary request 3 is subject to Article 13(2) RPBA 2020, according to which any amendment to a party's appeal case made after notification of a summons to oral proceedings must, in principle, not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.

Whether or not to admit an amendment to a party's appeal case under Article 13(2) RPBA 2020 is at the Board's discretion. When exercising its discretion, the Board may also rely on criteria as set out in Article 13(1) RPBA 2020 (see T 172/17, Reasons 5.4).

2.2 It was disputed between the parties whether the added subject-matter objection raised by the Board in its communication under Article 15(1) RPBA 2020 was different from the added subject-matter objection which

had previously been raised by the appellant in its statement of grounds of appeal.

- 2.3 In its communication, the Board concurred with the appellant's view that claim 1 of auxiliary request 1 relied on an unallowable intermediate generalisation, referring to the features of the coating being wettable and the inner diameter being fluid-permeable (see features (i) and (ii) listed on page 3). These features had also been objected to as missing by the appellant in its statement of grounds of appeal.

However, as explained in point 3.2 of the Board's communication, the Board did not find these features to be inextricably linked with the fluid-impermeable nature of the outer diameter, as the appellant had argued; rather, it considered them to be linked with the feature that a portion of the elongate member was coated. Moreover, while the Board agreed with the appellant that the coating could not be just any coating, it did not consider the list of particular coatings disclosed in paragraph [0033] of the description as filed as being exhaustive, contrary to the appellant's argument. Thus, the Board provided a technical reasoning for the existence of an unallowable intermediate generalisation, which deviated substantially from the reasoning the appellant had developed in its statement of grounds of appeal.

The respondent was first confronted with this new technical reasoning after receiving the Board's communication and therefore could not have reacted to it before the notification of the summons.

- 2.4 It was also immediately apparent why the features added to claim 1 of auxiliary requests 2 and 3 overcame the



Board's objection as to an unallowable intermediate generalisation, as they correspond in substance to those pointed out by the Board. Since the appellant's other objections had not been found convincing (points 3.3 and 4 to 6 of the Board's communication), all of the issues that the Board had mentioned as relevant in its communication had been resolved by this amendment.

2.5 This amendment triggered, however, a clarity objection against claim 8 of auxiliary request 2, which was raised for the first time during the oral proceedings before the Board. The respondent reacted thereto by filing auxiliary request 3 during the oral proceedings, in which claim 8 had been deleted. This immediately resolved the issue.

2.6 Hence, the amendments contained in auxiliary request 3 as compared to the patent as maintained by the opposition division were strictly limited to overcoming the objections which had been raised for the first time either by the Board in its communication under Article 15(1) RPBA 2020 or by the appellant during the oral proceedings before the Board. They did not give rise to any new objections. Furthermore, they did not create any additional burden for the other party. Overall, although the respondent amended its appeal case by filing auxiliary request 3 in the oral proceedings before the Board, it did so in a manner which was not detrimental to procedural economy.

2.7 For these reasons, in exercising its discretion the Board found that exceptional circumstances within the meaning of Article 13(2) RPBA 2020 applied and therefore decided to admit auxiliary request 3 into the proceedings.

**3. Added subject-matter**

3.1 Contrary to the appellant's contention, the amendments in claim 1 of auxiliary request 3 do not introduce added subject-matter. It is indeed implicit from the wording of claim 1 that the coating is necessarily arranged on the outer surface of the elongate member; otherwise the coating could not be contacted and wetted by the inner diameter of the fluid-containing member. In addition, the application as filed also provides support for a coating arranged elsewhere than at the distal end of the elongate member. This is derivable for example from paragraph [0026] of the description as filed, which does not specify a particular location for the coating. The arrangement at the distal end to which the appellant referred is merely optional, as shown by the expression "may comprise" as used in paragraph [0033] and by the nature of claim 18 as filed being dependent on claim 1.

3.2 Furthermore, the added subject-matter objections that the appellant had initially raised against claim 1 of auxiliary request 1, as far as they further apply to claim 1 of auxiliary request 3, are also unfounded.

The fluid-impermeable nature of the outer diameter of the fluid-containing member is not functionally or structurally linked to the nature of the package itself. Making the outer diameter fluid-impermeable is disclosed in the description as filed as being merely an optional measure to prevent the package from being wetted by fluid escaping the fluid-containing member, irrespective of whether the package is fluid-impermeable or absorbent. This follows, for example, from the last few sentences of paragraph [0063] to which the appellant referred.

There is also no inextricable link between the length of the fluid-containing member and the presence, let alone the length, of an outer member. The outer member, possibly having a particular length, is disclosed as an optional feature of the catheter assembly, as shown by the expressions "may comprise" and "may have" as used in paragraph [0037].

Therefore, contrary to the appellant's objection, the omission of these features from claim 1 does not lead to unallowable intermediate generalisations.

3.3 It follows that the subject-matter of claim 1 of auxiliary request 3 does not contain added subject-matter.

#### **4. Sufficiency of disclosure**

4.1 It is established case law that a person skilled in the art may use common general knowledge to supplement the information contained in the patent and may even recognise and rectify errors in the description on the basis of such knowledge.

4.2 In the present case, a person skilled in the art would have no difficulty or undue burden in selecting appropriate materials, for example among the materials mentioned in paragraphs [0032] and [0033] of the contested patent, to form a fluid-containing member and to provide it with a fluid-impermeable outer diameter as claimed. The fact that some fluid-impermeable materials such as aluminium - to which the appellant referred but which is not cited in the patent - may not be suitable does not prevent the person skilled in the art from finding other appropriate materials, even if

such materials are not explicitly disclosed in the description.

- 4.3 It is true that, as submitted by the appellant, some fluid will naturally be contained in the wetted coating. However, the person skilled in the art would not recognise any contradiction with the subject-matter of claim 9.

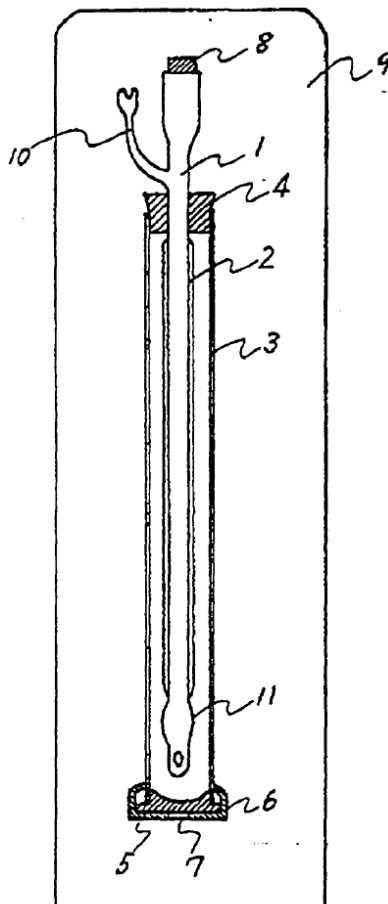
Indeed, in the context of the patent the feature of claim 9, according to which "the fluid-containing member is the only device containing fluid in the container", simply means that the fluid-containing member is the only source of wetting fluid in the assembly. This is described, for example, in paragraph [0051], which states that "the sleeve 20 contains all or nearly all of the fluid that is arranged in the container 12 and is in direct contact with a coating of the tube 14". This configuration advantageously prevents unnecessarily wetting other portions of the catheter, unlike other catheter assemblies known in the art, in which the whole catheter is exposed to a wetting fluid loosely provided within the package (paragraph [0012]).

- 4.4 The Board therefore concludes that the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

## **5. Novelty over D1**

- 5.1 The appellant's novelty attack against claim 1 of auxiliary request 3 relies on the interpretation that the hydrophilic resin tube 2 and the glass tube 3 of the catheter assembly disclosed in D1 (see e.g.

Figure 1 of D1, reproduced below) form in combination a fluid-containing member as claimed.



5.2 This interpretation of D1 is artificial and has not convinced the Board.

Contrary to the appellant's view, the person skilled in the art considering D1 would not dissociate the coating initially deposited on the catheter shaft from the resin tube 2 subsequently applied onto it. As disclosed in D1a, page 7, last paragraph, both have the same composition. The initial coating merely improves the adhesion of the resin tube 2 to the catheter ("adhered more firmly") so that the catheter eventually obtained is a "catheter having a thick hydrophilic resin covering". When wetted, this "thick hydrophilic resin covering" provides the catheter with a slippery outer

surface, aiding insertion of the catheter into the patient, as disclosed in D1a, page 2, second paragraph. Accordingly, the person skilled in the art would regard the "thick hydrophilic resin covering" in D1 as corresponding to the coating of the coated portion defined in claim 1.

Therefore, the Board concurs with the respondent's view that the person skilled in the art considering D1 would at best identify the glass tube 3 alone as being the fluid-containing member specified in claim 1. This is also the interpretation that the opposition division adopted (point 3.3 of the decision under appeal).

5.3 The glass tube 3 merely contains an aqueous liquid but does not comprise a material which swells when exposed to a fluid and which absorbs and retains fluid as required by claim 1. As a result, contrary to the appellant's submissions, the subject-matter of claim 1 of auxiliary request 3 is novel over D1.

## **6. Inventive step starting from D1**

6.1 According to the appellant, the person skilled in the art would have arrived at the subject-matter of claim 1 via a mere routine adaptation of the catheter assembly disclosed in D1. The appellant has not provided any specific arguments as to why, in particular, the person skilled in the art would have provided a material which swells when exposed to a fluid and which absorbs and retains fluid within the glass tube 3 of the assembly of D1.

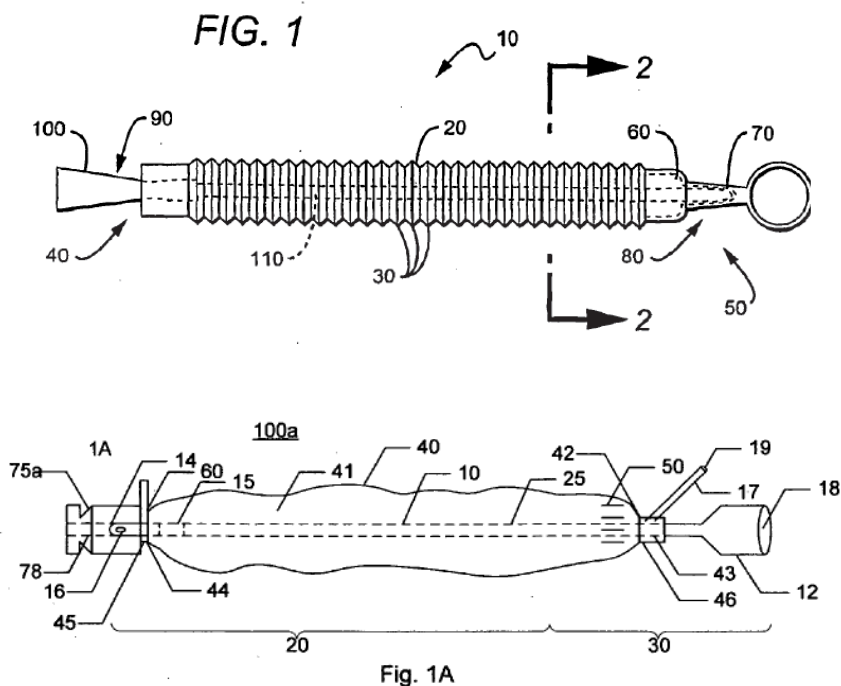
6.2 D1 does not address the issue of fluid spillage. In the absence of any indication to that effect in D1, the person skilled in the art would not have included such

a material in the assembly of D1 without exercising inventive skill.

6.3 Contrary to the appellant's contention, the subject-matter of claim 1 of auxiliary request 3 thus does involve an inventive step over D1.

**7. Inventive step starting from D2 or D3**

7.1 It is common ground that each of D2 and D3 discloses a catheter assembly comprising an elongate member (catheter 110 in D2, Figure 1; 10 in D3, Figure 1A; see both figures reproduced below), on which a sleeve (20 in D2; 40 in D3) is arranged.



The sleeve forms a fluid-containing member containing a fluid for wetting a hydrophilic surface of the catheter, such as a coating (paragraph [0008] of D2; see also paragraphs [0012] and [0055] of D3). This fluid is retained between an inner diameter (coincident

with the catheter surface, hence fluid-permeable) and an outer diameter (the wall of the sleeve, which is fluid-impermeable; paragraphs [0022] of D2 and [0059] of D3).

As a result, the subject-matter of claim 1 differs from these known catheter assemblies at least in that the fluid-containing member comprises a material which swells when exposed to a fluid and which absorbs and retains fluid, arranged in a wall between an inner diameter and an outer diameter of the fluid-containing member.

- 7.2 Referring to paragraph [0029] of the contested patent, the appellant argued that this difference solves the objective technical problem of providing the wetting fluid in a more stable form.
  
- 7.3 Even if the person skilled in the art starting from D2 or D3 had recognised this problem, which the respondent disputes, the person skilled in the art would not have arrived at the subject-matter of claim 1 in an obvious manner, contrary to the appellant's argument.
  
- 7.3.1 It is true that D5 (see e.g. Figure 7, reproduced below) discloses a catheter assembly including a catheter 2 having a hydrophilic coating 6 and a fluid-containing member 25 containing a liquid for wetting this coating, wherein this liquid is retained in a spongy material or an absorbing gel arranged within the fluid-containing member (page 4, last paragraph; page 12, lines 25-27).



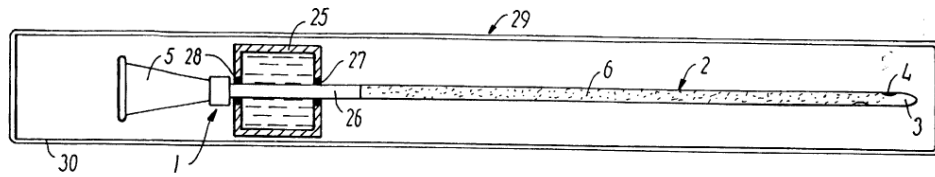


FIG. 7

However, D5 consistently discloses that the wetting liquid should be kept away from the coating during storage so that it can be applied to it only immediately before use. For this purpose, in the embodiment of Figure 7, the fluid-containing member 25 is a short container arranged on a proximal portion of the catheter outside the coating 6 (page 12, lines 10-11). When the catheter is to be used, it is withdrawn through the short container to bring the wetting liquid into contact with the coating. This strongly contrasts with the catheter assembly according to claim 1, in which the whole length of the coated portion is already wetted during storage by the fluid contained in the fluid-containing member.

Therefore, as argued by the respondent, the teaching of D5 leads away from the invention of the contested patent. Applying the teaching of D5 to the catheter assemblies of D2 or D3 would at best have led to retaining the wetting fluid in a spongy material or an absorbing gel within a short container separated from the hydrophilic portion. Without the benefit of hindsight, the person skilled in the art would not have formed this short container with the same length as that of the hydrophilic portion. Furthermore, spongy materials and absorbing gels do not necessarily "[swell] when exposed to a fluid". The combination of D5 with D2 or D3 would therefore not have led the person skilled in the art to the subject-matter of claim 1.

Moreover, as argued by the respondent, including a storage material for retaining the wetting fluid inside the fluid-containing members in D2 or D3 would in fact make it difficult, if not unfeasible, to retract the latter as required to use the catheters. The person skilled in the art would therefore not have contemplated such a modification.

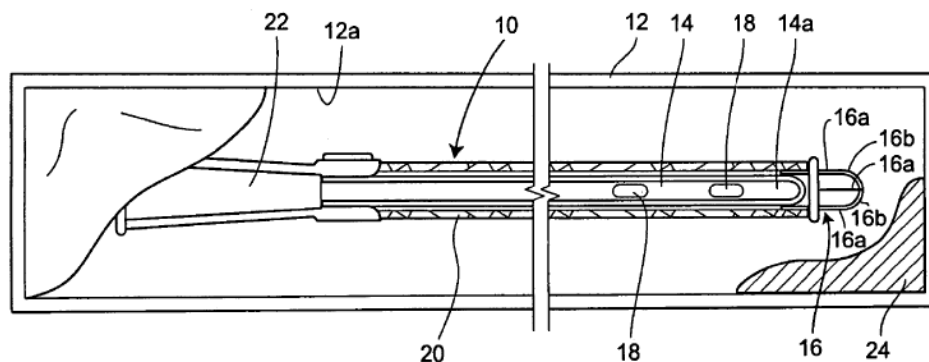
7.3.2 The appellant's other line of argument, based on a combination with D8, has not convinced the Board either.

While D8 also recognises the need for hydrophilic coated catheters that prevent fluid spillage from the package (column 2, lines 10-13), D8 discloses a different wetting mechanism for this purpose, namely that the coating of the catheter is pre-hydrated by vapour hydration, and not by direct contact with a wetting liquid like the catheters of D2 or D3. Starting from D2 or D3, the person skilled in the art would therefore have had no motivation to consult D8 to solve the problem above.

The function of the "liquid sequestering element" disclosed in D8, to which the appellant referred, is to hold an amount of liquid that can evaporate and produce a vapour hydration atmosphere within the package cavity (column 3, lines 30-41). It is true that D8 teaches that the "liquid sequestering element" must reliably hold the liquid while preventing any spillage (column 3, lines 41-45). However, without the benefit of hindsight the person skilled in the art would not have isolated this teaching from the disclosure as a whole of the vapour-based wetting mechanism described in D8, nor would they have included, on the basis of

this isolated teaching, a "liquid sequestering element" within the fluid-containing members of D2 and D3 to retain the wetting fluid contained therein.

The appellant also referred to the hydrogel sleeve 20 arranged around the catheter of D8 (column 5, lines 10-15 and 49-53; see Figure 1, reproduced below).



**FIG. 1**

While permitting vapour to penetrate and hydrate the coating of the catheter, the sleeve itself, however, plays no role in the hydration process. It simply makes the catheter easier to handle after its surface, once vapour-hydrated, has become slippery (column 3, lines 45-61). The person skilled in the art would have had no incentive to include such a sleeve in the catheter assemblies of D2 and D3. These assemblies already allow the catheter to be manipulated via the fluid-containing member without requiring direct contact between the user and the slippery hydrophilic portion.

Moreover, as already indicated in the last paragraph of point 7.3.1 above, the provision of a "liquid sequestering element" or a hydrogel sleeve in the assemblies of D2 or D3 would have hindered the retraction of the fluid-containing member along the

catheter. The person skilled in the art would not have contemplated these modifications either.

- 7.4 The Board therefore concludes that the subject-matter of claim 1 of auxiliary request 3 also involves an inventive step over D2 and D3.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:
  - claims: claims 1-9 filed as auxiliary request 3 in the oral proceedings before the Board
  - description: pages 2-5 and 12 of the patent specification and pages 6-11 as filed in the oral proceedings before the Board
  - drawings: figures 1-14 of the patent specification

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated