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**Datasheet for the decision
of 6 March 2024**

Case Number: T 1189/21 - 3.2.02

Application Number: 11175010.5

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Language of the proceedings: EN

Title of invention:
Vapor hydration of a hydrophilic catheter in a package

Patent Proprietor:
HOLLISTER INCORPORATED

Opponent:
Coloplast A/S

Headword:

Relevant legal provisions:
EPC Art. 76(1), 84, 123(2), 56
RPBA 2020 Art. 12(4), 12(6)

Keyword:

Divisional application - main request - subject-matter extends beyond content of earlier application (yes)

Amendments - main request - extension beyond the content of the application as filed (yes)

Claims - clarity (yes) - support in the description (yes) - conciseness (yes)

Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern
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Case Number: T 1189/21 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 March 2024

Appellant: HOLLISTER INCORPORATED
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
27 May 2021 concerning maintenance of the
European Patent No. 2423125 in amended form.

Composition of the Board:

Chair M. Alvazzi Delfrate
Members: A. Martinez Möller
Y. Podbielski

Summary of Facts and Submissions

- I. Appeals were filed by the patent proprietor and by the opponent against the interlocutory decision of the opposition division finding that the then third auxiliary request met the requirements of the EPC.
- II. Oral proceedings before the Board took place on 6 March 2024.

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

The appellant/proprietor ("proprietor") requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed with the statement of grounds of appeal. As an auxiliary measure they requested that the patent be maintained on the basis of the first auxiliary request, which corresponds to the version found to be allowable by the Opposition Division, i.e. that the opponent's appeal be dismissed and the decision be upheld.

- III. Claim 1 of the **main request** reads as follows:

"A ready-to-use hydrophilic catheter assembly (10, 110, 310, 410, 510, 610, 710, 810), comprising:
a gas impermeable package (12, 312, 412, 512, 812) having a sealed cavity,
a hydrophilic coated catheter (10, 110, 310, 410, 510, 610, 710, 810) including a tube (14, 114, 314, 414, 514, 614, 714, 814) and a hydrophilic surface coating

adhered to at least a portion thereof within the package;
an amount of liquid disposed within the sealed cavity;
characterised by
a flexible, collapsible sleeve (20, 120, 320, 720) surrounding the tube to permit gripping the tube or shaft through the sleeve (20, 120, 320, 720)."

IV. Claim 1 of the **first auxiliary request**, with amendments as compared with the main request highlighted, reads as follows:

"A ready-to-use vapor hydrated hydrophilic catheter assembly (10, 110, 310, 410, 510, 610, 710, 810), comprising:
a gas impermeable package (12, 312, 412, 512, 812) having a sealed cavity,
a hydrophilic coated catheter (10, 110, 310, 410, 510, 610, 710, 810) including a tube (14, 114, 314, 414, 514, 614, 714, 814) and a hydrophilic surface coating adhered to at least a portion thereof within the package;
an amount of liquid disposed within the sealed cavity causing water vapor to be formed;
characterised by
a flexible, collapsible sleeve (20, 120, 320, 720) surrounding the tube to permit gripping the tube or shaft through the sleeve (20, 120, 320, 720);
wherein the ready-to-use condition of the catheter is due at least in part to hydration by reason of exposure to the water vapor."

V. The following documents are relevant to the present decision:

D3 US 4,062,363

D4 WO 98/11932

D7 US 6,090,075

D8 US 3,854,483

D10 US 6,059,107

D11 Decision of the Landgericht Düsseldorf of
21.09.2021 in the matter 4c O 19/19

D12 Proprietor's submissions to the Landgericht
Düsseldorf in the matter 4c O 19/19 dated 12.08.2021

VI. The opponent's arguments relevant to the present
decision can be summarised as follows.

Admittance of documents D10 to D12

Documents D10 to D12 should be admitted into the appeal proceedings. D11 and D12 could not have been filed earlier and served to prove the surprising claim interpretation submitted by the proprietor in national infringement proceedings. That surprising interpretation justified the admittance of D10 and of the new objections of lack of inventive step starting from D10. D10 was cited in the application as filed and the proprietor was thus familiar with its disclosure.

Main request - added subject-matter

The parent application and the application as filed presented hydration of the catheter by vapour as an essential feature of the invention. The feature was present in all independent claims as filed and never described as optional. Liquid hydration was only mentioned in connection with prior art systems. There was thus no basis for omitting the feature in claim 1, so that the main request did not comply with Articles 76(1) and 123(2) EPC.

First auxiliary request - added subject-matter

Claim 1 comprised added subject-matter.

The parent application taught that activation took place by vapour. In the absence of any indication to the contrary, this was understood to mean any and all activation, i.e. vapour hydration alone was the principle of activation of the coating. The replacement of the word "activation" by the word "hydration" and the change of wording connected to the ready-to-use condition being now due "at least in part to hydration by reason of exposure to the water vapor" permitted the interpretation submitted by the proprietor that the catheter was partly activated by vapour and partly by liquid and resulted in new technical information. The parent application did not disclose that the "due at least in part" related to the activation principle rather than the ready-to-use condition. Moreover, claim 1 could be construed to encompass embodiments in which the catheter's coating was initially activated by means other than vapour (e.g. liquid) and in which vapour only contributed to keep the catheter's coating in an activated state. However, the parent application did neither disclose vapour hydration to be only one out of different options for activation of the catheter, nor any differentiation between an initial activation and a sustained activated state.

Thirdly, the omission of the feature that the liquid had to be present outside the sleeve resulted in added subject-matter. The parent application disclosed that in all embodiments with a sleeve, liquid was introduced into the package externally of the sleeve and, after sealing, vapour hydrated the catheter's hydrophilic coating (page 5, lines 3 to 8). This disclosure, as

well as further passages describing each of the embodiments, made it clear that hydration was by vapour and not by direct liquid contact. The limitation that liquid was outside the sleeve was also required by the combined wording of claims 1 and 9 of the parent application, which specified that the liquid was vapour donating and that it was the vapour that activated the catheter's coating. There was thus no basis for the omission of this feature.

Hence, the first auxiliary request contravened Articles 76(1) and 123(2) EPC.

First auxiliary request - Article 84 EPC

The application did not disclose structural means or features that would achieve activation of the catheter coating by a principle other than vapour hydration. In view of the last feature of claim 1, this resulted in claim 1 being unclear and lacking support.

Claim 1 was not concise because it was inconsistent in that it defined a "vapor hydrated" catheter assembly (i.e. entirely vapor hydrated) while the last feature only required the catheter to be partly hydrated by vapor.

First auxiliary request - Inventive step

The subject-matter of claim 1 was rendered obvious in view of D4 (catheter assembly in the embodiment of Figure 1) combined with any of D3, D7 or D8.

The only feature distinguishing the subject-matter of claim 1 from D4 was a flexible sleeve as defined in claim 1. The sleeve had the effect to facilitate

handling of the lubricious catheter while permitting sterile insertion. The same effect was achieved by the package 7 in D4. The objective technical problem was thus how to provide an alternative way of facilitating catheter insertion without risk of contamination.

Each of D3, D7 and D8 disclosed a sleeve as a means of facilitating contamination-free insertion of urinary catheters. The person skilled in the art would have no difficulty in applying the sleeve of D3, D7 or D8 to the catheter tube of D4 and would appreciate that it can be attached to the connector member 5 by ordinary measures such as by heat welding.

The difference in the mechanism used to provide the catheter surface with its low-friction properties (hydrophilic coating in D4 and lubricated with gel in D3, D7 and D8) did not disqualify the disclosures of D3, D7 and D8, nor would it have led the person skilled in the art to adopt gel lubrication because the lubrication mechanism was unrelated to the problem to be solved. Moreover, the passage starting on page 18, line 32 of the parent application showed that a collapsible sleeve was a feature that had been considered for hydrophilic coated catheters.

Activation of the catheter of D4 was not impaired by the addition of a sleeve. The structure of the assembly of D4 enabled activation of the catheter by vapour. A vapour-permeable or water-permeable sleeve could be used. Moreover, liquid could flow from the storage body 14 into the catheter through the urine outlet (rear) opening in the connector member 5 and, after passing through the lumen, exit through the inlet openings 4 and reach the catheter's coating. Hence, the assembly of D4 and its intended mode of operation were in no way

incompatible with the provision of a sleeve, even if the sleeve would be sealed. In any event, the package 7 provided a tightly sealed barrier preventing the ingress of contaminants, so that the person skilled in the art would not have sealed the sleeve when applied to the assembly of D4.

VII. The proprietor's arguments relevant to the present decision can be summarised as follows.

Admittance of documents D10 to D12

The appealed decision did not rely on any of D10 to D12. There was no reason for filing the new documents only on appeal. Since D10 was cited in the application as filed, the opponent should have filed any objection based on D10 in the first-instance proceedings. Documents D11 and D12 related to national proceedings and were irrelevant to the appeal.

Main request - added subject-matter

Claim 1 did not comprise added subject-matter. There was basis for omitting in claim 1 the feature that the catheter is at least in part vapour hydrated.

According to the parent application, it was clear that the claimed invention was based on the provision of a flexible, collapsible sleeve. Page 2, lines 22 to 28 identified disadvantages of hydrophilic catheters related to their handling (slippery surface and contamination) and page 4, lines 24 to 26 taught that these disadvantages were overcome by using a sleeve. This applied irrespectively of any vapor hydration, which was presented on page 4, lines 12 to 15 as

addressing a different disadvantage related to spilling.

Moreover, the parent application disclosed in the Background section and in connection with Tests 1 and 2 a catheter hydrated by swelling in contact with a hydrating liquid. A catheter assembly with a wide polyethylene sleeve - mentioned on page 17, lines 2 to 10 - also allowed activation by immersion.

According to the parent application, vapour hydration made it possible to use a liquid impermeable sleeve (page 12, lines 16 to 28, in connection to the embodiment of Figure 3b). Since a liquid permeable sleeve was also disclosed (on page 7, line 32) and there was no disclosure that a liquid permeable sleeve had any connection to vapour hydration, hydration by direct liquid contact was contemplated.

First auxiliary request - added subject-matter

Claim 1 of the first auxiliary request did not comprise added subject-matter.

The parent application disclosed that the hydrophilic coating became hydrated by reason of exposure to the water vapour formed, thereby placing the catheter assembly in a ready-to-use condition. It further disclosed assemblies wherein liquid could contact the hydrophilic coating, so that there could be partial hydration by vapour.

The parent application disclosed in connection with Figure 1 that liquid water was placed loosely within the cavity. Liquid could pass through the open end of the sleeve and contact the hydrophilic coating. There

was thus basis for a catheter assembly without the further limitation that liquid was present only outside the sleeve.

First auxiliary request - Article 84 EPC

The application as filed disclosed that liquid was placed loosely within the cavity and so could contact the hydrophilic coating. It was clear that the ready-to-use condition was due at least in part to hydration by reason of exposure to water vapour.

First auxiliary request - Inventive step

An inventive step had to be acknowledged.

D4 did not disclose *inter alia* a flexible collapsible sleeve. D3, D7 and D8 each dealt with a gel coated catheter, which was a different category of catheters. In each of these documents, a sheath was fixedly attached to an introducer which contained a gel lubricant. The construction was incompatible with the hydrophilic catheter of D4.

Moreover, D4 disclosed that the liquid was confined within the storage body, and squeezed out from it 30 seconds prior to use. Hydration would have been insufficient if D4 had included a sleeve. In D4, liquid inside the catheter tube was not desired.

Reasons for the Decision

1. The patent

It is common for catheters such as those used for the urinary system to be provided with a surface treatment

using a lubricant to reduce friction in order to allow for easier and less traumatic insertion. There are two major categories of catheters with lubricated surfaces, gel coated catheters and hydrophilic coated catheters.

In a hydrophilic coated catheter, the coating is typically activated by swelling in contact with a hydrated liquid such as water, wherein direct contact of the liquid with the entirety of the hydrophilic coated surface must be ensured. When the catheter is provided in a dry state, the user needs to pour water into the package prior to its use to activate the hydrophilic coating. In some hydrophilic coated catheters, loose liquid is already provided within the package, either in the same compartment in which the catheter is located or in a separate compartment that must be open prior to use.

These hydrophilic coated catheters have some disadvantages: the immersion liquid has a tendency to spill from the package; the catheter has an extremely slippery surface which makes it difficult for the user to handle during insertion; and direct handling by the user has the risk of introducing micro-organisms onto the surface of the catheter which can cause infectious problems after introduction into the body.

The patent addresses these issues by providing a ready-to-use assembly with a hydrophilic coated catheter disposed within a gas impermeable package having a sealed cavity with an amount of liquid disposed therein. A flexible, collapsible sleeve surrounds the catheter's tube to permit gripping the tube or shaft through the sleeve. Moreover, the patent teaches activation of the hydrophilic coating by exposure to

based on those interpretations in opposition proceedings, so that any objection based on D10 should have been submitted in the first-instance opposition proceedings (Article 12(6), second sentence, RPBA). The fact that D10 was cited in the application as filed only emphasises that an objection based on it should have been submitted earlier. The Board therefore decided not to admit D10 and the objections of lack of inventive step based on D10 into the appeal proceedings.

2.3 D11 and D12, dated after the appealed decision, relate to infringement proceedings in Germany concerning the opposed patent. According to the opponent, they proved that the proprietor put forward a surprising claim interpretation in those proceedings. A claim interpretation submitted in national proceedings is irrelevant to the present appeal case before the EPO and, as set out in connection with D10, cannot serve to justify new objections based on new prior art documents. In view of the lack of relevance of D11 and D12, the Board decided not to admit them into the appeal proceedings.

2.4 Further documents, the admittance of which was also disputed, were admitted into the appeal proceedings. These documents were ultimately not relevant to the present decision and their admittance is therefore not discussed here.

3. Main request - added subject-matter (Articles 76(1) and 123(2) EPC)

3.1 The proprietor contests the Opposition Division's conclusion that the main request did not comply with the requirements of Article 76(1) and 123(2) EPC

because of the omission in claim 1 of the feature that the catheter is at least in part vapour hydrated.

- 3.2 All independent claims of the parent application (WO 2005/014055 A2) expressly limit the claimed subject-matter to a "vapor hydrated" catheter assembly (assembly claims 1, 21, 46, 59, 112) or to activation of the catheter by vapour (method claims 83 and 97). Moreover, according to the summary of the invention on page 4 of the parent application and to the penultimate paragraph on page 26, lines 3 to 13, the invention provides a vapour hydrated catheter.
- 3.3 Instead, a sleeve is presented as optional (see page 4, lines 23 to 24 and claims 1 and 9 of the parent application), and is not presented as an alternative to vapour hydration. Hence, the Board is not convinced by the proprietor's submission that according to the parent application it was clear that the claimed invention was based on the provision of a flexible, collapsible sleeve. The fact that some of the disadvantages addressed by some embodiments of the invention are overcome by the sleeve rather than by vapor hydration does not equate to the disclosure of an assembly without vapor hydration.
- 3.4 The proprietor further submits that the parent application disclosed in the Background section and in connection with Tests 1 and 2 a catheter hydrated by swelling in contact with a hydrating liquid.
- 3.5 The references to hydration by swelling in the Background section relate to prior art, conventional catheters. This is in contrast to the vapour hydrated catheter of the invention as described starting on page 4, line 12.

- 3.6 In Test 1, hydration by immersion is carried out to highlight the disadvantages of traditional systems, in particular when combined with thinner, more flexible sleeves (page 19, line 30 to page 20, line 8 and page 22, lines 17 to 18).
- 3.7 The description mentions in connection with Test 2 that some free liquid water may remain in the package without being a spill hazard, but that the amount of water should occupy less than 20% of the volume (page 20, lines 9 to 22; see also the Table on page 23, which shows a percentage of water of up to 5%). This is followed by indicating that in the embodiment of Figure 1, the loose water should preferably occupy less than 10% of the volume and most preferably less than 5% of the volume (see also page 13, lines 10 to 17, describing vapour activation in the embodiment of Figure 1 and page 16, lines 19 to 25, describing that larger amounts of water may be used with a liquid sequestering element without a spill hazard). These values are then contrasted with the higher amount of liquid used for immersion of catheters for liquid activation, typically filled to 45-60% of their capacity (page 20, lines 28 to 30). It is thus clear that the disclosure in relation to Test 2 and Figure 1 does not refer to liquid activation but to vapour activation, even if some loose water may be present.
- 3.8 Hence, neither the Background section nor the disclosure in connection with Tests 1 and 2 provide a basis for omitting vapour hydration in claim 1.
- 3.9 The proprietor refers to the disclosure of a wide polyethylene sleeve within the embodiment of Figure 7 (page 17, lines 2 to 10), which would allow activation

of the catheter by immersion as done with the catheters used in Test 1. However, the parent application does not disclose activation of the assembly with the wide polyethylene sleeve by immersion, but only that "the catheter assembly can be provided in a package such as any of those described above in order for vapor hydration to ensure complete activation" (page 17, lines 11 to 13). It is therefore irrelevant whether or not it might be possible to activate the catheter of the embodiment of Figure 7 by immersion, as is done in the conventional devices described in Test 1.

3.10 The proprietor also argues that, according to the parent application, vapour hydration made it possible to use a liquid impermeable sleeve. Since a liquid permeable sleeve was also disclosed and there was no disclosure that a liquid permeable sleeve had any connection to vapour hydration, hydration by direct liquid contact was contemplated.

3.11 This argument is flawed. The relevant question is not whether or not use of a liquid permeable sleeve in combination with hydration by direct liquid contact is possible or could be contemplated. Instead, it must be established whether or not an assembly as defined in claim 1 - without vapor hydration - is directly and unambiguously disclosed in the parent application. The embodiment of Figure 3b comprises a liquid sequestering element 330' "to fully absorb the liquid water" (page 10, line 13 and page 12, lines 3 to 5). The parent application does not disclose a modification of the embodiment of Figure 3b or of any other embodiment by using a water permeable sleeve combined with hydration by direct liquid contact.

3.12 There is thus no basis for the disputed omission. It follows that the subject-matter of claim 1 extends beyond the content of the parent application (Article 76(1) EPC).

3.13 The patent is based on a divisional application which was filed as a copy of the parent application. Hence, the same reasons provided above for Article 76(1) EPC applies to Article 123(2) EPC when considering the corresponding passages of the application as filed.

3.14 In summary, the main request infringes Articles 76(1) and 123(2) EPC.

4. First auxiliary request

4.1 Added subject-matter (Articles 76(1) and 123(2) EPC)

4.1.1 The opponent contests the Opposition Division's conclusion that claim 1 did not comprise added subject-matter. Two features are disputed.

(1) Feature "due at least in part to hydration" and alleged "initial activation"

4.1.2 Claim 1 of the first auxiliary request relates to a "ready-to-use vapor hydrated hydrophilic catheter assembly". The disputed feature reads "the ready-to-use condition of the catheter is due at least in part to hydration by reason of exposure to the water vapor".

4.1.3 Hydration of the hydrophilic coated catheter results in its activation. Hence, the phrase "due at least in part to hydration by reason of exposure to the water vapor" in claim 1 means that hydration (and thus activation) by vapour has occurred and has contributed to the

ready-to-use condition. The Board is satisfied that nothing else is disclosed by the corresponding feature of claims 1, 21 and 113 of the parent application.

- 4.1.4 The opponent argues that the wording "due at least in part" in claim 1 of the first auxiliary request meant that hydration was due only in part to exposure to vapour. However, the wording "due at least in part" in claim 1 refers to the ready-to-use condition, as in claim 1 of the parent application ("the ready-to-use condition of the catheter is due at least in part to the vapor donating liquid producing a vapor atmosphere").
- 4.1.5 The opponent further argues that claim 1 of the first auxiliary request only required that the coating of the catheter was kept in an activated (hydrated) state by a contribution from vapour. However, as indicated above, claim 1 of the first auxiliary request requires that the ready-to-use condition is due at least in part to hydration (and thus activation) by vapour. Neither claim 1 of the first auxiliary request nor any of claims 1, 21 or 113 of the parent application defines any initial activation or distinguishes between initial activation and maintenance of the activated state. Hence, they provide the same technical information.
- 4.1.6 It follows that the objection of added subject-matter in relation to the feature "due at least in part to hydration by reason of exposure to the water vapor" is not convincing.

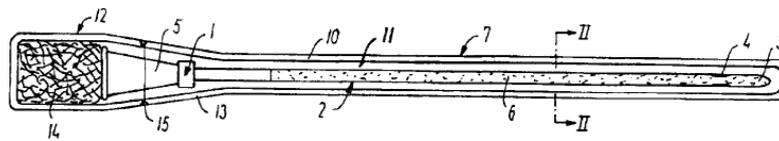
(2) Omission of the feature that liquid can only be present outside the sleeve

- 4.1.7 The parent application discloses that in the embodiments having a sleeve, the liquid introduced into the package during manufacture is located externally of the sleeve and that, after the package is sealed, the catheter tube is hydrated by vapour generated within the package (page 5, lines 3 to 8). This disclosure does not exclude that some liquid may contact the catheter tube after manufacture and partly hydrate it, i.e. the passage does not specify that the catheter tube is hydrated only by vapour. Hence, contrary to the opponent's submissions, there is no conflict between this passage and the possibility of having liquid within the sleeve during the process of activation.
- 4.1.8 Claim 1 of the first auxiliary request leaves open whether some liquid may contact part of the catheter tube and activate that part. Claim 1 of the parent application requires that the vapour atmosphere activates **at least a portion of** the hydrophilic coated catheter. Claim 9 of the parent application specifies that the catheter includes a tube and a sleeve surrounding the tube. Hence, also the combination of claims 1 and 9 of the parent application does not exclude that some liquid may contact part of the catheter tube and activate that part. Moreover, the fact that the liquid in claim 1 of the parent application is defined as "vapor donating" does not mean that all the liquid must become vapour, i.e. it does not exclude that some liquid may instead directly contact the tube and hydrate it. Thus, the limitation that the liquid is present only outside the sleeve is not implied by the combination of claims 1 and 9 of the parent application. The opponent highlighted that claim 1 of the first auxiliary request was not a literal combination of claims 1 and 9 of the parent application. However, the change of wording (discussed

above in relation with the other objection of added subject-matter) has no impact as to the necessity for liquid to be only outside the sleeve.

- 4.1.9 Hence, the absence of the feature that liquid can only be present outside the sleeve does not result in subject-matter extending beyond the content of the parent application as filed.
- 4.1.10 The same reasons set out above for Article 76(1) EPC apply to Article 123(2) EPC when considering the corresponding passages of the application as filed. It follows that none of the objections of added subject-matter against the first auxiliary request is convincing.
- 4.2 Clarity, conciseness and support by the description (Article 84 EPC)
- 4.2.1 Claim 1 does not specify that activation is achieved by a principle other than vapour hydration. As set out above in relation to the objection of added subject-matter, claim 1 requires that the ready-to-use condition is due at least in part to hydration (and thus activation) by vapour, so that the ready-to-use condition may be due in part to factors other than hydration by reason of exposure to the water vapour. The meaning is thus clear. Moreover, it is also apparent to the person skilled in the art that hydration by exposure to vapour may be one of the factors contributing to the ready-to-use condition. Therefore, there is no lack of support within the meaning of Article 84 EPC introduced by the amendments after grant.

- 4.2.2 The opponent argues that claim 1 lacked conciseness because there was an inconsistency between the features of "a vapor hydrated" catheter assembly and the last feature that the ready-to-use condition was due at least in part to hydration by reason of exposure to vapour. The Board holds that there is no such inconsistency. Neither feature specifies that the catheter assembly must be entirely hydrated by vapour, only that it must have been hydrated by vapour.
- 4.2.3 The Board is thus not convinced by the objections of lack of clarity, lack of conciseness and lack of support under Article 84 EPC.
- 4.3 Inventive step (Articles 52(1) and 56 EPC)
- 4.3.1 The opponent contests the conclusion by the Opposition Division that the subject-matter of claim 1 involved an inventive step when starting from D4.
- 4.3.2 D4 discloses in the embodiment of Figure 1 (reproduced hereinafter) a ready-to-use catheter assembly (page 3, lines 6 to 7). The assembly comprises a gas impermeable package 7 having a sealed cavity 11, a hydrophilic coated catheter tube 2 (page 7, lines 21-23) and an amount of liquid disposed within the sealed cavity 11 and maintained in liquid state by confining it in a storage body 14 which may be of a spongy or gel-like material (page 8, lines 8 to 10 and 17 to 22). Prior to the intended use, an external pressure is applied to squeeze the liquid out from the storage body 14 and allow it to flow into the cavity 11 so that the catheter is in a ready-to-use condition in a period of about 30 seconds (page 8, lines 28 to 33 and page 9, lines 8 to 12).



- 4.3.3 It is undisputed that D4 - in the embodiment of Figure 1 - defines a valid starting point for assessing whether the subject-matter of claim 1 involves an inventive step.
- 4.3.4 It is likewise undisputed that D4 does not disclose at least the feature "a flexible, collapsible sleeve surrounding the tube to permit gripping the tube or shaft through the sleeve". This feature has the technical effect of facilitating handling of the lubricious catheter while also permitting a sterile insertion (see paragraph [0014], lines 33 to 35 of the patent specification).
- 4.3.5 According to D4, the same technical effect is achieved by using the package 7 as an applicator (page 9, lines 28 to 31). As submitted by the opponent, the problem to be solved can be regarded as providing an alternative way of facilitating insertion of the catheter of D4 without risk of contamination.
- 4.3.6 The opponent argues that D3, D7 and D8 each disclosed a sleeve for facilitating catheter manipulation without risk of contamination, and that such a sleeve would be readily combined with the assembly of D4 when faced with the problem above, resulting in an assembly with a package and a sleeve as defined by claim 1.
- 4.4 The assembly disclosed by each of D3, D7 and D8 is designed to provide for gel lubrication of the catheter upon insertion. None of these documents disclose that sterile catheter insertion is facilitated by provision

of a sleeve in isolation. This is only disclosed for the combination with other related features such as the introducer to which the sleeve is tightly secured at the insertion/distal end and which comprises the lubricant (D3: handpiece 13 with dilator 15, see also column 4, lines 10 to 15; D7: introducer 15, see also column 7, line 65 to column 8, line 3; D8: introducer 28, see also column 2, lines 14 to 17). Hence, the person skilled in the art consulting any of these documents would not consider incorporating into the assembly of D4 an isolated sleeve.

4.5 Moreover, D4 teaches that the package may be used for sterile manipulation/insertion of the catheter (page 9, lines 28 to 31). The addition of a sleeve within the cavity of the package of D4 would result in the sleeve duplicating this function of the package, so that the sleeve would be completely superfluous. The person skilled in the art looking for an alternative way of facilitating sterile manipulation would thus discard such a combination and, if at all, seek to replace the package with a sleeve (and the closely related features as taught in D3, D4 or D8), thus not arriving at an assembly as defined in claim 1.

4.6 In any event, addition of a sleeve within the package would not only be redundant, but the resulting assembly would have disadvantages as compared to the assembly of D4. In particular, D4 teaches rapid activation and operation of the catheter when the user squeezes the liquid out from the storage body 14 (page 8, lines 28 to 33 and page 9, lines 8 to 12). A sleeve surrounding the hydrophilic catheter would be an obstacle for the liquid to reach the catheter, impairing the rapid activation taught by D4. The interference of a sleeve with the activation of a hydrophilic catheter by

immersion is also acknowledged in the contested patent (see paragraph [0009], 2nd sentence, as well as paragraphs [0067], [0068] and [0079]).

4.7 The opponent argues that the sleeve would not impair activation because the catheter of D4 would be activated by vapour. This is however contrary to the teaching of D4 in connection with the embodiment of Figure 1 that the liquid is confined in the storage body 14 until activation by liquid is required immediately prior to use (see page 4, lines 20 to 33 and page 8, lines 17 to 22). The opponent submits that the liquid from the storage body 14 would enter the outlet 5, pass through the tube and the distal inlet openings 4 and reach and hydrate the outer surface of the tube regardless of the presence of the sleeve. D4 discloses such a liquid flow in connection with the embodiment of Figure 9 (see page 13, lines 1 to 18), which includes an ampoule 35 that, upon compression, releases the liquid only through the outlet part 37 into the outlet 5 and into the catheter tube. However, D4 discloses that in other embodiments the liquid is transferred directly through the package cavity "without having to flow internally through the catheter tube" (see page 15, lines 5 to 17). Hence, in the embodiment of Figure 1 the liquid flow alleged by the opponent would not occur.

4.8 The opponent puts forward that the person skilled in the art would consider using a vapour-permeable sleeve or even a liquid-permeable sleeve to facilitate hydration of the catheter. This is not supported by a corresponding disclosure in D3, D7 or D8. The opponent also argues that the person skilled in the art would not seal the sleeve to the catheter tube of D4, neither proximally nor distally, because the package already

provided a barrier against contaminants. However, each of D3, D7 and D8 discloses that the sleeve is tightly secured / sealed at both sides to the catheter tube (see passages cited above), in particular also using an introducer at the distal/insertion end. The person skilled in the art would not have done - without use of inventive skill - the additional modifications suggested by the opponent without any indication in the prior art.

4.9 The person skilled in the art starting from the catheter assembly of D4 would therefore refrain from adding a sleeve that is superfluous and that results in a poorer hydration of the catheter. The objections of lack of inventive step starting from D4 are thus not convincing.

5. In summary, there are no objections prejudicing maintenance of the patent on the basis of the first auxiliary request, which corresponds to the request found to be allowable in the contested decision.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chair:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated