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**Datasheet for the decision  
of 7 July 2009**

**Case Number:** T 1917/06 - 3.2.02

**Application Number:** 97901879.3

**Publication Number:** 0959930

**IPC:** A61M 25/01

**Language of the proceedings:** EN

**Title of invention:**

Hydrophilic urinary catheter having a water-containing sachet

**Patentee:**

Astra Tech AB

**Opponent:**

Willy Rüschi GmbH

**Intervener:**

TELEFLEX MEDICAL GMBH

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 52(1), 56, 87

**Relevant legal provisions (EPC 1973):**

-

**Keyword:**

"Admissibility of new request (yes)"

"Priority claim (valid)"

"Inventive step (yes, after amendment)"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 1917/06 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 7 July 2009

**Appellant:** Astra Tech AB  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
11 December 2006 concerning maintenance of  
European patent No. 0959930 in amended form.

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** S. Chowdhury  
M. J. Vogel

## Summary of Facts and Submissions

- I. European patent application 97 901 879.3, filed on 22 January 1997 and claiming a priority date of 25 January 1996, matured into European patent No. 0 959 930.

Following an opposition filed under Article 99 EPC and an intervention filed under Article 105 EPC, the interlocutory decision of the opposition division was dispatched on 11 December 2006.

The opposition and the intervention were based, inter alia, on Article 100(a) EPC in respect of both novelty and inventive step.

On 18 December 2006 the intervener filed an appeal against this decision and paid the appeal fee on the same day. The statement of grounds of appeal was received on 5 April 2007. The intervener and the opponent are hereinafter referred to jointly as the appellant opponents.

On 19 February 2007 the patent proprietor (hereinafter referred to as the appellant proprietor) filed an appeal against this decision and paid the appeal fee on the same day. The statement of grounds of appeal was received on 20 April 2007.

- II. The following documents were principally relied upon during the appeal proceedings:

D4: US-A-3 967 728

D5: US-A-4 269 310

D6: W0-A-94/16747  
D11: SN 9600276-1 (Priority document of the Opposed Patent)  
D12: EP-B1-0 923 398 (cited under Article 54 (3) EPC)  
D14: DE-A-2 317 839  
D18: Notice of opposition by Astra Zeneca AB to European Patent No. 0 923 398  
D19: W0-A-86/06284.

The appellant opponents argued that the patent in suit was not entitled to its claimed priority date so that D12 was a prior art document under Article 54(3) EPC.

III. Oral proceedings took place on 7 July 2009.

#### Requests

The appellant proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 12 filed at the oral proceedings, description pages 2 to 6 filed at the oral proceedings, and Figures 1 to 8 as granted.

The appellant opponents requested that the decision under appeal be set aside and that the European patent No. 0 959 930 be revoked.

IV. Claim 1 reads as follows:

"A wetting apparatus (10) for wetting a hydrophilic urinary catheter prior to use comprising a wetting receptacle (1) which defines a wetting fluid receiving area (2), wherein the wetting fluid receiving area forms an elongate pocket, and a hydrophilic urinary

catheter (3) having a distal insertion end and arranged in said receptacle (1) wherein the elongate pocket accommodates the insertable length of the catheter, characterised in that the apparatus further comprises a wetting fluid container (6) containing a wetting fluid and being openable to enable the wetting fluid to be discharged from the wetting fluid container, that the wetting fluid container (6) is integrated with the wetting receptacle (1) that the wetting fluid container (6) is fully contained within the bounds of the wetting receptacle (1), that a discharge outlet of the wetting fluid container (6) is disposed within the bounds of the wetting receptacle (1) and arranged outside the elongate pocket and in a part of the wetting receptacle located opposite to said distal end of the catheter, that the discharge outlet of the wetting fluid container (6) is in fluid communication with the wetting fluid receiving area (2), and that opening of the discharge outlet of the wetting fluid container enables the wetting fluid to be discharged into the wetting fluid receiving area (2) and, thereby, to wet at least an insertable length of the hydrophilic urinary catheter (3)."

Claims 2 to 12 are dependent claims.

V. The parties submitted the following arguments:

Appellant opponents

The new request filed at the oral proceedings cancelled the words "at least". However, the corresponding objection was made about two and half years ago but not addressed until now, so it should not be admitted.

The term "wetting fluid" was not supported by the priority document D11, which disclosed the use of water or saline as being a "key feature" of the invention. The sole reference to a liquid was water or saline and D11 disclosed no other liquid or gas.

The term "distal end" was not directly disclosed in D11 and the opposition division failed properly to consider whether the actual features recited in claim 1 relating to the position and form of the wetting fluid container were actually disclosed in D11. D11 clearly stated that the location of the container inside the bag was not critical whereas present claim 1 specified the location precisely, so that claim 1 was not directed to the same "invention" as taught in D11.

Although present claim 1 specified the location of the fluid container precisely D11 did not indicate the location of a sachet clearly. The drawing was a two dimensional view and it was not clear whether the sachet was on or outside the package, particularly in view of the statement that its location was not critical. In the case of any inconsistency the text took precedence over the drawing.

D11 described two separate embodiments, a wetting device and a urine collection bag, but only the latter was described in connection with an enclosed packaging having an elongated pocket and an integrated fluid container for releasing liquid into the pocket for wetting a hydrophilic catheter housed therein. Only when the wetting apparatus was realised as a urine collection bag by sealing it were the claimed features

taught to be applicable. The claimed wetting device had a significantly broader scope than a urine collection bag.

In view of the preceding arguments the priority claim of the patent in suit was not valid and D12 was a novelty destroying document, accordingly.

The patent in suit was not concerned with the form or construction of a catheter, this was conventional, it was concerned with its packaging. A conventional catheter and a conventional liquid were packaged in a form convenient for the end user. Therefore, the relevant person skilled in the art was one of packaging of catheters in general and he would consider documents describing hydrophilic catheters as well as gel coated catheters since both had the same packaging problems.

D19 (or D6) was the closest prior art document because it was concerned with improving a packaging for catheters. It disclosed a packaging for wetting a hydrophilic catheter before use, but it needed a separate source of water. This was not a problem initially since catheterisation was performed in a hospital environment, only later did social conditions change and self- catheterisation was performed at home or even outside the home or a comfort environment where water might not be readily available. This problem would become apparent upon use of the catheter.

The solution to this problem was disclosed in each of D4, D5, and D14, which highlighted the above problem and disclosed packaging a lubricant together with the

catheter. The opposed patent used the same solution, which was obvious.

Alternatively, starting from D14, this document disclosed all the features of claim 1, save that a gel catheter was shown. It would be obvious to similarly package a hydrophilic catheter and a liquid instead of an ordinary catheter and the gel.

Appellant proprietor

The patent proprietor had not amended the wording "at least" before the oral proceedings because the Board's communication indicated that this wording was acceptable.

The term "wetting fluid" was supported by the priority document D11, which disclosed the use of a liquid (water or saline) and because the use of gas made no technical sense in the context.

The term "distal end" had a well defined meaning in the art. Regarding the location of the sachet the opposed patent in suit was completely consistent with D11 which stated that the location of the container inside the bag was not critical as long as its contents could be released into the pocket.

The overall disclosure of D11 described all the features of claim 1 and whether the device was termed a wetting device or a urine collection bag was to do with its use and not its construction.



## Reasons for the Decision

1. The appeals are admissible.
2. *Admissibility of the claims filed at the oral proceedings*

At the oral proceedings the Board gave its decision that claim 1 of the main request and the first auxiliary request filed on 30 August 2007 were not entitled to the claimed priority date because claim 1 included the words "at least" and thereby encompassed the second embodiment described and claimed in the patent in suit, which embodiment was not disclosed in D11. In response to this decision the patent proprietor promoted its second auxiliary request, which is limited to the first embodiment in which the wetting fluid container is fully contained within the bounds of the wetting receptacle, to the main request. The new claim 1 includes the wording of granted claim 7.

However, the words "at least" remained in new claim 1, so that the claim was inconsistent with itself and with the proprietor's intention of limiting the scope of the claim to the first embodiment only.

This was an obvious oversight on the proprietor's part. In fact, at the oral proceedings the appellant opponents' representative stated that when reading granted claim 7 it would be implicit that the words "at least" were no longer applicable in claim 1. Therefore, the removal of these words amounts to the correction of an obvious oversight and is allowable.

3. *Amendments*

Claim 1 of the main request combines the wording of claims 1 and 7 as granted and there is no objection to it under Article 123(2) or (3) EPC.

4. *Priority claim of the patent in suit*

4.1 D11, the Swedish application from which priority is claimed, describes wetting a hydrophilic catheter by "a liquid (water or saline)" on page 1, lines 11 to 12. There are further references to the use of water or saline, including a statement on page 2, lines 32 to 33 that "The key feature of the invention is the provision of a container containing water or saline". Nevertheless, claim 1 of the patent uses the much broader term "fluid" in this respect, which term includes not only liquids other than water or saline but also gases.

However, in the present context the Board considers the term "fluid" to exclude gases because it is unrealistic to expect a gas to activate a catheter for use by wetting it within a reasonable time. The appellant opponents' fear, that the patent might be making a far sighted attempt at covering possibilities which may arise in the future, is also unrealistic because of the impractical time that would be required by any gas to activate the catheter adequately. By this term is clearly meant a liquid in the context, accordingly.

The wording "a liquid (water or saline)" on page 1 of D11 clearly discloses the use of a liquid, but the appellant proprietor argues that, in view of the above

statement on page 2 of D11, "liquid" is limited to water or saline.

The Board disagrees. The term "hydrophilic" implies that a water-based or aqueous solution must be involved in the activation of the catheter. The person skilled in the art would understand that tap water, for example, together with an additive such as in tablet form as in D19 would be satisfactory for wetting the catheter. Moreover, "key feature of the invention" on page 2 of D11 refers primarily to an openable container able to release its contents into the pocket, consistent with page 4, and not to water or saline. Therefore, the wording "a liquid (water or saline)" is not limiting.

4.2 The crux of the invention of D11 is the provision of an openable container able to release its contents into the elongate pocket, as stated on page 2, last paragraph and page 4 of D11. The precise location of the container is not critical. This is also featured in claim 1 of the patent in suit, according to which the elongate pocket accommodates the insertable length of the catheter, a wetting fluid container is integrated with the wetting receptacle and is openable to enable the wetting fluid to be discharged into the pocket to thereby wet at least an insertable length of the catheter. In this respect, therefore, the claim is fairly based on D11.

4.3 The Board has no doubt as to what is meant by the distal end of the catheter, this is normal usage of the term and means the rounded end of a catheter which is to be inserted into a body, the other end, which is sometimes flared (as in the patent), being the proximal

end. Both the patent and D11 show the same arrangement of catheter with its distal end in the elongated pocket.

4.4 D11 describes a wetting device for a hydrophilic catheter and a urine collection bag incorporating the device. This application has a drawing which is practically identical with Figure 1 of the patent in suit, which illustrates the first embodiment now exclusively claimed. The aim of this invention is set out at the end of page 2 of D11, and for achieving this aim it is immaterial whether the device is used as a wetting device or as a urine collection bag. The latter only implies that the device must be large enough to contain urine and be closed.

Accordingly, D11 describes a wetting device comprising a wetting receptacle (1) which defines a wetting fluid receiving area, wherein the wetting fluid receiving area forms an elongate pocket (2), and a hydrophilic urinary catheter (3) having a distal insertion end and arranged in said receptacle (1) wherein the elongate pocket accommodates the insertable length of the catheter, wherein the apparatus further comprises a wetting fluid container (6) containing a wetting fluid and being openable to enable the wetting fluid to be discharged from the wetting fluid container, the wetting fluid container (6) is integrated with the wetting receptacle (1) and is fully contained within the bounds of the wetting receptacle (1), a discharge outlet of the wetting fluid container (6) is disposed within the bounds of the wetting receptacle (1) and arranged outside the elongate pocket and in a part of the wetting receptacle located opposite to said distal end of the catheter, the discharge outlet of the

wetting fluid container (6) is in fluid communication with the wetting fluid receiving area (2), and that opening of the discharge outlet of the wetting fluid container enables the wetting fluid to be discharged into the wetting fluid receiving area (2) and, thereby, to wet at least an insertable length of the hydrophilic urinary catheter. This is a wetting device which may be used as a urine collection bag.

Claim 1 is fully supported by D11, accordingly.

4.5 For these reasons claim 1 is entitled to the claimed priority date.

5. *Novelty*

Since claim 1 is entitled to the claimed priority date D12 is no longer prior art under Article 54(3) EPC. This was the only document cited under a novelty objection, so that the question of novelty of the claim subject-matter is no longer an issue to be decided.

6. *Inventive step*

6.1 The closest prior art document and other prior art to be considered

According to the appellant opponents the patent in suit relates to the problem of packaging of hydrophilic catheters and the neighbouring field of gel catheters is relevant to the presently claimed invention because the two types of catheters share common packaging problems. The Board disagrees with this.

The problems associated with packaging gel catheters are different to those associated with hydrophilic catheters. Gel is routinely packaged with the catheter in order to avoid situations where no gel is readily available, whereas in the case of hydrophilic catheters the hydrophilic material is carried by the catheter itself and only water needs to be added, and since water is a ubiquitous substance it is not packaged with the catheter.

Initially catheterisation was performed in hospitals, but later for some categories of patients intermittent self-catheterisation in a home environment became possible. The present patent envisages an extension of the usage of such catheters outside a comfort environment such as the home. Accordingly, the patent in suit sets out, for the first time, the problem that since the wetting liquid for the pocket has to be supplied separately by the patient, this might lead to problems because a sterile supply of wetting liquid is not necessarily always on hand and there is also the possibility of spillage of the liquid. See (paragraph [0007] of the patent).

According to the appellant opponents since self-catheterisation was initially performed in a hospital there was no need for the presently claimed invention. Later on there was a social change and the demand for self-catheterisation in a public environment arose, and then the present problem would have presented itself upon use of the catheter. According to the appellant proprietor, however, self-catheterisation using hydrophilic catheters had been known since the late 1970s yet no one had come up with the present problem.

In the absence of any evidence one way or the other the Board must accept the appellant proprietor's argument in this respect.

This problem is exclusive to the field of hydrophilic catheters because in the case of gel catheters a lubricant is always carried by the packaging, as exemplified by D4, D5, and D14. Therefore, the closest prior art document must be one dealing with hydrophilic catheters. The solution to this problem must also be sought in other documents relating to hydrophilic catheters, for only in these documents could a solution to the present problem be found.

The appellant opponents have defined the problem too broadly (packaging) and not taken into consideration the actual achievement of the patent over the prior art. This has resulted in an ex post facto consideration of the problem and solution.

6.2 D19 is the closest prior art document. It discloses a wetting apparatus for use in intermittent self-catheterisation having two pockets, one for wetting and one for drying catheters for repeated use. D19 does not disclose any of the characterising features of claim 1. Starting from D19 the problem is as set out in paragraph [0007] of the patent.

6.3 Nothing in this problem would lead the skilled person to the field of gel catheters, so the skilled person would not consult D4, D5, or D14. In any case, none of these documents suggests providing a fluid container as recited in the characterising part of claim 1.

6.4 The appellant opponents contend that the embodiment described with reference to Figure 3 of D14 suggests the solution as set out in the characterising part of claim 1. This is not correct.

This device comprises a lubricant container 7 which is squeezed to empty its contents into an area adjacent a constriction 6a in a pocket 2, and the catheter 1 is pushed past the constriction so that upon withdrawal ("beim herausziehen" see claim 1 of D14) it is coated with the lubricant. This method is not suitable for coating a hydrophilic catheter because this requires a holding time of some 30 seconds in order to be activated (see page 4 of D11 or paragraph [0038] of the patent).

6.5 The appellant opponents contend that D19, at lines 22 to 25 on page 3, also refers to gel catheters. This is not correct. The tenor of the entire document D19 is that it relates exclusively to hydrophilic catheters (see page 2, lines 28 to 29) and consequently mentions the use of a liquid throughout. The cited passage on page 3, also mentions wetting a catheter in a liquid and, in the context, this must be in connection with a hydrophilic catheter. That the catheter has no surface coating could mean that the catheter itself is of a hydrophilic material, or at most this passage is ambiguous. In any case, there is no clear disclosure of a gel catheter here.

D14 is, for the reasons given above, not a suitable starting point for developing a hydrophilic catheter.



6.6 The Board has considered document D18, which is a notice opposition against the European Patent D12. In that opposition the present appellant proprietor argued that the skilled person would consider documents relating to both hydrophilic catheters and to lubricant catheters as a matter of course, which is the opposite to what it is arguing in the present case.

Whether or not a document is to be considered in the examination of inventive step depends on the specific technical problem at hand as explained in point 6.1 above. In the present case the Board has identified an objective technical problem to be solved, which is associated with hydrophilic catheters, and come to the conclusion that the skilled person would not expect to find a solution therefor in the field of lubricant catheters. This objective analysis trumps anything which the present appellant proprietor may have stated in a previous case whose facts, in any case, are different to the facts of the present case.

6.7 In view of the foregoing considerations the subject-matter of claim 1 involves an inventive step.

## Order

### For these reasons it is ordered that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of the first instance with the order to maintain the patent on the basis of the following documents:
  - claims 1 to 12 filed at the oral proceedings,
  - description pages 2 to 6 filed at the oral proceedings,
  - Figures 1 to 8 as granted.

The Registrar

The Chairman

D. Sauter

M. Noël