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**Datasheet for the decision
of 14 June 2007**

Case Number: T 1023/05 - 3.2.02

Application Number: 98906111.4

Publication Number: 0959935

IPC: A61M 25/10

Language of the proceedings: EN

Title of invention:
Suprapubic drainage catheter

Applicant:
Cook Urological Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 84

Keyword:
"Clarity (yes)"
"Novelty and inventive step (yes, after amendments)"

Decisions cited:
T 0068/85

Catchword:
-



Case Number: T 1023/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 14 June 2007

Appellant: Cook Urological Inc.
1100 West Morgan Street
P.O. Box 227
Spencer
IN 47460 (US)

Representative: Jehan, Robert
Williams Powell
Morley House
26-30 Holborn Viaduct
London EC1A 2BP (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 March 2005
refusing European application No. 98906111.4
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
E. Dufrasne

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal on 13 May 2005 against the decision of the examining division posted on 11 March 2005 refusing the European patent application 98906111.4. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 4 July 2005.
- II. The examining division held that the application did not meet the requirement of Article 84 (lack of clarity of claims 1 and 6 to 8), and that the subject-matter of claims 1, 2 and 3 was not novel with respect to D2 = US-A-2 642 874.
- III. Additionally the following document, cited in the search report, has been considered for the present decision:

D1 = US-A-4 705 502.
- IV. Oral proceedings took place on 14 June 2007.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of:

Claims: 1 to 12 filed during the oral proceedings,
Description: pages 1 and 3 to 10 as published
pages 2 and 2a filed during the oral proceedings,
Figures: 1 to 4 as published.

V. Claim 1 reads as follows:

"Bladder drainage catheter apparatus (10) for percutaneous insertion into the bladder of a patient, said apparatus comprising an elongated member (11) having a drainage passage (12) extending at least to one or more catheter drainage ports (16) in a drainage portion (14) for draining fluid from the bladder, means (18) for preventing seepage of fluid from around the percutaneous insertion site, and a seal arrangement (17) on a part of the catheter distal from the drainage port(s) for sealing and preventing fluid from entering a prostatic urethra of the bladder wherein a distal end (13) of the catheter is closed and extends distally beyond the seal arrangement (17) so as to be able to extend through the anastomotic site into the prostatic urethra to maintain patency of the anastomosis and the urethra; wherein the length of the drainage portion (14) ranges from 2 to 20 cm so that the means (18) and the seal arrangement (17) are operable to maintain the drainage portion in the bladder and the distal portion in the urethra."

Reasons for the Decision

1. The appeal is admissible.
2. *Clarity*
 - 2.1 The board agrees to the finding of the first instance that the following features of claim 1 merely describe the function of an element of the claimed apparatus

instead of defining the element in terms of its structural, technical features:

- means for preventing seepage of fluid from around the percutaneous insertion site,
- a seal arrangement ... for sealing and preventing fluid from entering a prostatic urethra of the bladder.

According to the case law of the boards of appeal of the EPO, technical features may be expressed in functional terms if, from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the invention, and if these features provide instructions which were specifically clear for the expert to put the invention into practise without undue burden (see for example T 68/85; OJ EPO, 1987, 228).

Since the present application clearly describes that both the means for preventing seepage and the seal arrangement are not restricted to a balloon as shown in the drawings, and since it can be expected that the skilled person in the field of medical technology is capable to provide means for preventing seepage and a seal arrangement for sealing as defined in claim 1 without undue burden, both of these requirements are met in the present case.

- 2.2 Furthermore, it is also true that the following feature refers to the relationship between a dimension of the claimed apparatus and the dimension of an urethra:

- a distal end of the catheter is closed and extends distally beyond the seal arrangement so as to maintain the patency of the anastomosis and the urethra.

However, this feature clearly describes the structure of the distal portion of the catheter, e.g. that it comprises a distal end portion which is closed and extends distally beyond the seal arrangement and only additionally gives the information that the length of this end portion has to be selected so as to maintain the patency of the anastomosis and the urethra. Since the size of the urethra and anastomosis may vary, it is obvious that catheters having various lengths are covered by claim 1. This may result in a certain range for the length of the distal end, but it does not mean that the claim lacks clarity. In particular, since it is unquestionable that the dimensions of the human prostatic urethra lie within a relatively narrow range of values.

The same applies in view of the dimension of a bladder with respect to the feature according to which

- the length of the drainage portion ranges from 2 to 20 cm so that the means (for preventing seepage) and the seal arrangement are operable to maintain the drainage portion in the bladder and the distal portion in the urethra.

2.3 With respect to the above findings, the present version of the application is not objectionable under Article 84 EPC.

3. *Amendments*

Claim 1 is derived from the original claim 1, from page 2, lines 19 to 22 and from page 8, lines 9 to 13 of the description.

Claim 2 is derived from the original claim 2, claims 3 to 10 from claims 4 to 11; claims 11 and 12 from claims 18 and 19;

The description has been adapted to the new filed claims.

Consequently the amendments made are allowable with respect to Article 123(2) EPC.

4. *Novelty*

D1 discloses a bladder drainage catheter apparatus for percutaneous insertion into the bladder of a patient, said apparatus comprising an elongated member (12) having a drainage passage (14) extending at least to one or more catheter drainage ports (34) in a drainage position for draining fluid from the bladder, and means (balloon 16) for preventing seepage of fluid from around the percutaneous insertion site.

However, D1 does not disclose a seal arrangement on a part of the catheter distal from the drainage port(s) for sealing and preventing fluid from entering a prostatic urethra of the bladder wherein a distal end of the catheter is closed and extends distally beyond the seal arrangement so as to be able to extend through the anastomotic site into the prostatic urethra to

maintain patency of the anastomosis and the urethra; wherein the length of the drainage portion ranges from 2 to 20 cm so that the means and the seal arrangement are operable to maintain the drainage portion in the bladder and the distal portion in the urethra.

The further documents of the state of the art are further away from the claimed invention.

Accordingly the subject-matter of claim 1 is novel.

5. *Inventive step*

Starting from D1, which is considered to represent the closest state of the art cited, the object underlying the present application has to be seen in providing a suprapubic bladder drainage catheter apparatus which is able to maintain patency of the urethra during the healing process following an anastomosis and prevents fluid from entering the prostatic urethra of the bladder.

This object is achieved by the distinguishing features of claim 1 over D1 (see paragraph 4 above).

There are no hints in the available prior art which can lead to the claimed invention in an obvious way.

D1 teaches the opposite of the invention, since its aim is not to prevent fluid from entering the prostatic urethra, but to keep the urethra passage open so that the patient can discharge the urine through it as soon as possible and without the need of removing the catheter (see D1, column 1, lines 28 to 40).

Furthermore, the purpose of D1 is to keep the catheter far from the anastomotic site (see D1, column 3, lines 12 to 15).

D2 is farther away from the invention since it discloses a urethral catheter suitable for supplying medicinal substances to and draining fluid from the prostate gland and not a bladder drainage catheter for percutaneous insertion as the invention.

With respect to the above findings, the subject-matter of the claim 1 involves also an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of:

Claims: 1 to 12 filed during the oral proceedings,

Description: pages 1 and 3 to 10 as published
pages 2 and 2a filed during the oral proceedings, and

Figures: 1 to 4 as published.

The Registrar:

The Chairman:

V. Commare

T. Kriner