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**Datasheet for the decision  
of 11 February 2016**

**Case Number:** T 2525/12 - 3.2.02

**Application Number:** 02748637.2

**Publication Number:** 1404403

**IPC:** A61M25/01, A61M25/00

**Language of the proceedings:** EN

**Title of invention:**

A CATHETER DEVICE

**Patent Proprietor:**

Coloplast A/S

**Opponents:**

Hollister Incorporated  
Astra Tech AB

**Headword:**

**Relevant legal provisions:**

EPC Art. 52, 54, 56, 83, 87(1), 100(a), 100(b), 100(c),  
111(1), 123(2)  
EPC R. 43(7)  
RPBA Art. 12(1), 12(4)

**Keyword:**

First auxiliary request - admitted (yes)  
Remittal to the department of first instance - (no)  
Amendments - added subject-matter (no)  
Sufficiency of disclosure - (yes)  
Priority - basis in priority document (yes)  
Novelty - (yes)  
Inventive step - (yes)

**Decisions cited:**

G 0009/91, G 0010/91, T 0390/07, T 0023/10

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 2525/12 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 11 February 2016**

**Appellant:**  
(Patent Proprietor)

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**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
12 October 2012 concerning the maintenance of  
European Patent No. 1404403 in amended form.**

**Composition of the Board:**

**Chairman**            M. Stern  
**Members:**            D. Ceccarelli  
                              O. Loizou

## **Summary of Facts and Submissions**

- I. The patent proprietor, opponent 1 and opponent 2 have all appealed the Opposition Division's decision, dispatched on 12 October 2012, that European patent 1 404 403 as amended according to the then pending auxiliary request 1 complied with the EPC.
- II. The patent was opposed on the grounds of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step.
- III. The patent proprietor's notice of appeal was received on 20 December 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 22 February 2013.
- IV. The notice of appeal of opponent 1 was received on 21 December 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 22 February 2013.
- V. The notice of appeal of opponent 2 was received on 12 December 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 22 February 2013.
- VI. Each of the patent proprietor, opponent 1 and opponent 2 replied to the statements of grounds of appeal of the other parties by letters received respectively on 5, 10, and 5 July 2013.
- VII. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 9 November 2015.

VIII. Opponent 2 stated by letter dated 11 January 2016 that it would not attend the oral proceedings.

IX. The patent proprietor and opponent 1 filed further written submissions by their respective letters dated 11 January 2016.

X. Oral proceedings took place on 11 February 2016 in the absence of opponent 2.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the first auxiliary request filed on 22 February 2013, or, in the alternative, of one of the second auxiliary request filed on 22 February 2013 and the third to sixth auxiliary requests filed on 5 July 2013.

Opponent 1 requested that the decision under appeal be set aside and that the patent be revoked.

Opponent 2 had requested in writing that the decision under appeal be set aside and that the patent be revoked.

XI. The following documents are referred to in the present decision:

- D2: DE-A-24 62 537;
- D4: EP-A-1 023 882;
- D9: DE-A-38 16 906;
- D10: WO-A-00/30575;
- D12: US-A-3,894,540;
- D15: US-A-4,583,967;
- D17: WO-A-91/05577;
- D18: WO-A-99/30761;

D19: SE-C-505 615;  
D20: EP-A-0 471 429;  
D21: WO-A-98/06642;  
D29: Danish patent application No. 2001 01041;  
D34: WO-A-03/002043;  
D35: WO-A-03/002178.

XII. Claim 1 of the first auxiliary request reads as follows:

"A kit for preparing a catheter for draining a human bladder via the urethra, the kit comprising at least two catheter sections (20; 21; 26; 30; 42; 44; 62; 64) defining a passage therein, the sections being adapted to be arranged in a first mutual configuration wherein the passages are joined into one passage and the sections together constitute a catheter of a length larger than the length of each individual section and having such a rigidity that the catheter is manipulatable for insertion of a proximal one of the catheter sections (20; 30; 42; 62) into the urethra by manipulation of another one of the catheter sections (21; 26; 44; 64) and a second mutual configuration wherein the kit is shorter than when the sections are arranged in the first mutual configuration, characterised in that said sections (20; 21; 26; 30; 42; 44; 62; 64) comprise a pair of separate sections joined by a telescopic joint (24; 31; 50; 69), and in that at least that part of the catheter, which extends a connecting zone between the catheter sections, has a bending moment of at least 0.6 MPamm<sup>4</sup>, the bending moment being defined as the product between E-modulus and moment of inertia."

Claims 2 to 11 are dependent claims.

XIII. The patent proprietor's arguments may be summarised as follows:

a) *Admissibility of the first auxiliary request*

The present first auxiliary request had been filed with the statement of grounds of appeal and formed part of the proceedings at first instance. In the oral proceedings before the Opposition Division the patent proprietor had changed the ranking of its requests for the sake of procedural efficiency, as a reaction to the Opposition Division's conclusion that the subject-matter of claim 1 of the patent as granted lacked novelty over D4 and D18, in particular. If one were to accept that conclusion, the amendments carried out in claim 1 of the present first auxiliary request could not establish novelty over those documents either. Hence, there was no reason for having the present first auxiliary request formally examined at first instance, before the request eventually found allowable. The change in the ranking of the requests had not been done to avoid a decision at first instance on the present first auxiliary request. In fact, the substantive issues of the latter had already been addressed in the discussion of the subject-matter of the patent as granted. Decisions T 390/07 and T 23/10 cited by opponent 1 were not relevant, since the first related to a case in which a request was withdrawn at first instance and then re-instated on appeal and the second related to a case in which a request which could have been presented in opposition proceedings was withheld and then presented for the first time on appeal. For these reasons the first auxiliary request had to be



admitted into the appeal proceedings and a remittal to the Opposition Division would not be appropriate.

*b) Basis in the application as filed*

The wording in claim 1 of the first auxiliary request "said sections comprise a pair of separate sections" found a basis in claim 10 of the application as filed, in which the expression "at least two sections are divided into a pair of separate sections" had the same technical meaning. The addition of reference signs did not extend beyond the content of the application as filed, since reference signs had no limiting effect in view of Rule 43(7) EPC. It followed that the first auxiliary request did not violate Article 123(2) EPC.

*c) Sufficiency of disclosure*

Claim 1 of the first auxiliary request defined the term "bending moment" as "the product between E-modulus and moment of inertia", the latter being two well-known parameters. Whether there existed some literature according a different definition to "bending moment" was irrelevant, since the definition used in the context of the patent was included in the claim, leaving no room for misinterpretation.

According to established case law, an invention was sufficiently disclosed if at least one way was clearly indicated enabling the person skilled in the art to carry out the invention. The patent indicated several materials with several different

radii, in particular in paragraphs [0014] to [0017], for achieving the claimed value of bending moment of at least  $0.6 \text{ MPa} \cdot \text{mm}^4$ . Whether that value was low was irrelevant as long as the skilled person could reproduce the claimed device without an undue burden.

Moreover, the claim did not only require at least that value of bending moment at the connecting zone between the catheter sections. It also required that the catheter should be manipulatable for insertion in a specific way. Both requirements would be taken into account by the skilled person for carrying out the invention over its whole scope. The fact that non-working embodiments may be comprised in the scope of the claim was not decisive, since the skilled person would not consider them.

d) *Novelty*

The subject-matter of claim 1 of the first auxiliary request was novel over the cited prior art.

D2, D10 and D17 did not disclose a pair of catheter sections joined by a telescopic joint.

D4, D18 and D21 did not disclose a catheter having such a rigidity that the catheter was manipulatable for insertion of a proximal catheter section into the urethra by manipulation of another catheter section, as also explained, for example, in paragraph [0053] of the patent.

D15, D19 and D20 did not disclose a catheter

suitable for draining a human bladder via insertion into the urethra.

D34 and D35 did not belong to the state of the art, since the priority claim of the patent from D29 was valid for the subject-matter of claim 1 of the first auxiliary request. In particular, D29 disclosed the claimed value of the bending moment of at least  $0.6 \text{ MPa} \cdot \text{mm}^4$  on page 4, lines 28 to 31, and a telescopic connection as claimed on page 5, lines 1 to 7.

e) *Inventive step*

D4, D18 or D21 could be considered the closest prior art. The differentiating features of claim 1 over the closest prior art addressed the problem of providing a catheter kit that allowed insertion of a proximal section of the catheter without the need to touch it. None of the cited documents taught that a solution to that problem could be obtained by implementing the differentiating features in the devices of D4, D18 or D21. It followed that the subject-matter of claim 1 was inventive.

XIV. The arguments of opponent 1 may be summarised as follows:

a) *Admissibility of the first auxiliary request*

The first auxiliary request should not be admitted into the proceedings as the Opposition Division's decision had not adversely affected the patent proprietor with respect to this request. The patent proprietor had decided to have its requests

renumbered. Evidently, it had considered the request finally allowed by the Opposition Division more important than the present first auxiliary request. The renumbering of the requests was equivalent to a withdrawal of the present first auxiliary request, since, as a result, this request was not examined at first instance. In accordance with the conclusions drawn in decisions T 390/07 and T 23/10, the patent proprietor should not be allowed to hide away the present first auxiliary request at first instance and then let it re-emerge only in appeal. In the event that the first auxiliary request was admitted, a remittal to the department of first instance was requested, in order to have the case examined at two degrees of jurisdiction.

b) *Basis in the application as filed*

The expression "said sections comprise a pair of separate sections" in claim 1 of the first auxiliary request added subject-matter compared to the wording "at least two sections are divided into a pair of separate sections", present in claim 10 as originally filed. Due to the term "comprise", the subject-matter of claim 1 of the first auxiliary request included embodiments with more than two sections, while the language in original claim 10 made it clear that there were only two sections. Moreover, the term "divided" in original claim 10 implied that the sections were "physically apart", whereas the subject-matter of claim 1 of the first auxiliary request included embodiments where the two sections were not physically apart.

In claim 1 of the first auxiliary request reference numerals were present, which were not included in the claims as originally filed. They broadened the interpretation of the features to which they were associated, thereby adding subject-matter compared to the application as originally filed.

c) *Sufficiency of disclosure*

A catheter with a uniform bending moment of 0.6 MPa·mm<sup>4</sup> according to the definition of claim 1 of the first auxiliary request would be very soft. It could not support its own weight. The patent taught that the connecting zone could be the most rigid zone of the whole catheter. If followed that a catheter with a bending moment of 0.6 MPa·mm<sup>4</sup> at the connecting zone could not be manipulatable for insertion as defined in claim 1. Hence, the lower limit of the bending moment defined in the claim was completely out of range and could not be obtained for a functional catheter. As a result, the invention was not sufficiently disclosed over its whole scope.

d) *Novelty*

D2 was novelty-destroying for the subject-matter of claim 1 of the first auxiliary request. In particular, in its figures 1 and 2, D2 disclosed a catheter with an inner tube (1) which could be extended over an outer tube (2) by sliding. That corresponded to a telescopic connection within the meaning of the claim.

D4 was also novelty-destroying. In particular, in

the embodiment of figure 4, package 4 and catheter 1 represented the catheter sections according to the definition of the claim. By holding catheter 1 through package 4 in a condition where the catheter was partially exposed through the package, the catheter could be manipulated for insertion by manipulation of the package. Hence the catheter of D4 was manipulatable for insertion according to the definition of claim 1 of the first auxiliary request.

D17 was also novelty-destroying. In particular handle 33 and catheter 31 in figure 3 represented the catheter sections according to the definition of the claim. On page 9, lines 6 to 10, it was disclosed that the sections could be held together by an interference fit. Such a coupling was identical to a telescopic joint as claimed.

D18 was also novelty-destroying. In particular, in the figures, package 2 and catheter shaft 3 represented the catheter sections according to the definition of the claim. On page 7, lines 6 to 16, it was disclosed that an intermediate section 2b of the package could be "formed as a tube member made from a material having a larger stiffness than the remaining sections of the package" in order to "facilitate handling of the catheter assembly during catherization [sic]". These passages made it crystal clear that the catheter was manipulatable for insertion of shaft 3 by manipulation of catheter section 2b, in accordance with the definition of claim 1 of the first auxiliary request.

D19 and D20 were also novelty-destroying. In

particular, the claimed intended use for insertion into the urethra should be given little limiting effect in interpreting the claim.

D21 was also novelty-destroying. In connection with figures 1 and 2, for example, catheter 12 represented one section and package 11, or guide member 15, or both elements together represented another catheter section according to the definition of the claim. By holding catheter 12 through package 11 or by the means of guide member 15, one catheter section could be manipulated for insertion by manipulation of the other section. Moreover, if the connecting zone between the two catheter sections had the claimed bending moment, as was the case between the catheter sections of D21, the fact that the catheter was manipulatable for insertion in accordance with the definition of the claim had to follow as a consequence. Hence the catheter of D21 was manipulatable for insertion according to the definition of claim 1 of the first auxiliary request.

e) *Inventive step*

D4, D18 or D21 could be considered the closest prior art. The problem to be solved was how to insert the catheter in a touch-free way. That was a trivial problem, addressed for example in claim 6 of D4, on page 7, lines 12 to 16 of D18 and on page 38, lines 8 to 11 of D21. Hence, the subject-matter of claim 1 of the first auxiliary request did not involve an inventive step.

XV. The arguments of opponent 2 may be summarised as follows:

a) *Sufficiency of disclosure*

The definition of "bending moment" in claim 1 of the first auxiliary request was not a scientifically accepted definition. Further, in the literature, the "bending moment" was normally measured as a force multiplied by a distance. Hence its unit of measure could not be  $\text{MPa} \cdot \text{mm}^4$ . What was referred to as "bending moment" in the claim was normally called "bending stiffness" in the literature. D9 discussed catheters with a bending stiffness falling within the range specified in the claim.

The parameter "bending moment" in the claim was not only in itself ambiguous. The contested patent was completely silent on how to measure it and to provide a catheter with parts having a "bending moment" exceeding  $0.6 \text{ MPa} \cdot \text{mm}^4$ , if one were to assume that this "bending moment" was something different from what was common in any urinary catheter commercially available at the time the patent was filed.

Moreover,  $0.6 \text{ MPa} \cdot \text{mm}^4$  was a very low value and it was not apparent how catheter products having such low bending moments could be used as urinary catheter assemblies.

Accordingly, the skilled person was left very much in doubt about how to exercise the invention, so that the contested patent did not disclose the invention in a manner sufficiently clear and



complete for it to be carried out by a person skilled in the art. Consequently, the patent violated Article 83 EPC, and should be held invalid under Article 100(b) EPC.

b) *Novelty*

The feature of the claim that the catheter had "such a rigidity the the catheter is manipulatable for insertion of a proximal one of the catheter sections [...] by manipulation of another one of the catheter sections" was very vague. In particular it did not define anything in respect of the telescopic joint, which was the object of claim 2. The required rigidity to fulfil was only  $0.6 \text{ MPa} \cdot \text{mm}^4$  or even lower, outside the connecting zone of the sections.

D4 was novelty-destroying for the subject-matter of claim 1 of the first auxiliary request. In particular, in the embodiment of figure 4, package 4 and catheter 1 represented the catheter sections according to the definition of the claim. They formed a catheter manipulatable for insertion as claimed, in view of the appropriate interpretation of that feature as explained above. Moreover, with reference to figure 4, when catheter 1 was exposed from package 4 there was a tight connection between stop member 17 and the catheter shaft and between the rearward end of connector 3 and package 4. Accordingly, a high bending moment would be present at the connecting zone of the catheter sections, and the catheter of D4 was manipulatable for insertion according to the definition of claim 1 of the first auxiliary request.

D10 was also novelty-destroying. In particular it disclosed a urinary catheter within a package, which could be used as an extension for the catheter. For such a use, a forward end of the package was connected to a catheter connector (figure 7) and thereafter a shaft of the catheter was telescopically withdrawn from the package (figure 8).

D15 was also novelty-destroying. In particular, although the catheter of D15 was not primarily intended for draining urine, the features of claim 1 relating to an intended use of the defined catheter had to be disregarded when assessing novelty.

D18 was also novelty-destroying. In particular, in the figures, package 2 and catheter shaft 3 represented the catheter sections according to the definition of the claim. They formed a catheter manipulatable for insertion as claimed, in view of the appropriate interpretation of that feature. Moreover, on page 7, lines 6 to 16, it was disclosed that an intermediate section 2b of the package could be "formed as a tube member made from a material having a larger stiffness than the remaining sections of the package" in order to "facilitate handling of the catheter assembly during catherization [sic]". These passages made it clear that the package serving as catheter extension had a rigidity enabling manipulation of the catheter, in accordance with the definition of claim 1 of the first auxiliary request.

D19 and D20 were also novelty-destroying. In

particular, the catheters disclosed in those documents were at least suitable for insertion into a natural urethra.

D21 was also novelty-destroying. In connection with figures 1 and 2, for example, catheter 12 represented one section and package 11 represented another catheter section according to the definition of the claim. The package comprised a relatively stiff guide arrangement (14) arranged to manipulate the catheter during insertion into the urethra. Hence the catheter of D21 was manipulatable for insertion according to the definition of claim 1 of the first auxiliary request.

The priority claim of the patent, in particular from D29, was not valid for the subject-matter of claim 1 of the first auxiliary request. For example, that document did not disclose a bending moment at a connecting zone of at least  $0.6 \text{ MPa} \cdot \text{mm}^4$  or a telescopic joint between the claimed catheter sections. Since the priority claim was not valid, D34 and D35 belonged to the state of the art under Article 54(3) EPC and deprived the subject-matter of claim 1 of the first auxiliary request of novelty.

c) *Inventive step*

D4, D18, D19, D20 or D21 could be considered the closest prior art. It was common practice to use a part of a package/catheter section to manipulate the insertable part of the catheter, in order to avoid direct touching of this part and thereby alleviate problems with urinary tract infections,

etc. It had therefore to be assumed that insertion of the catheters of the mentioned documents of the prior art would occur in this way. Direct guidance as to such application was found in e.g. D10, D12 and D21. Hence the subject-matter of claim 1 of the first auxiliary request lacked inventiveness.

### **Reasons for the Decision**

1. The appeals are admissible.
2. Although duly summoned by communication dated 9 November 2015, opponent 2 was not present at the oral proceedings as announced by letter dated 11 January 2016. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party, who is treated as relying only on its written case.
3. *The invention*

The invention as defined in claim 1 of the first auxiliary request relates to a kit for preparing a catheter for draining the human bladder via the urethra. Such catheters are typically used by patients who cannot urinate voluntarily. They can be of the intermittent type, to be inserted and kept in place only for the time needed to urinate, or of the indwelling/permanent type, kept in place for a longer period.

The claimed kit comprises two catheter sections adapted to be arranged in a first mutual configuration in which they form a catheter of a length larger than the length of each individual section, and a second mutual configuration wherein the kit is shorter.

In use, the two catheter sections are brought into the first configuration by being joined via the telescopic joint. The catheter so obtained is claimed to have such a rigidity that it can be manipulated at one section for insertion of the other section. Moreover, a part of the catheter extending a connecting zone between the catheter section is claimed to have a "bending moment" exceeding a defined value.

The kit can be packaged with the sections in the second configuration, which results in a relatively short package, easier to handle and carry compared to other existing catheters (paragraph [0008] of the patent).

4. *Admissibility of the first auxiliary request*

Article 12 RPBA defines the basis of the appeal proceedings. In particular, according to paragraph (1)(a), it includes the statement of grounds of appeal. Paragraph (4) allows the Board to hold inadmissible requests which could have been presented or were not admitted in the first instance proceedings.

In the present case, as the patent proprietor pointed out, the first auxiliary request was included in the statement of grounds of appeal and also formed part of the proceedings at first instance. However, as opponent 1 argued, the requests pending at first instance were renumbered during the oral proceedings, so that the Opposition Division did not have to decide on the present first auxiliary request, since it found a higher-ranking request to be allowable.

In the Board's view, in line with the arguments of opponent 1, one of the aims of Article 12(4) RPBA is to prevent a patent proprietor from deliberately hiding

away requests in the proceedings at first instance, in order to have them considered for the first time on appeal. As stated in decisions G 9/91 and G 10/91 (point 18 of the Reasons), the purpose of the appeal procedure inter partes is mainly to give the losing party a possibility to challenge the decision of the Opposition Division on its merits. The substantive conclusions drawn in decisions T 390/07 and T 23/10 go in the same general direction.

In the present case, however, the Board does not see the patent proprietor's renumbering of its requests in the first instance proceedings as a deliberate attempt to introduce new matter for consideration in the appeal procedure for the first time. The patent proprietor pointed out - and the other parties did not contest it - that in the oral proceedings at first instance the Opposition Division announced its conclusion that the subject-matter of claim 1 of the patent as granted lacked novelty over both D4 and D18. It is undisputed that the same conclusion would have applied to the subject-matter of claim 1 of the present first auxiliary request too, since the amendments carried out in the latter merely eliminated an alternative which was unrelated to the novelty objections based on D4 and D18. Accordingly, the substantive issues underlying the present first auxiliary request were in fact considered by the Opposition Division in a manner which adversely affected the patent proprietor. Under these circumstances, the renumbering of the requests at first instance cannot be seen as an abuse, but rather as an attempt to increase procedural efficiency.

For these reasons, the Board admits the first auxiliary request into the proceedings.

In view of the Board's conclusion that the Opposition Division considered this request in substance, there is also no reason to accede to the request of opponent 1 to remit the case to the department of first instance under Article 111(1) EPC for further prosecution on the basis of the first auxiliary request.

5. *Basis in the application as filed*

The subject-matter of claim 1 of the first auxiliary request is based in particular on claims 1, 10, 11 and 13, page 2, lines 10 to 23 and page 4, lines 23 to 28 of the application as originally filed.

The combination of original claims 1 and 10 disclosed that the catheter kit comprised "at least two sections", and that "at least two sections [were] divided into a pair of separate sections". As a consequence, a catheter kit comprising more than two sections was not excluded, as it is not excluded according to the definition of claim 1 of the first auxiliary request. As for the objection of opponent 1 that the sections were originally disclosed as being physically apart, claim 1 of the first auxiliary request defines the sections as "separate sections". In the Board's view, this expression implies no less physical separation than that implied by the term "divided into" employed in claim 10 as originally filed.

Opponent 1 also submitted that the reference numerals present in claim 1 of the first auxiliary request broadened the interpretation of the features with which they were associated. However, Rule 43(7) EPC expressly states that "reference signs shall not be construed as limiting the claim". Hence, this argument of opponent 1 must fail too.

It follows that Articles 100(c) and 123(2) EPC do not prejudice the maintenance of the patent on the basis of the first auxiliary request.

6. *Sufficiency of disclosure*

Both opponents objected to the definition of the parameter "bending moment of at least  $0.6 \text{ MPa} \cdot \text{mm}^4$ ", which they argued rendered the invention according to claim 1 of the first auxiliary request not sufficiently disclosed in the patent.

The Board agrees with opponent 2 that the concept of "bending moment" is normally understood as a force multiplied by a distance. However, in claim 1 it is expressly defined that the parameter "bending moment" is to be understood as "the product between E-modulus and moment of inertia" and that it is measured in " $\text{MPa} \cdot \text{mm}^4$ ". It is apparent that such a definition, as also acknowledged by opponent 2, corresponds to what is normally called "bending stiffness" in the literature. As a consequence, the skilled person reading the claim with a mind willing to understand would immediately know what the defined parameter means and how it is measured and calculated.

Both opponents also argued that a catheter with a "bending moment" of  $\text{MPa} \cdot \text{mm}^4$ , i.e. the lower limit of the range defined in claim 1, was too soft and could not be inserted into the urethra.

The Board observes that a connecting zone of a telescopic joint with that "bending moment" can be manufactured by the skilled person employing known materials and providing suitably thin cross sections. The information provided in paragraphs [0014] to [0017]



of the patent as well as the common general knowledge would clearly enable the skilled person to perform this task. The fact that D9 may disclose catheters with a "bending moment" falling within the range specified in the claim or that a "bending moment" in that range may be common in urinary catheters of the prior art, as argued by opponent 2, cannot be seen as an obstacle but rather as useful information for the skilled person trying to put the invention into practice.

The Board does not question that the resulting connecting zone of the telescopic joint would be "very soft" and that a catheter with a uniform "bending moment" of  $0.6 \text{ MPa} \cdot \text{mm}^4$  or even less in some of its sections might not be manipulatable for insertion as claimed or might not support its own weight. However, on a proper reading, claim 1 of the first auxiliary request does not require that, because of the claimed "bending moment" of the connecting zone, the catheter should be suitable for insertion into the urethra. Nor does it require that the connecting zone should be the most rigid part of the catheter. Rather, it requires that "at least that part of the catheter, which extends a connecting zone between the catheter sections has a bending moment of at least  $0.6 \text{ MPa} \cdot \text{mm}^4$ " and, at the same time, that the catheter has "such a rigidity that the catheter is manipulatable for insertion of a proximal one of the catheter sections into the urethra by manipulation of another one of the catheter sections".

Hence, the skilled person desiring to put the invention into practice would select an appropriate extension of the connecting zone and an appropriate "bending moment" within the claimed range in order also to fulfil the requirement of suitability for insertion into the urethra. If, for a given extension of the connecting

zone, a higher "bending moment" at that zone and in the remaining sections of the catheter was required, the skilled person would simply foresee that higher "bending moment". If, on the other hand, a very short extension of the connecting zone made it possible to have a lower "bending moment" still permitting insertion, the skilled person could foresee that lower "bending moment", as long as it lay within the claimed range. Clearly, not all combinations of extension of the connecting zone and claimed "bending moment" within or outside that zone will result in an insertable catheter as claimed. However, the skilled person would not envisage technically unworkable embodiments.

It follows that Articles 100(b) and 83 EPC do not prejudice the maintenance of the patent on the basis of the first auxiliary request.

7. *Novelty*

- 7.1 Opponent 2 argued that the priority claim of the patent was not valid for the subject-matter of claim 1 of the first auxiliary request. As a result, D34 and D35 belonged to the state of the art under Article 54(3) EPC.

*According to Article 87(1) EPC, "any person who has duly filed in [...] any State party to the Paris Convention for the Protection of Industrial Property [...] an application for a patent [...] shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application".*

In view of the requirements set out in

Article 87(1) EPC, it was disputed that the priority document D29, a Danish patent application filed by the patent proprietor, disclosed the same invention as the one defined in claim 1 of the first auxiliary request.

The Board, however, notes that D29 provides a basis for the subject-matter of claim 1 of the first auxiliary request in claims 1, 10, 11 and 13, page 2, lines 15 to 26, page 4, lines 24 to 31, and page 5, lines 1 to 7.

In particular, the claimed bending moment at a connecting zone of at least  $0.6 \text{ MPa} \cdot \text{mm}^4$  is clearly disclosed on page 4, lines 28 to 31, which read:

*"the connection is preferably provided so that at least the part of the catheter extending the connection zone, has a bending moment defined as the product between E-modulus and moment of inertia of at least  $0.6 \text{ MPa} \cdot \text{mm}^4$ ".*

The claimed telescopic joint is disclosed in claim 13, which reads:

*"A kit according to claims 10 12, wherein the connecting means defines a telescopical joint".*

It follows that the subject-matter of claim 1 of the first auxiliary request enjoys priority from D29, filed on 29 June 2001. Consequently, D34 and D35, for which the earliest priority date claimed is also 29 June 2001, do not belong to the state of the art.

Therefore, the novelty objection of opponent 2 based on D34 and D35 fails.

7.2 Some of the novelty objections raised by the opponents are based on a disputed interpretation of the meaning of some features of claim 1 of the first auxiliary request.

7.2.1 In particular, the opponents argued that the functional features according to which the catheter defined in the claim is "for draining a human bladder via the urethra" and "for insertion into the urethra" should be given little or no limiting effect.

In the present case, it is a requirement of the claimed catheter that it is suitable for the defined field of application, i.e. for draining the human bladder via the urethra and for insertion into the urethra. Whether a catheter satisfies these requirements is assessed by the skilled person, in view of the known problems and peculiarities of the defined field of application. A catheter that does not possess this suitability does not fall under the definition of claim 1 of the first auxiliary request.

7.2.2 The opponents also disputed the limiting effect to be attributed to the feature according to which the catheter defined in claim 1 of the first auxiliary request has "such a rigidity that the catheter is manipulatable for insertion of a proximal one of the catheter sections [...] by manipulation of another one of the catheter sections".

The Board notes that the claim expressly refers to a "rigidity" of the catheter, resulting in the fact that the catheter is manipulatable for insertion as defined. Such a reference makes it clear to the skilled person that the catheter as claimed is to be construed as being able to transfer a certain force to a proximal section from a region of application of this force on another

section which is remote from the proximal section. This applies in particular to the telescopic joint and the part of the other section included between the region of application of the force and the joint itself. This claim construction is fully supported by the description of the patent, for example in paragraph [0053] cited by the proprietor, where it reads:

*"it is an important aspect to provide a connecting zone wherein the first catheter section and the second catheter section firmly engages. Thereby, insertion and orientation of the first section is possible merely by manipulation of the second section and without the sections mutually sliding in the telescopic connection. It is furthermore important to assure that the first catheter section does not slip out of the second section in which case the first catheter section might disappear into the urethra".*

Interpreting the claim such that it also encompassed catheters where insertion of a proximal section could only be possible by manipulation of another section if the proximal section itself was manipulated together with the other section, e.g. by holding the catheter at the connecting zone between the two sections or by directly holding the proximal section through the other section, would ignore the cited paragraph of the description of the patent and also incorrectly assign no meaning to the reference to the "rigidity" of the catheter in the claim.

7.3 The opponents raised novelty objections based on D2, D10 and D17.

All these documents relate to catheter assemblies for

draining a human bladder via the urethra. However, none of them disclose a pair of separate sections joined by a telescopic joint as claimed in claim 1 of the first auxiliary request.

As regards D2, the joint consisting of tubes 1 and 2 in figures 1 and 2, in which, in use, tube 1 is made to extend out of tube 2 by application of pressure, is not a telescopic joint according to its common meaning in the art.

Similarly, the connections between hose member 4 and catheter 1 of D10 (figures 7 and 8) do not constitute telescopic joints. The fact that there can be a sliding movement between an inner tube (catheter 1) and an outer tube (hose member 4) as such does not make a joint as claimed.

Finally, an interference fit between two sections as in D17 (handle 33 and catheter 31 in figure 3) does not, as such, correspond either to a telescopic joint as normally understood by the skilled person.

It follows that D2, D10 and D17 do not deprive the subject-matter of claim 1 of the first auxiliary request of novelty.

7.4 The opponents based further novelty objections on D15, D19 and D20.

These documents concern catheter assemblies for various applications. None of them disclose catheters for draining a human bladder via the urethra wherein the catheter is for insertion into the urethra.

D15 relates to a catheter shunt system of the kind used

to treat hydrocephalus. It is not derivable from it that such a catheter could be suitable for draining the human bladder.

D19 concerns a catheter "for patients who have undergone a surgical colostomy, urology of similar procedure" (page 1, first paragraph). The catheter is intended to be introduced through a stoma into a reservoir within the body (page 1, second paragraph). D20 concerns a percutaneous catheter for insertion into the bladder. A catheter insertion into a stoma and a percutaneous insertion require a degree of stiffness and a length generally not compatible with those needed for safe insertion into the urethra. Hence, D19 and D20 do not disclose catheters that are suitable for insertion into the urethra within the meaning of claim 1 of the first auxiliary request.

As a consequence, D15, D19 and D20 do not deprive the subject-matter of claim 1 of the first auxiliary request of novelty either.

7.5 Finally, the opponents raised novelty objections in view of D4, D18 and D21.

All of these documents relate to kits for preparing catheters for draining the human bladder via the urethra, the kits comprising two catheter sections joined by a telescopic joint and capable of assuming the first and second mutual configurations as claimed in claim 1 of the first auxiliary request.

However, the respective catheters obtained when the sections are in the first mutual configuration do not have such a rigidity that the catheters are manipulatable for insertion of a proximal one of the

catheter sections into the urethra by manipulation of another one of the catheter sections within the meaning of the claim, as explained in point 7.2.2 above.

As far as D4 is concerned, the Board does not see in particular any implicit or explicit disclosure that the joint between stop member 17 and connection member 3 in figure 4 could have such a rigidity as to transmit the force necessary for catheter 1 to be inserted. In contrast to the submissions of opponent 2, D4 is completely silent on whether that joint is supposed to be tight or not.

The situation is similar for D18. In particular, there is no disclosure that the telescopic joint between package 2 and catheter 1, formed in particular by terminal member 6 and gateway 2d (figure 4) could take up a sufficient force. The passage on page 7, lines 6 to 16, referred to by the opponents, relates to the stiffness of the intermediate section (2b) of package 2. It says nothing about the joint. In particular, the Board does not see how "facilitat[ing] handling of the catheter assembly during catherization [sic]" may imply that catheter 1 could be inserted by manipulating section 2 within the meaning of the claim, as explained in point 7.2.2 above.

In D21, according to the opponents, referring for example to figures 1, 2 or 29 to 31, catheter 12 could be considered a proximal catheter section and package 11, or guide member 15, or both elements together could be considered another catheter section according to the definition of claim 1 of the first auxiliary request. Irrespective of whether guide member 15 may be considered a catheter section or a part of it, the guide member has no portion remote from catheter 12,



i.e. the proximal catheter section, since it is placed over the latter in every configuration. Hence, in order for D21 to deprive the claim of novelty, it would have to be disclosed that catheter 12 could be inserted into the urethra by manipulation of catheter package 11 remotely from the joint between the sections, as explained in point 7.2.2 above. However, there is no disclosure in D21 that catheter package 11 could take up and transmit a force necessary for catheter 12 to be inserted within the meaning of the claim. As for the argument of opponent 1 that if the connecting zone between the two catheter sections had the claimed "bending moment", the fact that the catheter was manipulatable for insertion in accordance with the definition of the claim had to follow as a consequence, the Board notes that the claim defines these as separate requirements, as also explained in point 6 above.

As a consequence, D4, D18 and D21 do not deprive the subject-matter of claim 1 of the first auxiliary request of novelty either.

7.6 It follows that Article 100(a) EPC, in conjunction with Articles 52 and 54 EPC, does not prejudice the maintenance of the patent on the basis of the first auxiliary request.

8. *Inventive step*

The opponents raised objections as to a lack of inventive step of the subject-matter of claim 1 of the first auxiliary request based on D4, D18 or D21 as the closest prior art.

As explained in point 7.5 above, none of these documents disclose a catheter having such a rigidity that the

catheter is manipulatable for insertion of a proximal one of the catheter sections into the urethra by manipulation of another one of the catheter sections within the meaning of the claim.

This feature has the effect that the insertion of the catheter does not require touching the part which is to be inserted into the urethra (patent in suit, paragraph [0012], first two sentences).

The objective technical problem to be solved is how to ensure insertion of a sterile catheter.

Irrespective whether D4, D18 and D21 referred to by opponent 1 are concerned with the objective technical problem, they do not disclose the claimed solution to this problem, as already explained. D10 and D12 referred to by opponent 2 do not disclose catheter sections building up a telescopic joint and a catheter possessing the claimed rigidity as claimed. Hence, from these cited documents the skilled person would not derive any clear teaching in order to arrive at the subject-matter of claim 1 of the first auxiliary request in an obvious way either.

Opponent 2 argued that D19 or D20 could also be considered as the closest prior art.

The Board notes that these documents do not concern catheters that are suitable for insertion into the urethra (point 7.4 above). Hence, the skilled person would see them as more remote from the claimed invention and would not consider them as the closest prior art. In any case, no arguments were provided - and the Board does not see any either - why the skilled person would modify the catheters disclosed in these documents,

changing their field of application in order to make them suitable for insertion into the urethra.

For these reasons the subject-matter of claim 1 of the first auxiliary request is inventive over the cited prior art.

It follows that Article 100(a) EPC, in conjunction with Articles 52 and 56 EPC, does not prejudice the maintenance of the patent on the basis of the first auxiliary request.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of:
  - claims 1 to 11 of the first auxiliary request filed on 22 February 2013;
  - description and figures of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

M. Stern

Decision electronically authenticated