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Datasheet for the decision of 13 March 2015

Case Number: T 1767/10 - 3.2.02

Application Number: 02754547.4

Publication Number: 1420845

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:
A METHOD OF PRODUCING A CATHETER AND A CATHETER

Patent Proprietor:
Coloplast A/S

Opponent:
Astra Tech AB

Headword:

Relevant legal provisions:
EPC Art. 100(c), 54, 56, 84, 123(2)

Keyword:
Novelty - main request (yes)
Late-filed auxiliary requests - admitted (yes)
Added subject-matter - first auxiliary request (yes) - main, second and third auxiliary requests (no)
Clarity - third auxiliary request (yes)
Inventive step - main and second auxiliary requests (no) - third auxiliary request (yes)

Decisions cited:

Catchword:

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Case Number: T 1767/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 March 2015

Appellant: (Patent Proprietor)	Coloplast A/S Holtedam 1 3050 Humlebaek (DK)
Appellant: (Opponent)	Astra Tech AB Aminogatan 1, P.O. Box 14 431 21 Mölndal (SE)
Representative:	Lind, Urban Arvid Oskar Awapatent AB Södra Hamngatan 37-41 404 28 Göteborg (SE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 June 2010 concerning maintenance of the European Patent No. 1420845 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	M. Stern

Summary of Facts and Submissions

I. The appeals of the patent proprietor and the opponent are directed against the intermediate decision of the Opposition Division posted on 29 June 2010.

II. The notice of appeal of the appellant-patent proprietor was filed on 7 September 2010 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 9 November 2010.

III. The notice of appeal of the appellant-opponent was filed on 23 August 2010 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 9 November 2010.

IV. Oral proceedings took place on 13 March 2015.

The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, in the alternative, one of the first to fourth auxiliary requests, all filed with letter dated 2 March 2015.

Subsidiarily, the appellant-patent proprietor requested that documents D21 and D22 be not admitted into the proceedings.

Subsidiarily, the appellant-patent proprietor further indicated that it did not wish to maintain the objection against the admissibility into the proceedings of document D20 present in the written proceedings.

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

Subsidiarily, the appellant-opponent indicated that it did not wish to maintain the objection pursuant to Article 100(b) EPC introduced with its statement setting out the grounds of appeal.

V. The following documents are cited in this decision:

D1: EP-B-1116567
D2: WO-A-90/00960
D3: EP-A-1034811
D10: US-A-5167647
D13: EP-A-0925802
D14: EP-A-0824930
D15: EP-A-0958911
D16: WO-A-96/19254
D17: US-A-6149996
D18: WO-A-01/32240
D20: EP-A-0980892
D21: US-A-3947175
D22: US-A-4957682
D23: DE-U-20007733

VI. The different versions of the independent claims read as follows (amendments over granted version underlined by the Board):

Claims 1 and 8 according to the **main request** read as follows:

"1. A method for producing a urinary catheter (1) with parts having different characteristics, said method comprising the steps of:

- injecting at least two different fluid catheter materials into a mould formed to define an insertable catheter tip (3) suitable for insertion into urethra and a body (4), and subsequently
- solidifying the material therein."

"8. An injection moulded urinary catheter (1) with an insertable catheter tip (3) suitable for insertion into urethra and a body (4), the catheter being made of at least two different catheter materials, the materials being joined during the moulding process in which both materials are injected into a mould in fluid state and solidified therein."

Claims 1 and 8 according to the **first auxiliary request** read as follows:

"1. A method for producing a catheter (1) with parts having different characteristics, said method comprising the steps of:
- injecting at least two different fluid catheter materials into a mould formed to define an insertable catheter tip (3) and body (4) having an internal conduit, wherein the insertable catheter tip seals off the internal conduit and at least one drainage hole is formed in the vicinity of the tip to allow urine from a bladder to enter the hollow tubular body, and subsequently
- solidifying the material therein."

"8. An injection moulded catheter (1) with an insertable catheter tip (3) and a body (4), having an internal conduit, wherein the insertable catheter tip seals off the internal conduit and at least one drainage hole is formed in the vicinity of the tip to allow urine from a bladder to enter the hollow tubular

body, the catheter being made of at least two different catheter materials, the materials being joined during the moulding process in which both materials are injected into a mould in fluid state and solidified therein."

Claims 1 and 7 according to the **second auxiliary request** as considered allowable by the OD read as follows:

"1. A method for producing a catheter (1) with parts having different characteristics, said method comprising the steps of:
- injecting at least two different fluid catheter materials into a mould formed to define an insertable catheter tip (3) and body (4), the two materials being injected in more than one injection cycle to form a catheter with individual sections in length, and subsequently
- solidifying the material therein."

"7. An injection moulded catheter (1) with an insertable catheter tip (3) and body (4), the catheter being made of at least two different catheter materials, the two materials being injected in more than one injection cycle to form a catheter with individual sections in length, the materials being joined during the moulding process in which both materials are injected into a mould in fluid state and solidified therein to form a urinary catheter with individual sections in length."

Claims 1 and 8 according to the **third auxiliary request** read as follows:

"1. A method for producing a urinary catheter (1) with parts having different characteristics, said method comprising the steps of:
- injecting at least two different fluid catheter materials into a mould formed to define an insertable catheter tip (3) and a body (4), wherein the radial size of the tip is larger than the radial size of the rest of the catheter, and subsequently
- solidifying the material therein."

"8. An injection moulded urinary catheter (1) with an insertable catheter tip (3) and a body (4), the catheter being made of at least two different catheter materials, the materials being joined during the moulding process in which both materials are injected into a mould in fluid state and solidified therein, wherein the radial size of the tip is larger than the radial size of the rest of the catheter."

Claims 1 and 7 according to the **fourth auxiliary request** (as considered allowable by the Opposition Ddivision) read as follows:

"1. A method for producing a catheter (1) with parts having different characteristics, said method comprising the steps of:
- injecting at least two different fluid catheter materials into a mould formed to define an insertable catheter tip (3) and body (4), the two materials being injected in more than one injection cycle to form a catheter with a laminated structure, and subsequently
- solidifying the material therein."

"7. An injection moulded catheter (1) with an insertable catheter tip (3) and body (4), the catheter

being made of at least two different catheter materials, the two materials being injected in more than one injection cycle to form a catheter with a laminated structure, the materials being joined during the moulding process in which both materials are injected into a mould in fluid state and solidified therein to form a catheter with a laminated structure."

VII. The arguments of the appellant-patent proprietor relevant for the decision can be summarised as follows:

Main request

Claim 1 - Added subject-matter

The fact that different parts of the catheter could be made of different materials was disclosed for instance on page 4, lines 6 and 7 in the general part of the description, which also applied to claim 9 of the application as filed.

Furthermore, the wording "injection cycle" was not a complete moulding step but only an opening and closing of the nozzle. This was in line with the concept of the multi-component injection moulding process disclosed on page 2, lines 29 to 32 or page 3, lines 11 to 13. Such a process did not require an intermediate solidifying between the different injections.

Claim 1 - Novelty

Claim 1 stated that the fluid materials were injected into a mould formed to define an insertable catheter tip and body, which meant that the claimed process required at least these two parts to be made in the mould. The documents disclosing manufacturing methods

in which the catheter body was introduced into a mould before the hub or the tip was moulded onto it could therefore not take away the novelty of the subject-matter of claim 1.

The wording of claim 1 further required the injection of two materials into the mould, which could not mean the injection of a mixture of materials but meant the injection of two separate materials, so documents disclosing the injection of a mixture could not anticipate the subject-matter of claim 1 either.

Concerning the lack of novelty objection based on D1, it had to be remembered that claim 1 as granted was not limited to urinary catheters. In the context of urinary catheters, paragraph [0007] of the patent in suit clearly indicated that an insertable length in the size of 70 mm had been found suitable for most female individuals. In other words, the person skilled in the art knew that the shorter lengths disclosed in this paragraph were not suitable for use as urinary catheters.

None of the documents D1, D2, D3, D20 could therefore take away the novelty of the subject-matter of claim 1 of the main request.

Claim 8 - Novelty

The arguments of the lack of suitability developed in relation to claim 1 remained valid for the subject-matter of claim 8. In addition, the step that the materials should be joined during the moulding in which both materials were injected into the mould in a fluid state left a typical structure on the finished product due for instance to the injection points in the mould,

the joining line of different mould parts as well as the melting and partial mixing of the two materials at the juncture surface. This structure was different when the catheter was extruded, when the tip or hub was glued, or even welded to an existing catheter body.

In the present case this meant that none of the documents cited by the appellant-opponent against novelty disclosed the product-by-process feature of claim 8.

Claim 1 – Inventive step

The wording of claim 1 implied that two different materials had to be injected into the mould to define the catheter body and the catheter tip, and that these two materials had to solidify together in the mould.

For this reason, whether starting from D6 or D16, D1 could not suggest the subject-matter of claim 1 because in the manufacturing process disclosed in this document not only were the catheter body and the catheter tip made of the same material, but there was no explicit disclosure of the two materials solidifying together in the mould.

The subject-matter of claim 1 was therefore inventive.

First auxiliary request

Claim 1 – Added subject-matter

Although the specific wording that the tip sealed off the internal conduit of the catheter was not present in the description of the application as filed, this feature was clearly disclosed in Figures 1 to 3 and 5,

which showed closed distal ends, so the requirements of Article 123(2) EPC were fulfilled.

Second and third auxiliary requests – Admissibility

The appellant-opponent filed new documents D20 to D22 with its statement setting out the grounds of appeal, and the Board might consider these documents admissible into the proceedings. Second and third auxiliary requests were an answer to this possible admission of the documents, and the subject-matter added was not complex, so the opponent had no difficulties to deal with them. In addition, the third auxiliary request was based on the claim 10 as granted.

These requests therefore had to be admitted into the proceedings.

Second auxiliary request

Claim 1 - Added subject-matter

The solidification step was already in claim 1 of the application as filed, and the addition of a feature of the general part of the description on page 4, last paragraph, could not lead to added subject-matter.

Claim 1 - Inventive step

The combination of D16 with D1 could not lead to the subject-matter of claim 1, because in D1 the tip and the body of the catheter were made of the same material, whereas in the present claim the tip and the body were meant to be of different materials in individual sections in length, and the material of the

hub or connector was not addressed. For these reasons the subject-matter of claim 1 was inventive.

Third auxiliary request

Claim 1 - Added subject-matter – Clarity

The feature of the radial size of the tip being larger than the radial size of the rest of the catheter was explicitly disclosed in the general part of the description on page 5, lines 13 and 14, of the application as filed, so its addition to claim 1 did not contravene Article 123(2) EPC. Furthermore, for a mind willing to understand it was self-evident that the "rest" of the catheter could only be the catheter body, since it was the tip dimension that was compared to it, and the body was the part immediately adjacent the tip, so this feature also fulfilled the requirements of Article 84 EPC.

Claim 1 – Inventive step

A catheter with an enlarged tip (facilitating insertion) could not be produced by extrusion, so there was a link between the enlarged tip and the manufacturing method. With respect to the enlarged tip feature, the person skilled in the art would not find any hint to it in D23, because this document dealt with another type of catheter, namely for insertion in the ureter and not in the urethra. An indication that the enlarged tip could facilitate insertion into the urethra could not be found in D23. Furthermore, this catheter was for delivery of a fluid into the ureter, and not for draining any fluid from the bladder. A method of manufacturing was not mentioned in D23 either. In any case, injection moulding was not

suitable given the dimensions of the catheter disclosed in D23.

Moreover, the person skilled in the art would not consider D1 when looking for an improved manufacturing method of a urinary catheter with an enlarged tip because this document was about intravascular catheters and this kind of catheter did not have enlarged tips.

Hence, the subject-matter of claim 1 was inventive.

VIII. The arguments of the appellant-opponent relevant for the decision can be summarised as follows:

Main request

Claim 1 - Added subject-matter

In the application as filed the injection of two different fluid materials into a mould was only disclosed in combination with more than one injection cycle, and the feature of two materials being used was not disclosed in relation to different characteristics to be obtained. Claim 9 as filed indicated neither that different materials should form the different parts nor that both materials were solidified after both being introduced in a fluid state into the mould. The passages of the description mentioned by the appellant-patent proprietor were about distinct process steps.

For this reason claim 1 did not fulfil the requirements of Article 123(2) EPC.

Claim 1 - Novelty

Documents D1, D2, D3 and D20 took away the novelty of the subject-matter of claim 1 of the main request.

All these documents disclosed a method of manufacturing a urinary catheter (or a catheter suitable for use as a urinary catheter) by injecting two materials into a mould. The wording of claim 1 did not require anything more.

The intravascular catheter disclosed in D1 was suitable for use as a female urinary catheter when it had the largest dimensions indicated in the document in paragraph [0031]. These dimensions fell into the ranges mentioned in paragraph [0007] of the patent in suit. The connector type at the proximal end of the catheter had no importance for the suitability, since urinary catheters could be used without being connected to a collecting bag.

Claim 8 - Novelty

The wording of this claim included a product-by-process feature, namely that the catheter was made of at least two different catheter materials, the materials being joined during the moulding process, in which both materials were injected into a mould in a fluid state and solidified therein. Such a product-by-process feature did not mean that in order to anticipate the claimed feature the prior art catheter had to be made according to this process, but only that the features present on the claimed catheter due to the use of this particular manufacturing process had to be found on the prior art catheter.

In the present case this meant that, in addition to D1, D2, D3 and D20, all the documents D10 and D13 to D18 anticipated the subject-matter of claim 8.

Claim 1 - Inventive step

The wording of claim 1 simply stated that the two materials were injected into a mould which defined at least a catheter body and a catheter tip, and that these two materials solidified in the mould. This did not mean that the catheter tip and the catheter body were necessarily the elements made of the two materials, nor that the two materials had to solidify at the same time.

The subject-matter of claim 1 was not inventive over any combination of either D6 or D16 with either D1 or D10. In particular, D1 disclosing an injection moulding process in which two materials were injected into a mould and solidified therein for the manufacturing of intravascular catheters suggested the subject-matter of claim 1.

First auxiliary request

Claim 1 – Added subject-matter

The figures showed that there were holes in the tips of the catheter so that these tips did not seal off the internal conduit but, on the contrary, allowed fluid to enter and exit such conduit. For this reason the requirements of Article 123(2) EPC were not fulfilled.

Second and third auxiliary requests – Admissibility

These requests added new features which were not relevant up to now, and there was no reason for adding these features since no new documents had been filed. Furthermore, these requests were not converging with the existing requests because they did not address the laminated structure and were not based on claim 10. Therefore these requests should not be admitted into the proceedings.

Second auxiliary request

Claim 1 - Added subject-matter

The provision of individual sections in length was only disclosed on page 2 as being made in different process steps, i.e. with intermediate solidification. This was not in claim 1, so claim 1 did not fulfil the requirements of Article 123(2) EPC.

Claim 1 - Inventive step

The subject-matter of claim 1 was not inventive over a combination of D16 and D1 for the same reasons as for the subject-matter of claim 1 of the main request. The wording of the claim still did not require the tip and body of the catheter to be of different materials.

Third auxiliary request

Claim 1 - Added subject-matter – Clarity

In the application as filed, the feature of the radial size of the tip being larger than the radial size of the rest of the catheter was not disclosed in relation to the catheter having different parts made of different materials, so claim 1 did not fulfil the

requirements of Article 123(2) EPC. In addition, the wording was not clear because the "rest" of the catheter was not defined, and hence, could be any part of the catheter, so claim 1 did not fulfil the requirements of Article 84 EPC either.

Claim 1 – Inventive step

The subject-matter of claim 1 was not inventive over a combination of D16, D1 and D23. The enlarged tip feature of the catheter and the way of manufacturing the catheter were two solutions of two different problems which were not linked to one another and were separately solved respectively by D23 and D1. D23 suggested the enlarged tip and D1 the manufacturing method by injection moulding of two materials. Therefore the subject-matter of claim 1 was not inventive.

Reasons for the Decision

1. The appeals of the appellant-patent proprietor and of the appellant-opponent are admissible.

2. The invention

In the state of the art the method of manufacturing a urinary catheter generally included adding a glued-on catheter tip to a standard tube, drilling or punching the draining holes into the tip and adding a glued-on connector to the standard tube. This process is said to be time-consuming, inefficient and involving a large number of defective products.

The invention proposes to manufacture the catheter as a whole in one moulding process, with injection of

different materials for the different parts that have to fulfil different functions (slippery part, soft part, gripping part, connector, etc).

3. Main request

3.1 Claim 1 - Added subject-matter

The appellant-opponent considered that in the application as filed the injection of two different fluid materials into a mould was only disclosed in combination with more than one injection cycle, and it was not disclosed that the different materials were for parts with different characteristics.

The Board does not share this opinion. Original dependent claim 9 specifies that "different catheter materials are injected into the mould" without reference to the number of injection cycles (present in dependent claim 10). Original claim 1 is general in that it requires the injection of a fluid material into the mould and its subsequent solidifying. It follows that when claim 9 (dependent on claim 1) requires the injection of different materials into the mould, there is a general disclosure of injecting several materials into the mould and then solidifying them therein. In addition, the injection of different materials already implicitly indicates that different parts will be present having different characteristics. The wording of claim 1 of the main request does not require anything more.

Therefore, the ground for opposition according to Article 100(c) EPC does not hold against claim 1 of the main request.

3.2 Claim 1 - Novelty

Concerning D1, the appellant-opponent essentially submitted that, although this document primarily disclosed a manufacturing method of intravascular catheters, such catheters would be suitable for use as a urinary catheter (at least for women), so the methods of D1 for producing such suitable catheter took away the novelty of the subject-matter of claim 1.

D1 describes a manufacturing method (with three variants) for intravascular catheters. The catheter tube or body and hub are made as a one-piece element using a gas-assisted injection moulding process, whereby fluid plastics material is injected into the mould and gas is introduced during the injection moulding process along the axis of the lumen in order to create it. According to the third variant, two different materials are injected into a single mould (paragraphs [0056] to [0059]), one in order to form the hub and another one in order to form the body and the tip. The typical dimensions of the intravascular catheters produced are indicated in paragraph [0031].

In the opinion of the Board, this document cannot be considered novelty-destroying already because the person skilled in the art would consider even the longest indicated intravascular catheter (56 mm) to be too short for use as a urinary catheter. The patent in suit (paragraph [0007] of the patent) states that the suitable insertable length for female individuals is a length in the size of 70 mm, which is clearly longer than the maximal length disclosed in D1. In this respect, the Board agrees with the appellant-patent proprietor that the shorter indicated lengths in the said paragraph of the patent were not disclosed to be

for urinary catheters. On top of that, the Board considers that even though urinary catheters may be used without being connected to a bag, the person skilled in the art would not consider an intravascular catheter with a luer lock (e.g. paragraph [0017]) to be a urinary catheter.

D2 discloses an injection moulding process for manufacturing thin-walled tubes with a connection means. A mixture of polymers can be used as the injected material (page 5, first paragraph), but the injection of a mixture of materials cannot be considered equivalent to the injection of different materials, and there is no mention of the injection of two different materials into the mould.

D3 discloses an injection moulding process for making an intravascular catheter. Material is injected into a two-part mould, whereby one part of the mould is movable. Once the injected plastics material is cold enough, the movable part is displaced to extend or stretch one part of the moulded element to make the tube. Mixtures of materials can be used (paragraphs [0038] to [0045]), but there is no indication that different materials may be injected in the mould.

D20 discloses multi-layered moulded products (paragraphs [0052] to [0056]), but only mentions very generally the use for tubes in paragraph [0056]. Catheters are mentioned in paragraph [0006], but not in relation to multi-layered products, and urinary catheters are not mentioned at all.

Hence, the subject-matter of claim 1 according to the main request is novel.

3.3 Claim 8 - Novelty

The subject-matter of claim 8 being a urinary catheter as well, the argument of the suitability developed above in relation to the catheter disclosed in D1 applies here as well. The arguments in relation to D2, D3 and D20 apply here as well.

In addition, the wording of claim 8 includes a product-by-process feature, namely that the catheter is made of at least two different catheter materials, the materials being joined during the moulding process, in which both materials are injected into a mould in fluid state and solidified therein. The Board shares the opinion of the appellant-patent proprietor that such a way of joining the materials leaves a typical internal structure on the finished catheter, as well as visible marks (injection point, jointure) which are different from those left on extruded tubes, for instance, or left by gluing or welding.

Apart from the fact that the documents do not all disclose urinary catheters, none of the documents cited discloses a catheter in which two materials have been joined in a fluid state in the mould for producing the catheter tip and body, as required by the wording of claim 8.

D10 discloses a method for manufacturing an angiographic catheter, whereby in the variant according to Figure 4, column 3, line 45 onwards, two different materials are moulded onto a catheter tube or body to form the hub part. According to claim 8, the injection moulded catheter must have a tip and a body, so for this reason alone D10 is not novelty-destroying for claim 1. In addition, urinary catheters are not

mentioned in D10, and the angiographic catheter of D10 with its pigtail-type tip is not suitable for use as urinary catheter.

D13 discloses a tube for catheters made of two different materials. The two materials can be fed into a moulder 54 for extruding a two-material tube (Figure 6, paragraph [0030]). The application to urinary catheters is not mentioned and it is not mentioned how the tip is made.

D14 discloses a method in which the catheter tube is held in a mould and the hub is moulded around the catheter tube. Urinary catheters are not mentioned.

D15 discloses a medical tube made of two layers, the outer layer being harder than the inner layer. At the tip portion the outer layer is removed to have a softer tip. There is no mention of application to urinary catheters.

D16 discloses a method for manufacturing a urinary catheter in which the catheter tip alone is injection moulded with the desired holes and with a diameter adapted to standard tubes so that it can subsequently easily be joined to the standard tube.

D17 discloses a method of moulding a tip onto a standard tube. Application to a urinary catheter is not mentioned.

D18 discloses a method of manufacturing a multi-channel catheter with a tip moulded onto the catheter tube. There is no mention of urinary catheters.

Hence, none of D10 and D13 to D18 anticipates the subject-matter of claim 8.

3.4 Claim 1 - Inventive step

Interpretation of claim 1

The injection step requires at least two materials to be injected in fluid form into a mould, and the mould must define the catheter tip and body. Contrary to the opinion of the appellant-patent proprietor, the Board considers that this wording does not imply that the tip and the tube must necessarily be the parts of the catheter made of the two different materials. In the opinion of the Board, the wording of claim 1 leaves it open which part or parts of the catheter is or are made of different materials. This interpretation is in line with the broad indication in the fourth sentence of paragraph [0011] of the patent: "*Alternatively, the connector part may be made from a material different from the material of the proximal insertion section.*" The only requirements of claim 1 in this respect are thus that there are at least two parts made of two different materials (having different characteristics) and that the mould defines at least a catheter tip and a catheter body.

Starting from D16, the Board considers the following. D16 discloses a manufacturing method for catheters, in particular for catheters intended for insertion into the urethra (page 1, lines 5 to 9), whereby the tip is injection moulded and then joined with a standard tube in a joining operation (page 3, lines 15 to 22). The tip can be of the same or a different material than the standard tube (page 7, lines 25 and 26), and the tip can have a terminal eye (page 7, lines 28 and 29). It

goes without saying that such urinary catheters usually also have a hub to allow connection to a collection bag.

As recognised in the patent in suit, the process of joining a separate tip to an existing tube is cumbersome and time-consuming, and leads to a large number of defective products.

The objective problem to be solved can thus be seen as one of improving the production process for urinary catheters.

The Board considers that the person skilled in the art dealing with urinary catheters and wishing to improve their manufacturing methods would consider solutions to the problem in neighbouring fields also dealing with the manufacture of other kinds of catheter meant for introduction into the living body. D1, disclosing a manufacturing method for intravascular catheters, would therefore be considered by the person skilled in the art.

As explained under point 3.2 above, D1 discloses three related methods for manufacturing integral one-piece catheters, all three methods being based exclusively on injection moulding, which is the manufacturing method already used for the tip in D16. In all three methods, the catheter hub, body and tip are formed in the same mould. In the first method described in D1, one material is used for the whole catheter. This material is injected into a mould, whereby the lumen is formed by injecting gas into the catheter tubular portion. In the third method two materials are injected into the same mould in two injection cycles, one to form the hub and the next to form the tubular part and the tip

(paragraphs [0055] to [0059]). The person skilled in the art would immediately recognise that such an injection moulding process for whole catheters is less cumbersome and more reliable than any jointure procedure of the prior art using gluing, welding or the like. Furthermore, the person skilled in the art would recognise that this manufacturing process is, at least, adapted for the production of catheters having a size around the size of the intravascular catheters disclosed in D1, in which the tip of the catheter is made of the same material as the catheter body, and with a tip having a terminal eye (as described in D16). Hence, according to the Board, no inventive step can be seen in the combination of the teachings of D16 with that of D1. By doing so, the person skilled in the art would thus arrive at the subject-matter of claim 1 without an inventive step. In particular, by using the third of these processes, he would arrive at a catheter formed in a single mould, in which the body and tip would be of the same material but the hub would be of a different material, which, as explained further above, is covered by the wording of claim 1.

In the opinion of the Board, the argument of the appellant-patent proprietor that in the manufacturing process according to D1 it would not be known whether the materials would both solidify together, i.e. at the same time, in the mould, does not find any basis in the wording of claim 1. Claim 1 only requires that both materials solidify in the mould. This is also the case in the third embodiment of the method disclosed in D1.

Hence, the subject-matter of claim 1 according to the main request is not inventive.

4. First auxiliary request

4.1 Claim 1 - Added subject-matter

In claim 1 of the first auxiliary request it has been added that the catheter has an internal conduit and that its tip "*seals off the internal conduit and at least one drainage hole is formed in the vicinity of the tip to allow urine from a bladder to enter the hollow tubular body*".

According to the appellant-patent proprietor, although the specific wording that the tip seals off the internal conduit was not present in the description of the application as filed, there was clear support in Figures 1 to 3 and 5 showing that the tip closed the internal conduit of the catheter.

The Board does not share this opinion. According to the language used in the patent application, the tip (reference numerals 10, 20 respectively in Figures 2 and 3) is a part of the catheter different from the catheter body and follows the catheter body or tube at its distal end. This is already clear from the introductory part of the patent, which explains the problems of the prior art arising from the necessity of connecting the tip to the catheter body or tube by adequate means, and which the invention seeks to solve. In Figures 2 and 3 the tip is provided with drainage holes, so it cannot be said that the tips shown in these figures seal off the internal conduit of the catheter, because they precisely allow the fluid to flow through the holes made in the tip into the internal conduit of the catheter. Figures 1 and 5 are not precise enough to be able to deduce any relevant information relating to the above feature.

For the above reason, claim 1 according to the first auxiliary request contains subject-matter extending beyond the application as filed, contrary to Article 123(2) EPC.

5. Admissibility of the second and third auxiliary requests

The appellant-opponent considered that these requests should not be admitted into the appeal proceedings because admissible requests should be converging towards the existing requests relating to the laminated structure of the catheter as claimed in the request considered allowable by the opposition division. Moreover, claim 1 according to the third auxiliary request, which was said to be based on claim 10 as granted, did not take over the precise wording of that claim.

The Board does not share this opinion. The appellant-opponent filed new documents D20 to D22 with its statement setting out the grounds for appeal, so the appellant-patent proprietor should be given an opportunity to reply to the new lines of arguments based on these documents. Moreover, the concept of having different sections in length made of different materials is not complex and is in line with what has already been discussed in relation to the existing requests in respect of the tip and the body, and the amendment introduced with the third auxiliary request is based on granted claim 10, which the appellant-opponent must have been prepared for. Whether the precise wording of claim 10 should have been taken over is a matter for discussion once the requests have been admitted into the proceedings.

For these reasons the Board decides to admit these requests into the appeal proceedings.

6. Second auxiliary request

6.1 Claim 1 - Added subject-matter

Contrary to the opinion of the appellant-opponent, the Board considers that the addition fits with the general teaching from the paragraph starting at the end of page 4 (in particular lines 35 and 36) of the application as filed. Claim 1 according to the second auxiliary request does not therefore contravene Article 123(2) EPC.

6.2 Claim 1 - Inventive step

The subject-matter of claim 1 is not inventive, for the same reasons as the subject-matter of claim 1 of the main request is not inventive. The present wording, in particular that different segments in length should be made of different materials, does not require more than having, for instance, the connector or hub on the one side, and the catheter body on the other side being made of different materials (as would be obtained by the combination of the teachings of D16 with D1, as explained above). Furthermore, in D1 the two materials are also injected in more than one injection cycle (paragraphs [0056] and [0057]), so the application of the teaching of D1 to the manufacturing method of D16 would also bring about this feature.

For the above reasons the subject-matter of claim 1 according to the second auxiliary request is not inventive.

7. Third auxiliary request

7.1 Claim 1 - Added subject-matter and clarity

The appellant-opponent considered that claim 1 contained added subject-matter because the application as filed did not disclose that the shape of the tip now being claimed could be associated with a catheter made of two different materials having different characteristics. It further considered that the added wording was not clear because it did not define which radial part of the tip was concerned or which part of the catheter should be considered to be the "rest" of the catheter.

The Board does not share the opinion of the appellant-opponent. The added feature is supported word by word by the application as filed on page 5, lines 13 and 14. The addition of this general feature to claim 1 does not infringe Article 123(2) EPC, since it is clear from the application as filed that such a general feature was intended to be combined with any of the embodiments.

The Board also considers that the wording satisfies the requirements of Article 84 EPC, because it is clear for the person skilled in the art that the "rest" of the catheter can only designate the main part of the catheter, namely the body. This is also implicit from the function of the enlarged tip described in the description page 5, lines 12 and 13, which is said to be to reduce the resistance against insertion into the body canal. In other words, the part of the catheter behind the tip, namely the body, being of a smaller radial size than the tip, will facilitate insertion. Furthermore, it would make no sense, in this context,

to compare the size of the tip with any other part of the catheter not meant for insertion.

For the reasons above the requirements of Article 123(2) and 84 EPC are fulfilled by claim 1 according to the third auxiliary request.

7.2 Claim 1 - Inventive step

The appellant-opponent considered that the subject-matter of claim 1 according to the third auxiliary request was not inventive over a combination of D16 with D1 and D23. The essential reason for this was that the injection moulding feature of the method of manufacturing and the feature of the enlarged tip solved two different problems, not linked with each other, and were suggested by D1 and D23 respectively.

The Board does not share this opinion. It agrees with the appellant-patent proprietor that when an enlarged tip is present on the catheter the latter cannot be manufactured by extrusion anymore, so another way of manufacturing it must be found.

Starting from the manufacturing method of D16 in which the injection moulded tip is joined to a standard tube by any means, the objective problem may thus be seen as one of improving the manufacturing method for a catheter with an enlarged tip which facilitates the insertion and guidance of the catheter.

In the opinion of the Board, the manufactured catheter is inventive so the manufacturing method is inventive as well. As a matter of fact, D23 does not suggest that the use of an enlarged tip for a urinary catheter could facilitate its insertion. It is questionable whether

the person skilled in the art would take into consideration D23 when wishing to improve the insertion qualities of the catheter according to D16. D23 is concerned with a different type of catheter, namely a catheter for delivering medicine or a similar fluid into the ureter (not the urethra as in D16) of a patient and not to drain urine from the bladder. Compared with the prior art presented in it, the invention in D23 is to provide the tip of the ureter catheter with side holes for the delivery of the fluid instead of the hole at the distal end of the tip as in the there-cited prior art. The provision of side holes in the tip in combination with the fluid delivery provokes a widening of the vessel and the creation of a fluid layer between the catheter tip and the vessel wall which will facilitate insertion of the catheter into the ureter and reduce the risk of damage to that vessel (page 2, line 41 to page 3, line 3). According to an improvement, the tip of the catheter can have an ellipsoidal shape to enhance this widening of the ureter (page 3, lines 29 to 32). The catheter presented in D23 has a length in the order of magnitude of 60 cm and a diameter in the order of magnitude of 2mm.

From the above, it follows that D23 not only does not deal with urinary catheters within the meaning of the patent in suit (to empty the bladder) but also does not at any place in the document teach that the enlarged tip of the ureter catheter would facilitate its insertion into the urethra. At most, D23 teaches that side holes in the tip could improve insertion properties.

It follows that the person skilled in the art would not find any hint in this document towards a possible

easier insertion of a urinary catheter into the urethra.

Furthermore, D23 does not mention any manufacturing method for the catheter disclosed therein. According to the Board it is doubtful that a catheter of 2 mm of diameter and 60 cm long could be easily manufactured by injection moulding. This is an additional element indicating that this document could not even implicitly suggest using an injection moulding method for the manufacturing of a urinary catheter.

Furthermore, the Board is of the opinion that the person skilled in the art would not look for a manufacturing method for a urinary catheter with an enlarged tip in the field of intravascular catheters of the type manufactured according to the method described in D1, because such intravascular catheters do not have and do not need to have any such enlarged tips. Intravascular catheters are combined with a needle to facilitate introduction into the blood vessel.

Hence, the subject-matter of claim 1 according to the third auxiliary request is inventive.

7.3 Claim 8 – Inventive step

As Claim 8 includes the feature of the enlarged tip and the product-by-process feature that the two materials are joined during a moulding process in which both materials are injected into a mould in fluid state and solidified therein, its subject-matter is inventive for the same reasons as that of claim 1.

7.4 The Board is satisfied that the description has been correctly adapted to the amended claims. The opponent-appellant had no objections against it.

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 on the basis of:
- claims 1 to 10 of the third auxiliary request filed with letter dated 2 March 2015,
- columns 1 to 7 of the adapted description filed during the oral proceedings, and
- the figures of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated