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Datasheet for the decision of 8 May 2007

Case Number: T 0788/05 - 3.2.02

Application Number: 95109512.4

Publication Number: 0688576

IPC: A61M 29/02

Language of the proceedings: EN

Title of invention:
Vascular catheter

Patentee:
TERUMO KABUSHIKI KAISHA

Opponent:
Boston Scientific Scimed, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 87(1), 88(1), 123(2),(3)

Keyword:
"Priority right, claim by the same applicant - Prior art document not considered as first application "
"Disclaimer unallowable *a posteriori*"
"Feature replacing a disclaimer without violating Article 123(3) EPC"
"Inventive step (yes, fifth auxiliary request)"

Decisions cited:
G 0001/93, G 0001/03

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0788/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 8 May 2007

Appellant 1: (Patent Proprietor)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 22 April 2005 concerning maintenance of European patent No. 0688576 in amended form.**

Composition of the Board:

Chairman: T. Kriner
Members: M. Noël
M. Vogel
R. Ries
A. Pignatelli

Summary of Facts and Submissions

I. By interlocutory decision dated 22 April 2005, the opposition division decided to maintain the European patent No. 0688576 in an amended form.

II. An appeal was lodged against this decision by both the appellant 1 (patentee) and the appellant 2 (opponent) by notices received on 21 June 2005 and 22 June 2005, respectively. The appeal fees were paid in due course.

III. A statement setting out the grounds of appeal was filed by the appellant 1 on 22 August 2005, and by the appellant 2 on 31 August 2005.

IV. Oral proceedings were held on 8 May 2007, at the end of which the requests of the parties were as follows:

Appellant 1 requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or auxiliary on the basis of claims 1 and 9 pursuant to the first to fourth auxiliary requests or on the basis of claims 1 to 11 pursuant to the fifth auxiliary request, all filed during the oral proceedings.

Appellant 2 requested that the decision under appeal be set aside and that the European patent No. 0688576 be revoked.

V. The following documents are of importance for the present decision:

D1: EP-A-0608853
D2: US-A-5279562
D4: US-A-5250069
D5: EP-A-0437795
D6: US-A-4960410
D7: WO-A-93/04722

VI. The independent claims according to the various requests read as follows:

Main request (claim 1 as granted):

"A vascular catheter having a body (2) comprising a main portion (6) and a tip portion (7) and defining a lumen (3) formed from a proximal end (8) to a distal end (13) said main portion (6) being made up of an inner tube (4) and an outer tube (5) formed of a synthetic resin covering the outside surface of said inner tube (4);

said inner tube (4) having one or more spiral slits (9A, 9B) in its distal end portion;

said outer tube (5) having a portion extending from the distal end of said inner tube (4) to form said tip portion (7) of the catheter body (2) **characterized** in that said inner tube is formed of a metal or an alloy, preferably steel, tungsten, copper or steel alloy, tungsten alloy, copper alloy, with exclusion of superelastic or pseudoelastic alloys."

First to fourth auxiliary requests:

the preamble of claim 1 of the main request and the following characterising portions:

First auxiliary request:

"**characterized** in that said inner tube is formed of a metal or an alloy, preferably steel, tungsten, copper or steel alloy, tungsten alloy, copper alloy, with exclusion of superelastic or pseudoelastic alloys and said tip portion (7) has a length of 5 to 30 cm."

Second auxiliary request:

"**characterized** in that said inner tube is formed of austenitic stainless steel, marageing stainless steel or tungsten alloys."

Third auxiliary request:

"**characterized** in that said inner tube is formed of austenitic stainless steel."

Fourth auxiliary request:

"**characterized** in that said inner tube is formed of austenitic stainless steel, and in that said spiral slit is gradually reduced in pitch or gradually increased in width toward the distal end of said austenitic stainless steel."

Fifth auxiliary request:

"1. A vascular catheter having a body (2) comprising a main portion (6) and a tip portion (7) and defining a lumen (3) formed from a proximal end (8) to a distal end (13) said main portion (6) being made up of an inner tube (4) and an outer tube (5) formed of a synthetic resin covering the outside surface of said inner tube (4);

said inner tube (4) having one or more spiral slits (9A, 9B) in its distal end portion;

said outer tube (5) having a portion extending from the distal end of said inner tube (4) to form said tip portion (7) of the catheter body (2) **characterized** in that said inner tube is formed of austenitic stainless steel, and in that a tip portion and a main portion of said outer tube (5) are formed of a synthetic resin, the synthetic resin of the tip portion being softer than the synthetic resin of the main portion."

"8. A vascular dilatation instrument comprising

an inner tube (21) defining a first lumen extending between an open distal end and a proximal portion,

an outer tube (22) disposed coaxially around said inner tube, having a distal end retracted a predetermined distance from the distal end of said inner tube and a proximal portion, and defining a second lumen with the outside surface of said inner tube,

an inflatable member (23) having one end attached to said inner tube (21) and another end attached to said outer tube (22), and defining an interior space in fluid communication with said second lumen in the vicinity of said distal end of said outer tube (22),

a first opening disposed in the proximal portion of said inner tube in communication with said first lumen, and

a second opening disposed in the proximal portion of said outer tube in fluid communication with said second lumen, **characterized** in that

at least one of said inner tube (21) and outer tube (22) includes a main body section (6) made up of a tube formed of austenitic stainless steel, and a distal section (7) made of a synthetic resin and extending beyond the distal end of the tube formed of said austenitic stainless steel

wherein said tube formed of said austenitic stainless steel has one or more spiral slits in its distal ends portion, a synthetic resin covering said slits, and in that a distal section of said outer tube is formed of a synthetic resin, and the synthetic resin of said distal section is softer than the synthetic resin covering the surface of said austenitic stainless steel tube."

VII. Appellant 1 presented the following arguments:

Although the applicant Terumo was common in document D1 and in the application as filed, two different applicants were designated in D1 so that the legally

qualified "person" referred to in Article 87(1) EPC was not identical in both documents. Therefore, D1 was not the "first application" within the meaning of Article 87(1) EPC. Consequently the priority date of the present application was valid and D1 represented a state of the art under Article 54(3) EPC.

A disclaimer was validly introduced in claim 1 of the main request during the examining procedure with the purpose to re-establish novelty vis-à-vis the conflicting application D1, since superelastic and pseudoelastic alloys were the sole materials used in this document. Moreover, the disclaimer did not change the nature of the present invention, principally based on the structural features of the catheter or the dilatation instrument. The disclaimer, therefore, was allowable and could not result in an extension of the claimed subject-matter precluded by Article 123(2) EPC.

D5 represented a non-accidental state of the art under Article 54(2) EPC. However it was not so relevant as to challenge the inventive step of claim 1 of the main request since it disclosed independent embodiments (Figures 1 to 3) comprising either an inner tube devoid of spiral slits in its distal end portion or an outer tube without any tip portion extending from the distal end of the inner tube. Further, the grooves made in the inner tube were not equivalent to traversing slits. Therefore, D5 did not jeopardise the allowability of the disclaimer, following the criteria set out in G 1/03.

The dimensional feature added to claim 1 of the first auxiliary request represented an additional limitation

and was fairly supported by the application as filed. This feature, therefore, did not introduce new matter.

The subject-matter of claim 1 according to the second to fifth auxiliary requests was further limited to materials such as austenitic stainless steel which, clearly, were neither superelastic nor pseudoelastic alloys. Therefore, these materials could validly replace the materials excluded by the disclaimer without contravening Article 123(3) EPC. Moreover materials such as austenitic stainless steel were not suggested by the state of the art for use in catheters having the structural features as claimed.

As to the independent claims 1 and 8 of the fifth auxiliary request, none of the cited prior art suggested to form the different portions of the outer tube with synthetic resins having different properties, the synthetic resin of the tip portion being softer than the synthetic resin of the main portion in order to create a boundary region of gradual flexibility and improved reluctance to kink. These claims, therefore, involved an inventive step over the state of the art in accordance with Article 56 EPC.

VIII. Appellant 2 presented the following arguments:

Terumo was designated as an applicant both in the present application and in D1. Therefore, this applicant had to be regarded as the "person" referred to in Article 87(1) EPC, who was entitled to a priority right, regardless of the designation in D1 of a second applicant. Since, moreover, the invention was the same in both documents, D1 had to be considered as the first

application. As a consequence, the priority claimed for the present application was not valid and D1 represented a state of the art under Article 54(2) EPC.

Moreover, D1 was not an accidental anticipation and was relevant for assessing the inventive step of claim 1 according to the main request. Also D5 which represented another prior art document under Article 54(2) EPC disclosed (Figure 3) a metallic inner tube having a distal portion with spiral grooves in order to provide elasticity to said distal portion and an outer tube made of synthetic resin and protruding from the distal portion of the inner tube so as to form a tip portion. Accordingly, D5 disclosed all the positive features of claim 1 of the main request and, therefore, was highly relevant for assessing the inventive step thereof. Consequently, the disclaimer which was originally introduced to restore the novelty of claim 1 vis-à-vis document D1, turned out to be unallowable following the criteria set out in G 1/03, in particular point 2.6.2. The disclaimer, therefore, could not be maintained since it was introduced in violation of Article 123(2) EPC.

The limitation made to claim 1 of the first auxiliary request had never been considered before the oral proceedings and, therefore, had to be refused. Moreover, the dimensional feature added to claim 1 was restricted to the specific example illustrated by Figure 1 to 3 of the present application and, consequently, resulted in a generalisation of the claimed subject-matter, contrary to Article 123(2) EPC.

The use of austenitic stainless steel instead of superelastic or pseudo elastic alloys was an obvious choice of material for a skilled person versed in the field of catheters, as disclosed by D2 or D7. Starting from D5, this feature alone was, therefore, insufficient to confer an inventive step to the subject-matter of claim 1 according to the second and third auxiliary requests.

A stainless steel tube having spiral slits gradually reduced in pitch in order to increase the flexibility of the tube towards its distal end, was also known from D7. Therefore, the subject-matter of claim 1 of the fourth auxiliary request did not involve an inventive step either.

In order to provide variable flexibility to the catheter along its length, various solutions were proposed in the prior art documents, e.g. in D5 or D7, by selectively varying the configuration of the different portions of the catheter or the number, the thickness or the materials used for making different tubular layers constituting the catheter. The further selection of two synthetic resins having different softness represented a mere matter of discretion among a plurality of solutions, all regarded as equivalent and obvious to a person skilled in the art. Therefore, the subject-matter of the independent claims 1 and 8 of the fifth auxiliary request did not involve an inventive step within the meaning of Article 56 EPC.

Reasons for the Decision

1. The appeal is admissible.

2. *Priority right*

Article 87(1) EPC states: "A person who has duly filed ... an application for a patent ..., or his successors in title, 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."

The term "a person" in Article 87(1) EPC (or "an applicant" in Article 88(1) EPC) implies that the applicant be the same for "the first application" (or "previous application" in Article 88(1) EPC) and for the later application for which a priority right is claimed. The required identity for the applicants originates in that the priority right is part of the applicants right.

In the case of D1 in which two co-applicants (Terumo and Tokin) are present, this means that the priority right belongs simultaneously and jointly to the two applicants, who thus constitute a legal unity unless one of them decides to transfer his right to the other applicant, who then becomes his successor in title and this before the filing of the later application. Since no evidence for such a transfer was submitted to the Board, D1, independently of the question of the same invention, could only serve as a basis for claiming a priority right for the filing of a later application

designating both applicants. But since the present application was only filed by one applicant (Terumo), D1 could not represent the "first application" within the meaning of Article 87(1) EPC.

It results therefrom that the current priority date of 20 June 1994 is valid and that D1 represents a state of the art under Article 54(3) EPC.

3. *Disclaimer - main and first auxiliary requests*

Claim 1 according to the main and the first auxiliary request comprises the following disclaimer; "with exclusion of superelastic or pseudoelastic alloys".

This disclaimer, which is not disclosed in the application as filed, was introduced by the appellant 1 during the examination procedure with the purpose of establishing novelty of the claimed subject-matter with respect to D1, which was then considered as a prior art document relevant under Article 54(3) EPC.

A disclaimer, which is not disclosed in the application as filed, is only allowable if it is introduced to overcome a novelty objection based on an accidental disclosure or to delimit a claim against a state of the art under Article 54(3) and (4) EPC (See G 1/03). In the present case the relevant prior art is represented by documents D1 and D5. To be allowable the disclaimer has to fulfill the conditions cited above in relation to both documents (see G 1/03, point 2.6.2).

As far as D1 is concerned, this document discloses (see Figures 24 to 26) a vascular catheter having all the

structural features contained in claim 1 of the main or the first auxiliary request, in particular an outer tube formed of a synthetic resin and an inner tube formed of a metal or an alloy. Knowing that a pure metal can never be superelastic or pseudoelastic, the "metal tube" improperly referred to in D1 is actually exclusively made of a superelastic or pseudoelastic alloy e.g. of a material exhibiting shape memory properties (see D1, page 18, lines 12 to 26). Consequently, at the time of its introduction, the disclaimer appeared to be appropriate since the material claimed for the inner tube was then restricted to a metal or an alloy other than superelastic or pseudoelastic. This limitation was sufficient to restore novelty vis-à-vis document D1, in accordance to the criteria set out in G 1/03.

D5, which is cited as a relevant document in the European search report annexed to the present application, represents a state of the art under Article 54(2) EPC. This state of the art is not an accidental anticipation in the sense that its disclosure is not so unrelated and remote that the person skilled in the art would never have taken it into consideration when working on the invention, the more since D5 like D1 belongs to appellant 1 (see G 1/03, point 2.2.2).

As D5 is not a state of the art under Article 54(3) and (4) and is not an accidental disclosure, the disclaimer would only be allowable if it did not add subject-matter in the sense of Article 123(2) EPC, i.e. if the disclaimer did not become relevant for the assessment of inventive step.

Going into details, D5 discloses (Figure 1) a vascular catheter having a body comprising a main portion 4a and a tip portion 4b and defining a lumen 6 formed from a proximal end to a distal end, said main portion being made up of an inner tube 2 and an outer tube 3 formed of synthetic resin and covering the outside surface of the inner tube and having a portion 4b extending from the distal end of said inner tube to form the tip portion of the catheter body.

The same is true with respect to the embodiment of Figure 3, although the tip portion of the outer tube, extending from the distal end of the inner tube, is restricted to a thin portion covering the distal end of the inner tube around the lumen opening 5. Furthermore, the inner tube is provided with spiral grooves in its distal end portion 4 in order to improve the elasticity thereof (see column 6, lines 4 to 8). In the present situation grooves must be considered as slits since both terms do not imply that the recess or incision goes completely through the tube in order to provide more flexibility.

Like D1, the metallic inner tube of D5 is formed of superelastic alloys throughout the disclosure, so that the disclaimer is also relevant with respect to D5. Therefore, it becomes relevant for assessing the inventive step of the subject-matter of claim 1 and adds subject-matter within the meaning of Article 123(2) EPC (see G 1/03, point 2.6.1). Moreover, since the disclaimer has effects with respect to D5, which go beyond its purpose, it has become inadmissible

and cannot be maintained in the claims (see G 1/03, point 2.6.5).

It results therefrom that the subject-matter of claim 1 of the main and the first auxiliary request is not acceptable under Article 123(2) EPC.

4. *Second and third auxiliary requests*

The preamble of claim 1 according to the second and third auxiliary requests is identical to that of claim 1 of the main request. The characterising portion of claim 1 states, *inter alia*, that the inner tube is formed of austenitic stainless steel. The other materials such as marageing stainless steel or tungsten alloys cited in claim 1 of the second auxiliary request are optional.

As demonstrated above, D5 (Figure 3) discloses all features of the preamble of claim 1. The subject-matter of claim 1 according to the second or the third auxiliary request, therefore, differs from the catheter of D5 only in that the inner tube is formed of austenitic stainless steel. According to D5 the material used for making the inner tube consists of superelastic alloys, exclusively (see column 3, line 56 to column 4, line 6). However, regardless of the question of the admissibility of this feature in claim 1 as replacement for the features excluded by the disclaimer, the Board considers that the skilled person is aware that stainless steel or austenitic stainless steel alloys are commonly and generally used in the field of catheters and sometimes considered as equally suitable as are superelastic or shape memory materials

for making one of the concentric tubes of the catheter, as mentioned for example in D2 (column 13, lines 9 to 12), D6 (column 4, line 2), D7 (page 15, lines 10 to 13) or D4 (column 6, lines 47 to 53). D4 is also referred to in the background of D5 (column 1) in the form of a parent document EP-349640. Therefore, the selection of austenitic stainless steel is the obvious first choice of material the skilled person would think of, when faced with the problem of replacing a superelastic alloy.

Consequently, the subject-matter of claim 1 of the second and third auxiliary requests does not involve an inventive step when starting from D5 and considering the teaching of either one of the above-mentioned documents.

5. *Fourth auxiliary request*

With respect to the third auxiliary request, claim 1 according to the fourth auxiliary request contains the following additional feature: "and in that said spiral slit is gradually reduced in pitch or gradually increased in width towards the distal end of said metal or alloy tube".

This feature is disclosed by D7 (see Figures 1 to 3 and 8) which describes a flexible device made of stainless steel for use as catheter, having a plurality of spiral windings or slots of a predetermined configuration which are cut into a thin walled metal tube at predetermined spacing, depth and pattern so as to provide the tube with a desired flexibility (see page 8, lines 30 to 34; page 15, lines 8 to 13 and 21

to 25; page 18, lines 14 to 16). The slots may be totally cut (page 15, line 33). Moreover, the configuration of the slots may be varied along the length of the tube so as to provide varying characteristics along its length (see page 18, lines 22 to 25). For example, the distal end of the catheter typically may be very flexible, while other areas of the catheter may be stiffer to improve the transmission of torque. This can be made by using more longitudinally displaced windings at the distal end of the catheter or by varying the configuration of the slots correspondingly (see page 13, lines 8 to 17; page 19, lines 6 to 18 and page 20, lines 16 to 24).

Therefore, the provision of a spiral slit as described in claim 1 of the fourth auxiliary request is obvious, and the subject-matter of this claim does not involve an inventive step vis-à-vis D5 in combination with the teaching of D7.

6. *Fifth auxiliary request*

6.1 Amendments

6.1.1 With respect to independent claims 1 and 9 of the version as granted, the feature "(a tube) formed of a metal or an alloy, preferably steel, tungsten, copper or steel alloy, tungsten alloy, copper alloy, with exclusion of superelastic or pseudoelastic alloys" was replaced by the following feature in independent claims 1 and 8 of the fifth auxiliary request: "(a tube) formed of austenitic stainless steel".

This feature is validly supported by the application as filed (published version) on page 4, line 58 to page 5, line 2 and on page 7, lines 2 to 4, respectively, depending on whether this feature refers to a vascular catheter (claim 1) or a vascular dilatation instrument (claim 8).

In above section 3 it was decided that the non-disclosed disclaimer was not allowable under Article 123(2) EPC. In such a situation, the patent can only be maintained if there is a basis in the application as filed for replacing the disclaimer without violating Article 123(3) EPC (see G 1/93). In the present case where the replacement material (austenitic stainless steel) is not a superelastic or pseudoelastic alloy, the disclaimer was replaced by a positive, more restrictive, fairly supported and compatible feature. The replacement feature, therefore, is acceptable without violating Article 123(3) EPC.

6.1.2 As to the remaining amendments, the claims of the fifth auxiliary requests are supported by the application as filed (published version) in the following manner:

Independent claim 1 is formed by a combination of features taken from the original claim 1 and a feature (lumen 3) taken from the description (page 3, line 28). The last feature ("and in that a tip portion ... softer than the synthetic resin of the main portion") is supported by the original claim 5 and the description (page 5, lines 41 to 42).

Independent claim 8 is formed by a combination of features taken from the original claims 9 and 10. The

last feature ("and in that a distal section ... softer than the synthetic resin covering the surface of said austenitic stainless steel") is supported by the original claim 13 and the description (page 7, lines 17 to 18 and page 10, lines 24 to 27).

The dependent claims are generally supported by the claims as filed, after replacement of the previous materials by "austenitic stainless steel" wherever needed:

claim 2 is supported by the description on page 6, line 50;
claims 3 and 4 are supported by original claims 3 and 4, respectively;
claim 5 is supported by the original claim 6 and by informations drawn from the description on page 7, lines 11 to 15;
claim 6 is supported by original claim 8;
claim 7 is supported by the description on page 4, line 46;
claims 9, 10, 11 are supported by original claims 11, 12, 14, respectively.

It results therefrom that Article 123(2) EPC is met. Moreover, since all amendments result in a limitation of the claimed subject-matter and of the scope of protection, Article 123(3) EPC is also met.

6.2 Inventive step

With respect to D5 which is considered as the closest prior art, the subject-matter of independent claim 1 of the fifth auxiliary request, illustrated by Figures 2

to 4 in the present application, differs not only by the material used, but also essentially by the last feature according to which "a distal section of said outer tube is formed by a synthetic resin, and the synthetic resin of said distal section is softer than the synthetic resin covering the surface of said austenitic stainless steel".

The object of this feature is to assist in solving the problem stated generally in the application as filed (see page 2, lines 33 to 34) to provide a vascular catheter with improved turnability, flexibility and reluctance to kink, and more specifically to provide the catheter with variable flexibility along its length, i.e. higher flexibility towards its distal end in order to facilitate its introduction into tortuous vessels. Simultaneously, kinking should be avoided at the boundary between the more rigid main portion and the more flexible tip portion of the catheter.

These objects are achieved by the features as claimed, in particular by the specific combination of the slit end portion of the austenitic stainless steel inner tube and the softer tip portion of the synthetic resin outer tube. Since a synthetic resin outer tube made of two portions having different synthetic resin softness is neither disclosed nor suggested by any of the cited documents, the combination of claim 1 according to the fifth auxiliary request involves an inventive step within the meaning of Article 56 EPC.

A similar feature is present in independent claim 8 of the fifth auxiliary request, which refers to the embodiment according to Figures 6 and 7 of the present

application. But this time the softer synthetic resin refers to the distal section 7 of the outer tube while the less soft resin covers the metallic tube (either inner or outer) of the main body section 6. For the same reasons as above, the subject-matter of claim 8 of the fifth auxiliary request involves an inventive step. The remaining claims which depend on independent claims 1 and 8 are also acceptable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of claims 1 to 11 according to the fifth auxiliary request filed during the oral proceedings and the description to be adapted thereto.

The Registrar: The Chairman:

V. Commare T. Kriner