Datasheet for the decision of 1 December 2009

Case Number: T 1008/07 - 3.2.02
Application Number: 99970931.4
Publication Number: 1131128
IPC: A61M 29/02

Language of the proceedings: EN

Title of invention:
Catheter having improved bonding region

Patentee:
Boston Scientific Limited

Opponent:
Terumo Kabushiki Kaisha

Headword:
-

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

Relevant legal provisions (EPC 1973):
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Keyword:
"Extended subject-matter (yes)"
"Inventive step (no)"

Decisions cited:
-

Catchword:
-
Case Number: T 1008/07 - 3.2.02

DECISION of the Technical Board of Appeal 3.2.02 of 1 December 2009

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Composition of the Board:
Chairman: D. Valle
Members: C. Körber
M. J. Vogel
Summary of Facts and Submissions

I. The appellant I (patentee) lodged an appeal on 27 June 2007 against the decision of the opposition division posted on 17 April 2007 to maintain the patent in amended form. The appeal fee was paid simultaneously and the statement setting out the grounds for appeal was received on 27 August 2007.

II. The opponent (appellant II) also lodged an appeal on 15 June 2007 against the above decision and paid the appeal fee simultaneously. The statement setting out the grounds for appeal was received on 17 August 2007.

III. The following documents are relevant for the decision:

D3 = EP - A - 0 707 865

IV. Oral proceedings took place on 1 December 2009.

The appellant I (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or on the basis of the first auxiliary request, both filed the 30 October 2009, or on the basis of the second auxiliary request filed during the oral proceedings before the Board.

The appellant II (opponent) requested that the decision under appeal be set aside and that the patent be revoked.
V. Claim 1 of the main request reads as follows:

"A catheter shaft comprising:

a first tube (46; 102; 202; 302; 402; 502; 602; 702; 802) including a lumen, an inside wall surface, and an outside wall surface;

a second tube (58; 105; 205; 305; 405; 505; 605; 705; 805) disposed partially within said first tube, said second tube having a length, a lumen therethrough, an inside wall surface and an outside wall surface; and

a bonding region (851) bonding said second tube outside wall surface to said first tube outside wall surface, said second tube inside wall surface being formed of a second material for a majority of said second tube length, said first tube wall having a layer of a first material extending for a majority of said first tube length, said first material being different from said second material."

Claim 1 of the first auxiliary request reads as follows:

"A catheter shaft comprising:

a first tube (46; 102; 202; 302; 402; 502; 602; 702; 802) including a lumen, an inside wall surface, and an outside wall surface;

a second tube (58; 105; 205; 305; 405; 505; 605; 705; 805) disposed partially within said first tube, said second tube having a length, a lumen therethrough, an inside wall surface and an outside wall surface; an orifice in a proximal portion of said first tube (46; 102; 202; 302; 402; 502; 602; 702; 802); and

a bonding region (851) proximal of said orifice bonding said second tube outside wall surface to said first
tube outside wall surface, said second tube inside wall surface being formed of a second material for a majority of said second tube length, said first tube wall having a layer of a first material extending for a majority of said first tube length, said first material being different from said second material."

claim 1 of the second auxiliary request reads as follows:

"A catheter shaft comprising:

a first tube (46; 102; 202; 302; 402; 502; 602; 702; 802) including a lumen, an inside wall surface, and an outside wall surface;
a second tube (58; 105; 205; 305; 405; 505; 605; 705; 805) disposed partially within said first tube, said second tube having a length, a lumen therethrough, an inside wall surface and an outside wall surface;
an orifice in a proximal portion of said first tube (46; 102; 202; 302; 402; 502; 602; 702; 802), a bonding region (850, 851) proximate said orifice bonding said second tube outside wall surface to said first tube wall surfaces, said second tube inside wall surface being formed of a second material for a majority of said second tube length, said first tube wall having a layer of a first material extending for a majority of said first tube length, said first material being different from said second material;

wherein said bonding region (851, 850) includes a proximal bonding region (851) between said first tube outside wall surface and said second tube outside wall surface extending proximal of said orifice and said bonding region (850, 851) includes a distal bonding region (850) between said first tube inside wall
surface and said second tube outside wall surface extending distal of said orifice, and wherein the first and second tubes have longitudinal axes, respectively, which are parallel to each other along the length of the distal bonding region (850)."

**Reasons for the Decision**

1. The appeals are admissible.

2. **Main request**

   The feature contained in claim 1 of the main request:

   
   "[... bonding said second tube outside wall surface to said first tube] outside [wall surface]"

   violates Article 123 (2) EPC, being an intermediate generalisation, since bonding in an outer-to-outer configuration has been originally disclosed only in the region proximal to the orifice, see reference number 851 in Figure 2 and the corresponding passages in the description of the application as originally filed.

   The appellant I argued that the feature was implicitly disclosed in the original application. The original application, see page 9, line 18 to page 10, line 4, listed different alternatives for the position of the bonding region. There was no necessary link between the different alternative positions listed therein and an outer-to-outer bonding. Any possible position of an
outer-to-outer bonding was therefore originally disclosed.

Nevertheless, the original disclosure does not contain the information that an outer-to-outer bonding can be positioned anywhere, but only that it is positioned in the region proximal to the orifice. The fact that there are listed different alternatives for the position of the bonding does not mean that for all these alternative an outer-to-outer bonding is possible or foreseen.

The appellant I argued further that an outer-to-outer bonding was implied by claim 1, since claim 1 required that the second tube was disposed partially within the first tube, this necessarily implying the presence of an orifice and an outer-to-outer bonding proximal thereof.

However, the formulation of the claim would cover also an embodiment as disclosed in D26, where the end portion of the outer tube (flexible sheath 27") is inverted inwardly, and the outside surface of this outer tube is bonded to the outside surface of the inner tube (tubular member 15). Embodiments of this kind are, however, nowhere disclosed in the application as filed.

Accordingly, claim 1 of the main request does not comply with Article 123 (2) EPC.
3. First auxiliary request

3.1 Novelty

D3, see in particular Figure 4, discloses a catheter shaft comprising a first tube (41) including a lumen, an inside wall surface, and an outside wall surface, a second tube (44) disposed partially within said first tube, said second tube having a length, a lumen therethrough, an inside wall surface and an outside wall surface, an orifice (42) in a proximal portion of said first tube, and a bonding region (43) proximal of said orifice bonding said second tube outside wall surface to said first tube outside wall surface.

However, D3 does not disclose that said second tube inside wall surface is formed of a second material for a majority of said second tube length, said first tube wall having a layer of a first material extending for a majority of said first tube length, and said first material being different from said second material.

The appellant I argued that Figure 4 does not disclose a "bonding" region. Column 3, line 22 of D3 speaks of "fixing" and not of "bonding". Furthermore it is not clear that D3 discloses a bonding "region". More likely, D3 provides for a point bonding involving only the head of the inner tube.

However, in D3, "fixing" means in particular "bonding" in the form of glueing or ultrasonic welding, see column 2, lines 51 to 53, column 3, lines 15 and 16. Fixing by bonding appears on the other hand to be the usual method in the field. Furthermore, D3 clearly
discloses a bonding "region", see Figure 4, reference number 43 and column 3, line 23, where the wall "section" 43 is cited.

The appellant II argued that also the feature that the two tubes are (at least) partially made of different materials is implicitly disclosed by D3 and that therefore the subject-matter of claim 1 of the first auxiliary request is not novel against D3. He referred to column 1, lines 12 to 22 and column 3, lines 10 to 16. The need for the guidewire lumen to have a smooth surface requires a lubricious material which, together with the sealing requirements, necessarily leads the skilled person to choose two different materials for the tubes.

However it is not proved that the skilled person should necessarily choose two different materials for the tubes of the catheter according to D3. D3 does not give any indication in this sense.

3.2 Inventive step

Starting from the teaching of D3, the objective problem of the invention can be seen in improving the known catheter.

The measure of choosing different materials for the two tubes appears however banal. It is clear that the skilled person will choose, according to the circumstances, the most suitable material for each tube and he is not bound in any way to have the same material for both tubes. Moreover, no special advantage can be seen in the fact that these different materials
can be limited to portions of the tubes as specified in the claims.

The appellant I argued that the problem of the invention was to be seen in finding a good balance between the desired relevant characteristics of the catheter, in particular suitability for bonding, flexibility and pushability. The merit of the invention was to have found that that could be attained by choosing different materials for the two tubes.

However, the problem can not be formulated in such a specific way, since not all choices of material covered by the wording of the claim assure the sought balance.

Accordingly, claim 1 of the first auxiliary request does not involve an inventive step (Article 56 EPC).

4. Second auxiliary request

The second auxiliary request contains the additional feature that the first and second tubes have longitudinal axes, respectively, which are parallel to each other along the length of the distal bonding region.

This feature is not originally disclosed. Appellant I was not able to point to any passage in the original description and claims which positively discloses such a feature. He argued however that the feature was implicitly disclosed in the drawings. The skilled person could verify that in all the embodiments depicted in the drawings the axes of the two tubes were parallel to each other along the distal bonding region.
However, the drawings disclose the parallelism of the axes only for the location and length of the distal bonding region as depicted in the figures and not generally for any length and position of the distal bonding region extending distal of the orifice as claimed in claim 1 of the second auxiliary request. Arbitrarily selecting from the drawings of a patent application one single aspect which had not been in any way highlighted in the original disclosure is further not allowable because it represents an extension of the original disclosure itself.

Accordingly, claim 1 of the second auxiliary request does not comply with Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Sauter D. Valle