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**Datasheet for the decision
of 21 July 2010**

Case Number: T 1643/07 - 3.2.02

Application Number: 98906726.9

Publication Number: 0914175

IPC: A61M 25/01

Language of the proceedings: EN

Title of invention:

Guide wire with hydrophilically coated tip

Patentee:

Boston Scientific Scimed, Inc.

Opponent:

Terumo Kabushiki Kaisha

Headword:

-

Relevant legal provisions:

EPC Art. 52, 54, 56

RPBA Art. 13

Relevant legal provisions (EPC 1973):

-

Keyword:

"Novelty (yes)"

"Inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1643/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 21 July 2010

Appellant:
(Opponent)

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Respondent:
(Patent Proprietor)

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Representative:

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 17 July 2007
rejecting the opposition filed against European
patent No. 0914175 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
J. Geschwind

Summary of Facts and Submissions

- I. The appeal was lodged by the opponent against the decision of the Opposition Division dated 17 July 2007 to reject the opposition.

The notice of appeal was filed on 26 September 2007 and the appeal fee paid the same day. The statement setting out the grounds of appeal was filed on 27 November 2007.

- II. A preliminary opinion of the Board was communicated to the parties on 10 June 2010.

- III. Oral proceedings were held on 21 July 2010.

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

The respondent (patentee) requested that the appeal be dismissed or, as an auxiliary request, that the patent be maintained in amended form on the basis of claims 1 to 15 filed on 8 July 2010.

During the oral proceedings the appellant requested an opportunity to present a new line of argument against inventive step starting from document D5 (see below) as the closest prior art.

- IV. Claim 1 as granted (main request) reads as follows:

"A guide wire (20,120,220,320,420) having a distal end and a proximal end comprising:

an elongate core (28,128,228,328,428) having a distal core portion, an intermediate core portion proximal of the distal core portion and a proximal core portion proximal of the intermediate core portion;

a lubricous distal guide wire portion (22,122,222,322,422); and

a proximal guide wire portion (26,126,226,326,426) proximal of said distal guide wire portion (22,122,222,322,422) and less lubricous than said distal guide wire portion (22,122,222,322,422), characterised by:

an intermediate guide wire portion (24,124,224,324,424) intermediate said distal portion (22,122,222,322,422) and said proximal guide wire portion (26,126,226,326,426), said intermediate guide wire portion (24,124,224,324,424) being less lubricous than said distal guide wire portion (22,122,222,322,422) and said proximal guide wire portion (26,126,226,326,426)."

V. The following documents are relevant for the present appeal decision:

D1: EP-A-0661073

D3: EP-A-0519604

D5: JP-A-04-009162 (and D5t: the translation into English)

D11: WO-A-89/10088

Exhibit A: "Experiment Report" provided by the opponent on 5 June 2007

Djp: English translation of a Japanese court decision of 5 January 2010 on an appeal concerning Japanese

patent application H10-538563 (filed by the appellant with letter of 21 June 2010).

VI. The appellant's arguments can be summarised as follows:

Novelty

The guide wire according to claim 1 of the patent lacked novelty over the state of the art according to document D5. The guide wire according to figure 1 of document D5 comprised an elongated core composed on a first linear body 2, a second linear body 3 and a ring-like member 4 connecting the first linear body and the second linear body.

The two extremities of the first linear body and the second linear body connected by the ring-like member constituted the intermediate core portion. The rest of the second linear body 3 constituted the distal core portion and the rest of the first linear body 2 constituted the proximal core portion.

On the first linear body, a first synthetic layer 8 was applied, while on the second linear body, a second synthetic layer 5 was applied. A surface coating 7 was additionally applied on the layer 5 of the distal portion of the guide wire to increase lubricity in humid state. It followed from the above that the proximal guide wire portion was less lubricous than the distal guide wire portion.

The intermediate guide wire portion was constituted by the surface of the ring-like member 4. Nowhere in document D5 was it mentioned that the ring-like member 4 was coated or should be coated with a synthetic resin

layer forming a lubricating surface. On the contrary, it was clear to the man skilled in the art when looking at figure 1 that the ring-like member 4 was not coated. It was also mentioned in document D5 that the lubricating surface 7 was formed only on the second synthetic resin layer 5 and it could be seen from figure 1 that the resin layer 5 did not cover the ring-like member 4. The ring-like member 4 was thus free of any coating.

In document D5 it was mentioned that the ring-like member 4 was preferably made of a shape-memory alloy. As the proximal guide wire portion was covered with a coating 8 reducing to some degree frictional resistance, it was clear that the intermediate surface of the ring-like member was less lubricous than the surface of the proximal guide wire portion. This was proven by the experiment report filed as "Exhibit A", confirming that a surface formed of a PTFE resin provided less frictional resistance than the surface of a body made of a shape-memory alloy such as a Ni-Ti alloy. Where necessary, this experiment report should be introduced into the proceedings in view of its relevance.

Consequently, the guide wire according to claim 1 was not novel over the disclosure of document D5.

Inventive step

Starting from D5

D5 had been in the proceedings since the start of the opposition proceedings so that neither the Board nor the respondent should have difficulty in understanding

or arguing the case relating to inventive step starting from this document.

Starting from D11

The guide wire according to document D11 comprised several portions: an intermediate guide wire portion constituted by a tapering intermediate core portion 54 encased in a helical coil 56, a proximal portion 26, 28 and a distal guide wire portion constituted by a distal rounded joint 62. Claim 1 did not define the distal guide wire portion very precisely and, in particular, did not define its length so that distal joint 62 of the guide wire according to document D11 could be regarded as falling under this definition.

The proximal guide wire portion 26, 28 had a surface which was constituted by low friction polymer coating 46. The intermediate guide wire portion 54, 56 was less lubricous than the surface of the proximal guide wire portion, the higher friction surface of the intermediate guide wire portion helping to anchor the guide wire against a vessel wall (see page 12, lines 5 to 8, of document D11). It was clear that the rounded distal joint 62 acted to shield the vessel wall from the sharp end of the wire but document D11 did not contain a statement in respect of the degree of lubricity of the distal guide wire portion 62.

The difference between the subject-matter of claim 1 and the guide wire disclosed in document D11 was thus that in claim 1 the distal end portion was more lubricous than the proximal one.

A more lubricous distal end would have the effect of helping to minimise the resistance when the guide wire was introduced.

The objective problem could thus be seen as being to facilitate the introduction of the guide wire into the vessel.

This problem was solved in the various prior art documents D1, D3 and D5, which all taught that a high lubricity at the distal portion of a guide wire facilitated the introduction of the guide wire into the vessels. The man skilled in the art would have applied this teaching and increased the lubricity of the tip portion 62 of the guide wire according to D11 and would have arrived at the subject-matter of claim 1 without any inventive step.

VII. The respondent's arguments can be summarised as follows:

Novelty

The guide wire according to document D5 did not have any intermediate portion within the meaning of claim 1. The ring-like member was described as one of the means of connecting the two core parts. Document D5 essentially disclosed a two-portion guide wire.

In any case, the ring-like member did not exhibit the properties required by claim 1. In particular, there was no indication in the document D5 that the surface of the ring member was left bare. The layer 7 was applied after connection of the two core parts and

there was no reason why the coating should stop at the ring-like member.

The drawings in document D5 were not precise enough for it be deduced from them that the ring-like member was not coated. In addition, to fulfil the anchoring function, the intermediate portion had to have a certain length, as was specified in paragraphs [0016] or [0019] of the patent in suit. No such minimum length required to fulfil an anchoring function was specified for the guide wire according to document D5.

Nor did document D5 contain any teaching as to a particular lubricity of the ring member.

Hence, the subject-matter of claim 1 was novel over D5.

Inventive step

The object of the patent in suit was to obtain a guide wire which was easily manoeuvrable but anchored once positioned at the desired place.

The guide wire described in document D11 was composed of three sections 26, 28, 30 having different flexibilities. And the last section 30 included the tip 62.

In the guide wire according to document D11, the intermediate section 28 was more lubricous than the distal section 30, which was contrary to the invention.

Completing the tip 62 with a lubricous coating reversed the teaching of document D11 because, according to this document, it was the distal section which was used for

anchoring and not the intermediate section as in the present invention.

Additionally, it was clear to the man skilled in the art that the distal portion according to the invention had to be of a certain length to be able to fulfil its manoeuvring function. The rounded tip 62 of the guide wire of D11 could therefore not be a distal portion within the meaning of the patent in suit. In this context, it had to be borne in mind that such guide wires were very thin, their diameter being approximately 2 mm, so that it was unlikely that the man skilled in the art would give a significant function to one of such a short element as the tip 62.

The subject-matter of claim 1 therefore had to be considered inventive.

Reasons for the Decision

1. The appeal is admissible.
2. *Procedural matters - late-filed submissions*
 - 2.1 Pursuant to Article 13(1) RPBA (Rules of Procedure of the Boards of Appeal), the Japanese Court decision (Djp) is not admitted by the Board into the present appeal proceedings because it was proposed belatedly by the appellant and merely for information without precise indications as to how it should be used in the proceedings and without arguments or comments on relevant passages, and because the subject-matter of

the claim considered in that decision is different from that at issue in the present case.

- 2.2 Pursuant to Article 12(4) RPBA, Exhibit A which was not admitted into the proceedings by the Opposition Division is not further admitted by the Board into the appeal proceedings since the Board could not detect any misuse of the discretionary power of the first instance. Moreover, the tests presented in Exhibit A are regarded as irrelevant for the present decision. Besides, at the oral proceedings, the admissibility of this document was not further pursued by the appellant.

- 2.3 New line of argument

At the oral proceedings the appellant wished to present a new line of argument against inventive step starting from D5.

Pursuant to Article 13(3) RPBA, concerning the amendment of a party's case, amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party cannot reasonably be expected to deal with without adjournment of the oral proceedings.

In the present case, the appellant wished to present a new line of argument starting with document D5. Such a line of argument, which was not present in the file prior to the oral proceedings before the Board of Appeal, would have required that according to the problem-solution approach, the differences between the subject-matter of claim 1 and the guide wire disclosed in D5 be defined precisely in order to examine what

effects the distinguishing features would have on the guide wire according to D5, to define what could have been the objective problem to be solved by the man skilled in the art and, finally, to analyse whether the available state of the art would have made the solution obvious for the man skilled in the art. The Board considers that it would have been inequitable to expect the unprepared other party to fairly deal with all these aspects at the oral proceedings, which would consequently have had to be postponed to allow both the Board and the other party to study this completely new line of argument.

For this reason, the Board decided not to admit this new line of argument into the proceedings.

3. *Novelty*

In order to facilitate introduction into small or meander-like vessel parts but nevertheless keep a rigid main body portion, document D5 discloses a guide wire having a two-section core, the more distal section being more flexible than the proximal section and coated to show a higher lubricity than the proximal section. Before any coating is applied, the two core sections are connected. This is done either by fitting or soldering the two end portions together, or in the most preferred embodiment, by using a ring-like member made of shape-memory alloy, this ring-like member being fitted around the two end parts to be connected (see D5t, page 14, second paragraph).

This preferred embodiment is also shown in figure 1 of the drawings. Figure 1 more specifically shows a main

body portion 10 and a front end portion 12, at the end of which an element 6 is visible which is said to be detectable by x-rays. A synthetic resin layer 5 is visible on the surface of the front end portion. A ring-like member 4 is also visible and it overlaps with the surfaces of the distal end of the main body portion and the proximal end of the front end portion, at the contact face of these two portions. Reference numerals 7 and 8, which are said respectively to stand for the lubricating surface on the front end portion and the synthetic resin layer on the main body portion, are indicated in figure 1, but the corresponding layers 7 and 8 are not depicted.

From the last paragraph on page 28 of document D5T onwards, a more precise embodiment of the guide wire according to figure 1 is described. The main body portion is said to be 1500 mm and the front end portion 300 mm in length. After the two portions have been connected by a ring of shape-memory alloy, the outer face of the front end portion 12 is said to receive a coating of a first synthetic resin layer 5 before being entirely coated with a second resin layer 7, thereby forming the lubricating surface (see page 31, lines 15-16). In the last paragraph on page 29, it is also mentioned that the element 6 allowing x-ray detection has a diameter of 0.30 mm and is 2 mm long.

In the Board's opinion, it follows from the above that there is no teaching whatsoever in document D5 that the ring-like member, when used to connect the main body portion to the front end portion, should not be coated. On the contrary, in figure 1, if anything, the front end portion is shown to extend to the middle of the

ring-like member. There is also no reason to leave the ring-like member bare as nowhere in the document is mention made of any particular function of this ring-like member other than that of connecting the front end portion with the main body portion. A man skilled in the art reading document D5 would thus see no reason to give this ring-like member any other particular significance, such as for example an anchoring function.

The appellant argued that since it was not mentioned in document D5 that the ring-like member should be coated, the man skilled in the art would infer a teaching that it was not to be coated.

The Board cannot share this opinion. The teaching of a document has to be assessed on the basis of what the skilled man would understand after having considered the document as a whole. In the present case, no particular importance is given to the ring-like member apart from its function as a connecting means, and other alternative connecting means are mentioned for connecting the main body portion to the front end portion, so that, again, the skilled man has no reason to consider that when using a ring-like member, it should not be coated and should be given any anchoring function.

It should further be noted that, even if the ring-like member were left bare, it could not, in the Board's opinion, fulfil any anchoring function as it is far too short. As a matter of fact, if figure 1 is considered a true-to-scale drawing, and the element 6 is 2 mm in length as mentioned above, then the ring-like member

can scarcely be any longer, and the Board does not see how such a short element of 2-3 mm in length could have any anchoring ability, especially as the patent in suit (see [0016], [0019]) states that the intermediate guide wire portion, which is intended to have the anchoring function, should preferably be between 20 and 30 cm in length.

Consequently, in the Board's opinion, the ring member shown in figure 1 of D5 cannot be considered an intermediate guide wire portion within the meaning of the patent in suit.

Hence the subject-matter of claim 1 is novel over D5.

4. *Inventive step*

4.1 The teaching of D11 concerns a three-section guide wire (see page 5, lines 14 to 16: "*The wire has three sections with progressively greater flexibility, and different lubricity or sliding properties*"), the most distal portion being the least lubricous (see page 9, lines 22 to 29: "*The two segments making up the core of the intermediate section of the wire are covered along their length by a flexible polymer covering 46. The major function of the covering is to provide a lubricious (low-friction) surface along the intermediate section, and more particularly, a surface which is more lubricious than the surface of the adjacent distal segment of the wire and of the wire core.*").

4.2 The problem solved in the present invention by the characterising features of claim 1, namely to provide a

guide wire easily manoeuvred into position across a tight lesion, but yet providing stability and resistance to movement once the guide wire is in position, it not addressed in D11.

- 4.3 On the contrary that the distal section should have a higher coefficient of friction is mentioned in D11 as an important feature of the invention: (see page 12, first paragraph: *"According to an important feature of the invention, the distal section of the wire, including the sleeve encasing the wire core in this section, is less lubricious, i.e., has a higher frictional coefficient, than that of the adjacent intermediate section. The higher-friction surface in this section functions specifically, during a catheter placement operation, to help anchor the distal section against a vessel wall at a vessel junction, as will be seen below."*)

Hence the man skilled in the art understands that it is a fundamental feature of the teaching of D11 to have the anchoring portion at the distal end of the guide wire.

To change the order of the lubricities along the length of the guide wire or to add a fourth distal portion, as would be required to arrive at the subject-matter of claim 1, the skilled man would have to depart from the teaching of D11, add a more lubricous part distally of the anchoring portion, and choose the lubricities as defined in claim 1.

The Board sees no reason why the man skilled in the art would make such drastic changes when the whole teaching

of D11 clearly is that the distal portion should fulfil an anchoring function.

- 4.4 The appellant considers the distal portion comprising the coil in D11 to be the intermediate part within the meaning of claim 1 and the joint 62 at the very distal end to be the distal guide wire portion within the meaning of claim 1.

Such an interpretation of the terms of claim 1 is impermissible. In the Board's view, when the meaning of a term in a claim is at stake, the first source of interpretation is the patent itself. A patent is a teaching as to how a problem existing in the state of the art can be solved and as a rule the vocabulary used in a patent is uniform, depending on the technical field of the invention but also on the writer's own preferences. A term in a claim therefore cannot be given a specific meaning which, when considering the patent as a whole, does not appear to have been meant.

In the present case, the question is whether the term "distal guide wire portion" used in claim 1 can cover the tip 62 shown in figure 1 of D11. It is clear that the primary function of this joint or tip 62 is to attach the coil to the core (see page 11, lines 14 to 17: *"Attachment of the coil to the core is preferably by two or three solder or weld joints, including a proximal joint 60 and a rounded distal joint 62."*). In D11 it is also mentioned that the joint 62 should be rounded to protect the walls of the vessels (see page 11, lines 33, 34: *"The rounded joint at the end of the wire acts to shield vessel walls from the sharp end of the wire core."*), but this is not sufficient to give

this joint the particular manoeuvring function of the distal guide wire portion of the guide wire according to the present invention (see for example patent column 1, lines 31-38 or column 8, lines 7-11).

As a matter of fact, in the patent in suit, in figure 4, an embodiment is shown in which the distal tip is also a soldering or welding point for attaching the coil to the core (see [0022]: "*Combined coil 342 is attached to core 328 proximally with solder at 341 and distally with either solder or welding at 338.*"). And in the case of this embodiment with a coil attached to the core by a distal welding point, the distal guide wire portion according to the invention with the higher lubricity given by a hydrophilic coating 336 is unmistakably shown in figure 4 to extend proximally from the distal tip on part of the coil 325. In fact, the length of the distal guide wire portion is similar in all figures in the patent in suit. Interpreting the term "distal guide wire portion" of claim 1 as meaning only the length of the welding point is therefore not in line with the meaning implied by the patent in suit as a whole, since it is clear from the patent which part of the guide wire should be the "distal guide wire portion" when the guide wire comprises a coil soldered to the distal part of the core.

Thus, even if the man skilled in the art were to give the tip a higher lubricity, this would still not make it a "distal guide wire portion" within the meaning of the patent in suit.

- 4.5 Documents D1, D3 and D5 cited by the appellant make no difference to the above.

Documents D1, D3 and D5 actually show distal parts which are more lubricous than a more proximal part; however, all these documents generally disclose two-portion guide wires and not three-portion guide wires like that claimed or that disclosed in D11.

To arrive at the subject-matter of claim 1, the man skilled in the art would have to go against the teaching of D11 and abandon the idea in D11 that the most distal part is the one with the highest friction coefficient, accept the need to create a four-portion guide wire and, in addition, have three different lubricities arranged as required by claim 1. None of the documents D1, D3 and D5 render such amendments obvious.

4.6 Hence, claim 1 fulfils the inventive step requirement imposed by Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

M. Noël