BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 26 August 2011

Case Number: T 0841/08 - 3.2.02

Application Number: 02002109.3

Publication Number: 1208868

IPC: A61M 25/01

Language of the proceedings: EN

Title of invention:
Method of fabricating a Zebra exchange guide wire

Patentee:
BOSTON SCIENTIFIC CORPORATION

Opponent:
Haag, Wolfgang

Headword:
-

Relevant legal provisions:
EPC Art. 56, 113

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (yes)"
"Right to be heard (yes)"

Decisions cited:
T 0156/84, T 0113/96, T 0426/97, T 0855/96, T 0098/94, J 0007/82, T 0142/97, T 0164/89, G 0009/91, G 0010/91, T 0385/97

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0841/08 **-** 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 26 August 2011

Appellant: (Opponent)
Haag, Wolfgang
Melkweg 7
D-46487 Wesel (DE)

Representative:
Brötz, Helmut
Rieder & Partner
Patentanwälte - Rechtsanwalt
Corneliusstraße 45
D-42329 Wuppertal (DE)

Respondent: (Patent Proprietor)
BOSTON SCIENTIFIC CORPORATION
One Boston Scientific Place
Natick MA 01760 (US)

Representative:
Williams, Ceili
Stevens Hewlett & Perkins
1, Pemberton Row
London EC4A 3BG (GB)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 10 March 2008 rejecting the opposition filed against European patent No. 1208868 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: D. Valle
Members: M. Stern
J. Geschwind

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal on 22 April 2008 against the decision of the Opposition Division posted on 10 March 2008 to reject the opposition. The fee for the appeal was paid on the same day and the statement setting out the grounds for appeal was received on 10 July 2008.

II. The patent was opposed on the basis of Article 100(a) EPC for lack of novelty and lack of inventive step.

III. Following documents and other evidence have been considered in the present decision:

a) submitted during opposition proceedings:

a1) together with the statement of grounds of 1 August 2006:

E1: EP-A-0 519 604
E2: US-A-5 084 022
E3: WO-A-91/00051
E4: DE-U-8 905 642;

a2) with letter of 18 January 2008, after the expiry of the opposition period:

E5: EP-A-0 550 258
E6: US-A-4 830 023
E7: DE-U-8 811 408
E8: US-A-5 114 401
E9: EP-A-0 456 342

A3: Affidavit (eidesstattliche Versicherung) of Dieter Heuser
A4: Affidavit (eidesstattliche Versicherung) of Reiner Grassinger
Further, Mr Dieter Heuser and Mr Reiner Grassinger were nominated as witnesses in order to illustrate the declarations contained in their affidavits.

b) submitted during the appeal proceedings:

b1) together with the statement of grounds of 8 July 2008:

E10: US-A-5 111 829;
Further, Mr Reiner Hoffman was nominated as a witness.

b2) submitted with letter of 21 July 2011:

Prior use by the company Boston Scientific Corporation of claimed invention supported by documents OVB1 to OVB6 and by the nomination of witnesses Mr Stewart J. Bellus and Mr Daniel Nikolajko
E11: David E. Fleischer et al., "A Marked Guide Wire Facilitates Esophageal Dilatation", The American Journal of Gastroenterology, vol. 84, No. 4, 1989
A5: declaration of Prof. Dr. med. K. E. Grund
US-A-5 379 779.
Further, the hearing of Prof. Dr. med. K. E. Grund as a witness was offered in order to illustrate his declaration.

IV. Claim 1 as granted reads as follows:

"A method for fabricating an exchange guidewire for positioning and exchanging medical catheters within a bodily passage during a medical procedure which uses an endoscope, said method comprising:
providing a core wire 45-450 cm long, having a proximal end about 0.25-1.27 mm (0.01-0.05 inch) in diameter and a distal end of a diameter not greater than that of said core wire proximal end;
providing a wire/coil assembly by surrounding said core wire distal end with a flexible coil about 1-10 cm long and of a diameter between about 0.25 mm (0.01 inch) and approximately the diameter of said core wire proximal end, said coil having a proximal end and a distal tip, at least a portion of at least one of said coil and said core wire distal end being radiopaque, said coil distal tip being fixed to said core wire distal end;
pre-marking a sleeve of low-friction shrink-wrappable material with an endoscopically discernible pattern of indicia marked along the entire length of said sleeve, wherein said pattern has a background colour and striping of a contrasting colour;
shrink wrapping said pre-marked sleeve around said wire/coil assembly from said core wire proximal end to said coil distal tip to form a jacketed guidewire in which said sleeve is tightly fitted and conforms to said wire/coil assembly, so that the position of said exchange guidewire indicia relative to an optical lens of said endoscope may be monitored through said optical lens."

V. Oral proceedings then held on 26 August 2011.

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

The respondent (patentee) requested that the appeal be dismissed.

VI. The appellant argued essentially as follows.

1) The decision of the opposition division was flawed by a fundamental procedural violation since it did not introduce into the proceedings the evidence a2) filed with letter of 18 January 2008 (see point III) even though this was prima facie relevant and because it did not contain any reason, in support for that. This evidence should be introduced in any case into the appeal proceedings.

1a) The evidence was not filed too late. In the communication annexed to the summons to oral proceedings the Opposition Division gave as the final date for making any written submission and/or amendments 21.01.2008, according to Rule 71a EPC 1973. Since the contested documents were submitted on 18.01.2008, they were not late-filed, see T 156/84, T 113/96, T 426/97, T 855/96, T 142/97, T 164/89. The filing of the evidence was triggered by the communication of the Opposition Division. Only in the communication did it become evident that pre-marking of the sleeve was the essential distinguishing feature of the invention.

1b) The documents were prima facie relevant, in particular since they showed that an important feature (pre-marking of a sleeve) was known in the state of the art. This feature was considered in the decision to form the basis for the inventive step of the claim. The decision was therefore contradictory.

1c) Furthermore, the decision of lack of relevance was not reasoned. Not taking into account relevant arguments submitted by a party represented a breach of the right to be heard, see T 98/84 and J 7/82.

1d) For all the above reasons, the documents a2) should be introduced into the appeal proceedings and the witnesses heard, see G 9/91, G 10/91, T 385/97, T 855/96.

2) Also E10, submitted with the statement of grounds of appeal, should be introduced into the proceedings and the offer of the witness should be taken up.

3) Furthermore, the evidence b2), submitted with letter of 21 July 2011, should also be introduced into the proceedings because prima facie highly relevant.

4) The patent in suit contained extended subject-matter. The consideration of this objection was required for the sake of equity, even if this objection had not been raised with the grounds for opposition.

5) The subject-matter of claim 1 did not involve an inventive step having regard to a combination of E2 or E3 with E4, or E1 with E2 and E4.

The respondent contested the arguments of the appellant and argued in particular that the late-filed documents and submissions should be disregarded and that the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Documents and other evidence

2.1 Evidence filed during opposition proceedings

a) Documents E5 to E9, A3 and A4 and the related offer of witnesses were late-filed. The communication annexed to the summons to oral proceedings according to Rule 71a EPC 1973 does not automatically reopen the terms for filing new evidence. The letter of 18 January 2008, with which the evidence was introduced, does not set out the circumstances that prevented the appellant from mentioning the evidence earlier, see T 156/84, cited by the opponent, point 4 of the Headnotes. The filing of new evidence cannot be considered to have been triggered by the communication of the Opposition Division as the opponent already knew since the filing of the statement of grounds that pre-marking was an essential distinguishing feature of the invention, see page 14 of the statement of grounds. The communication did not essentially change such findings.

The case law cited by the appellant in this regard is not relevant: T 113/96, T 426/97 and T 855/96 concern the introduction of evidence with the statement setting

out the grounds for appeal, T 142/97 concerns the refusal of the opposition division to accept evidence submitted in time, T 164/89 concerns the admission of documents considered highly relevant for the decision.

b) The appellant argued that it was self-evident that the documents were relevant because they were concerned with the only feature considered relevant for inventive step, that is the "pre-marking of a sleeve".

However, these documents are not "prima facie" relevant. E5 to E7 disclose dimensional values of the coil, see letter of 21 July 2011, page 29. E8 and E9 (and additionally E7) disclose merely guidewires with colour markings (see the above-cited letter, page 30), whereas A3 and A4 are declarations of witnesses whose reliability would be impossible to determine at first sight, that is without an evaluation of the accompanying circumstances of the facts stated therein. The very fact that the appellant offered witnesses to support the statements contained in the affidavits A3 and A4 is an indication that the affidavits were considered insufficient in order to decide "prima facie" their relevance. Furthermore, A3 does not refer to guidewires specifically, but merely to the markably broader field of medical devices.

c) Contrary to the assertion of the appellant, the opposition division did not make any fundamental procedural error in disregarding the documents a2), but acted within the limits of its power of decision. A decision to disregard late-filed evidence on the basis of an evaluation of lack of "prima facie" relevance cannot, by its very nature, be detailed, see T 156/84,

cited by the appellant, point 3 of the Headnotes. The Board believes that the statement contained in point II of the reasons for the decision that the documents submitted were not relevant to novelty and prima facie not relevant either for a decision relating to the presence of inventive step was sufficient to support a decision of lack of relevance "prima facie". Of the case law cited by the appellant, T 98/84 is not concerned with "prima facie" relevance, whereas J 7/82 refers to the general obligation to take into account arguments submitted by a party and to the fact that the decision should be based on grounds on which the party has had an opportunity to comment.

d) Since nothing has changed in this respect in the appeal proceedings, there is no reason either to revise the decision of the first instance on this point. G 9/91, G 10/91 and T 385/97, cited by the appellant, concern the extent of the power of an Opposition Division or of a Board of Appeal to examine a case and these decisions do not go against the above findings. T 855/96 confirms the general rule that evidence should be taken into account in appeal proceedings only when this does not cause an undue delay in the proceedings.

Accordingly, the evidence a2) is not introduced into the proceedings and the first instance did not commit any fundamental procedural violation by not introducing it into the first instance proceedings.

2.2 Evidence filed during appeal proceedings

2.2.1 Evidence filed with the statement of grounds

a) Newly-introduced document E10

E10 was submitted by the appellant together with the statement of grounds in the appeal proceedings. This document is late-filed. It has not been directly used in the attack on inventive step, but it has merely been qualified as equivalent to E3, see page 27 of the statement of grounds. The document is not introduced into the proceedings because it is not more relevant than E3.

b) Offer of witness Mr Rainer Hoffmann

The appellant argues at point B.3 of the statement of grounds that it belonged to the general knowledge of the skilled person to use contrasting coloured ring strip patterns in the endoscopic field in order to obtain a visual control of the advancement of the instrument. For example, papillotome and contrast means catheters for ERCP were well known. These instruments had a sheath made of PTFE having coloured ring strips at the distal end for a length of 5-8 cm. In order to support this statement the appellant offered as a witness Mr Rainer Hoffmann, who is an employee of the appellant.

However, the subject on which the witness would be ready to speak is not particularly relevant for the decision. The features which are claimed as known anticipate only in part the distinguishing features of

the invention. Furthermore, the testimony of one witness is not suitable to support a piece of general knowledge. General knowledge, as its name indicates, should be found in well-known manuals and/or supported by evidence coming from several independent sources. An employee of the appellant is not the most suitable source to support a claim of general knowledge. Lastly, the statement of the appellant does not contain any indication of where, when and under what circumstances this general knowledge is supposed to have been made available to the witness himself. For all these reasons, a hearing of the witness is not considered to be appropriate in this case.

2.2.2 Evidence b2) filed with letter of 21 July 2011

According to the Rules of Procedure of the Boards of Appeal of the European Patent Office, Article 12(2), the statement of grounds of appeal must contain a party's complete case and expressly specify all the facts, arguments and evidence relied on; all documents referred to must be attached as annexes. According to Article 13(1) RPBA, any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the Board's discretion. That discretion must be exercised in view inter alia of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

Taking into account the complexity of the new subject-matter submitted, the state of the proceedings and the need for procedural economy, the Board decides not to introduce the above evidence into the proceedings. This

new evidence was filed on 21 July 2011, i.e. about 3 years after the filing of the statement of grounds of appeal (10 July 2008) and about one month before the date of the oral proceedings. Furthermore it is contested by the respondent. The respondent requested further the remittal of the case to the first instance in order to have two stages of proceedings in the event that the new evidence was admitted into the proceedings. Lastly, it requires complex evaluation: The following documents have been submitted to support the prior use: a copy of the trademark application "Zebra", a copy of a commercial label, commercial papers, a test report, letters, an article and a patent document.

The appellant argued that it was self-evident that the new submissions would reverse the decision of the first instance regarding inventive step. The Board does not agree. The very fact that the appellant needed so many documents in order to support his statement is a strong indication of the contrary. The appellant put also forward that the new evidence could only be presented at such a late stage because of the complexity of the search for it, in particular regarding the gathering of information about the guidewire marketed under the trademark "Zebra". However, the Board noted that the designation "Zebra" was already known by the appellant at the date of filing of document A3 (18 January 2008), that is about 3 years before the filing of the prior use in question. That means that it has not been proved beyond any reasonable doubt that the appellant used all due care in submitting the evidence in his possession as soon as possible.

Accordingly, the evidence b2) is not introduced into the proceedings.

3. *Extended subject-matter*

The objection of extended subject-matter has been raised during the appeal proceedings but did not form part of the original statement of grounds for opposition. According to the request of the respondent and in consideration of the fact that the objection is late-filed, this request is not admitted into the proceedings.

4. Inventive step

4.1 Starting from E2

E2, cited in the description of the patent in suit, discloses a method for fabricating an exchange guidewire for positioning and exchanging medical catheters within a bodily passage during a medical procedure which uses an endoscope, said method comprising: providing a core wire 45-450 cm long, having a proximal end about 0.25-1.27 mm (0.01-0.05 inch) in diameter and a distal end of a diameter not greater than that of said core wire proximal end, providing a wire/coil assembly by surrounding said core wire distal end with a flexible coil about 1-10 cm long and of a diameter between about 0.25 mm (0.01 inch) and approximately the diameter of said core wire proximal end, said coil having a proximal end and a distal tip, at least a portion of at least one of said coil and said core wire distal end being radiopaque, said coil

distal tip being fixed to said core wire distal end.

However, E2 does not disclose:

- that the core wire is 45-450 cm long, has a proximal end about 0.25-1.27 mm (0.01-0.05 inch) in diameter and a distal end of a diameter not greater than that of said core wire proximal end;
- that the flexible coil is about 1-10 cm long and of a diameter between about 0.25 mm (0.01 inch) and approximately the diameter of said core wire proximal end, (column 6, line 28 of E2 gives the value of 0.045 inches);
- pre-marking a sleeve of low-friction shrink-wrappable material with an endoscopically discernible pattern of indicia marked along the entire length of said sleeve, wherein said pattern has a background colour and striping of a contrasting colour; shrink wrapping said pre-marked sleeve around said wire/coil assembly from said core wire proximal end to said coil distal tip to form a jacketed guidewire in which said sleeve is tightly fitted and conforms to said wire/coil assembly, so that the position of said exchange guidewire indicia relative to an optical lens of said endoscope may be monitored through said optical lens.

The appellant argues that E2 discloses a sleeve of heat-shrinkable material (Teflon), see column 6, line 6, column 3, lines 11-12. Column 3, lines 21 to 24 further disclose marking Teflon coated guidewires. Finally, the coating can be extended from said core wire proximal end to said coil distal tip, see column 3, lines 21 to 28.

However, E2 does not disclose pre-marking of the sleeve as the invention, nor does a background colour and striping of a contrasting colour. On the contrary the marking of E2 is performed on the Teflon-coated guidewire by laser etching.

The purpose of the invention has therefore to be seen in improving the known device, in particular in facilitating the checking of the position of the guidewire during operation and in streamlining the production method.

A combination of the teaching of E2 with E4 cannot lead to the claimed invention in an obvious way. E4 is concerned with marking a catheter sleeve. E4 does not disclose pre-marking of a guidewire sleeve and subsequent shrink-wrapping, nor visible markings.

Accordingly, the subject-matter of claim 1 involves an inventive step having regard to the combination of the teaching of E2 and E4.

4.2 Starting from E3

E3 discloses a method for fabricating an exchange guidewire for positioning and exchanging medical catheters within a bodily passage during a medical procedure which uses an endoscope, said method comprising providing a core wire 450 cm long (page 4, line 33), having a proximal end about 0.89 mm (0.035 inch, page 6, lines 34-35) in diameter and a distal end of a diameter not greater than that of said core wire proximal end; providing a wire/coil assembly by surrounding said core wire distal end with a flexible

coil about 3-5 cm long (page 6, last paragraph) and of a diameter of 0.018 inch (0.046 cm, page 6, last paragraph), said coil having a proximal end and a distal tip, at least a portion of at least one of said coil and said core wire distal end being radiopaque (page 5, lines 34-35), said coil distal tip being fixed to said core wire distal end (page 7, lines 11-13).

However, E3 does not disclose pre-marking a sleeve of low-friction shrink-wrappable material with an endoscopically discernible pattern of indicia marked along the entire length of said sleeve, wherein said pattern has a background colour and striping of a contrasting colour; shrink-wrapping said pre-marked sleeve around said wire/coil assembly from said core wire proximal end to said coil distal tip to form a jacketed guidewire in which said sleeve is tightly fitted and conforms to said wire/coil assembly, so that the position of said exchange guidewire indicia relative to an optical lens of said endoscope may be monitored through said optical lens.

The appellant argues that E3 discloses a shrinkable sleeve of PTFE (page 3, line 16; page 6, lines 15-19). However, the first passage cited (page 3, line 16) refers only to the sleeve covering the distal region. The second passage cited refers to Figure 1, where a composite construction is disclosed, made of a three-section sleeve 32, 24, 34. The description discloses that only the sections 32 and 34 can be made of a suitable material, inter alia PTFE. E3 therefore does not disclose a sleeve of low-friction shrink-wrappable material around said wire/coil assembly from said core wire proximal end to said coil distal tip.

A combination of the teaching of E3 with E4 cannot lead to the claimed invention in an obvious way for the same reasons as detailed above in connetion with E2.

4.3 Starting from E1

E1 (Figures 1 and 3) discloses a method for fabricating an exchange guidewire suitable for positioning and exchanging medical catheters within a bodily passage during a medical procedure which uses an endoscope, said method comprising providing a core wire (18, column 2, line 36) 180 cm long (i.e. in the claimed range of 45-450; column 2, line 27 and lines 42-44), having a proximal end of 0.018 inch (0.46 mm) (i.e. in the claimed range of about 0.25-1.27 mm (0.01-0.05 inch)) in diameter, see column 3, line 2, and a distal end of a diameter not greater than that of said core wire proximal end (see figures); providing a wire/coil assembly by surrounding said core wire distal end with a flexible coil (column 7, lines 27-32, Figure 3), said coil having a proximal end and a distal tip, at least a portion of at least one of said coil and said core wire distal end being radiopaque, see column 7, lines 38-39, said coil distal tip being fixed to said core wire distal end, see column 7, lines 34-36.

However, E1 does not disclose:

- that the flexible coil is about 1-10 cm long and of a diameter between about 0.25 mm (0.01 inch) and approximately the diameter of said core wire proximal end.

The appellant wants to derive such values from the drawings of E1. However it is not reliable to derive such values from drawings of a patent document since the drawings are not necessarily represented to scale.

- pre-marking a sleeve of low-friction shrink-wrappable material with an endoscopically discernible pattern of indicia marked along the entire length of said sleeve, wherein said pattern has a background colour and striping of a contrasting colour; shrink-rapping said pre-marked sleeve around said wire/coil assembly from said core wire proximal end to said coil distal tip to form a jacketed guidewire in which said sleeve is tightly fitted and conforms to said wire/coil assembly, so that the position of said exchange guidewire indicia relative to an optical lens of said endoscope may be monitored through said optical lens.

The appellant maintains that E1 discloses a sleeve made of Teflon, see column 6, lines 1-3, column 5, lines 21-25, reference number 40 in Figure 1, which is a low-friction shrink-wrappable material cited also in the patent in suit.

However, the sleeve of E1 is only partially made of Teflon. The distal end 42 is made of polyurethane,which is not necessarily a shrink-rappable and low-friction material. On the contrary the patent in suit repeatedly stresses that the low-friction shrink-wrappable material extends from guidewire end 20 to end 22, see column 2, lines 34 to 39, column 5, lines 22 to 25 and 47 to 51, column 6, lines 8 to 11, point 12, E1, column 6, lines 2 and 3.

The appellant further points to the passage of E1, column 6, lines 3 to 6, which explains that the sleeve of polyurethane is "reformed" around the core wire. However, it is not an essential feature of polyurethane that it can be shrink-wrapped. Even if some types of polyurethane were shrink-wrappable - which is not proved - it does not belong to the disclosure of E1 to use a shrink-wrappable polyurethane or to shrink-wrap it.

The purpose of the invention has therefore to be seen in improving the known device, in particular in facilitating the monitoring of the position of the guidewire during operation and in streamlining the production method.

Contrary to the arguments of the appellant, E1 alone does not make the subject-matter of claim 1 obvious. The hatching in the figures, contrary to the statement of the appellant (page 19 of the statement of grounds), are far from suggesting the distinguishing features of the claim.

A combination of the teaching of E1 with E2 or E4 cannot lead to the invention in an obvious way for the following reasons.

E2 (see also above, point 4.1) discloses a guidewire with indicia or markings along at least a substantial portion of the axial length of the guidewire in order to ascertain the distance by which the guidewire extends into a body vessel. Among several methods for forming the marks, in column 3, lines 11-12, E2 cites "Teflon as material and coloured hydrophilic polymer".

The citation is found within a long, rather cursory list and it is not clear. Column 3, lines 21 to 24 disclose marking Teflon-coated guidewires by laser, etching, but not pre-marking it as in the invention, nor providing it with a background colour and striping of a contrasting colour. The passage at column 1, lines 34-42 discloses indicia provided by electro-chemical etching of the metal guidewire. However, E2 does not disclose the whole set of distinguishing features nor does it give sufficient hints to allow a choice among the disclosed features of those which would partially match the claimed invention. In particular it does not disclose the succession of claimed method steps of pre-marking the sleeve and then shrink-wrapping it. The additional consideration of the teaching of E4 could not change these findings for the reasons given above, starting from E2.

4.4 For the above reason the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe D. Valle