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) [X] To Chairmen
(D) [ ] No distribution

D E C I S I O N
of 11 October 2001

Case Number: T 0127/99 - 3.2.2

Application Number: 92304557.9

Publication Number: 0519604

IPC: A61M 25/01

Language of the proceedings: EN

Title of invention:
Intravascular guide wire and method of manufacturing thereof

Patentee:
SCIMED LIFE SYSTEMS, INC.

Opponent:
TERUMO CORPORATION

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (all requests) - no"
"Plurality of partial problems; solutions to be considered separately"

Decisions cited:
T 0130/89, T 0687/94, T 0176/84, T 0195/84

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0127/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 11 October 2001

Appellant: (Proprietor of the patent)
SCIMED LIFE SYSTEMS, INC.
6655 Wedgwood Road
Maple Grove, MN 55369-7503 (US)

Representative:
Baverstock, Michael George Douglas
BOULT WADE TENNANT
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT (GB)

Respondent: (Opponent)
TERUMO CORPORATION
Shonan Center, 1500 Inokuchi, Nakai-machi
Ashigarakami-gun, Kanagawa Pref.259-01 (JP)

Representative:
Vollnhals, Aurel, Dipl.-Ing.
Patentanwälte
Tiedtke-Bühling-Kinne & Partner
Bavariaring 4
D-80336 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 7 December 1998 revoking European patent No. 0 519 604 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiss
Members: M. G. Noel
R. T. Menapace

Summary of Facts and Submissions

I. By decision of 7 December 1998 the Opposition Division revoked European patent No. 0 519 604 on the grounds of lack of inventive step vis a vis the state of the art.

II. The appellant (patentee) lodged an appeal against this decision on 1 February 1999. Its statement of grounds was filed on 15 April 1999.

III. Following some postal exchanges between the parties, the Board, in a communication sent on 31 May 2001, suggested to focus the discussion at the oral proceedings principally on documents E1 and E6 upon which the contested decision was based.

IV. Oral proceedings were held on 11 October 2001 at the end of which the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main or the auxiliary request filed during the oral proceedings.

The respondent requested that the appeal be dismissed.

V. Claim 1 according to the main request reads:

"A guide comprising:

a core (18), having a proximal and distal end portion, and a plastic jacket (38) enclosing said core, characterised in said plastic jacket comprises:

a proximal jacket portion (40) extending distally from the proximal end of the guide wire formed of a first plastic material, and

a distal jacket portion (42) formed of a second plastic material and extending over and covering the distal end of the core,

the distal end of said proximal jacket portion and the proximal end of said distal jacket portion being of equal outer diameters so as to form a smooth transition between said proximal and said distal jacket portions,

said distal jacket portion having a coating of lubricious material applied to it whereas said proximal jacket portion has no lubricious coating applied to it."

Claim 1 according to the auxiliary request is distinguished from the main request by introducing the expression "having a manipulable but low friction surface" after the words "plastic material" in the first characterising feature.

VI. The following documents were relied upon in the appeal proceedings and are relevant for the present decision:

E1: EP-A2- 0 405 823

E2: EP-A1- 0 407 965

E6: US-A- 4 884 579

E7: EP-A2- 0 334 640

E11: US-A- 4 841 976

At the oral proceedings the parties argued as follows:

(i) The appellant

- Document E2 represents the closest prior art since it discloses a one-part plastic jacket enclosing the core entirely, i.e. this type of catheters which the patent aims at improving. Documents E1 and E6 are regarded as more remote because they refer to another type of catheter guides such as the third design referred to in the background part of document E11, ie of the type having a distal tip portion ending with an uncoated helical coil for increasing the friction at the distal end. This known guide wire suffers from the drawback, that its proximal end is too slippy to be manipulated.

- Starting from document E2, the problem underlying the present patent is to adapt the surfaces of the end portions of the jacket to their different functions. The solution is to make up the jacket in two portions and to select suitable materials in relation to their intended use. Accordingly, the subject-matter of claim 1 is to provide a plastic jacket in two portions made of different materials, only the distal jacket being coated with a lubricious material in order to provide the distal portion of the guide wire with improved sliding facilities whereas the uncoated proximal portion can be handled more readily.

- Document E1 does not suggest to make the jacket in

two parts, still less of different materials.

- Document E7 relates to catheters, a technical field quite remote from guide wires because the problem of heading for a specific body location is not addressed in the same way. While a guide catheter may also be inserted on its own, its structure and dimensions are however not the same as for a guide wire so that the requirements differ significantly from each other. A jacket made of two portions has been known for catheters for a long time. However, nobody considered to use the same principle for the construction of guide wires before the filing date of the present patent. Therefore, the solution as claimed is not obvious.

- Claim 1 according to the auxiliary request is more restricted than claim 1 of the main request since the proximal jacket portion is now additionally characterised by a "low friction surface", a feature more specific than the mere specification of "no lubricious coating applied to it".

(ii) The respondent

- Document E7 relates to catheters generally, ie including also guide catheters where similar problems as for guide wires arise. The same technical field is, therefore, concerned. Document E7 discloses a two-part jacket made of different materials, whereas document E1 suggests to leave the proximal jacket portion of a guide wire uncoated in order to facilitate manual handling and control, a requirement also present in E7. For

a person skilled in the art it is thus evident to provide the appropriate location of the jacket with the most suitable material. Hence, it is obvious to modify a catheter of the type disclosed in document E2 in the manner suggested by the patent.

- the features introduced in claim 1 according to the auxiliary request are not clearly defined. They do not actually amend the previous situation.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The amendments made to the claims of either request are all fairly supported by the application as filed and are such as to restrict the protection as granted. Therefore, they are not open to objection under Article 123 EPC.

3. *Novelty (main request)*

The Board agrees with the parties that a guide wire of the type disclosed in document E2 represents the prior art coming closest to the invention. It discloses (see figure 1) all the features recited in the precharacterising portion of claim 1, namely a guide wire comprising a core and a plastic jacket enclosing said core completely, that is both the proximal and the distal end portions. Moreover, the outer surface of the

plastic jacket may be covered with a lubricious coating applied to it for adjusting the sliding facility of the guide wire (cf page 4, lines 5 to 6). However, the jacket is integrally made of the same material.

Document E1 discloses also a jacket made in one part form. But the jacket does not fully enclose the length of the central core since the distal end portion thereof is not covered by the plastic jacket.

Document E6 discloses (see figure 1) a catheter guide wire comprising three portions. However, the proximal end portion is not provided with any kind of jacket within the meaning of the present patent. Said proximal end portion is formed directly by the core or it may be coated with a less lubricious protective coating material (cf. column 5, lines 64 to 66) in order to provide for a higher friction surface allowing better handling without slippage (cf. column 10, lines 47 to 52). But a simple coating cannot be regarded as a jacket (compared with the plastic jacket 48 provided with coating 50 in the intermediate portion).

Document E7(see figure 1) discloses a guide catheter comprising elongated tubular members. More specifically, it comprises an inner sheath surrounded by an outer sheath, this latter forming a two-part jacket having two abutting portions 22, 24. The catheter body being made tubular, it has no core.

Since no document discloses all the claimed features in combination, the subject-matter of claim 1 according to the main request is novel within the meaning of Article 54(1) EPC.

4. *Inventive step (main request)*.

4.1. With respect to the closest prior art document E2, the subject-matter of claim 1 essentially differs by the following features:

- the plastic jacket is formed of a proximal portion and a distal portion having abutting ends of equal outer diameters so as form a smooth transition

- the two jacket portions are made of different plastic materials

- only the distal jacket portion has a coating of lubricious material applied to it.

These features solve two separate partial technical problems, namely;

- a first problem of creating a guide wire the distal part of which ideally performs its function inside the body vessel and the proximal part of which is easy to manipulate by the physician, and

- a second problem of firmly but with smooth transition joining two jacket portions.

The first problem is solved by providing only the distal portion of the guide with a lubricious coating on its outer surface, so as to facilitate the insertion and passage of the guide wire through a catheter or a vessel, whereas the uncoated proximal portion provides for easy handling.

The second problem is solved by the remaining features

according to which the jacket consists of two portions made of different materials but having the same outer diameter so as to form a smooth transition.

The subject-matter of claim 1 thus comprising two independent groups of features, these groups may be examined separately for the presence of an inventive step (see T 130/89, OJ EPO 1989, 514, points 5.7 and T 687/94, 23 April 1996, point 5).

4.2 Having regard to the first problem, document E1 is most relevant. In the embodiment illustrated in figure 2, the hydrophilic coating 23 which is normally applied to the outer surface of the jacket in order to reduce the friction (cf. column 1, line 33) does not cover the proximal portion of the jacket, precisely for the purpose of facilitating both gripping and control of the guide wire during its use (cf. column 4, lines 36 to 40). In this respect, the Board observes that as far as friction and sliding characteristics are concerned, it matters little whether the jacket is made in one or two parts having the same or different materials, since only the low friction proximal portion emerges from the lubricious coating. This is more apparent from figure 2 of document E1 than from figure 1 of the patent where the coating is not shown. Therefore, the solution to the first problem is disclosed by document E1.

4.3 Having regard to the second problem, document E7 discloses a catheter having a tubular body portion and a tubular tip portion, both comprising an inner sheath and an outer sheath. The outer sheath as a whole thus constitutes a jacket having a body or proximal portion 22 and a tip or distal portion 24 as illustrated in figure 1, both portions being of equal

diameter and placed in abutting relationship. The two portions may be of different materials, namely a rigid and a soft polymeric material, respectively (cf. column 5, lines 6 to 11 and 19 to 21). In particular, there is specified that the rigid polymeric material used for the outer sheath forming the proximal portion has a Shore hardness from about D 50 to about D 80, preferably D 55 or D 63 (column 5, lines 31 to 37) and that the soft polymeric material used for the outer sheath forming the distal portion includes materials such as polyurethane (column 5, lines 21 to 27). These materials are similar if not identical to those used in the present patent, ie Teflon (Shore hardness in the range of D 50 to D 65) for the proximal jacket and polyurethane for the distal jacket, and are used in view of the same favourable characteristics. Further, a smooth transition is achieved between abutting ends of the outer sheaves since any excess of polymeric material may be removed from the outer surface of the catheter once the welding process is completed (column 7, lines 17 to 19). Thus document E7 discloses the solution to said second problem.

Contrary to the appellant's view, document E7 is relevant because it relates to the general technical field of catheters, which includes guide catheters as well as guide wires, two neighbouring fields in which the same insertion problems arise (cf. T 176/84, OJ EPO 1986, 50 and T 195/84, OJ EPO 1986, 121). The catheters disclosed in document E7 (cf. column 1, lines 12 to 14) may be construed to act as guide ways through which other catheters are directed to a specific body

location. They are therefore called "guide catheters" (cf. column 4, lines 19 to 23). Since the guide wires referred to in the present patent are also used for guiding catheters to a target site, they are related to guide catheters by this common function.

Moreover, all the documents cited and the patent in suit were assigned the same class and subclass of the International Classification (A61M 25/00), which is a further indication that the skilled person would consider them to belong to the same technical field.

4.4 It results from the foregoing that, starting from document E2 the subject-matter of claim 1 according to the main request is obvious having regards to the combination of document E1 and E7.As a consequence, it does not involve an inventive step within the meaning of Article 56 EPC.

5. *Auxiliary request*

The feature added to claim 1 according to the auxiliary request ("having a manipulable but low friction surface") to further characterise the proximal jacket portion is vague and indefinite, so that a great number of plastic materials may be suitable. This feature, therefore, does not provide any restriction to the subject-matter of claim 1 which could have distinguished it from the state of art.

For example, document E2 (cf. page 3, lines 32 to 39) suggests to form the plastic jacket with polyurethane, preferably with Teflon (PTFE) which represents a good compromise between proper sliding facility and easy manual handling. In the same way, document E1

recommends (cf. column 3, lines 53 to 55) using any suitable materials such as polyurethane for the uncoated end of the proximal jacket in order to remain easily manipulable (cf. column 4, lines 36 to 40).

Consequently, the subject-matter of claim 1 according to the auxiliary request does not involve an inventive step over the prior art, either.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiss