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D E C I S I O N
of 30 May 2000

Case Number: T 0317/97 - 3.2.2

Application Number: 89312612.8

Publication Number: 0380873

IPC: A61M 29/02

Language of the proceedings: EN

Title of invention:

Rapidly exchangeable coronary catheter

Patentee:

Medtronic AVE, Inc.

Opponent:

SciMed Life Systems, Inc.
Schneider (Europe) AG
Advanced Cardiovascular Systems Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 52, 54, 56

Keyword:

"Novelty (no)"
"Inventive step (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0317/97 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 30 May 2000

Appellant: SciMed Life Systems, Inc.
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 18 February
1997 concerning maintenance of European patent
No. 0 380 873 in amended form.

Composition of the Board:

Chairman: W. D. Weiß

Members: R. Ries
R. T. Menapace

Summary of Facts and Submissions

I. European patent No. 0 380 873 was granted on 4 May 1994 on the basis of European patent application No. 89 312 612.8.

II. The granted patent was opposed by three opponents on the grounds that its subject matter lacked novelty and lacked an inventive step with respect to the state of the art (Articles 100(a), 54 and 56 EPC).

III. With its interlocutory decision posted on 18 February 1997 the Opposition Division held that, taking into account the amendments made by the patent proprietor during the opposition proceedings, the patent met the requirements of the Convention. The following documents were inter alia considered in the opposition proceedings:

D1: EP-A-0 274 129 (& D1a: US-A-4 748 982)

D3: US-A-5 040 548 (publication date 24 May 1990)

D5: Drawing 2030 - Monorail Piccolino Catheter

D7: Review of Hardware for PTCA by Werns and Topol, Journal of Interventional Cardiology, 1988, vol. 1, No. 3, pages 209 to 219

D11: Coronary Angioplasty, publication by Bernhard Meier, Grune & Stratton Inc., 1987, pages 13 to 15

D12: "The new balloon on a wire device" by Myler et al., Catheterization and Cardiovascular Diagnosis, 1988, vol. 14, pages 135 to 140

- D13: Brochure for Bard "Probe" PTCA Dilatation System
(published 1987)
- D14: Brochure for SciMed "ACE" fixed-wire catheter
(published 1987)
- D15: Catalogue for Monorail Bonzel Coronary Dilatation
System (published October 1988)
- D16: Brochure for Monorail Piccolino (published October
1988)
- D17: "Clinical Experience with the Monorail Balloon
Catheter for Coronary Angioplasty" by Finci in:
Catheterisation and Cardiovascular Diagnosis 1988,
vol. 14, pages 206 to 212
- D21: Declaration of Mr E. Hofman
- D29: File wrapper copy of U.S. Ser. No. 06/852,197
(identical with the printed U.S. patent US-A-5040
548)

During the appeal proceedings enclosed with its letter
of 28 April 2000, opponent I submitted the documents

- D37: Monorail Bonzel Coronary Dilation System Drawing
Nr. 2005, dated 11 December 1987,
- D38: Monorail Bonzel Coronary Dilation System Drawing
Nr. 2002 (addition to Drawing 2005), dated
8 December 1987

All parties appealed against the interlocutory decision
of the Opposition Division.

IV. A notice of appeal was filed on:

- 11 April 1997 by opponent I: SCIMED LIFE SYSTEMS INC.,
- 19 March 1997 by opponent II: SCHNEIDER EUROPE
- 18 April 1997 by the patentee: MEDTRONIC AVE INC.,

each notice being accompanied by a written statement of the grounds of appeal.

The appeal filed on 10 April 1997 by ADVANCED CARDIOVASCULAR SYSTEMS was withdrawn by letter of 16 April 1998.

In response to the summons to oral proceedings, the patentee submitted amended sets of claims and referred to document

D40 Brochure "Express" catheter of SciMed Life Systems, 1991 (published after the priority date of the patent in suit).

V. Oral proceedings were held before the Board on 30 May 2000. At the oral proceedings, the opponents submitted copies of document D5 and of document

D37: Drawing 2005 of the Monorail-Bonzel Coronary Dilatation System, 11 December 1987

which were not on file.

The appellants (opponents) requested that

- the appeal of the patentee be dismissed,
- the decision under appeal be set aside and
- the patent be revoked in its entirety.

The appellant (patentee) requested that the appeals of the opponents be dismissed and that the patent be maintained in amended form, namely

- as granted, the word "whereby" in the characterizing part of claim 1 being replaced by "wherein" (main request) or
- according to the auxiliary requests I to IV as submitted during the oral proceedings.

V. Claims 1 according to the main request reads as follows:

1. A balloon dilatation catheter for percutaneous transluminal coronary angioplasty, the catheter having proximal, intermediate and distal segments (28,30,32) the intermediate segments (30) being plastic and elongate and attached to the distal end of the proximal segment (28) and having two lumens formed therethrough including an inflation lumen (40) terminating in an outlet port (42) and a guidewire lumen (44) extending parallel to the first lumen and being adapted to receive a guidewire, the guidewire lumen (44) having a proximal opening (46) in the region of the juncture of the intermediate and proximal segments (28,30); the distal segment (32) being attached to the distal end of the intermediate segment (30) and defining an elongate lumen (48) in communication with and a continuation of

the distal end of the guidewire lumen (44) of the intermediate segment, and terminating, at its distal tip, in a distal outlet (33); a dilatation balloon (34) having proximal and distal ends, the distal end of the balloon being mounted on the distal segment and the proximal end of the balloon being mounted on the intermediate segment, the interior of the balloon being in communication with the outlet port of the inflation lumen, the proximal segment (28) being elongate and substantially stiffer than the intermediate segment (30);

characterised in that the proximal segment (28) has a single inflation lumen (36) extending therethrough and is substantially smaller in diameter than the intermediate segment, the proximal segment (28) having sufficient column strength to resist buckling when advanced through a patient's arteries wherein when a guidewire is received in the guidewire lumen (44) the catheter will have continuous column support fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

In claim 1 of the auxiliary requests I to IV only the characterized part has been amended. The amendments having been highlighted by the Board are shown in bold letters, these claims read as follows:

Auxiliary request I:

characterised in that the proximal segment (28) **is formed from metal**, has a single inflation lumen (36) extending through **it in fluid communication with the inflation lumen of the intermediate segment**, and is substantially smaller in diameter than the intermediate segment, the proximal segment (28) having sufficient

column strength to resist buckling when advanced through a patient's arteries **in which** when a guidewire is received in the guidewire lumen (44) the catheter will have continuous column support fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

Auxiliary request II:

characterised in that the proximal segment (28) **is formed from metal**, has a single inflation lumen (36) extending through **it in fluid communication with the inflation lumen of the intermediate segment**, and is substantially smaller in diameter than the intermediate segment, the proximal segment (28) having sufficient column strength to resist buckling when advanced through a patient's arteries **in which** when a guidewire is received in the guidewire lumen (44) the catheter will have continuous column support **provided by the proximal segment and the guidewire** fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

Auxiliary request III:

characterised in that the proximal segment (28) has a single inflation lumen (36) extending therethrough **in fluid communication with the inflation lumen of the intermediate segment**, and is substantially smaller in diameter than the intermediate segment, the proximal segment (28) **is formed of metal and has** sufficient column strength to resist buckling when advanced through a patient's arteries, **wherein the proximal end (46) of the guidewire lumen (44) in the intermediate**

segment (30) overlaps longitudinally the distal end of the proximal segment in which when a guidewire is received in the guidewire lumen (44) the catheter will have continuous metallic column support fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

Auxiliary request IV:

characterised in that the proximal segment (28) has a single inflation lumen (36) extending therethrough and is substantially smaller in diameter than the intermediate segment, the proximal segment (28) **being formed from metal and having** sufficient column strength to resist buckling when advanced through a patient's arteries **wherein the proximal end (46) of the guidewire lumen (44) in the intermediate segment (30) overlaps longitudinally the distal end of the metal proximal segment (28), in which** when a guidewire is received in the guidewire lumen (44) the catheter will have continuous column support fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

VI. The arguments put forward by the opponents can be summarized as follows:

The subject matter of claim 1 of the main request lacks novelty with respect to the "Monorail Bonzel Snake" percutaneous transluminal coronary angioplasty (PTCA) catheter (the "Snake") which is illustrated in detail in documents D11, D15 and the drawings given in documents D37 and D38. The "Snake" is essentially identical with the "Piccolino" PCTA catheter, except for a smaller balloon and a stiffening wire reinforcing

the proximal shaft of the "Piccolino" catheter. Like the claimed PTCA catheter, the "Snake" catheter consists of three segments, a single lumen proximal segment, a bi-luminal intermediate segment and a distal segment comprising the balloon. It is apparent from cross-sections B-B and D-D in the detailed drawing 2005 given in document D37 that the diameter of the proximal segment is smaller than that of the intermediate segment. In particular, cross-section C-C depicts the transition zone between the proximal/intermediate segment including the proximal opening of the second lumen for the guidewire. It also shows that - despite the presence of two lumina - enough plastic material remains in this segment in order to guarantee sufficient stiffness and column strength in this area. Moreover, the legend to Figure 14 given in document D11 emphasizes that the distal end of the catheter is made of transparent PVC, a material that is more flexible than white polyvinyl chloride which the proximal portion of the catheter shaft is made of. This construction ensures that the catheter portion, even when unsupported by the guidewire, can be pushed without kinking. The term "continuous column support" in claim 1 is not a feature commonly known in the art and does not represent an independent technical feature. Rather, it results from the catheter design and merely describes a combination of the properties "pushability" and "trackability" which are known in the art.

Having regard to the technical feature "that the proximal segment (28) is formed from metal", the subject matter of claim 1 of the first to fourth auxiliary request is novel with respect to the cited prior art. However, it lacks an inventive step in view

of the technical teaching disclosed in document D3 which - apart from the "Snake" and the "Piccolino" - is regarded as representing the closest prior art when read in combination with the review publication D7. Alternatively, the claimed catheter lacks an inventive step having regard to a combination of document D3 with document D13 which specifically relates to the construction and properties of the so-called "Probe" catheter.

Starting from document D3, the problem underlying the patent in suit is seen in providing a PTCA catheter shaft which exhibits a high degree of column strength and enables the catheter to be pushed from its proximal end without buckling within the guide catheter (i.e. having a high "pushability"). In addition thereto, the proximal segment of the shaft should not obstruct the injection and flow of the radiopaque contrast liquid necessary to visualize the patient's coronary arteries.

Apart from the proposal of a polyvinyl chloride or polyethylene shaft or a reinforced proximal shaft to increase the "pushability", document D7 mentions that enhanced proximal contrast delivery is provided by a using a very small catheter shaft made from a Teflon coated stainless steel hypodermic tube ("hypotube") which the "Probe" catheter is provided with and which allows increased manoeuvrability and pushability of the catheter (see also the "Probe", document D13). Given that there were only two particularly plausible classes of materials available (plastic or metal) from which to construct a relatively stiff proximal section of the catheter shaft, the claimed solution was obvious to a person skilled in the art looking for a solution to the problem confronting him.

VII. The patentee submitted the following arguments:

The present inventors aim at the realization of a rapid exchange ("monorail") catheter exhibiting an optimum contrast fluid delivery, good pushability and trackability, and the capacity of crossing even very tight stenosises. To meet these requirements, the claimed monorail catheter comprises a proximal shaft segment substantially smaller and stiffer than the intermediate segment, and in which all segments provide continuous column support sustained fully along the catheter length when a guidewire is received in the guidewire lumen. This favourable combination of properties imparts a high resistance to kinking and buckling when the catheter is advanced through the guide catheter and through the patient's arteries. Having regard to the closest prior art, the proximal segment of the "Piccolino" or the "Snake" catheter disclosed in documents D5 and D16 does not have these properties. The "Piccolino" contains - as a reinforcement to increase pushability - a stiffening wire in addition to the "Snake" catheter (D11, D15, D17) whose pushability is even poorer. However, the stiffening wire support in the proximal shaft of the "Piccolino" ends before the guidewire lumen starts which results in an unsupported gap. Due to the absence of sufficient column strength, both catheters tend to buckle and bend when advanced through the guide catheter, as is demonstrated in document D40, 3rd page, Push Comparison. Hence, neither the "Snake" nor the "Piccolino" catheter exhibit a "continuous column support" fully along its length as claimed in the patent. Consequently, the claimed balloon dilation catheter given in claim 1 is clearly distinguished from the prior art and is, therefore, novel.

As to inventive step, the review of hardware for PTCA catheters given in document D7 states on page 211, right hand column that "monorail" or "over-the wire" catheter shafts are constructed either of polyvinyl chloride (PVC) or polyethylene (PE). For maximum pushability, the catheter is provided with a PVC shaft or by a reinforced proximal shaft. Only the "Probe" catheter combines a very small proximal shaft consisting of a Teflon coated stainless steel hypodermic tube with the lowest balloon profile available (see D7, page 215, left hand column). However, given that the "Probe" is a "fixed-wire" catheter, i.e. embodies a totally different catheter design - it behaves in practice like a guide wire and is, therefore, completely different compared to the "Snake" or the "Piccolino". Since the manoeuvrability of the "Probe" requires that the torque and push imposed on the proximal end of the shaft must be transferred to the distal tip, a stiff proximal shaft consisting of a stainless steel hypodermic tube is the optimal solution. For a rapid exchange monorail catheter, however, torque easily causes the guidewire to become intertwined with the shaft and, therefore, torque must be avoided in all circumstances. The physician's attention is drawn to this danger in the operation manuals for rapid exchange catheters. Moreover, due to the immediate impulse and the spontaneous reaction of the catheter provided by the hypodermic steel tube proximal shaft and transferred to the distal tip, the medical practitioner risks to hurt or even perforate the arteries or vessels of the patient. It would, therefore, be in no way obvious for the cardiologist or medical engineer to use a relatively stiff metallic hypodermic tube, as applied in the "Probe" catheter, for constructing the proximal

segment of a rapid exchange monorail catheter like the "Snake" or the "Piccolino".

Besides, the use of stainless steel hypotube would bring about other technical problems when connecting the metallic proximal shaft with the plastic intermediate segment. Documents D5 and D37 relating to the "Snake" or "Piccolino" teach in this respect that the plastic materials of the proximal and intermediate segments are joined by heat shrinking, which technique would not provide a reliable connection between a plastic material and a metal tube. Thus, also from an engineering point of view, it was not obvious to replace the PVC proximal segment of the "Snake" or "Piccolino" catheter with a hypodermic stainless steel tube. Through the technical features given in claim 1 of the main request and the subsidiary requests, the rapid exchange catheter claimed in the patent is novel and also involves an inventive step.

Reasons for the Decision

1. The appeals are admissible.
2. *Main request*
 - 2.1 The PTCA balloon dilatation catheter defined in claim 1 of the main request belongs to the so-called "Monorail" type catheters, where the guidewire lumen extends only through a relatively short section of the catheter but not through its entire length. Thus, the guidewire runs for a long distance outside of and along the catheter shaft. Due to the short guide wire lumen, the catheter can readily be removed from the body over the in-place

guide wire, and the physician can introduce a replacement monorail catheter to again position the balloon within the lesion. This type of catheter is also called "rapid exchange catheter".

Monorail catheters are disclosed in document D3 and in documents D5, D11, D15 to D17 as well as D37 and D38 which relate to the Schneider monorail Bonzel "Snake" or to the Schneider monorail "Piccolino" catheter.

The monorail catheters (such as the "Snake" or "Piccolino") available in 1988 consisted of

- a single inflation lumen proximal segment substantially smaller in diameter than the intermediate segment (cf. for instance D37, sections B-B and D-D; D15, page 5, Cross section monorail Bonzel system; D16 Monorail Piccolino design specifications; D3, Figure 3A),
- a dual lumen intermediate segment
- a distal segment including the balloon

and exhibited all the technical features of the pre-characterizing part of claim 1 of the patent at issue. Therefore, the above cited documents represent the closest prior art.

As to the characterizing portion of claim 1, the "Snake" catheter of Schneider Shiley exhibits a proximal segment having a single inflation lumen and being stiffer than the intermediate segment to provide sufficient column support (see D17, D37 section B-B). The difference in stiffness is confirmed by the

reference to the Schneider Shiley monorail catheter depicted in Figure 14 on page 14 of document D11 which states that "the distal end of the catheter is made of transparent PVC which is more flexible than the proximal portion of the catheter shaft made of white PVC to ensure that the catheter portion not supported by the guidewire may be pushed without kinking". This difference in flexibility (or stiffness) between the single lumen proximal segment and the two-lumen intermediate segment is corroborated by the declaration of Mr. Hofmann (document D21) in point 36. It is noted in this context that the term "continuous column support" does not mean "constant column support". In particular, document D37 shows that the part of the "Snake" shaft between sections B-B and E-E comprising the guidewire exit port and the proximal end of the dual lumen intermediate shaft is designed so that sufficient plastic material is maintained in order to guarantee "continuous" column support in combination with the reinforcing effect provided by the inserted guidewire. Hence, there is no evidence for a stiffness gap in the shaft of the "Snake" or "Piccolino" catheter. Contrary to the position of the patentee, it has, therefore, to be concluded that the proximal segment of the "Snake" has a higher stiffness than the intermediate segment **and** exhibits sufficient strength to resist buckling when the catheter is advanced through the patient's arteries. When the guidewire is inserted, all segments of the shaft will have "continuous column support" fully along the catheter length thus meeting the respective features of claim 1. Hence, the wording of claim 1 of the main request fails to distinguish the subject matter claimed therein from the monorail "Snake" catheter disclosed in the prior art.

This statement is also true with respect to the "Piccolino" catheter which differs from the "Snake" by a smaller balloon and by a even stiffer proximal shaft segment. The "Piccolino" is disclosed in more detail in documents D16 and D5. In particular, Figures 1 and 2 of document D16 show the coaxial guidewire lumen in the larger 3.2 French dual lumen intermediate segment, and the smaller 3.0 French single lumen proximal segment reinforced by a stiffening wire to provide sufficient column strength. Since claim 1 does not specify where the reinforcing effect of the stiffening wire in the proximal segment of the catheter shaft ends, also the "Piccolino" catheter is covered by the wording of claim 1 of the main request.

Consequently, the subject matter of claim 1 of the main request lacks novelty with respect to the technical design either of the "Snake" or the "Piccolino" catheter.

3. *First to fourth auxiliary requests*

Apart from the documents relating to the "Snake" or "Piccolino", also document D3 US-A-5 040 548 represents pertinent prior art. As regards the publication date of document D3, a reference is made in document D1a (US-A-4 748 982) to the copending US Serial No. 857,197 (D29), filed on April 15, 1986, now abandoned (cf. D1a, column 1, lines 9, 10, column 5, lines 7 to 9). Under 37CFR §1.146(b) of the U.S. patent law, an abandoned application referred to in the text of a U.S. patent is open to public inspection. Hence, the original application documents (D29) forming the basis for D3 US-A-5 040 548 have been available to the public since 7 June 1988 (i.e. before the priority date of the

patent at issue) and, consequently, document D3 represents prior art in the sense of Article 54(2) EPC. This view regarding the technical content given in documents D3 and D29 and its public availability has not been challenged by the patentee.

The monorail catheter disclosed in document D3 which is regarded as closest prior art comprises all the technical features of the claims 1 of the first to fourth auxiliary requests, except for the material (metal) the proximal catheter shaft segment is made from. Particular reference is made to the embodiment depicted in Figure 3a of document D3 showing that the proximal ends of the guidewire tube 36 and of the tubular member 42 overlap longitudinally the distal end of the smaller proximal single lumen segment. The flexible tubular member 42 of the intermediate segment is formed of a suitable material such as heat shrinkable plastic so that it can be shrunk onto the distal end of the plastic tubular member 36 to form an air-tight seal and to provide continuous support (cf. D3, column 3, lines 9 to 15; 36 to 42). Hence, the only distinction between the claimed catheter and the prior art D3 is the requirement that the proximal segment of the claimed catheter is formed from metal and, in consequence thereof, is substantially stiffer than the intermediate segment which is formed from plastic.

One of the difficulties associated with the monorail catheters is the tendency of the catheter shaft which is unsupported by the guidewire to buckle within the guide catheter, thereby impairing the ability of the catheter to be pushed along the guidewire. This phenomenon has been known in the art for a long time. One approach to solve this problem was the use of a

"harder" plastic material to stiffen the catheter shaft. A further approach to improve the stiffness consisted in reinforcing the proximal segment of the catheter shaft by means of a wire, for which the "Piccolino" catheter is an example. On the other hand, the cross-section of the diameter of the proximal catheter shaft segment has to be designed as small as possible to guarantee an optimized flow of the radiopaque contrast liquid through the guide catheter, thus facilitating the injection of contrast liquid into the patient's coronary arteries.

Starting from this prior art, the problem underlying the patent at issue, therefore, consisted in designing the proximal segment of the monorail catheter shaft which is unsupported by the guidewire in a manner

(a) which minimizes buckling, thereby increasing the "pushability", and

(b) which allows optimum radiopaque contrast liquid to flow through the guide catheter.

The solution to this problem consisted in selecting a single lumen proximal segment made of metal, or, in the most preferred embodiment, of a stainless steel hypodermic tube.

For the following reasons, however, this solution to the above mentioned problem is obvious to a skilled person, who in the present case is either a medical practitioner, i.e. a cardiologist, or a catheter manufacturer who in cooperation with the cardiologist steadily aims at improving the properties of his products. The call for the treatment of complex and

multi vessel diseases requires thorough consideration of exchange properties, steerability, trackability and stiffness (pushability) of the chosen catheter (cf. D17, Introduction). Given that a single, multipurpose catheter which is suitable for all kinds of lesions does not exist, the cardiologist, therefore, must be familiar with and able to use all types of catheters, including "fixed wire", "over-the-wire" and "monorail" type catheters depending on the stenosis. A skilled person faced with the above mentioned problem, therefore, is aware of the different materials which had been used for constructing the catheter shaft of the "fixed wire", "over-the-wire" or "monorail" catheters. The properties, behaviour, advantages and disadvantages of the different catheter designs are summarized in document D7. Beside the fact that document D7 (see page 211, right hand column, paragraph 1) mentions that catheter shafts are generally constructed of PVC or polyethylene (PE), a plastic material which is also mentioned in document D3, the particular attention of the expert reader of this document is also drawn to the "Probe" fixed-wire catheter which has the smallest catheter shaft profile and, therefore, enables excellent contrast liquid injections (cf. D7, page 215, left hand column, paragraph 2 bridging right hand column, paragraph 1). The "Probe" catheter which is described in more detail in document D13, page 2 or D12, page 135 comprises a shaft consisting of a stainless steel Teflon coated hypodermic tube for increased manoeuvrability, superior proximal dye delivery and pushability. The stainless steel hypotube shaft is connected to a PE coaxial neck extension to reduce friction and enhance trackability. Thus, apart from the possible selection of a relatively stiff PVC shaft, a stainless steel hypodermic tube was

the only alternative material for the expert to construct a catheter shaft which should exhibit a high stiffness combined with a low profile. In this respect, it has to be considered that the stainless steel hypotube was a readily available commercial material and had already proved to provide an excellent match in pushability and dye delivery in the fixed-wire "Probe" catheter.

The expert who had decided to use the stainless steel hypotube as a proximal segment in order to modify the monorail catheter given in document D3 or of the monorail "Snake" or "Piccolino" catheter would do so by cutting the catheter near the guidewire exit port and connecting the hypotube in the manner illustrated in Figure 3a of document D3. Since the problem of reliably joining a metal hypodermic tube to a plastic tube has already been solved when realizing the "Probe" catheter, the skilled person, having made this obvious step, would have arrived at a catheter comprising all the features of the claims 1 according to the first to fourth auxiliary requests.

In view of these considerations, the subject matter of claim 1 of the first to the fourth auxiliary request does not involve an inventive step.

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:

S. Fabiani

W. D. Weiß