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## Datasheet for the decision of 24 November 2011

Case Number:	T 0016/09 - 3.2.02
Application Number:	99117818.7
Publication Number:	1088568
IPC:	A61M 25/01

Language of the proceedings: EN

# Title of invention:

Guiding aid for a medical instrument

### Patentee:

Schneider (Europe) GmbH

### Opponent:

Terumo Kabushiki Kaisha

## Headword:

-

# Relevant legal provisions:

EPC Art. 54(1)(2), 56, 114(1)(2) RPBA Art. 12(4)

### Keyword:

"Late filed evidence (not admitted)" "Novelty (yes)" "Inventive step (yes)"

# **Decisions cited:** T 0092/92, T 0204/83

### Catchword:

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Boards of Appeal

Chambres de recours

**Case Number:** T 0016/09 - 3.2.02

#### DECISION of the Technical Board of Appeal 3.2.02 of 24 November 2011

Appellant:	Terumo	Kabushi	ki Kaisha	
(Opponent)	44-1,	Hatagaya	2-Chome	
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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted 6 November 2008 rejecting the opposition filed against European patent No. 1088568 pursuant to Article 101(2) EPC.

Composition of the Board:

Chairman:	D.	Valle
Members:	С.	Körber
	Α.	Pignatelli

#### Summary of Facts and Submissions

- I. On 6 November 2008 the Opposition Division posted its interlocutory decision to reject the opposition against European patent No. 1 088 568.
- II. An appeal was lodged against this decision by the opponent (appellant) by notice received on 30 December 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 13 March 2009.
- III. By communication of 12 September 2011, the Board issued a summons to oral proceedings and forwarded its provisional opinion to the parties.
- IV. By letter of 24 October 2011, the patent proprietor (respondent) indicated that it did not intend to attend the oral proceedings.
- V. Oral proceedings were held on 24 November 2011.
- VI. The final requests of the parties were as follows:

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

The respondent requested dismissal of the appeal.

VII. The following documents are of importance for the present decision:

El: WO 99 22797 A E2: WO 96 32980 A E7: US 5 639 276 A

E13: Fujita, M. et al.: "Selective catheterization of abdominal blood vessels by means of shaped guide wire", Japanese Journal of Clinical Radiology, 39, 325-328, 1994 (English translation)

- El4: Diagnostic Imaging Seminar 2, Points of Angiography Technique (1993) pp. 31-35
- E14ac: English translation of E14
- E15: Extract of the Medicyclopaedia Lexicon
- E16: PTCA Technique (1995-07-01) pp. 21-23
- El6a: English translation of El6 (erroneously denoted as El4a in the statement of grounds of appeal).
- VIII. Claim 1 as granted reads as follows (with the feature denotation used in the impugned decision added in square brackets).

"Guidewire for use within a vascular system comprising [a] a flexible preformed shaft (2) comprising [a1] a first bent section (4) having a first curvature  $K_1$ , [a2] at least one further bent section (6) located proximal of the first bent section (4) and having a second curvature  $K_2$ , and [a3] a straight intermediate section (8) between said first bent section (4) and said second bent section (6), wherein said shaft (2) comprises [a4] a straight end section (10) distal to the first bent section (4), [a5] with said bent sections (4, 6) of said shaft (2)

having the same sign of curvature and being located substantially in the same plain (E),

## characterized in that

[a6] the radius of curvature of said first bent section (4) is smaller than the radius of the curvature of said second bent section (6), and in that [a7] the straight end section (10) and the straight intermediate section (8) forms a first obtuse angle ( $\alpha_1$ ) of between 120° and 150°, and [a8] said straight intermediate section (8) and the axis (12) of the shaft forms a second obtuse angle ( $\alpha_2$ ) of between 120° and 150°, wherein [a9] the first bent section and the second bent section result in a total bend of between 60° and 120°".

Claims 2 to 11 are dependent claims.

IX. The appellant's arguments are summarised as follows:

Documents E1 and E2 had already been cited by the opponent in the opposition brief and should therefore have been admitted into the proceedings by the Opposition Division. Documents E14/E14a and E15 were filed with the statement of grounds of appeal in reaction to the decision of the Opposition Division. When the additional documents were being prepared, a further document E16 (in Japanese) was considered and this was submitted with letter dated 24 October 2011 together with its translation E16a (which, by mistake, was filed as translation E14a of the already filed document E14) and with the correct translation E14ac of document E14.

Document El disclosed a guiding catheter, wherein a first guiding catheter 13 acted as a guide wire to guide a second guiding catheter 14 along the first guiding catheter. The system of El was clearly provided for use within the vascular system. Figure 3 showed an embodiment having two bent sections and a straight intermediate section in between. The angles, as also mentioned in the description, were exactly within the ranges outlined in the characterising part of claim 1. The radius of curvature of the first bent section was smaller than the radius of curvature of the second bent section. The embodiment having three bent sections shown in Figure 6 was also relevant. Due to the definition of the term "guide wire" given in the opposed patent and the understanding of a skilled man, the first guiding catheter of E1 had to be considered a kind of guide wire. Thus, document E1 was clearly novelty destroying.

The term "guide wire" had to be understood as a guiding aid to advance instruments, for example catheters, to a desired location within the vascular system. Document E2 disclosed a flexible tubular catheter (Figure 2), which was brought into the desired shape by a shaping wire (Figure 3). Measuring the angles resulted in  $\alpha_1$ being about 133°,  $\alpha_2$  about 144° and the total bend angle about 98°. There was a straight intermediate section between the two bent sections, and the radius of curvature of the first bent section was smaller than the radius of the curvature of the second bent section. The features of the preamble of claim 1 were also disclosed in E2.

Figure 1 of E13 disclosed various twisted (see types 3, 5 and 6) and not twisted guide wires. The insertion of a catheter into the hepatic artery was shown in Figure 2. When introduced into a lumen, the guide wire was bent and the shape of the guide wire transformed.

From the first picture of Figure 2 it could be seen that this guide wire had exactly the shape of the guide wire of the opposed patent. Measuring revealed a first obtuse angle  $\alpha_1$  of about 140°, a second obtuse angle  $\alpha_2$ of about 142°, with an angle between the first bent section and the second bent section of about 105°. Further, the radius of curvature of the first bent section was smaller than the radius of curvature of the second bent section. Thus, all characterising features of claim 1 were fulfilled. Figure 2 showed the insertion by means of a guide wire clearly in line with the features of claim 1 of the opposed patent, and there was no reason to assume that Figure 2 of document El3 showed a guide wire having a three dimensional shape with angles other than the measured angles mentioned above.

Document E7 disclosed in Figure 6 a flexible guide wire, which could be straight and have a flexible J-tip at a distal end, wherein the curved segments extended to an arc of approximately 150° and typically had a radius of 3.0 to 6.0 mm. Furthermore, in Figure 6A an alternative configuration was disclosed having an angled segment and a J-tip, the angle being 135°. All features of the preamble of granted claim 1 were also disclosed by E7.

According to the opposed patent, the characterising features were intended to have the effect that the guide wire could easily be introduced into a branching of a vessel system, wherein the shape could be chosen according to the shape of the vessel. Document E13 dealt exactly with the same problem and sought for a solution to enable, by a simple construction, a safe insertion of a catheter into the hepatic artery. It was clear from Figures 6A and 6B and the description of E7 that, in line with the opposed patent, the radius of curvature of the first bent section was smaller than the radius of curvature of the second bent section. Trying the shape and angles clearly disclosed in Figure 2 of E13 resulted directly and unambiguously in a design as claimed by claim 1, which was therefore obvious from E7 and E13.

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The same applied to a combination of document E7 with document E1, document E7 with document E2 or document E7 with document E14.

Taking Figure 2 of E13 as a starting point, the only distinguishing feature of claim 1 was [a6]. In view of the shaping properties of the guide wire addressed at page 2 of E13, the skilled person would take into consideration the respective teaching of E2, which disclosed in Figure 3 a shaping wire with radii of curvature as defined in feature [a6], and would thus arrive at the subject-matter of claim 1 in an obvious manner.

X. The respondent's arguments are summarised as follows:

In the opposition brief, E1 and E2 had only been cited in respect of some of the dependent claims, and the opposition had not been substantiated in terms of E1 and E2 as far as claim 1 was concerned.

The introduction of E14 and E15 into the appeal proceedings was not justified since these documents had not been cited during the opposition proceedings. E14a was not a translation of E14, and the appellant's argumentation in this regard was inherently inconclusive. E14 and E14a should thus be disregarded since the appeal was not sufficiently substantiated in this respect.

El concerned a guiding catheter system for ablating heart tissue and did not disclose a guide wire, let alone any geometrical details thereof, but rather a catheter to be advanced along such a wire.

E2 merely disclosed a shaping wire which as such, due to its rigidity, could not be inserted into the vasculature. E2 failed to disclose any details of a guide wire to be used for insertion of a catheter.

E13 related to a guide wire but failed to describe any specific shape thereof. Figure 2 was a schematic drawing and thus not suitable for deriving any measurements. Some of the guide wires shown in Figure 1 were denoted as "twisted", i.e. of a tortuous shape that was three-dimensionally deformed. From the twodimensional illustration depicted in Figure 1 it was therefore impossible to tell what shape the guide wires should have in reality.

The device of E7 was intended to be placed directly in the heart, the J-tip being provided so as to define an atraumatic leading edge that minimized trauma to the tricuspid valve when the guiding member was being placed within the heart. In contrast, the guide wire of the opposed patent had been specifically designed to navigate through the vasculature and particularly to facilitate the threading of the guide wire through a branching within the vasculature. If the angle of 150° mentioned in E7 with respect to the embodiment shown in Figure 6 was measured according to the rules applied in the opposed patent, this angle would correspond to 330°. Reshaping the J-tip of the guide wire of E7, which was bent at an acute angle, into an obtuse angle would be directly against the teaching of E7. For this reason, and due to the basic and fundamental differences between a flexible guide wire and a guiding catheter as disclosed in E1 or a shaping wire as disclosed in E2, the skilled person would not have any incentive to take into account the teachings of these documents, and even if he did so, he would not arrive at the subject-matter as claimed. The combination with E13 would not lead to the invention either since the latter document failed to disclose the specific geometry of the guide wire as defined in the characterising portion of claim 1. Accordingly, none of the cited combinations of documents rendered obvious the claimed subject-matter.

# Reasons for the Decision

- 1. The appeal is admissible.
- 2. Admissibility of evidence

### 2.1 E1 and E2

The Opposition Division disregarded documents E1 and E2 as late-filed evidence under Article 114(2) EPC because the "additional lines of reasoning" based thereon with respect to lack of novelty and inventive step presented at the oral proceedings constituted evidence not submitted in due time and because both documents were not prima facie relevant (see points 2 to 4 of the Reasons of the impugned decision and page 2, third and fifth paragraphs of the minutes of the oral proceedings before the Opposition Division).

In its opposition brief dated 22 May 2006, the appellant had introduced documents E1 to E13 (point I) and opposed the subject-matter of granted claim 1 on the ground of lack of novelty vis-à-vis document E13 (point II) and of lack of inventive step starting from E7 in combination with E13 or E4 (point III). Documents E1 and E2 were cited against some of the dependent claims (point IV).

Article 114(2) EPC provides that facts or evidence which are not submitted in due time by the parties concerned may be disregarded. However, the EPC makes a clear distinction between "facts or evidence" on the one hand (Article 114(2) EPC) and "facts, evidence and arguments" on the other hand (Article 114(1) EPC), i.e. Article 114(2) EPC does not refer to arguments. Arguments, in this context, may be understood to include the parties' submissions as to the consequences that result from applying the law to the facts and evidence submitted in due time (cf. T 92/92, point 2 of the Reasons).

In the present case, the "evidence" at issue is represented by documents E1 and E2. The "facts" in question are the objections of lack of novelty and inventive step of the subject-matter of granted claim 1. These "facts and evidence" were submitted in due time and cannot therefore be disregarded under Article 114(2) EPC.

E14 to E16

E14, a document in the Japanese language, and E14a, evidently not representing an English translation of E14 as initially alleged by the appellant, were filed with the statement of grounds of appeal, i.e. after the nine-month opposition period. Their relevance could only be assessed after the appellant had provided the correct translation of E14, namely E14ac, and copies of the Japanese document E16 and its English translation, E16a, stated to be filed "by mistake" as E14a, as the appellant explained in its letter of 24 October 2011, i.e. more than one month after having received the Board's communication of 12 September 2011 annexed to the summons to oral proceedings.

Both documents, E14/E14ac and E16/E16a, are primarily concerned with catheters and their shape and handling (see captions of all figures and throughout the text of both documents). Guide wires are only briefly mentioned, without indication of any further details of their shape. The only relevant information can be found in the last paragraph of page 31 of E14ac, where an "angle type of a Radifocus guide wire M" is mentioned. However, the documents filed in due time disclose numerous examples of "angled" guide wires, and the information derivable from E14/E14ac does not go beyond those disclosures.

The appellant's argumentation is entirely based on the examples of **catheters** depicted in E14/14ac and

E16/E16a, which cannot be equated with guide wires, as is explained further below (see point 3.1). Moreover, even with respect to these catheters, both documents are entirely silent regarding radii of curvature and the angles formed between the various sections as defined in the characterising portion of claim 1. With respect to any information derivable from the figures, it has to be noted that values of dimensions or parameters obtained merely by measurements from schematic and diagrammatic drawings do not normally form part of the respective disclosure (T 204/83). With respect to those figures apparently representing photographs, it has to be kept in mind that a photograph is a two-dimensional projection of a threedimensional device and that a measurement of bend angles and or radii of curvature from a photograph is thus in principal problematic.

E15 merely documents the well-known meaning of the term "guide wire" as a device used for catheter insertion, catheter exchange and cannulation of vessels. It cannot be seen to support the appellant's view that no distinction is to be made between guide wires and catheters according to its interpretation of paragraph [0002] of the patent in suit. Accordingly, the Board sees no necessity to document an interpretation of the term "guide wire" which the skilled person would normally apply anyway.

Accordingly, the Board is of the opinion that latefiled documents E14/14ac, E15 and E16/E16a are not prima facie relevant and therefore they are not admitted into the proceedings under Article 12(4) RPBA and Article 114(2) EPC.

#### 3. Novelty

#### 3.1 Document E1

El discloses (Figures 1 and 3 or 6) a "first guiding catheter" (13 or 50) comprising features [a1] to [a5] and mentions values of bend angles falling within the ranges claimed in features [a7] and [a8] of claim 1 (page 5, penultimate paragraph; claims 2, 4 and 6). Some combinations of the disclosed values result in a total bend angle within the range defined in feature [a9]. However, E1 is entirely silent with respect to radii of curvature. Such information is not derivable from the schematic drawings either (cf. point 2.1 above). Accordingly, E1 fails to disclose feature [a6] and is thus not novelty-destroying.

In the Board's view, E1 furthermore does not disclose a "Guidewire" as stated at the beginning of claim 1. A normally thin and flexible but solid guide wire cannot be equated with a guiding catheter, which generally comprises a lumen (as also disclosed in E1, see reference numeral 15). It is true that the introductory part of the description of the patent in suit (e.g. paragraphs [0001] and [0002]) refers to the general term "guiding aid" to describe the general field to which the patent belongs. This generic term can be seen to encompass, among others, the specific examples of guide wires and guide catheters. This, however, does not imply that the two terms, "guide wire" and "guide catheter", refer to the same thing and can thus be equated with one another. The claim is clearly directed to one specific example of "guiding aids", namely a

"guidewire", which is to be distinguished from a guiding catheter as disclosed in E1. The fact that the first guiding catheter (13) of E1 serves to "guide" a second guiding catheter (14) does not change this finding since it is clear from page 8, lines 2 to 6, that the second catheter is disposed within the inner lumen of the first catheter.

Document El nowhere explicitly refers to guide wires. Mention is made at page 18, lines 8 to 11, that at the beginning of the treatment the first guiding catheter is introduced into the patient's arterial system, "preferably by means of the Seldinger technique", which, as known to the person skilled in the art, uses a guide wire which first is introduced into the vascular system of the patient and along which the "first guiding catheter" of E1 may then be inserted into the body. Thus, whereas the patent in suit is concerned with a guide wire to be introduced into the vasculature to serve as a means for introducing a catheter into the vasculature, document E1 is concerned not with a guide wire but rather with a catheter to be advanced along such a wire.

## 3.2 Document E2

Document E2 discloses a catheter (1) comprising a flexible tubular catheter body which, prior to insertion of the catheter into the vasculature, can be brought into a desired shape by the use of a relatively rigid shaping wire (4). Due to its explicitly desired rigidity (see line 8 of claim 1 of E2), this shaping wire as such is not to be inserted into the vasculature. It is rather used in advance of a

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transluminal intervention to bring the catheter into a desired shape. As in document El, in the system suggested in document E2 the catheter can be inserted into the vascular system by the aid of a guide wire that is inserted into a blood vessel or organ to be treated and along which the catheter is threaded when inserted into the body (see page 5, lines 16 to 20). Also as in document El, document E2 fails to indicate any details of the guide wire to be used for insertion of the catheter.

The requirements for a (rigid) shaping wire as provided for in document E2 are completely different from those to be met by a guide wire (the shaft of which is explicitly required to be flexible according to feature [a] of claim 1). Even with respect to the shaping wire, E2 does not describe any geometric details other than that it should have a curved intrinsic shape that is suitable for linking up the right coronary artery (page 2, lines 10 to 12; page 4, lines 35 to 36). Again, the drawings (in particular Figure 3) are entirely schematic and do allow any values of radii of curvature or bend angles to be derived. Accordingly, at least features [a6] to [a9] of claim 1 are not disclosed in E2.

#### 3.3 Document E13

E13 is clearly concerned with a guide wire. It explicitly describes (see in particular page 2) and illustrates (Figures 1 and 2) various geometrical shapes thereof. However, the text of the document is again entirely silent with respect to radii of curvature and bend angles.

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In the statement of grounds of appeal, the appellant primarily relies on Figure 2 of E13, which is a schematic drawing and per se is not suitable for deriving any measurements, as already mentioned above. Accordingly, at least features [a6] to [a9] cannot be derived directly and unambiguously from Figure 2.

Figure 1, to which the appellant referred during the opposition proceedings and which seems to be a photograph, does not allow any conclusions to be drawn with respect to radii of curvature and bend angles as defined in features [a6] to [a9] either since it is a two-dimensional representation of a three-dimensional device, as correctly stated in point 10 of the impugned decision. Most of the guide wires depicted in Figure 1 (see caption) and mentioned at the bottom of page 2 are denoted as having a "twist" (examples 3, 5 and 6) or "cobra" shape (examples 4, A and B). These terms refer to a tortuous shape, i.e. a shape that is threedimensionally deformed, in contrast to the requirement in feature [a5] that the bent sections are located in essentially the same plane. This also applies to example 5 on which the appellant primarily relied during the opposition proceedings. Neither this guide wire nor any of the other examples depicted in Figure 1 comprise straight intermediate and end sections as defined in features [a3] and [a4] of claim 1.

Accordingly, none of the various types of guide wire disclosed in E13 comprises in combination all the geometrical features required by claim 1.

3.4 Accordingly, the Board is satisfied that the subjectmatter of claim 1 is new (Article 54(1) and (2) EPC).

#### 4. Inventive step

4.1 Document E7, which represents the closest prior art, discloses (see the embodiments depicted in Figures 6, 6A and 6B) a guide wire comprising the features of the preamble of claim 1. In lines 21 to 25 of column 9 an angle of 135° is disclosed for the embodiment of Figure 6A. This angle is apparently measured between the adjacent sections of the guide wire, i.e. the shaft and the intermediate section, as defined in feature [a8] and falls within the claimed range of obtuse angles  $\alpha_2$ . In contrast, the angle of 150° mentioned in lines 12 to 14 of column 9 (with respect to the embodiment of Figure 6) indicates the angle between the axis of the free end of J-tip 66 and an imaginary line continuing the axis of the straight quide wire 64 as if there was no bend. This differs from the definition of the angle  $\alpha_1$  according to feature [a7], which relates to the angular relationship between the axis of the intermediate section and the axis of the end section of the guide wire (cf. Figure 7 of the patent in suit). Taking into account this definition, the abovementioned angle of 150° would give an angle of 330°, corresponding to an acute angle of 30°, if measured in the same way as the angles of the patent in suit. Accordingly, the value disclosed in E7 falls far outside the range of obtuse angles  $\alpha_1$  claimed in feature [a7] of claim 1. The total bend angle resulting from the above-mentioned values disclosed in E7 also falls outside the range defined in feature [a9]. Whilst certain values of the first curvature of the first bent

section are indicated in lines 12 to 16 of column 9 of E7, the document is entirely silent with respect to the second curvature. Accordingly, it fails to disclose feature [a6].

The device of E7 is intended to be placed directly in the heart (see Figures 11 and 12), the J-shape of the above-mentioned tip 66 being provided so as to define an atraumatic leading edge that minimizes trauma to the tricuspid valve when the guiding member is being placed within the heart (see column 4, lines 38 et seq. and column 10, lines 19 to 27). Such a J-shape type of tip forms part of all three embodiments shown in Figures 6, 6A and 6B.

- 4.2 The technical effect achieved by the specific geometrical shape of the guide wire defined by the combination of the distinguishing features [a6], [a7] and [a9] of claim 1 is that the guide wire can be threaded without buckling into branchings of blood vessels from large as well as small vessels as shown in Figures 5 and 6 and described in paragraphs [0006], [0008] and [0022] of the patent in suit.
- 4.3 The objective technical problem to be solved by the invention is to provide a guide wire that can be easily and reliably navigated in the vascular system and its branchings.
- 4.4 The person skilled in the art is aiming at designing a guide wire that facilitates navigation of the guide wire through the vasculature would not try to modify a device as shown in document E7, which is specifically designed for a different purpose, as mentioned in

item 4.1 above. Reshaping the J-tip of the guide wire of document E7, which is bent at an acute angle, into an obtuse angle would be directly against the teaching of document E7 to provide a catheter having an atraumatic tip.

4.5 The Board does not share the appellant's view that E13 deals with the same problem as that underlying the patent in suit and that the skilled person would use the indications concerning the shape of the guide wire shown in Figure 2 of E13 to modify the guide wire of E7 to facilitate its insertion into the vasculature. Figure 2 illustrates the insertion of a catheter into the aorta and into the hepatic artery, as mentioned at the bottom of page 2. At page 4 it is stated ("Step 2") that if it is impossible to insert the cobra-shaped or original angle guide wire from the catheter in the hepatic artery into the desired branch of the hepatic artery, another attempt is made with a guide wire "which is shaped or bent in conformity with the course of the desired vessel". This, however, is a merely general and rather self-evident statement. It gives no hint towards the solution according to the invention, i.e. the specific geometry of the guide wire and the advantages achievable thereby as indicated above. As mentioned in point 3.3, the text of document E13 is entirely silent with respect to radii of curvature and bend angles. Finally, bending the atraumatic tip of E7 into an obtuse angle as depicted in Figure 2 of E13 would be directly against the teaching of document E7.

4.6 Due to the fundamental differences between a "guide wire" on the one hand and a "catheter" to be guided on such wire on the other band, the appellant's argument

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that the skilled person would modify the shape of the guide wire suggested in document E7 so as to resemble the shape of the catheter shown in document El is not accepted by the Board.

Moreover, the bends of the first guide catheter 13 of document El, to which the appellant had referred as model for shaping the guide wire of document E7, serve a completely different purpose than the bends of the guide wire of the patent in suit. In particular, whereas in the guide wire of the patent the bends serve to facilitate threading the guide wire into branchings both from large as well as from small vessels, in the catheter system of document El the bends in the first and the second guiding catheters do not serve to facilitate navigation of the catheters through the patient's blood vessels, but rather serve to orient an instrument so that it points towards the endocardial surface of the heart chamber (see page 8, lines 6 to 9 and Figure 1). In fact, the shapes of these guiding catheters are not relevant for their insertion into the patient's vasculature. Rather, the initial placement of the guiding catheters within the vasculature, i.e. navigation thereof through the patient's blood vasculature to the target area, is done by the Seldinger technique as mentioned above, i.e. over a guide wire of which no details are disclosed in E1. Thereafter the first quiding catheter is advanced along the already placed quide wire into the left ventricle, and finally the second guiding catheter is inserted through the first guiding catheter. Evidently the first and second guiding catheters could not be inserted without a guiding aid, since both guiding catheters are explicitly disclosed as relatively stiff members (see

page 9, lines 17 to 21) so as to maintain during the treatment the position of an instrument that is introduced through the second guiding catheter. Starting from E7, the skilled person would thus not have any incentive to modify the shape of the guide wire disclosed in E7 so that it conforms to the shape of the first guiding catheter of El because he would immediately recognise that the geometric shape of the first guiding catheter has nothing to do with navigating an elongate member through the vasculature. Moreover, as already mentioned above, such a modification would be against the teaching of E7.

- 4.7 As indicated in point 3.2, document E2 is more remote from the invention in that a shaping wire is fundamentally different from a guide wire and in that the document is entirely silent with respect to bend angles and radii of curvature, let alone any advantages to be achieved thereby. Starting from E7, the skilled person would thus not have any incentive to modify the shape of the guide wire of E7 so that it conforms to the shape of the shaping wire 4 of E2. The drawings of E2 are only schematic and are used to illustrate a basic principle, i.e. shaping a flexible catheter by applying it onto a stiff pre-shaped shaping device. Accordingly, the skilled person would not combine the teachings of E7 and E2, and even if he did so, he would not arrive at the subject-matter of claim 1.
- 4.8 Document E13 is more remote as a starting point than E7. Contrary to the view of the appellant, [a6] is not the only distinguishing feature of claim 1 over E13. As shown above (point 3.3), E13 additionally fails to disclose at least features [a7] to [a9]. Furthermore,

the document gives no hint towards the technical effect to be achieved by the combination of features of the characterising portion of claim 1. For the same reasons as indicated above (point 4.7) the skilled person would not take into consideration the teachings of E2 when starting from E13.

4.9 From the above it follows that the subject-matter of claim 1 is not rendered obvious by the cited combinations of prior art documents. The Board is satisfied that it involves an inventive step within the meaning of Article 56 EPC.

# Order

# For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

D. Hampe

D. Valle