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Title of invention:
PERCUTANEOUS GUIDEWIRE

Patent Proprietor:
Medtronic CV Luxembourg S.à.r.l.

Opponents:
Zolyomi, Alexander
Boston Scientific Scimed, Inc.

Relevant legal provisions:
EPC Art. 54, 56, 123(2), 100(a), 100(c)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Grounds for opposition - added subject-matter (yes)

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Case Number: T 3031/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 6 September 2022

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Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 November 2018 concerning maintenance of the European Patent No. 2396067 in amended form.**

Composition of the Board:

Chairwoman	P. Acton
Members:	A. Björklund
	F. Bostedt

Summary of Facts and Submissions

I. The appeals were filed by the patent proprietor (appellant 1) and opponent 2 (appellant 2) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 1 (then on file), the patent in suit (the patent) met the requirements of the EPC.

Opponent 1 did not file an appeal and is thus a party as of right under Article 108 EPC.

II. Oral proceedings were held before the Board.

III. Appellant 1 (the proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted or that the patent be maintained according to one of auxiliary requests 1 to 9, filed with the statement setting out the grounds of appeal dated 23 January 2019, or according to one of auxiliary requests 10 to 18, filed with its reply dated 5 August 2019.

Appellant 2 and opponent 1 (the opponents) requested that the decision under appeal be set aside and that the patent be revoked.

IV. Claim 1 of the **main request** (patent as granted), with reference signs added, reads:

A A percutaneous guidewire comprising
B a distal end portion (15) that is pre-formed in a curve that turns through more than 270 degrees,

C the curve having a radius of curvature that decreases towards the tip (4) of the guidewire,

D wherein the stiffness of the guidewire decreases along the length of the curved distal end portion (15) towards the tip (4) of the guidewire,

E wherein the change in stiffness is continuous along the length of the curved distal end portion (15), and

characterised in that

F the decrease in stiffness of the guidewire starts on a straight portion (11) of the guidewire, proximally of a transition of the guidewire from a straight portion (11) to the curved portion.

Dependent claims 5 and 7 of the main request read:

5. "A guidewire according to any one of claims 1 to 6, comprising an inner core wire (13) within an outer coil and wherein the change in stiffness results from a change in diameter of the core wire (13)."

7. "A guidewire according to claim 6, wherein the rate of change of the radius decreases towards the tip (4) of the guidewire; and wherein the curvature of the distal end portion is
(a) a logarithmic spiral; or
(b) increases for every 90 degrees of curvature according to a Fibonacci sequence."

Auxiliary request 1 differs from the main request in that dependent claim 7 has been deleted and the remaining dependent claims renumbered as necessary.

V. The following documents are of relevance to the decision:

E1 WO 2007/006055 A2
E2 EP 1 105 181 B1
E3 EP 1 419 797 B1
E4 WO 2004/018031 A2
E6 US 4,917,102 A
E8 EP 0 260 711 A2
E15 JP H07-255856 A1
E15' Machine translation of E15

VI. The arguments of the proprietor can be summarised as follows.

Novelty

The subject-matter of claim 1 was new.

E1, Figures 5A to 5C disclosed a guidewire which had a transition from a larger to a smaller diameter. However, this transition was before the curved end portion which had a constant diameter. The stiffness of the curved end portion did not therefore change as required by Features D, E and F.

E2, Figures 1 and 4 disclosed a guidewire whose end portion was not pre-formed into a curve turning more than 270°, nor did the curve have a radius of curvature decreasing towards its tip. Features B and C were thus not disclosed in E2. Furthermore, Figure 6 did not disclose that the taper continued through the curve. Features D to F were therefore also not disclosed.

E3 did not describe the stiffness of the guidewire. The composite stiffness of the guidewire shown in Figure 4 was complex and dependent upon the manufacturing method, such as the annealing processes of the core and the coil, and also on how the coil and core were connected by brazing and soldering. Furthermore, the drawings showed an abrupt change of the coil windings around 11 o'clock. A continuous change in stiffness according to Features D to F was thus not directly and unambiguously disclosed in E3.

E6, Figures 2 to 4 disclosed a guidewire with an end portion which had a curve with a changing radius. It did not, however, decrease towards the tip of the guidewire according to Feature C. The opponents' reference to Figure 5 of the patent was irrelevant since this showed the guidewire when it was deformed by the surrounding heart tissue, not in its unbiased pre-formed state. Furthermore, it was not unambiguously disclosed that the stiffness of the guidewire changes according to Features D to F when the movable core 31 had a position intermediate to those of Figures 3 and 4 such that the curve of the distal end was just more than 270°.

E14, Figure 15A disclosed a guidewire with a curved end portion. However, the curve did not turn 270° or have a decreasing radius of curvature according to Features B and C. Furthermore, the stiffness of the distal end portion did not decrease according to Features D to F.

Inventive step

The subject-matter of claim 1 involved an inventive step.

The guidewire of E2 was intended for renal angioplasty and must be able to pass through a stenosis. Its distal end had a J-tip adapted for this use and already solved the problem of reducing the risk of penetration of a vessel by its rearward pointing tip. The subject-matter of claim 1 differed from this guidewire in Features B and C.

The guidewire disclosed in E1 has a distal end in the form of a spiral with a pitch. But this spiral end had a constant diameter, and the skilled person would have to disregard this teaching if they were to transfer only the shape of the spiral to the guidewire of E2.

E3 did not describe any advantages of the guidewire having a curved distal end turning through more than 270° over a J-tip as in the guidewire of E2.

The subject-matter of claim 1 was thus not obvious to the skilled person starting from the guidewire of E2 when considering E1 or E3.

The guidewire in Figure 15A of E14 had a distal end portion with a shape adapted for a specific vessel. The skilled person would thus not change the shape of this tip, but even if they did in view E1, E3 or Figure 5C of E14, they would not arrive at the guidewire of claim 1.

The guidewire of E4 was designed for insertion into the aortic arch and was therefore stiff into part of the first bend. The skilled person would not change this design since it was advantageous for the intended use. Furthermore, the distal end did not have a decreasing radius of curvature according to Feature C. The skilled person starting from this guidewire would thus not

arrive at the subject-matter of claim 1, even if considering E2.

The guidewire of Figure 8 of E15 did not unambiguously have a distal end portion with a tapering core diameter as this teaching was contradicted by Figure 3 and the descriptions of these embodiments. It was thus not unambiguously disclosed that the stiffness of the distal end portion decreased towards the tip. Neither E1, E3 or E4 would teach the skilled person to provide the guidewire of E15 with such a distal end section.

Extension of subject-matter

The subject-matter of claims 5 and 7 did not extend beyond the content of the application as originally filed.

Read in combination with claim 1, claim 5 defined that the change in stiffness was due to a reduction of the diameter of the core wire

The skilled person would understand from the wording of claims 1, 6 and 7 read in combination that the Fibonacci sequence started at the tip of the guidewire.

VII. The arguments of the opponents can be summarised as follows.

Novelty

The subject-matter of claim 1 was not new over the guidewires disclosed in E1 to E3, E6 and E14.

E1, Figures 5A to 5C disclosed a guidewire which had a diameter tapering from a straight portion into a fillet

which belonged to the curved distal end portion of the wire. The change of diameter led to a change in stiffness according to Features D to F.

E2, Figures 1 and 4 in combination with Figure 6 disclosed a guidewire having a distal end portion including a first bend, a J-tip and a portion there between which turned through more than 270°. It had a tapering core which led to a decreasing stiffness according to Features D to F.

E3, Figure 4 disclosed the manufacturing steps of a guidewire. As shown in the last two drawings on the right side, the space between the windings of the coil wound around the core increased closer to the tip. This was an unavoidable effect of the curve of the guidewire becoming smaller towards the tip. Due to the larger spacing between the windings of the coil closer to the tip, the stiffness of the tip decreased towards the tip according to Features D to F.

E6, Figures 2 to 4 disclosed a guidewire with a movable, stiffer core 31. This guidewire had a pre-formed configuration with a radius of curvature which decreased, similarly to in Figure 5 of the patent. When the movable core was in a position intermediate to those of Figures 3 and 4, its end portion was allowed to turn through just more than 270°. In this configuration, the guidewire had both the shape and the stiffness according to Features A to F.

E14, Figure 15A showed a guidewire having a curved tip which turned through more than 270° and a stiffness which decreased due to a reduction in diameter. Features B to F were thus disclosed in E14.

Inventive step

The subject-matter of claim 1 did not involve an inventive step starting from E2, E14, E4 or E15.

The subject-matter of claim 1 differed from the guidewires in Figures 1 and 4 of E2 in Features B and C. They solved the technical problem of reducing the risk of penetration of a vessel.

Both E1 and E3 addressed the same problem and showed guidewires having distal end portions curved according to Features B and C as a solution to this problem. In view of these teachings, it would be obvious to the skilled person to provide the guidewire of E2 with such tips, thus arriving at the guidewire according to claim 1.

The subject-matter of claim 1 differed from the guidewire in Figure 15A of E14 in Features B and C. Thus, the same problem was solved as when starting from the guidewire of E2, and the solution to the problem was equally obvious in view of E1 and E3 but also in view of Figure 5C of E14 itself.

The subject-matter of claim 1 differed from the guidewire in E4 in Feature F. The problem solved was thus to provide an alternative guidewire reducing the risk of penetration of a vessel. The starting point of the decreasing stiffness could only be in the curved distal end portion or the straight portion before it. Positioning this starting point in the straight portion was thus an obvious alternative which was also known from, e.g. E2, Figure 6.

The subject-matter of claim 1 differed from the guidewire disclosed in E15, Figure 8 in Feature C. This solved the problem of minimising the likelihood of puncturing a vessel. E1, E3 and E4 addressed this problem and disclosed that a curved distal end portion having a radius of curvature decreasing towards the tip solved the problem posed. Applying this teaching to the guidewire of E15 was therefore obvious to the skilled person.

Extension of subject-matter

Claims 5 and 7 extended beyond the content of the application as filed.

Claim 5 did not require that the change in stiffness be due to a reduction of the diameter of the core wire, but this was disclosed in claims 11 and 12 upon which this claim was based. Claim 7 did not require that the Fibonacci sequence start at the tip, but this was disclosed in claims 17 upon which this claim was based.

Reasons for the Decision

1. Main request - Novelty

The subject-matter of claim 1 of auxiliary request 1 is new for the following reasons.

1.1 E1

It is common ground that Figures 5A to 5C of E1 disclose Features A and B of claim 1.

The opponents submit that the guidewire in these figures also shows Features D to F. Since various parts of the guidewire were dimensioned, the drawings were technical drawings of high accuracy and not schematic drawings as commonly found in patent documents. The drawings showed that a tapering of the diameter of the guidewire started on a straight portion and that it continued via the fillet until the thinner curved end portion. Figure 5C showed that the fillet was tilted with respect to the straight portion and thus was part of the curved end portion of the guidewire. Since the stiffness of the guidewire was proportionate to its diameter, it followed that the stiffness of the wire decreased continuously starting from the fillet along the length of the distal end portion according to Features D, E and F.

However, although Figures 5A to 5C are partly dimensioned, these drawings are not so detailed and of such high quality that it could be deduced directly and unambiguously from them that the portion of the guidewire with the fillet belongs to the curved end portion.

Moreover, as pointed out by the proprietor, page 8, paragraph 2, lines 2 to 4 describe that the distal portion has an approximately 0.008 inch diameter which has been tapered by grinding, stretching, etc. to a diameter of approximately 0.004 inches to allow it to be formed into a smaller diameter spiral. This indicates that the spiral starts in the thinner section of the wire having the constant diameter of approximately 0.004 inches but not at the fillet. Since it is not directly and unambiguously disclosed that the fillet belongs to the spiral and since the cross sectional diameter of the guidewire beyond the fillet

is constant, Figures 5a – 5c of E1 do not disclose that the cross sectional diameter of the spiral (i.e. the curved end portion in the terminology of the claim) decreases anywhere along its length. A corresponding decrease in stiffness along the curved distal end portion is therefore also not directly and unambiguously disclosed.

The subject-matter of claim 1 thus differs from the guidewire of E1 in Feature D and consequently also Features E and F.

1.2 E2

The opponents submit that the guidewire in Figures 1 or 4 has a distal end portion according to Features B and C. The distal end portion started with the bend 14 and turned more than 270°. They also submit that since the core of the J-tip 25 was tapered as shown in Figure 6 and described in column 8, lines 14 to 17, the stiffness decreased according to Features D to F.

However, Features B and C define a pre-formed curve of the distal end portion of the guidewire and require that the radius of curvature of the curve decrease towards the tip. Thus, the radius of curvature must not increase in the curved distal end portion. However, the radius of curvature of the guidewire of E2 increases to infinity after the first bend 14 since that portion is straight. This guidewire does thus not have a distal end portion according to Features B and C.

The subject-matter of claim 1 thus differs from the guidewire of E2 in Features B and C.

1.3 E3

It is common ground that Figure 4 discloses a guidewire according to Features A and B of claim 1.

The opponents submit that the two lower drawings on the right side of Figure 4 show an increasing distance between the windings of the coil 16 (which is positioned around the core 11) towards the tip of the guidewire, most clearly around 11 o'clock. Such a change in distance between the coils was inevitable since the guidewire was a spiral. In their view, this led to a change of stiffness according to Features D, E and F.

It is true that these drawings seem to show that the distance of the windings of the coil becomes larger towards the tip of the guidewire. In theory, this could lead to a reduction of stiffness of the finished guidewire. However, as pointed out by the proprietor, the mechanical properties of the guidewire depend also on the material properties, which are greatly influenced by the heat treatments of the core and the coil described in paragraphs [0027] and [0031]. Furthermore, the core and coil are brazed or soldered after assembly. This also influences the stiffness of the finished guidewire, in particular at and around the connection points. This is due both to the mechanical connection(s) and the effect of heating the areas around the connection points during soldering and brazing. In the absence of any further information, the stiffness of the end portion of the guidewire of E3, in particular whether the stiffness changes, remains unknown. Features D to F are therefore not directly and unambiguously disclosed in E3.

The subject-matter of claim 1 thus differs from the guidewire of E3 in Features D to F.

1.4 E6

The guidewire in Figures 2 to 4 of E6 has a fixed core 33 with a pre-formed shape and a movable, stiffer core 31 (see, e.g. column 4, line 6). The shape of the distal end portion changes with the position of the movable core.

The opponents submitted that when the movable core 31 was positioned such that the curve of the distal end portion was just more than 270°, somewhere between its positions in Figures 3 and 4, the guidewire had a distal end portion curved according to Features B and C. In view of Figure 5 of the patent, which had a similar shape to that in Figure 4 of E6, Feature C was not restricted to a continuously decreasing radius of curvature but just needed to decrease somewhere along its length towards the tip. In this configuration, the stiffness of the guidewire decreased according to Features D and E. The decrease of the stiffness would start at the taper of the movable core 31, and this taper would be positioned in a straight portion of the guidewire as required by Feature F.

It is correct that Figure 5 of the patent shows the guidewire of the patent in a shape somewhat similar to that of the guidewire in E6. However, this figure shows the guidewire of the patent when it is positioned in and distorted by the walls of the heart. As set out above for E2, Features B and C define a pre-formed curve of the distal end portion of the guidewire, i.e. its undistorted shape, and require that the radius of

curvature of the curve decrease towards the tip. It must therefore not increase toward the tip.

The guidewire in E6 does not have such a curve. On the contrary, after the first 180° bend in Figure 4, the radius of curvature increases again, as is also described in column 4, lines 4 to 10. More importantly, however, the opponents consider the guidewire of E6 in a configuration when the movable core 31 is positioned such that the distal end portion has a curve turning just more than 270°. Yet the exact shape of the distal end portion of the guidewire in this configuration is neither shown in the figures nor described elsewhere in E6. Thus, it is not disclosed that the guidewire in this configuration has a curve with a radius of curvature that decreases towards the tip according to Feature C.

Furthermore, while the movable core 31 of the guidewire of E6 is stiffer than the fixed core 33 (see column 3, line 65 to column 4, line 10), the overall change in stiffness of the guidewire is not described in E6. It is possible that the stiffness is higher at the ball shaped tip 39 of the movable core 31 than at the thinner portion or at the taper behind this tip. Therefore, while the stiffness of the distal end portion of this guidewire changes, it is not directly and unambiguously disclosed that the stiffness decreases along the length of the curved distal end portion towards the tip. Feature D and consequently Feature E are thus not disclosed in E6.

Finally, even if the stiffness of the movable core 31 decreases from its constant diameter portion to its tapering portion, the position of this taper in the hypothetical 270° configuration referred to by the

opponents is not known. It is thus not directly and unambiguously disclosed that this taper would be in a straight portion of the guidewire as required by Feature F. Feature F is therefore not directly and unambiguously disclosed in E6 either.

The subject-matter of claim 1 thus differs from the guidewire of E6 in Features C to F.

1.5 E14

The guidewire in Figure 15A of E14 has a distal end section with a curve which first turns in one direction and just before the end turns in the other direction.

According to the opponents, the patent did not define how the angle of the curve should be measured. Figures 7A and paragraph [0031] of the patent suggested that it should be measured relative to the centre of curvature of the part of the curve which had the smallest radius of curvature. Measuring the outer angle through which the curved portion of the guidewire in Figure 15A turns relative to the centre of curvature, the angle was more than 270° as required by Feature B. Furthermore, as already set out for E6, Feature C did not require a continuously decreasing radius. The guidewire of E14 thus had a distal end portion curved according to Features B and C.

However, neither Figure 15A nor paragraph [0031] suggests that the only relevant centre of curvature should be the one relating to the smallest radius of curvature. Moreover, the skilled person would normally measure the degree by which a curve turns in the way an observer would turn when moving along the curve. Finally, the skilled person would understand Feature B

as referring to one (single) curve, while the end portion of the guidewire of E14 as being made of two curves, one turning in one direction, the second in the opposite direction. Therefore, E14 does not disclose Feature B.

Furthermore, the distal end portion of the guidewire has a curve having a radius of curvature which first decreases and then increases. As set out for E6, the skilled person would not see this as a curve having a radius of curvature that decreases towards the tip.

Features B and C are thus not disclosed in E14.

The subject-matter of claim 1 thus differs from the guidewire of E14 in Features B and C.

2. Main Request - Inventive step

The subject-matter of claim 1 involves an inventive step.

2.1 Starting from E2

As set out above, the subject-matter of claim 1 differs from the guidewire shown in Figures 1 and 4 of E2 in combination with the J-tip 25 provided with a tapered core as shown in Figure 6 in Features B and C.

2.1.1 The problem solved by these features is to reduce the likelihood of the guidewire tip penetrating the wall of a vessel.

2.1.2 The opponents submit that E1, page 8, lines 4 to 5 addresses the same problem and teaches a solution to this problem in the form of a spiral distal end portion

according to Features B and C. Providing the guidewire of E2 with such an end portion would be obvious to the skilled person and result in a guidewire according to claim 1.

However, as set out for novelty in view of E1, this document does not directly and unambiguously disclose that the cross sectional diameter of the spiral end portion decreases but rather that the spiral has a constant cross sectional diameter. The skilled person is thus taught by the disclosure of E1 that the solution to the problem of reducing the risk of the tip penetrating a vessel is a spiral end portion turning more than 270° and having a constant cross sectional diameter. There is no teaching in E1 which would induce the skilled person to apply the teaching of a curved end portion turning through more than 270° in isolation. Therefore, if they were to apply the teaching of E1 to the guidewire of E2, they would also apply the teaching of the spiral having a constant cross sectional diameter. The resulting guidewire would thus have a distal end portion with a constant cross sectional diameter, and this would not have a stiffness which decreases along the length of a curved distal end portion towards the tip as required by Features D to F.

The skilled person would thus not arrive at a guidewire according to claim 1 even if applying the teaching of E1 to the guidewire of E2.

2.1.3 The opponents further submit that E3, paragraph [0003] described that a loop shaped end portion would solve the problem posed. It would thus be obvious to the skilled person to provide the guidewire of E2 with a looped end portion as shown in Figure 4 of E3, and this would also result in the guidewire of claim 1.

However, as set out by the proprietor, paragraph [0003] of E3 does not explain that a looped end portion has any particular advantage over a J-tip.

E3 does thus not provide any reason for the skilled person to replace the J-tip of the guidewire of E2 with a looped end portion as shown in Figure 4 of E3. Furthermore, even if they did, they would apply the complete teaching of E3 on the distal end portion, and not just that it is looped. As set out above for novelty, the distal end portion of the guidewire of E3 does not have a decreasing stiffness according to Features D to F.

Providing the guidewire of E2 with a distal end portion as shown in E3 would thus not result in a guidewire according to claim 1.

2.1.4 The subject-matter of claim 1 is thus not obvious when starting from the guidewires in Figures 1 or 4 of E2.

2.2 Starting from E14

As set out for novelty, the subject-matter of claim 1 differs from the guidewire in Figure 15A of E14 in Features B and C.

The problem solved is thus the same as when starting from the guidewire of E2 and is to reduce the likelihood of the guidewire tip penetrating the wall of a vessel.

2.2.1 According to the opponents, it would be obvious to provide the guidewire in Figure 15A with a distal end portion according to Features B and C in view of E1, E3

or Figure 5C of E14 in order to solve the problem posed.

However, the tip of the guidewire in Figure 15A of E14 has a geometry adapted for entry into specific vessels. The very tip of the guidewire turns outwardly instead of curving inwardly. The skilled person would have no reason to change this carefully selected geometry of the distal end portion of this guidewire.

Furthermore, even if they did change the geometry of the distal end portion based on the teachings of E1, E3 or Figure 5C of E14, they would transfer the complete teaching on the distal end portion. As set out above, the distal end portions of the guidewires of E1 or E3 do not have a decreasing stiffness according to Features D to F. The opponents have not shown that the curved distal end portion in Figure 5C of E14 has a decreasing stiffness either. Thus, even if the skilled person were to modify the distal end portion of the guidewire in Figure 15A of E14 in accordance with the teachings of E1, E3 or Figure 5C of E14, they would not arrive at a guidewire according to claim 1.

2.2.2 The subject-matter of claim 1 is thus not obvious when starting from the guidewires in Figure 15A of E14.

2.3 Starting from E4

Figure 1 of E4 discloses a guidewire which has a stiff zone 3, a transition zone 11 to semi-stiff, a transition zone 13 to relatively flexible and a flexible zone 15. The stiff zone continues into the first bend of the guidewire. It is undisputed that this guidewire shows Features A, B, D and E.

2.3.1 According to the opponents, the subject-matter of claim 1 differs from this guidewire only in Feature F, which defines that the decrease in stiffness of the guidewire starts on a straight portion. In paragraph [0015] of the patent, this position is described to solve the problem of kinking, but this was already solved by E4. The objective technical problem was thus to provide an alternative guidewire reducing the risk of penetration of a vessel. The starting point of the decrease of stiffness could only be positioned in the bend or on the straight portion before it. Moving it to the straight portion would be an obvious alternative in view of, e.g. E2, Figure 6.

2.3.2 However, as pointed out by the proprietor, Figure 1 of E4 shows that the guidewire has a straight portion between the larger and smaller bends. The curve of the distal end portion does not therefore have a radius of curvature which decreases towards the tip as required by Feature C. The subject-matter of claim 1 therefore differs from the guidewire in E4, not only in Feature F but also in Feature C.

Furthermore, the guidewire of E4 is designed to be inserted into the aortic bend. The stiff part of the larger bend helps in positioning the guidewire correctly. Thus, even if the problem to be solved is seen as providing an alternative guidewire, the skilled person would not move the point of transition from the stiff to the semi-stiff zone out of the bend since this would be disadvantageous for the intended use of the guidewire of E4. Furthermore, even if the skilled person did so, the resulting guidewire would not have a distal end section with a curve having a decreasing radius of curvature according to Feature C.

2.3.3 The subject-matter of claim 1 is thus not obvious starting from the guidewire of E4.

2.4 Starting from E15

Figure 8 of E15 undisputedly discloses a guidewire according to Features A and B.

2.4.1 According to the opponents, paragraph [0030] of the translation E15' disclosed that the distal end portion had a tapered core. Consequently, it had decreasing stiffness. In Figure 8, it could be seen that the taper started in the straight portion of the guidewire. Furthermore, due to the decreasing radius of curvature, the distance between the windings of the coils were larger closer to the tip. For both these reasons, the stiffness decreased towards the tip of the distal end portion. Features D to F were thus disclosed in E15.

The subject-matter of claim 1 thus only differed in Feature C, which solved the problem of minimising the likelihood of puncturing a vessel.

E1, E3 and E4 all taught to make a curved distal end portion with a decreasing radius of curvature towards the tip to minimise the risk of puncturing a vessel. It would have been obvious to the skilled person to apply this teaching on the guidewire of E15 to solve the problem posed.

However, paragraph [0030] of E15' describes Figure 3 of E15 and not Figure 8. In Figure 3, the core tapers to a thinner cross section which seems to remain constant. Paragraph [0041] describes that Figure 8 is a distal end portion of the embodiment of Figure 3. It is therefore not clearly and unambiguously disclosed

whether the core of the guidewire in Figure 8 tapers all the way to the tip or whether it has a constant diameter in the curved distal end portion. Furthermore, as set out for E3, the overall stiffness of the guidewire depends not only on the geometry but also on the mechanical properties of the materials, which are heavily influenced by how they have been shaped and by heat treatments. It can therefore not be deduced from the figures alone that the stiffness of the curved distal end portion decreases along its length towards the tip. Feature D and consequently also Features E and F are therefore not directly and unambiguously disclosed in E15.

As set out above, neither E1 nor E3 directly and unambiguously disclose a guidewire having a distal end portion with a stiffness which decreases towards the tip according to Features D to F. Therefore, even if the skilled person were to apply the teaching on the distal end sections of these guidewires to the guidewire of E15, they would not arrive at a guidewire according to claim 1.

As also set out above, the guidewire of E4 does not show a radius of curvature according to Feature C, nor that a decrease in stiffness should start in a straight portion of the guidewire according to Feature F. Thus, even if the skilled person were to apply the teaching on the distal end section of the guidewire of E4 to the guidewire of E15, they would not arrive at a guidewire according to claim 1.

2.4.2 The subject-matter of claim 1 is thus not obvious when starting from the guidewire of E15.

3. Main request - Extension of subject-matter

The subject-matter of claim 5 does not extend beyond the content of the application as filed, but the subject-matter of claim 7 does.

3.1 Claim 5

Claim 5 is based upon claim 12 as originally filed and defines that the guidewire comprises an inner core within an outer coil and that the change in stiffness results from a change in diameter of the core wire.

Claim 12 as filed was dependent on claim 11 as filed, which defined that the change in stiffness resulted from a reduction in the diameter of the guidewire or a component thereof.

3.1.1 According to the opponents, since granted claim 5 did not require that the change in stiffness result from a reduction in the diameter of the guidewire, it extended beyond the content of the application as filed.

3.1.2 However, granted claim 5 explicitly defines that the change in stiffness results from a change in diameter of the core wire.

The only change in stiffness defined in the preceding claims can be found in Feature D of claim 1. It states that the stiffness decreases along the length of the curved distal end portion towards the tip of the guidewire. The change in diameter in the core wire of claim 5 must thus be a reduction.

Granted claim 5 therefore defines exactly what was disclosed in claim 12 as filed in combination with claim 11 as filed.

3.2 Claim 7

Claim 7 has its basis in claim 17 as originally filed. In alternative (b), it defines that that the curvature of the distal end portion increases for every 90 degrees of curvature according to a Fibonacci sequence.

Claim 17 as filed disclosed that "starting from the tip the radius of curvature of the distal end portion increases every 90 degrees of curvature according to a Fibonacci sequence" (emphasis added by the Board).

3.2.1 The patent proprietor submits that the skilled person would read claims 1, 6 and 7 in combination and that therefore claim 7 could only refer to the distal end portion. The wording thus referred to the entire curved distal end portion, not just a portion of it. Since the radius of curvature increased every 90 degrees, the entire curved distal end section must follow the Fibonacci sequence and thus started at the tip.

3.2.2 However, a curvature following a Fibonacci sequence always changes for every 90 degrees. The definition that the curvature increases for every 90 degrees therefore neither explicitly nor implicitly defines a starting point for the Fibonacci sequence. Claim 7 as granted also does not define that the entire distal end portion follows such a sequence.

Claim 7 thus encompasses embodiments where the Fibonacci sequence does not start at the tip but somewhere else along the distal end portion. Such a

distal end portion is not disclosed in claim 17 as filed.

Claim 7 as granted thus extends beyond the content of the application as filed contrary to Article 123(2) EPC.

4. Main Request - Summary

The ground for opposition under Article 100(c) EPC in conjunction with Article 123(2) EPC prejudices the maintenance of the patent as granted since the subject-matter of claim 7 as granted extends beyond the content of the application as filed.

5. Auxiliary Request 1

In Auxiliary Request 1, claim 7 as granted has been deleted.

The only reason for which the patent as granted cannot be maintained has thus been overcome. No objections which go beyond the grounds for opposition against the main request were raised against Auxiliary Request 1. It follows that Auxiliary Request 1 meets the requirements of the EPC and thus is allowable.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated