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

Datasheet for the decision of 28 November 2013

Case Number: T 2121/11 - 3.2.08

Application Number: 00300793.7

Publication Number: 1025812

IPC: A61F2/06

Language of the proceedings: EN

Title of invention:
An intravascular stent having tapered struts

Patent Proprietor:
Nitinol Development Corporation

Opponent:
Angiomed GmbH & Co. Medizintechnik KG

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54(3), 56
EPC 1973 Art. 54(4)

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2121/11 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 28 November 2013

Appellant: (Opponent)	Angiomed GmbH & Co. Medizintechnik KG Wachhausstrasse 6 76227 Karlsruhe (DE)
Representative:	HOFFMANN EITLE Patent- und Rechtsanwälte Arabellastrasse 4 81925 München (DE)
Respondent: (Patent Proprietor)	Nitinol Development Corporation 48501 Warm Springs Boulevard, Suite 117 Fremont, California 94539 (US)
Representative:	Mercer, Christopher Paul Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 August 2011 rejecting the opposition filed against European patent No. 1025812 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman: P. Acton
Members: M. Alvazzi Delfrate
D. T. Keeling

Summary of Facts and Submissions

I. By decision posted on 16 August 2011 the opposition division rejected the opposition against the European patent No. 1 025 812.

II. The appellant (opponent) lodged an appeal against this decision on 27 September 2011, paying the appeal fee on the same day. The statement setting out the grounds for appeal was filed on 21 December 2011

III. Oral proceedings before the Board of Appeal were held on 28 November 2013.

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

The respondent (patent proprietor) requested that the appeal be dismissed or that the patent be maintained in accordance with one of the auxiliary requests 1 to 3 filed with letter of 16 July 2012.

V. Claim 1 as granted (main request) reads as follows:

"A stent for insertion into a vessel of a patient, said stent comprising;

a) a tubular member having a thickness and having front and back open ends (81) and (82) and a longitudinal axis (83) extending therebetween, said member having a first smaller diameter for insertion into said vessel, and a second larger diameter for deployment into said vessel; and

b) said tubular member comprising a plurality of adjacent hoops (52) extending between said front and

back ends, said hoops comprising a plurality of longitudinal struts (60) each having opposing ends (90) and (92) and a center (94) therebetween, said ends of said struts are shaped to form a plurality of loops (62) connecting adjacent struts at said ends of said struts, said member further comprising a plurality of bridges (70) connecting adjacent hoops to one another which stent is a self-expanding stent, made from a Nickel Titanium alloy which exhibits superelastic properties at body temperature, said alloy comprising from about 50.5 percent to about 60 percent Nickel and the remainder comprising Titanium, characterised by each strut having a width which is greater at its ends than at its center."

The auxiliary requests are not relevant for the present decision.

VI. The following documents played a role for the present decision:

E1: WO -A- 99/16387;
E2: "Specifying NiTi Materials" from Johnson Matthey website;
E3: "Shape memory alloy" from Wikipedia;
E4: "Thermal Analysis in Metallurgy" (1992), pages 188-201;
E8: Kohl et al. "Stress-Optimised Integrated Linear Actuators with Shape Memory Effect" Actuator 96, 5th Int. Conference on New Actuators 26-28 June 1996, Bremen, Germany;
E9: Skrobanek et al. "Stress-Optimised Shape Memory Microactuator ", Third ICIM/ECSSM Lyon '96;
E10: Skrobanek et al. "Stress-Optimised Shape Memory Microvalves ",1997 IEEE;

E11: Kohl et al. "Linear Microactuators Based on the Shape Memory Effect" TRANSDUCERS 97 (1997);
E12: Kohl et al. "Linear microactuators based on the shape memory effect" Sensors and Actuators A70 (1998), pages 104-111;
E13: Kohl et al. "Development of stress-optimised shape memory microvalves" Sensors and Actuators 72 (1999)
E14: FR -A- 2 764 794;
E15: US -A- 5 860 999;
E17: US -A- 4 893 623;
E19: Pelton et al. "Experimental and FEM Analysis of the Bending Behavior of Superelastic Tubing", Proc. of the First Int. Conf. on Shape Memory and Superelastic Technologies, 1994;
E21: Trépanier et al. "In Vivo Biocompatibility Study of NiTi Stents", Proc. of the Second Int. Conf. on Shape Memory and Superelastic Technologies, 1997;
E22: WO -A- 96/26689;
E24: WO -A- 97/27959;
E26: EP -A- 0 812 928;
E27: US -A- 4 770 725;
E28: Phukaluan et al. "Effect of Ni-Content on Mechanical and Transformation Behavior of NiTi Shape Memory Alloys for Orthodontics Applications" The First TSME International Conference on Mechanical Engineering (2010);
E29: Balcon et al. "Recommendations on stent manufacture, implantation and utilization" European Heart Journal (1997), pages 1536-1547;
E30: Duerig et al. "A comparison of balloon- and self-expanding stents", Min Invas Ther & Allied Technol 2002: 11(4), pages 173-178;
E33: Duerig et al. "TiNi Shape Memory Alloys" in Material Properties Handbook Titanium Alloys (1994), pages 1035-1048;

E34: Duerig et al. "The Use of Superelasticity in Medicine", Metall- Fachzeitschrift für Handel, Wirtschaft, Technik und Wissenschaft (1996), pages 569-574; and
E35: Declaration of Wilson Tsang.

VII. The arguments of the appellant can be summarised as follows:

Novelty

Document E1 disclosed a stent with all the features of claim 1.

It was true that this prior art stent comprised also a hoop whose struts had a constant width. However, this was not excluded by the wording of claim 1, which merely required that the stent comprised a plurality of hoops whose struts had a width varying according to characterising portion of the claim.

Moreover, E1 disclosed that the stent was formed of a shape memory and/or superelastic Ni-Ti alloy. It was true that the composition of this alloy was not disclosed *expressis verbis*. However, the person skilled in the art, who was not a metallurgist but rather somebody who was employed in the production of stents, was aware that at the time of publication of this document the only Ni-Ti alloy used for the production of stents had a composition comprising 50.8 at% of Ni, as evidenced by documents E19, E21, E24, E26, E28, E33 and E34. Therefore, for the person skilled in the art a composition in accordance with claim 1 was also clearly and unambiguously disclosed in E1.

Hence, the subject-matter of claim 1 lacked novelty.

Inventive step

Starting from E22 as closest prior art, the object of claim 1 solved two partial problems.

The mechanical properties were optimised by the choice of the alloy composition, while the strut geometry defined in the characterising portion of the claim served to improve the fatigue lifetime.

Since the composition range defined in claim 1 comprised the standard shape memory alloy composition used for stents, it was obvious to choose it to solve the first partial problem.

As to the second partial problem, the improvement of fatigue lifetime was - as shown by E29 - a constant goal in the production of stents. Moreover, it belonged to the common general knowledge of the person skilled in the art that this result was to be achieved by the avoidance of stress concentration. This was obtained by a uniform distribution of the strain. The formula that governed this distribution for a rectangular beam was known to every undergraduate student. This formula rendered it obvious to avoid stress concentration by reducing the width away from the fixed end-point of the beam. In documents E8 to E13 this teaching was applied to components made of shape memory alloys. Hence, it was obvious to apply the same teaching to the stent of E22 by reducing the width of the struts in the portions which were far away from the loops. This could be done without difficulty, as evidenced in E17, where the strength of a stent had been improved by shaping the struts in such a way. Accordingly, it was obvious to try to improve the fatigue lifetime by a geometry in

accordance with claim 1. The fact that this had not been tried in the prior art was only dictated by economic considerations, due to the difficulties of producing such a shape by laser cut, rather than by technical considerations. These economic considerations, however, could not play a role in the assessment of inventive step.

Therefore, the subject-matter of claim 1 did not involve an inventive step.

VIII. The arguments of the respondent can be summarised as follows:

Novelty

The stent disclosed in E1 comprised also a hoop whose struts had a constant width. By contrast, the wording of claim 1 stipulated that each strut has a width which is greater at its ends than at its center.

Moreover, E1 did not clearly and unambiguously disclose that the stent was made of a Ni-Ti alloy with a composition in accordance with claim 1. The range of transformation temperatures disclosed on page 5, lines 22 to 25, did not identify a specific alloy composition. First, this passage did not specify which transformation temperature was intended. Furthermore, the transformation temperatures of shape memory alloys depended on the thermo-mechanical treatments and did not univocally identify an alloy composition, as evidenced by E2 to E4, E27 and E35.

As to the documents cited by the appellant, they could not substantiate the common general knowledge of the person skilled in the art and did not prove that only a

50,8 at% Ni was used in the production of stents at the publication date of E1.

Hence, the subject-matter of claim 1 was novel.

Inventive step

Starting from E22, the object to be achieved by the claimed invention was not merely an improvement of the fatigue lifetime, but rather a general amelioration of the stent properties. To this purpose the claimed stent relied on the geometry of the struts and on the composition of the alloy, which both provided an improved fatigue lifetime.

E22 itself did not suggest an amelioration in the stent by improving its fatigue lifetime.

Moreover, also considering this issue, the common general knowledge of the person skilled in the art would not have led him to the claimed solution. As evidenced by E29, E30 and E34 the behaviour of Nitinol and self-expanding stents was different from that of other materials and other type of stents, i.e. balloon expanding ones. Accordingly, the solutions developed for the latter materials and stents could not be transferred to the stent of E22.

Nor could E8 to E13, which related to a completely different field, have hinted at the claimed solution. As to E17, it was not concerned with the problem of fatigue, because it dealt with a stent for the prostate.

If any solution would have been considered by the person skilled in the art, this would have been the

solution envisaged by E14, whose stent had struts with a different shape from that proposed by claim 1.

Therefore, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Novelty.

2.1 E1 is a document belonging to the prior art under Article 54(3) EPC and Article 54(4) EPC1973 (which is applicable to the patent in suit). Accordingly, it is relevant solely to the issue of novelty.

2.2 For an invention to lack novelty, its subject-matter must be directly and unambiguously derivable from the prior art. The disclosure of the prior art is determined by what knowledge and understanding can and may be expected of the average skilled person in the technical field in question (see Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, I.C.3).

2.3 E1 relates to a stent which can be made of shape memory Ni-Ti alloy (see page 3, lines 18 to 20 and page 5, lines 13 to 15). However, no text passage indicates the composition(s) of this alloy.

Nor does the passage on page 5, lines 22 to 25, which discloses that the transformation temperature of the nickel-titanium alloy can be selected to be in a range

of, for example, 23°C to 36 °C, so that the stent can be radially collapsed without the need for a coolant, identify a specific alloy composition. First of all this passage does not specify which of the plurality of transition temperatures exhibited by a shape memory alloy (As, Af, Ms, Mf) is to be considered. Moreover, these temperatures are influenced by the thermo-mechanical treatments and do not unequivocally identify a specific alloy composition, let alone a composition in accordance with claim 1 (see E35, second page, first two paragraphs; E27, column 11, lines 43 to 48 or E4, page 195, second full paragraph).

2.4 The appellant submitted that the person skilled in the art, i.e. somebody who was employed in the production of stents, was aware that at the time of publication of E1 the only Ni-Ti alloy used for the production of stents had a composition comprising 50.8 at% of Ni, as evidenced by documents E19, E21, E24, E26, E28, E33 and E34.

E19 is a scientific article about the bending behavior of superelastic tubing which discloses tests carried out on a 50.8% Ni-Ti alloy (see drawings). E21 is also a scientific article, about in vivo biocompatibility of NiTi stents, disclosing that the samples were manufactured from a 50.8% Ni-Ti alloy (see page 424, last paragraph). E24, is a patent document which discloses a stent made of Ni-Ti superelastic material that typically is a binary material such as "NI(50.8 WT%) and TI or a ternary alloy such as NiTi-V" (see page 15, lines 17 to 19). E26 is also a patent document describing a method of treatment of shape memory alloys being binary, ternary and quaternary Ni-Ti alloys (see column 4, lines 50 to 57), to be used also in the production of stents (see column 6, lines 15 to 24); a

stent might be formed from a Ni-Ti binary alloy containing 50.5 to 52 at.% Ni (see column 7, lines 11 to 13). E28 is a scientific paper about the effect of Ni content on mechanical and transformation behaviour of NiTi shape memory alloys for orthodontics applications which discloses that nominal compositions with 50.4 and 50.6 at% Ni provide an Af transformation temperature close to the oral temperature. E33 is an extract from a properties handbook of titanium alloys published in 1994 and discloses that generally, Ti-Ni alloys with 49.0 to 50.7 at% Ti were commercially common, with superelastic alloys in the range 49.0 to 49.4 at% Ti and shape memory alloys in the range of 49.7 to 50.7 at% Ti (see bottom of page 1036). E34 is an article about the use of superelasticity in medicine, which discloses that although a large number of Ni-Ti ternary alloys have been introduced, none have been objectively shown to be superior to simple binary Ni-Ti with between 50.6 and 51.0 at% Ni (see first page, center column, first paragraph).

It is highly questionable whether this collection of documents, which comprises patent documents and scientific publications in the field of metallurgy, can represent the common general knowledge of a practitioner employed in the production of stents. Moreover and most important, although some of them disclose that a Ni-Ti alloy comprising 50.8 at% of Ni was used for the production of stents none of these documents discloses that, as submitted by the appellant, this alloy was the only Ni-Ti alloy used for the production of stents, let alone that this was part of the common general knowledge of the person skilled in the art in the field of E1.

Therefore, the appellant's argument is not convincing.

2.5 Hence, a stent with a composition in accordance with claim 1 is not directly and unambiguously derivable from E1.

Accordingly, the subject-matter of claim 1 is novel.

3. Inventive step

3.1 E22 represents the closest prior art and relates to a stent for insertion into a vessel, typically a blood vessel of a patient, comprising a tubular member having a thickness and having front and back open ends and a longitudinal axis extending therebetween (see the drawings). This member has a first smaller diameter for insertion into the vessel, and a second larger diameter for deployment into it (see claim 1). The tubular member comprises a plurality of adjacent hoops (16) extending between the front and back ends, those hoops comprising a plurality of longitudinal struts (18) each having opposing ends and a center therebetween, the ends of the struts being shaped to form a plurality of loops connecting adjacent struts at the ends of the struts (19a, 19b), said member further comprising a plurality of bridges (20) connecting adjacent hoops to one another (see the drawings).

3.2 However, the width of the struts depicted in the drawings is the same at their ends as at their center. Hence, E22 does not disclose that each strut has a width which is greater at its ends than at its center.

Moreover, although E22 discloses that Nitinol alloy may be used (see page 5, lines 14 to 15), it does not clearly and unambiguously disclose that this alloy

comprises from about 50.5 percent to about 60 percent Nickel and the remainder comprising Titanium.

3.3 The Board concurs with the appellant that the first of these distinguishing features, i.e. the shape of the struts, is conducive to the solution of the problem of improving fatigue lifetime, a constant goal in the production of stents (see E29, page 1539, left-hand column "Fatigue testing").

3.4 However, irrespective of whether the choice of the alloy's composition also contributes to the solution of this problem, the Board is not convinced that it was obvious to shape the struts of the stent of E22 to have a width which is greater at its ends than at its center for this purpose.

3.4.1 It is true that the formula for the calculation of the deflection of a rectangular beam fixed at its end point belongs to the common general knowledge of the person skilled in the art. However, the geometry of the stent of E22 is completely different from the geometry considered in that formula. Moreover, the known equation applies to homogenous, linearly elastic materials. By contrast, the behaviour of a superelastic alloy under stress is far from being assimilable to that of a linear material. Indeed it was known that results obtained for a given geometry or material could not simply be extrapolated to others (see E29, page 1537, right-hand column, second full paragraph; E34, last page, left-hand column, last paragraph). Therefore, the common general knowledge of the person skilled in the art would not suggest that the problem defined above could be solved by shaping the struts in accordance with claim 1.

3.4.2 Nor did the documents E8 to E13 or E17 teach in this direction.

E8 to E13 relate to a completely different field, namely linear actuators, and involve a different geometry, so that it would not have been obvious for the person skilled in the art to consult them in his search of a solution to the given problem.

As to E17, it relates to a stent which is not made of a superelastic material and, most important, is not subject to fatigue, since it is used in the treatment of hypertrophy of the prostate gland. Indeed the shape of the struts shown in its Figure 21, with the center narrower than the end portions, does not serve to improve fatigue lifetime but to minimize the amount of prosthetic material while maintaining sufficient strength. Therefore, E17 does not hint at the claimed solution either.

3.5 Accordingly, the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

V. Commare P. Acton

Decision electronically authenticated