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Datasheet for the decision of 6 November 2012

Case Number: T 0748/09 - 3.2.08

Application Number: 03002905.2

Publication Number: 1444993

IPC: A61L 27/04, A61L 31/02, A61L 31/18

Language of the proceedings: EN

Title of invention:
Improved metal alloy for medical devices and implants

Patentee:
W.C. Heraeus GmbH

Opponent:
Boston Scientific Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 83, 107, 123(2)
EPC R. 99(1)(a), (c)

Relevant legal provisions (EPC 1973):
EPC R. 64(b)

Keyword:
"Admissibility of appeals - yes"
"Disclaimer not allowable"
"Patentability of the subject-matter underlying the decision of the opposition division - yes"

Decisions cited:
G 0003/89, G 0011/91, G 0001/93, G 0001/03, G 0002/03, G 0002/10, T 0001/88, T 2164/10

Catchword:
Allowability of an undisclosed disclaimer (see point 2.3.3).

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0748/09 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 6 November 2012

Appellant I: (Patent Proprietor)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 6 February 2009 concerning maintenance of European patent No. 1444993 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
A. Pignatelli

Summary of Facts and Submissions

I. Opposition was filed against European patent No. 1 444 993 as a whole by present appellant I (opponent).

II. By its interlocutory decision dispatched on 6 February 2009 the opposition division held that the subject-matter of the claims according to the first auxiliary request then on file met the requirements of the EPC and that the patent could be maintained in amended form on the basis of this request.

III. On 1 April 2009, appellant I lodged an appeal against this decision, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 4 June 2009.

Appellant II (patent proprietor) lodged a further appeal against this decision on 9 April 2009, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 16 June 2009.

IV. On appeal, the following documents played a role:

D1: EP-A-1 403 390

D2: WO-A-02/05863 and

D3: US-A-6 478 815.

V. Oral proceedings took place before the Board on 6 November 2012.

The following requests were made:

The appellant I requested that the decision under appeal be set aside and the patent No. 1 444 993 be revoked.

The appellant II requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims according the first auxiliary request filed on 12 June 2009 (new main request). He further requested that the appeal of the opponent be dismissed.

All other requests filed during the appeal proceedings were withdrawn.

VI. Independent claim 2 of the new main request reads as follows:

"2. A medical implant or device fabricated, in any manner, from a metal alloy, said medical implant or device comprising components at least partially fabricated from a metal alloy comprising
(a) between 0.1 and 70 weight percent Niobium,
(b) between about 0.1 and 30 weight percent in total of at least one element selected from the group consisting of Zirconium and Molybdenum, Zirconium being present in amounts between 0.1 and 10 weight percent, Molybdenum being present in amounts between 0.1 and 20 weight percent,
(c) up to 5 weight percent in total of at least one element selected from the group consisting of Hafnium, Rhenium and Lanthanides, in particular Cerium,

(d) and a balance of Tantalum,
with the proviso that a metal alloy consisting essentially of 50 - 98.9 % Nb, 0.5 - 5 % Zr and 0.6 - 49.5 % Ta is excluded,
wherein the alloy provides for a uniform beta structure, which is uniform and corrosion resistant, and has the ability for conversion oxidation or nitridization surface hardening of the medical implant or device."

VII. Claim 1 underlying the decision of the opposition division reads as follows:

"1. A medical implant or device fabricated, in any manner, from a metal alloy, said medical implant or device comprising components at least partially fabricated from a metal alloy comprising
(e) between 5 and 25 weight percent Niobium,
(f) between about 0.1 and 30 weight percent in total of at least one element selected from the group consisting of Tungsten, Zirconium and Molybdenum, Tungsten being present in amounts between 0.1 and 15 weight percent, Zirconium being present in amounts between 0.1 and 10 weight percent, Molybdenum being present in amounts between 0.1 and 20 weight percent,
(g) up to 5 weight percent in total of at least one element selected from the group consisting of Hafnium, Rhenium and Lanthanides, in particular Cerium,
(h) and a balance of Tantalum,
wherein the alloy provides for a uniform beta structure, which is uniform and corrosion resistant, and has the ability for conversion oxidation or nitridization surface hardening of the medical implant or device."

VIII. The arguments of appellant I relevant to the present decision can be summarized as follows:

Admissibility of appeal

The deficiencies in the notice of appeal mentioned by appellant II, which had been addressed in the Board's first official communication, were remedied by the appellant's response to this communication. The appeal was therefore admissible.

New main request; disclaimer

The disclaimer featuring in claim 2 of the new main request *"with the proviso that a metal alloy consisting essentially of 50 to 98.9 % Nb, between 0.5 and 5 % Zr and between 0.6 and 49.5 % Ta is excluded"* which aimed at excluding the technical teaching of D1 was not admissible since the remaining subject-matter of claim 2 lacked original disclosure. Objection therefore arose under Article 123(2) EPC.

Request underlying the decision of the opposition division (auxiliary request)

Inventive step

Claim 1 as allowed by the opposition division defined a medical device fabricated from an alloy comprising inter alia 25% Nb, 0.1 to 15 W, the balance being Ta.

Claim 3 of D2 defined a stent made of a binary Ta-Nb alloy having a Nb content in the range of 25 to 52 wt%.

The known alloy thus could comprise 25% Nb and the balance being Ta. Table 2 of D2 provided typical or average values of other elements which were also present in the alloys discussed in D2. Turning to the 60%Ta-40%Nb example given in Table 2 of D2, the skilled person was taught that the Ta-Nb alloy as disclosed in D2 also contained at least small amounts of W.

Hence, the subject-matter of claim 1 differed from the disclosure of D2 by the tungsten content which in the 25%Nb-0.1-15%)W-Ta alloy set out in claim 1 was required to be at least 0.1 wt%, opposed to the average value of or close to 0.05 wt% given in D2.

Based on these considerations, the objective technical problem underlying the patent at issue was the provision of an alloy having an increased strength. The solution to this problem was given in D2, page 4 lines 23 to 25 or on page 10, lines 23 to 29 stating that the Ta-W alloys had approximately the same radio-opacity as pure Ta, but were substantially stronger than pure Ta and even stronger than stainless steel. This technical statement was supported by Table 1 of D2 which compared Ta with Ta-W alloys having different amounts of W. The addition of W to a 25%Nb-Ta alloy to increase the alloy's strength was therefore obvious to the skilled person.

Alternatively, when starting from the 90%Ta-2.5%W alloy also given in Table 2 of D2, the technical problem underlying the patent at issue was to provide an alloy which did not appear overly bright when being viewed by fluoroscopy. Since a positive correlation existed between material density and radio-opacity, as was

disclosed in D2, page 9, lines 10, 11, and Ta-Nb alloys with a high percentage of Nb (about 40%) were stronger and substantially less dense than pure Ta because Nb had an atomic mass of about half that of Ta, it was close at hand for the skilled person to add to the 90%Ta-2.5%W substantial amounts of Nb to reduce the alloy's density and, in consequence thereof, radio-opacity. Also from this point of view, the subject-matter of claim 1 lacked an inventive step.

Finally, the alloy composition featuring in claim 1 was obvious from the combined teaching of D2 and D3. The claimed alloy consisting of 25%Nb - 0.1 to 10% Zr - balance Ta differed from the disclosure of D2 by a Zr-content ranging from 0.1 to 10 wt%. Accordingly the technical problem resided in improving the alloy's mechanical properties.

The solution to this problem was obvious from D3 which disclosed in claim 1 a stent composed of a single homogeneous tubing consisting solely of Nb and 1% to 5% by weight of at least one additional metal selected from Zr, Ti or Ta for alloy formation and reinforcement. Specifically in column 4, lines 15 to 18, and lines 59 to 65, D3 disclosed that the hardness and the physical characteristics of the metal alloy could be improved by adding Zr. Therefore, the technical teaching of D2 combined with that of D3 led the skilled person in an obvious way to the solution given in the patent at issue.

Sufficiency of disclosure

Since claim 1 as maintained by the impugned decision comprised a plethora of Nb-Ta-(Zr,W,Mo) alloy compositions and therefore was very broad in scope, it was doubtful whether the technical effect aimed at was achieved over the whole range claimed. Moreover, the implant of the claimed Ta-Nb-X alloys was to exhibit a uniform beta structure without giving clear instructions as to how this microstructure was to be successfully obtained. Objection therefore arose under Article 83 EPC.

IX. The arguments of appellant II relevant to the present decision can be summarized as follows:

Admissibility of the appeal of appellant I

The notice of appeal of appellant I was submitted by "Boston Scientific Limited" whereas the notice of opposition was filed by "Boston Scientific Corporation", which was a different legal entity. Given this deficiency, the appeal did not comply with Article 107 EPC. Moreover, the appellant/opponent's appeal failed to identify the appellant's address and did not include a request defining the subject of appeal, contrary to the provisions of Rule 99(1)(a) and (c) EPC.

The appellant/opponent's appeal therefore should be rejected since it failed to comply with Article 107 and Rule 99(1)a) and (c) EPC.

New main request; disclaimer

Decision G 2/10 of the Enlarged Board of Appeal was essentially concerned with the problem of disclaiming subject-matter which was disclosed in the application as filed, so called "disclosed disclaimer". This decision was based on the general finding that any amendment to an application or patent must fulfil the requirements of Article 123(2) EPC, including amendments limiting the claim by disclaiming disclosed subject-matter (point 4.5.1). However, a fundamental difference existed between an "undisclosed disclaimer", the wording of which was totally determined by the state of the art according to Article 54(3) EPC and excluded that prior art, and a disclaimer, which disclaimed subject-matter that was disclosed as one embodiment of the invention in the application as originally filed.

In point 2.6.2 of G 2/03, which referred to "undisclosed disclaimers", the Enlarged Board discussed inter alia the situation of an anticipation which was prior art under Article 54(3) EPC. According the Headnote II.1 in G 2/03, a disclaimer was allowable in order to establish novelty by delimiting the claim against the state of the art under Article 54(3) EPC.

In the present case, the disclaimer excluded the subject-matter disclosed in document D1 which represented prior art in the sense of Article 54(3) EPC and, therefore, the "undisclosed disclaimer" met the requirements of Article 123(2) EPC. Hence the amendments to claim 2 of the main request were allowable.

Request underlying the decision under of the opposition division (auxiliary request)

Inventive step

The medical implant claimed in the patent at issue was clearly distinguished from D2 or D3 by the composition of its ternary of multi-component alloys it was made of. By contrast, D2 was concerned exclusively with binary Ta-W or Ta-Nb alloys, respectively. Nothing in D2 would have prompted the skilled reader to consider a ternary Ta-W-X or Ta-Nb-X alloy composition in order to modify the alloy's properties, contrary to the assumptions submitted by the appellant/opponent. Document D3 was concerned with stents of 95 to 99 % Nb rather than Ta-alloys comprising between 5 to 25 % Nb as claimed. The claimed medical implant was therefore neither obvious from D2 taken individually nor from its combination with the teaching of D3.

Sufficiency of disclosure

No evidence was submitted by the appellant/opponent proving that the favourable combination of properties aimed at by the claimed Ta-Nb alloy was not achieved over the whole range claimed. When discussing the distinguishing features between the claimed alloy and the prior art, the appellant/opponent did not address the beta-microstructure. This meant that in the assessment of the appellant/opponent the alloys of the prior art exhibited the same microstructure as defined in the patent and no specific mechanical or heat

treatment was required to obtain it. The requirements of Article 83 were therefore met.

Reasons for the Decision

1. Appeal of appellant I

1.1 Admissibility

Appellant II objected to the admissibility of the appeal of appellant I since it did not comply with Article 107 and Rule 99, paragraph 1(a) and (c) EPC.

1.1.1 Name of appellant I

In the opposition as filed, during the opposition proceedings and in the impugned decision, the opponent was identified as Boston Scientific Corporation. However, in the notice of appeal dated 1 April 2009, the appellant was identified as Boston Scientific Limited so that Boston Scientific Limited was not entitled to appeal. Only the legal entity, party to the proceedings in first instance, may appeal the decision (Article 107 EPC).

However, correction of the name of the appellant to substitute a natural or legal person other than the one indicated in the appeal is allowable under Rule 101 EPC if it was the true intention to file the appeal in the name of the party to proceedings in first instance and if it can be derived from the information in the appeal with a sufficient degree of probability that the appeal

has been filed by this person (cf. Case Law 6th Edition VII-7.5.2.a)

Appellant I submitted in its letter dated 19 October 2009 that the mention of "Boston Scientific Limited" as the appellant was due to an internal oversight of its representative which was representing in different files both legal entities and that the appeal was filed in the name of Boston Scientific Corporation.

The representative is the same as the representative of the opponent in the first instance and the application number and the publication number of the opposed patent, as well as the patentee are correctly mentioned in the notice of appeal. Moreover, the internal reference number of the representative indicated in the notice of appeal is the same as the one used in the representative's case in first instance.

Therefore, the Board considers the discrepancy between the registered opponent and the mentioned appellant as an error and holds that sufficient elements are provided in order to identify the true appellant and to establish that the true intention was to file the appeal in the name of the opponent in the first instance proceedings.

1.1.2 Address

The address of appellant I is missing in the notice of appeal dated 1 April 2009 as well as in the appellant's letter dated 19 October 2009, contrary to Rule 99(1)(a) EPC.

In response to the Board's official communication addressing this deficiency, the appellant I declared that the address of appellant I was the same as provided in the Notice of opposition. Hence this deficiency has been remedied under Rule 101(2) EPC.

1.1.3 Request

Rule 99(1)(c) EPC 2000 requires that the notice of appeal contains "a request defining the subject of the appeal". The appellant's initial request has to define the subject of the appeal and thereby the framework of the appeal proceedings. As a rule, the notice of appeal should already clarify whether the decision under appeal is contested as a whole or partially, and define the extent of the issues raised in the appeal proceedings (above-cited document CA/PL 5/02 Rev.1 Add 1.).

Lack of such a statement rarely presented a problem in appeals filed by an opponent. As a rule, an opponent would request that the impugned decision be set aside and the patent be revoked either partially or in its entirety, (Document CA/PL 5/02 Rev.1 Add 1., explanatory remarks, cited e.g. in Special edition N°5 OJ EPO, under Rule 99 EPC). The extent of the request made in appeal can be inferred interpreting the notice of appeal in an objective way (e.g. T 1/88 of January 26, 1989, not published in the OJ EPO; and Case Law of the boards of Appeal, 5th edition, VII D 7.4.1(b)), even when the notice of appeal contained no express statement in this respect.

In the present case, the notice of appeal indicates that it is filed against the decision of the opposition division. From the decision itself, it is clear that said decision is only directed to the maintenance of the patent in amended form (see point 8). Consequently, no request for setting aside only a part of that decision can be considered from the opponent.

Therefore, based on the notice of appeal of appellant I, the Board has no doubt about the subject of its appeal according to Rule 99(1)(c) EPC, which is to have the impugned decision set aside and the patent revoked in its entirety.

1.1.4 It follows from the above considerations that, contrary the position of appellant II, the appeal of appellant I is admissible.

1.2 Allowability

1.2.1 Formal aspects of the claims upheld by the opposition division; Article 123(2) EPC

The subject-matter of claim 1 results from a combination of the technical features given in claims 1 to 5 as originally filed. Dependent claims 2 to 12 correspond to originally filed claims 6 to 16 and relate to preferred embodiments of the medical device set out in claim 1. Hence there are no formal objections to these claims with respect to Article 123(2) EPC.

1.2.2 Novelty

The novelty of the subject-matter of claim 1 was not disputed by appellant I at the oral proceedings. The Board does not see any reason either as to why this assessment of the claimed subject-matter vis-à-vis the cited prior art should be wrong.

1.2.3 Inventive step

Appellant I argued that the claims underlying the impugned decision as upheld by the opposition division lacked an inventive step vis-à-vis the technical teaching of document D2 alone or to the combined teaching of D2 with D3.

It was common ground to the parties and the Board that document D2 qualifies as representing the closest prior art. Like the patent at issue, document D2 is concerned with a stent consisting of a Ta-Nb alloy which is sufficiently radiopaque to allow for good imaging of the stent under fluoroscopy, is not overly bright so that it does not obscure the image of the surrounding vessel lumen and exhibits sufficient strength. Specifically claims 2 and 3 of document D2 disclose a stent for implantation consisting of 25 to 52% by weight Nb, the balance being Ta. Thus, a punctual overlap exists for 25 % Nb-Ta of the claimed alloy composition with that of D2.

Starting from the technical disclosure of D2, the objective problem underlying the patent at issue resides in providing an alternative Ta-Nb alloy composition for a medical implant which is properly

balanced in its properties, in particular with respect to radio-opacity, exhibits minor artefacts in magnetic resonance imaging (MRI) and has sufficient strength (the patent specification, paragraph [0009]). The solution to this problem resides in the medical device consisting of the Ta-Nb-(Zr,Mo,W) alloy composition featuring in claim 1.

The skilled reader of D2 is taught by the description on page 4, lines 13 to 15, page 7, lines 17 to 19, page 10, lines 23 to 25, page 11, lines 16, l7 as well as in claims 1 to 3, 11, 14, 22, 23, 33 and 34 that this document is concerned with stents of binary Nb-Ta alloys rather than ternary or multi-component alloys as claimed in the patent at issue. Undoubtedly, the whole document D2 leads the skilled reader to conclude that, apart from Nb and Ta, no further components are intentionally added to the alloy. In the light of the overall technical disclosure of D2, the exemplifying alloys given in Table 2 of D2 only describe compositions of binary Ta-W or Ta-Nb alloys which could comprise residual elements and unavoidable impurities originating from the production process. Contrary to the appellant/opponent's allegation, no hint or indication whatsoever is found anywhere in D2 implying that, for instance, 0.5% niobium or more should been added intentionally to the 90%Ta-2.5%W alloy listed in Table 2 to modify the alloy's properties. There is no disclosure anywhere in D2 prompting the skilled person to add at least 0.1% of W and/or 0.1% Zr and/or 0.1% Mo as a third component to the known alloy to alter the properties of the medical stent or implant. Arguing in that way is only possible on the basis of hindsight. Therefore, contrary to the position of appellant I, it

was not obvious from document D2 taken individually to modify the known binary Ta-Nb alloy to come to the alloy chemistry used for the claimed medical implant.

The claimed subject-matter is not obvious from the combined technical teaching of D2 and D3 either for the following reasons. Specifically, D3 is concerned with a stent consisting solely of Nb except for a trace in a range of 1 to 5 wt% of at least one additional metal selected from the group of Zr and Ta for alloy formation and reinforcement (D3, claim 1). Given that D3 teaches a stent made of 95 to 99 wt% niobium, whereas in the alloys of D2 niobium is limited to 25 to 52%, there is no reason to pick features from D3 to associate with the teaching of D2, and even if this were done, the subject-matter of claim 1 would not be reached.

Since the available state of the art does not suggest the technical features of the claimed medical implant or device, the subject-matter of claim 1 upheld by the opposition division involves an inventive step.

1.2.4 Sufficiency of disclosure

Appellant I argued that the previously mentioned balance of properties aimed at for the claimed medical implant was not achieved over the whole compositional range of the claimed alloy. Moreover it alleged that the alloy was to exhibit a uniform beta structure without giving a specific heat-treatment how such a microstructure was obtained.

However, appellant I did not provide any convincing evidence in support of its allegation. On the contrary, in its view it was beyond doubt that the TaNb-alloys according to the prior art also exhibited the desired combination of radio-opacity and brightness in MRI and had the same uniform beta structure. The objections raised by appellant I under Article 83 EPC are therefore unfounded.

1.2.5 Therefore, the appeal of appellant I is not allowable.

2. Appeal of appellant II

2.1 Admissibility

The appeal of appellant II is admissible.

2.2 Allowability;

2.2.1 Claim 2 of the new main request contains the wording "*with the proviso that a metal alloy consisting essentially of 50 - 98.9 % Nb, 0.5 - 5 % Zr and 0.6 - 49.5 % Ta is excluded*". The amendment to claim 1 aims at excluding the alloy compositions disclosed in Table 1 of document D1, which represents prior art in the sense of Article 54(3) EPC. The amendment therefore constitutes the introduction of an "undisclosed disclaimer".

2.2.2 In decision G 2/10 of 30 August 2011, the Enlarged Board of Appeal (EBA) considered that in decision G 1/03 the EBA did not provide an exhaustive treatment of the conditions when an "undisclosed disclaimer" violates Article 123(2) EPC and when it does not

(G 2/10, page 34, first paragraph). Moreover, the EBA held that the gist of the questions referred to the EBA in cases G 1/03 and G 3/03 to which the EBA had to give an answer, was to establish whether, and if so, under which circumstances undisclosed disclaimers could be considered allowable at all, as a matter of principle, despite of the absence of a basis in the application as filed. It is this question and no more the EBA had answered in answer 2. The wording the EBA chose in the starting line of answer 2, reading "a disclaimer may be allowable", indicates that with the criteria set up in answer 2 the EBA did indeed not intend to give a complete definition of when an undisclosed disclaimer violates Article 123(2) ECP and when it does not.

The EBA further stated that neither decision G 1/93 nor decision G 1/03 intended to modify the general definition of the requirements of Article 123(2) EPC established in opinion G 3/89 (OJ EPO 1993, 117) and decision G 11/91 (OJ EPO 1993, 125), which definition has become the generally accepted "gold" standard for assessing any amendment for its compliance with Article 123(2) EPC. Consequently, the principle that any amendment to an application or a patent, and in particular to a claim, must fulfil the requirements of Article 123(2) EPC also applies to an amendment limiting the claim by disclaiming disclosed or undisclosed subject-matter. Therefore, as is the case for any other amendment, the test for an amendment to a claim by disclaiming subject-matter disclosed as part of invention in the application as filed, or subject-matter disclosed in a document representing prior art in the sense of Article 54(3) EPC, respectively, must

be that after the amendment the skilled person may not be presented with new technical information.

Put another way, the point of reference for assessing an amended claim for its compliance with Article 123(2) EPC, including amendments by introducing an undisclosed disclaimer, is the subject-matter which the claim contains after the amendment. Hence, the test to be applied is whether the skilled person would, using common general knowledge, regard the remaining claimed subject-matter as explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed. This opinion corresponds to the one given in T 2464/10.

2.2.3 The "remaining subject-matter test" applied to claim 2 of the new main request

Following the principles laid down in decision G 2/10 with respect to the "gold standard", the remarks in this decision must be interpreted as an instruction to the Board to apply the further test developed therein, in addition to the principles set out in decision G 1/03, in order to carry out a full assessment of whether an "undisclosed" disclaimer meets the requirements of Article 123(2) EPC.

The elemental limitations imposed by the disclaimer of claim 2 serves the purpose of excluding the Nb-Zr-Ta alloy compositions, which are disclosed in document D1, from the claimed Ta-alloys and - in consequence thereof - of establishing novelty vis-à-vis D1 which constitutes prior art in the sense of Article 54(3) EPC. However, by introducing into claim 2 the compositional

restrictions, which are exclusively based on document D1 rather than on the technical disclosure of the application, the skilled person is confronted with new subject-matter that he cannot derive clearly and unambiguously from the application as originally filed. To give an example, it is noted that the upper limit of less than 50% niobium now featuring in claim 1 is not disclosed anywhere in the application as filed and neither are the limits of less than 0.5% Zr and more than 5% Zr. It follows from the above considerations, that the disclaimer of claim 2 of the auxiliary request 1 does not satisfy the requirements of Article 123(2) EPC. Hence claim 2 of the new main request is not allowable.

2.2.4 The appeal is, therefore, not allowable.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner