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**Datasheet for the decision
of 10 November 2015**

Case Number: T 1709/13 - 3.3.10

Application Number: 07794680.4

Publication Number: 2026854

IPC: A61L31/02, A61L31/14

Language of the proceedings: EN

Title of invention:

DEGRADABLE MEDICAL DEVICE

Patent Proprietor:

Abbott Cardiovascular Systems Inc.

Opponent:

Boston Scientific Corporation

Headword:

Relevant legal provisions:

EPC Art. 100(c), 123(2), 123(3)

RPBA Art. 13(1)

Keyword:

Grounds for opposition - added subject-matter (yes)

Amendments - added subject-

matter (yes) first to tenth auxiliary requests -

broadening of claim (yes) eleventh to fourteenth auxiliary re
quests

Late-filed auxiliary requests -

admitted (no) fifteenth auxiliary request

Decisions cited:

T 0823/96

Catchword:



**Beschwerdekammern
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Case Number: T 1709/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 10 November 2015

Appellant: Abbott Cardiovascular Systems Inc.
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
23 May 2013 concerning maintenance of the
European Patent No. 2026854 in amended form.**

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
T. Bokor

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to maintain European patent No. 2 026 854 in amended form.
- II. Notice of opposition had been filed on grounds which included that of added subject-matter (Article 100(c) EPC).
- III. The opposition division concluded that the claims of the patent as granted and of the then pending first to seventh auxiliary requests contained added subject-matter since there was no basis in the application as originally filed for the combination of features "wherein said metal structure has a porosity of at least 50%" and "wherein said metal structure comprises a combination of two metals that form one or more internal galvanic couples".
- IV. The main request of the appellant in these appeal proceedings corresponds to the patent as granted. First to eighth auxiliary requests were filed with the statement setting out the grounds of appeal. The ninth to sixteenth auxiliary requests were filed with a letter dated 10 June 2015 and, lastly, a new fifteenth auxiliary request replacing the previous one was filed during the oral proceedings before the board, which took place on 10 November 2015.

Claim 1 of the main request and of the first and ninth auxiliary requests reads as follows:

"An implantable, biodegradable medical device having a porous, corrodible metal structure,

wherein said metal structure has a porosity of at least 50%, and

wherein said metal structure comprises a combination of two metals that form one or more internal galvanic couples."

Claim 1 of the second auxiliary request contains, in addition to the features of claim 1 of the main request, the following:

"wherein said two metals form an internal couple with a driving force of at least about 500 mV."

Claim 1 of the third auxiliary request contains, in addition to the features of claim 1 of the main request, the following:

"wherein the two metals are selected from Mg, Mn, K, Ca, Na, Cr, Fe, Cd, Al, Co, Sb, V, Cu and Mo, and from alloys based on such elements."

Claim 1 of the fourth auxiliary request contains, in addition to the features of claim 1 of the main request, that of claim 1 of the second and of the third auxiliary requests.

Claim 1 of the fifth and tenth auxiliary requests reads as follows:

"An implantable, biodegradable medical device having a porous, corrodible metal structure, wherein said medical device is a stent,

wherein said metal structure has a porosity of at least 50%, and

wherein said metal structure comprises a combination of two metals that form one or more internal galvanic couples."

Claim 1 of the sixth auxiliary request contains, in addition to the features of claim 1 of the fifth auxiliary request, the following:

"wherein said two metals form an internal couple with a driving force of at least about 500 mV."

Claim 1 of the seventh auxiliary request contains, in addition to the features of claim 1 of the fifth auxiliary request, the following:

"wherein the two metals are selected from Mg, Mn, K, Ca, Na, Cr, Fe, Cd, Al, Co, Sb, V, Cu and Mo, and from alloys based on such elements."

Claim 1 of the eighth auxiliary request contains, in addition to the features of claim 1 of the fifth auxiliary request, that of claim 1 of the sixth and seventh auxiliary requests.

Claim 1 of the eleventh and thirteenth auxiliary requests reads as follows:

"An implantable stent having a porous structure and formed of two metals,

wherein said metals form one or more internal galvanic couples; and

wherein said structure has a porosity of at least 50%."

Claim 1 of the twelfth and fourteenth auxiliary requests reads as follows:

"An implantable, biodegradable metallic stent, having a porous, corrodible metal structure and formed of two metals,

wherein said metals form one or more internal galvanic couples; and

wherein said structure has a porosity of at least 50%."

Claim 1 of the fifteenth auxiliary request reads as follows:

"An implantable biodegradable metallic stent, consisting of a porous, corrodible metal structure and formed of two metals,

wherein said metals form one or more internal galvanic couples; and

wherein said structure has a porosity of at least 50%."

Lastly, the sixteenth auxiliary request corresponds to the claims as upheld by the opposition division in the contested decision.

V. The arguments of the appellant relevant for the decision were the following:

Claim 1 of the patent as granted found a basis in claims 3 and 6 as originally filed. Although these claims were not mutually dependent, the skilled reader would have considered their content as disclosed in combination since they were both dependent on claim 1

and there was no technical reason not to combine them. Claim 1 of the patent as granted did not contain, therefore, any information which could not be directly derivable from the original claims. Thus, claim 1 of the main request and its counterpart in claim 1 of the first to tenth auxiliary requests did not contain added subject-matter.

Even if it was considered that the claims as originally filed did not provide the required basis for the amendments, the skilled reader could find a basis for the combination of features required by claim 1 in paragraphs [10] and [28] of the description and in claims 17 and 19 of the application as originally filed.

The arguments with respect to the patent as granted applied in the same manner to claim 1 of the first to fourth and ninth auxiliary requests.

Claim 1 of the fifth auxiliary request found a basis in claim 19 as originally filed, and the same reasoning applied to claim 1 of the sixth to eighth and tenth auxiliary requests.

Neither claim 1 of the eleventh nor claim 1 of the thirteen auxiliary requests extended the scope of protection conferred by the patent as granted. Claim 1 of these requests did not explicitly contain the features "biodegradable" and "corrodible" required by claim 1 as granted, but these features were the inevitable result of the remaining features of the claim and could, therefore, be omitted.

Claim 1 of the twelfth and fourteenth auxiliary requests contained the features "biodegradable" and

"corrodible", so that any issue with regard to Article 123(3) EPC which could be present in claim 1 of the eleventh and thirteenth auxiliary requests would thus be solved.

The fifteenth auxiliary request was a response to an objection under Article 123(3) EPC which had only been put forward during the oral proceedings before the board. Claim 1 thereof merely replaced the term "having" by "consisting of" and thus did not introduce any further issue which could not be dealt with during the oral proceedings. For these reasons, the fifteenth auxiliary request should be admitted into the proceedings.

VI. The arguments of the respondent (opponent) relevant for the present decision were the following:

Claim 1 of the patent as granted contained added subject-matter. The feature "porosity of at least 50%" could only be found in original claim 3, which was not dependent on claim 6, referring to galvanic couples. Also, the description of the application as originally filed did not disclose the combination of features defined in claim 1. The same objection also applied to claim 1 of the first to the fourth and ninth auxiliary requests.

Claim 19 as originally filed did not provide a basis for the features of claim 1 of the fifth auxiliary request, as it required the claimed stent to be formed of at least two metals, whereas claim 1 only required the porous structure to be formed of at least two metals. This objection applied in the same manner to claim 1 of the sixth to eighth and tenth auxiliary requests.

Claim 1 of the eleventh to the fourteenth auxiliary request extended the scope of protection of the patent as granted, since claim 1 of the eleventh and thirteenth auxiliary requests were not limited to biodegradable, corrodible stents and claim 1 of the twelfth and fourteenth auxiliary requests did not require that the porous structure of the stent comprised two metals, which was a feature of claim 1 as granted.

The fifteenth auxiliary request was late filed and raised new issues with respect to added subject-matter. For these reasons, it should not be admitted into the proceedings.

VII. The final requests of the parties were the following:

- The appellant requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or that the patent be maintained in an amended form on the basis of any of the first to the sixteenth auxiliary requests, where the first to eight auxiliary requests were filed with the grounds of appeal dated 2 October 2013, ninth to fourteenth and sixteenth auxiliary requests were filed with letter dated 10 June 2015 and the fifteenth auxiliary request was filed during the oral proceedings before the board. The sixteenth auxiliary request corresponds to the claims as upheld by the first instance.

- The respondent requested that the appeal be dismissed.

VIII. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request, amendments

2. Claim 1 of the patent as granted is directed to a medical device having a porous, corrodible metal structure and requires that said metal structure
 - has a porosity of at least 50%, and
 - comprises a combination of two metals that form one or more internal galvanic couples.
3. It needs to be examined whether the features "said metal structure has a porosity of at least 50%" and "wherein said metal structure comprises a combination of two metals that form one or more internal galvanic couples" had been disclosed, in combination, in the application as originally filed.
4. In order to determine whether or not the patent in suit contains added subject-matter, it has to be examined whether it discloses technical information which a skilled person would not have objectively and unambiguously derived, either explicitly or implicitly, from the application as originally filed.

Implicit disclosure means no more than the clear and unambiguous consequence of what is explicitly disclosed (see T 823/96, point 4.5 of the reasons, not published in OJ EPO), and should not be construed to mean matter that is not part of the content of the technical

information provided by a document but may be rendered obvious on the basis of that content.

5. *Alleged basis in claims 3 and 6 as originally filed:*

5.1 Claim 3 as originally filed contains the feature "said metal structure has a porosity of at least 50%" and claim 6 of the application as originally filed contains the feature "wherein said metal structure comprises a combination of two metals that form one or more internal galvanic couples".

It has not been disputed that each of claims 3 and 6 is only dependent from claim 1 and that, for this reason, the features of claims 3 and 6 as originally filed are not explicitly disclosed in combination.

It remains to be examined whether such a combination is, nevertheless, implicitly disclosed to the skilled reader.

5.2 The appellant argued that claims 3 and 6 as originally filed were both dependent from claim 1. That already taught the skilled reader that their content was combined.

The board can, however, not follow this argument since dependent claims can relate to alternative or to mutually exclusive embodiments and not necessarily to features which can be combined.

5.3 The appellant further argued that, in the present case, the skilled person would find reasons for combining the features of claims 3 and 6 as originally filed in the description of the application, which disclosed all the features of claim 1 except the required degree of

porosity. Paragraph [0010] disclosed that the degree of porosity was a feature essential for the claimed invention but did not provide any porosity boundaries. Having regard to paragraph [0010], the skilled reader found this essential information in claim 3 as originally filed and by doing so would arrive directly and unambiguously to the combination of all the features required by claim 1 as granted.

The description of the application as originally filed discloses that the claimed invention relates to medical devices intended to degrade after implantation [0002]. It acknowledges that corrodible Fe stents were state of the art at the date of filing [0005] and proposes different ways of enhancing metal corrosion rate.

On paragraph [0008], it discloses that the claimed invention contemplates, with respect to the metal component, the following means for enhancing metal corrosion rate:

- using metals which form an oxide layer that grows and flakes off,
- combining a relatively slowly corroding metal with another metal selected so as to provide an internal galvanic couple, and
- using a metal with a high propensity to dissolve in vivo, such as Mg.

Paragraph [0006] of the description indicates that, by selecting the metal and the degree of porosity, rates of degradation can be tailored to a wide range of applications. From this passage, the skilled reader understands that the degree of porosity depends both on the metal(s) used and on the intended application of the medical device.

Paragraph [0010] discloses that the degree of porosity imparted to the metal or combinations of metals is an essential element of the claimed invention. This passage thus indicates that the claimed medical devices are necessarily porous (see claim 1 as filed) but does not set any porosity boundaries.

The combined reading of paragraphs [0006], [0007] and [0010] indicates that, according to the invention, corrosion rate can be increased by:

- using metals whose oxides flake off,
- using galvanic couples,
- using metals which dissolve in vivo, and
- increasing porosity.

Since increasing porosity is only one possible strategy for increasing corrosion rate, the skilled person would not consider that the porosity limit indicated in claim 3 is necessarily disclosed for every metal or combination of metals. Thus, the argument of the appellant that the skilled person would regard the porosity disclosed in claim 3 as combined with the embodiment directed to a medical device comprising a galvanic couple cannot be followed.

5.4 The appellant further argued that there was no technical reason why a metal structure could not have, at the same time, a porosity of at least 50% and comprise a galvanic metal couple.

The absence of technical reason not to combine two features is a necessary but not a sufficient condition for combining them. For this reason, this argument cannot convince.

Notwithstanding the above, the description of the application discloses different means for increasing the corrosion rate of a medical device with respect to the choice of the metal(s) [0008], each of them requiring a different porosity [0006], which further needs to be adjusted to the intended use [0006]. The skilled person would thus have reasons not to combine the porosity disclosed in claim 3 with every embodiment of the patent application.

6. *Alleged basis on paragraph [0028] of the application as originally filed:*

The appellant further argued that paragraph [0028] of the application as originally filed would lead the skilled reader to seriously contemplate working within the porosity limits required by claim 1 as granted.

However, paragraph [0028] only relates to stents, whereas claim 1 is directed to medical devices, in general. According to the application as originally filed, the degree of porosity depends on the intended use of the claimed device (see paragraph [0006]). For this reason alone, the passage on paragraph [0028] fails to provide the alleged teaching.

In addition, paragraph [0028] discloses that stents preferably have a metal structure porosity of at least about 10%, more preferably 30-80% and most preferably 40-60% and thus does not disclose the porosity range of at least 50% required by claim 1.

7. *Alleged basis in claims 17 and 19 as originally filed:*

Lastly, the appellant argued that the skilled person

found in claims 17 and 19 the teaching that the required porosity could be applied to a device having a metal structure comprising two metals which form one or more galvanic couples.

However, claims 17 and 19 refer to stents and not to medical devices in general and, as mentioned above, the degree of porosity depends on the intended application of the medical device [0006], so the skilled person knows that this porosity is not necessarily suitable for every type of medical device.

8. For these reasons, it is concluded that the application as originally filed does not disclose the combination of features required by claim 1, with the consequence that the ground under Article 100(c) EPC precludes the maintenance of the patent as granted.

First to fourth and ninth auxiliary requests, amendments

9. The appellant has not challenged that, if claim 1 of the main request were considered to contain added subject-matter, the same conclusions would apply to claim 1 of the first to the fourth and of the ninth auxiliary request, which also require that the metal structure of the medical device has a porosity of at least 50% and that it comprises a combination of two metals that form one or more internal galvanic couples.

Since the board came to the conclusion that claim 1 of the main request contains added subject-matter, none of the first to fourth and ninth auxiliary requests are allowable.

Fifth auxiliary request, amendments

10. Claim 1 of the fifth auxiliary request is directed to an implantable, biodegradable stent having a porous corrodible metal structure, wherein said *metal structure* comprises a combination of two metals that form one or more internal galvanic couples.

11. The appellant argued that claim 19 as originally filed, which included the features of claim 17, provided the basis required by Article 123(2) EPC.

However, claim 19 refers to an implantable *stent* formed of at least two metals, wherein said metals form one or more internal galvanic couples.

Claim 19 as originally filed thus requires that the stent is formed of two metals, whereas claim 1 only requires that the porous structure, but not necessarily the whole stent, is formed of two metals. This represents new technical information not disclosed in the application as originally filed.

The appellant argued that the complete stent needed to be porous and corrodible in order to be biodegradable and, for that reason, the skilled reader would understand that its whole structure should be made of at least two metals. If claim 1 was interpreted in this manner, claim 19 as originally filed provided the required basis.

However, claim 1 is not limited to stents made of two or more metals and biodegradation may rely on processes other than corrosion as acknowledged in the application [0004]. There is no technical reason why the stent should not contain additional, non metallic parts.

For these reasons, claim 19 as originally filed fails

to provide the required basis for claim 1 of the fifth auxiliary request, with the consequence that this request is not allowable.

Sixth to eighth and tenth auxiliary requests, amendments

12. The appellant has not challenged that, if claim 1 of the fifth auxiliary request were considered to contain added subject-matter, the same reasoning would also apply to claim 1 of the sixth to the eighth and tenth auxiliary requests.

Since the board came to the conclusion that claim 1 of the fifth auxiliary request contains added subject-matter, for the same reasons none of the sixth to the eighth and the tenth auxiliary requests is allowable.

Eleventh and thirteenth auxiliary requests, amendments

13. Claim 1 of the eleventh and of the thirteenth auxiliary requests, directed to a stent, lacks the limitations that the claimed stent is "biodegradable" and that its metal structure is "corrodible", which were required by claim 1 of the patent as granted.

The question thus arises whether the former contains subject-matter extending the scope of protection beyond that of the latter (Article 123(3) EPC).

The appellant argued that these features were redundant as they were the unavoidable result of the remaining features of claim 1. Two metals which form one or more galvanic couples would necessarily be "corrodible" and thus a stent containing said metals was "biodegradable".

However, not every galvanic couple would provide a corrodible metal structure, since corrosion depends on the nature of the metal(s) and on the driving force of the galvanic couple and none of these features are defined in claim 1.

For this reason, it is concluded that claim 1 of the eleventh and thirteenth auxiliary requests extends the protection conferred by the patent in suit. These requests are thus not allowable.

Twelfth and fourteenth auxiliary request, amendments

14. Claim 1 of the twelfth and fourteenth auxiliary request is directed to a stent

- having a porous, corrodible metal structure, wherein said structure has a porosity of at least 50%
and
- formed of two metals that form one or more internal galvanic couples

Claim 1 of these requests, thus, is also directed to stents formed of two metals having a porous metal structure such as a stent comprising a porous structure formed of only one metal and a second non-porous structure formed of the second metal. In contrast, claim 1 as granted was only directed to medical devices having a porous structure comprising two metals.

For this reason alone, claim 1 of the twelfth and the fourteenth auxiliary requests encompasses embodiments which were not claimed in the patent as granted and contravene for this reasons the requirements of Article 123(3) EPC, with the consequence that these requests

are not allowable.

Fifteenth auxiliary request, admissibility into the proceedings

15. Claim 1 of the fifteenth auxiliary request, filed towards the end of the oral proceedings, is directed to an implantable, biodegradable metallic stent consisting of a porous, corrodible metal structure and formed of two metals.

The appellant argued that this request, by replacing "having" by "consisting of", merely limited the subject-matter of claim 1 of the twelfth and fourteen auxiliary requests and aimed at solving an objection under Article 123(3) EPC which had been raised with respect to the twelfth and fourteenth auxiliary requests only during the oral proceedings. For these reasons, the fifteenth auxiliary request should be admitted.

16. The fifteenth auxiliary request was filed towards the end of the oral proceedings and, as acknowledged by the appellant, modifies the features of claim 1 of the twelfth and fourteenth auxiliary requests in an attempt to overcome issues under Article 123(3) EPC raised for the first time during the oral proceedings.

However, claim 1 of the fifteenth auxiliary request does a priori not solve the objections raised against the previous requests and raises further issues such as whether the application as originally filed disclosed a stent consisting of a porous, corrodible metal structure excluding any further component. The appellant has not challenged that there is no word-by-word basis for claim 1, so that admitting this request into the proceedings would imply to examine whether

there could be a basis for the claimed stent having regard to the whole content of the application as originally filed, and it is not immediately obvious that it could be the case.

17. Since the fifteenth auxiliary request has been filed very late and raises new issues the board decides not to admit it into the proceedings, using its discretionary powers under Article 13(1) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated