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D E C I S I O N
of 21 October 2004

Case Number: T 0849/00 - 3.4.1

Application Number: 93203354.1

Publication Number: 0593136

IPC: A61N 5/10

Language of the proceedings: EN

Title of invention:
Device for the prevention of arterial restenosis

Patentee:
Fischell, Robert E., et al

Opponent:
Advanced Cardiovascular Systems Inc. (withdrew its opposition)
SciMed Life Systems, Inc.
C. R. Bard, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 100(c), 123(2), 76(1)

Keyword:
"Main request, Article 100(c) EPC, opposition grounds - extension of subject-matter - divisional application"
"Auxiliary requests, Article 123(2) EPC, amendments added subject-matter (yes)"

Decisions cited:
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Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0849/00 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 21 October 2004

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 17 July 2000 revoking European patent No. 0593136 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: G. Assi
M. G. L. Rognoni

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal, received on 15 September 2000, against the decision of the opposition division, dispatched on 17 July 2000, revoking the European patent No. 0 593 136 (application number 93203354.1). The appeal fee was paid on 15 September 2000. The statement setting out the grounds of appeal was received on 17 November 2000.

II. Oppositions I, II and III had been filed against the patent as a whole and were based on the ground pursuant to Article 100(a) EPC that the subject-matter of the patent was not patentable within the terms of Articles 52(1), 54, 56 and 52(4) EPC as well as on the grounds pursuant to Article 100(b) and 100(c) EPC.

In the decision under appeal, the opposition division held, *inter alia*, that the ground for opposition pursuant to Article 100(c) EPC prejudiced the maintenance of the patent unamended.

III. By letter dated 22 February 2001, the respondent I (opponent I) withdrew its opposition.

IV. On 20 July 2004, the parties were summoned to oral proceedings. By letter of 30 August 2004, the respondent III (opponent III) announced that it would not be represented at the oral proceedings.

V. Oral proceedings were held on 21 October 2004 in the presence of the appellant and the respondent II (opponent II).

VI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the following documents:

Main request:
The patent as granted.

First auxiliary request:
Claims:
No. 1 filed with a letter of 16 September 2004;
No. 2-7 of the patent as granted;
Description:
Columns 1-3 of the patent as granted with the amendment in column 2, lines 12-21, filed with the letter of 16 September 2004;
Drawings:
Figures 1-4 of the patent as granted.

Second auxiliary request:
Claims:
No. 1-4 filed with the letter of 16 September 2004;
Description:
Columns 1-3 of the patent as granted with the amendment in column 2, lines 12-21, filed with the letter of 16 September 2004;
Drawings:
Figures 1-4 of the patent as granted.

Third auxiliary request:
Claims:
No. 1-4 filed with the letter of 16 September 2004;
Description:

Columns 1-3 of the patent as granted with the amendment in column 2, lines 12-21, filed with the letter of 16 September 2004;
Drawings:
Figures 1-4 of the patent as granted.

Moreover, with the letter of 16 September 2004, the appellant maintained four conditional amendments filed with the statement of grounds of appeal. However, these amendments, which concern the description only, were not formally filed as requests.

VII. The respondent II requested that the appeal be rejected.

VIII. The respondent III did not submit any requests or observations.

IX. The wording of claim 1 according to the appellant's main request is as follows:
"*A thin wire comprising a radioactive tip for use in the prevention of restenosis of an artery following arterial trauma, said thin wire being configured so that said radioactive tip can be inserted temporarily at the site of an arterial wall trauma and then be withdrawn and serves when so inserted to prevent restenosis of the artery at the trauma site, said radioactive tip including a beta-particle emitter radioisotope and emitting beta-particles.*"

The wording of claim 1 according to the appellant's first auxiliary request is as follows:
"*A thin wire comprising a radioactive tip for use in the prevention of restenosis of an artery following arterial trauma, said thin wire being configured so*

that said radioactive tip can be inserted temporarily at the site of an arterial wall trauma and then be withdrawn and serves when so inserted to prevent restenosis of the artery at the trauma site, said radioactive tip, only, including a beta-particle emitter radioisotope and emitting beta-particles."

The wording of claim 1 according to the appellant's second auxiliary request is as follows:
"*A thin wire comprising a radioactive tip for use in the prevention of restenosis of an artery following arterial trauma, said thin wire being configured so that said radioactive tip can be inserted temporarily at the site of an arterial wall trauma and then be withdrawn and serves when so inserted to prevent restenosis of the artery at the trauma site, said radioactive tip, only, being coated with a beta-particle emitter radioisotope and emitting beta-particles.*"

The wording of claim 1 according to the appellant's third auxiliary request is as follows:
"*A thin wire comprising a radioactive tip for use in the prevention of restenosis of an artery following arterial trauma, said thin wire being configured so that said radioactive tip can be inserted temporarily at the site of an arterial wall trauma and then be withdrawn and serves when so inserted to prevent restenosis of the artery at the trauma site, said radioactive tip, only, being plated with a beta-particle emitter radioisotope and emitting beta-particles.*"

Reasons for the Decision

1. The appeal is admissible.

2. *Ground for opposition pursuant to Article 100(c) EPC in relation to the appellant's main request*

2.1 The patent in suit was granted with respect to a divisional application resulting from an earlier application EP-A-0 433 011.

Pursuant to Article 100(c) EPC, the subject-matter of the patent shall not extend beyond the content of the earlier application as filed.

2.2 The description of the earlier application as filed (published version) relates to the field of intra-arterial stents used for preventing restenosis due to intimal hyperplasia subsequent to balloon angioplasty or atherectomy. In particular, a radioactive stent has a tubular structure or, preferably, a helical wire spring structure as shown on Figures 1-4. However, the concept of utilizing a radioactive material within the stent structure is applicable to any design (column 1, lines 1-47; column 2, lines 48-52). The radioactive material used may consist of an alpha, beta or gamma emitter. Examples of suitable beta emitters are ^{48}V, ^{32}P and ^{198}Au (column 2, lines 13-41). As regards the claims 1-9 of the earlier application, they all relate to an intra-arterial stent.

Therefore, the whole explicit disclosure of the earlier application pertains to radioactive intra-arterial stents, unique exception being made in the sentence

bridging columns 2 and 3 of the description. Here, with the aim of temporarily placing a radioactive source at the site of the vessel trauma, the use of "*thin wire with a radioactive tip*" is envisaged, which wire can be withdrawn after a limited period of time.

2.3 The appellant submitted that the disclosure of the earlier application should be considered as a whole, to avoid individual sentences being read out of context. In its view, the earlier application taught the general concept of applying radioactivity generated by an alpha, beta or gamma emitter for the purpose of preventing restenosis. The earlier application also taught to realize this concept by means of a radioactive stent, in which case a beta emitter should preferably be used because of its low penetration length ensuring that only the tissue in close proximity to the stent would be affected. In the appellant's view, the paragraph bridging columns 2 and 3, read in the context of the whole teaching, was sufficient to prove that the mentioned concept could also be realized by means of a thin wire with a radioactive tip, the features of which, in the understanding of a skilled person, would correspond to those pertaining to the radioactive stent.

2.4 The appellant's view is not convincing for different reasons. The earlier application indeed seems to imply that the application of radioactivity has the effect of preventing restenosis independently of whether radioactivity is generated by a radioactive stent or by a thin wire with a radioactive tip. These devices are nevertheless different. A major difference consists in that a stent device is intended to be locked in place in contact with the vessel wall, once expanded, for

permanently holding the artery open, this result being further enhanced by the intimal hyperplasia inhibiting effect of radioactivity. On the contrary, a thin wire does not have any mechanical effect on the vessel wall and is removed after a limited time. This difference results in requirements concerning the structure, in particular the geometry, the materials and the appropriate radioactive source, which may not be the same for a stent and a thin wire. In other words, contrary to the appellant's statement, the features disclosed by the earlier application with regard to a radioactive stent do not necessarily apply to the thin wire with a radioactive tip. In fact, the appellant itself offered, with the conditional amendment 3, to delete the last sentence of the description of the patent in suit "*Other than being a thin wire with a radioactive tip, the principle and the materials are the same*". Moreover, as stressed by the respondent, according to the earlier application, the thin wire was envisaged for "*temporary*" placement at the site of the vessel trauma. It was thus withdrawn after a "*limited time*". This could clearly not apply to a stent device.

2.5 The fact that a thin wire with a radioactive tip including a beta emitter extends beyond the content of the earlier application, is also based on other considerations.

The earlier application merely disclosed a thin wire with a "*radioactive*" tip. On the other hand, according to claim 1 of the patent in suit, the radioactive tip includes a "*beta-particle emitter radioisotope*". Thus, in the patent in suit, the specific claimed feature concerning the beta radioactivity is deemed to be novel

over the generic disclosure in the earlier application concerning a "*radioactive*" tip. This indicates an inadmissible extension of the disclosure of the earlier application.

Furthermore, the earlier application discloses beta emitters having a half-life between 10 hours and 100 days (column 2, lines 13-15), in particular ^{48}Va, ^{32}P and ^{198}Au. If these emitters are suitable for a radioactive stent implanted permanently or at least for a long period of time, there is no evidence that they would deliver a dose sufficient for inhibiting restenosis when used in a thin wire left in place for a short time. This shows that the beta emitters envisaged by the earlier application for a radioactive stent are not necessarily suitable for a thin wire with a radioactive tip.

2.6 In conclusion, a single sentence in the earlier application is not considered to be sufficient basis for directly and unambiguously deriving the information that technical features disclosed in relation to a radioactive stent could also be used for a thin wire having different requirements. Thus, the subject-matter of claim 1 of the patent as granted combining the features of a thin wire with a radioactive tip and a beta emitter extends beyond the content of the earlier application as filed. This also applies with regard to the dependent claims 2-7. Hence, the main request is not allowable.

3. *Appellant's first, second and third auxiliary requests*

At the oral proceedings, the appellant accepted that the conclusion reached with respect to the main request would equally apply to the auxiliary requests which are also related to a thin wire comprising features originally disclosed in connection with a radioactive stent. Thus, for the same reasons mentioned above with regard to the main request, the appellant's auxiliary requests are not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher G. Davies