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**Datasheet for the decision
of 5 June 2009**

Case Number: T 1420/06 - 3.2.02

Application Number: 00946661.6

Publication Number: 1196113

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:

Device and method for treatment of mitral insufficiency

Applicant:

Edwards Lifesciences AG

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 114(2)
RPBA Art. 12, 13
EPC R. 137(3)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Late filed requests (not admitted)"

Decisions cited:

T 1282/05

Catchword:

-



Case Number: T 1420/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 5 June 2009

Appellant: Edwards Lifesciences AG
Au Glapin
CH-1162 Saint-Prex (CH)

Representative: Müller-Boré & Partner
Patentanwälte
Grafinger Strasse 2
D-81671 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 26 April 2006
refusing European application No. 00946661.6
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
A. Pignatelli

Summary of Facts and Submissions

- I. The present appeal is against the decision of the examining division dated 26 April 2006 to refuse the European patent application number 00946661.6.
- II. The application was refused because the subject-matter of claim 1 was neither considered to be clear nor to be new over the prior art.

Claim 1 forming the basis for the decision of refusal reads as follows:

"A medical implant for treatment of mitral annulus dilatation, characterised by an elongate body (8; 8'; 8") that it is adjustable between a delivery configuration, in which the elongate body (8; 8'; 8") has dimensions as to be deliverable into a coronary sinus (5), and a remodeling configuration, in which the elongate body (8; 8'; 8") is bent such that the elongate body (8; 8'; 8") presses a portion of the coronary sinus (5) against the mitral valve annulus (6) in order to remodel the mitral valve annulus (6)."

- III. The notice of appeal was filed on 27 June 2006 and the appeal fee paid on the same day. The statement of the grounds of appeal was filed on the 25 August 2006.

With the statement setting out the grounds of appeal the appellant filed a set of claims with the main claim being directed towards the third embodiment of the invention comprising several stents and bending and shortening means, and explained why this subject-matter was clear, novel and inventive. The appellant neither

defended the claim forming the basis of the impugned decision nor did the appellant file any claim based on claim 1 as originally filed.

The following claim 1 was filed with the statement of the grounds of appeal:

"A medical implant for treatment of mitral annulus dilatation,
comprising an elongate body having a first stent section and a second stent section,
the elongate body being adjustable between a delivery configuration and a remodelling configuration,
wherein the elongate body in the delivery configuration has dimensions as to be insertable into a coronary sinus, and
wherein the stent sections are adapted to be positioned and fixed in the coronary sinus at a distance from each other,
c h a r a c t e r i s e d in that
the implant further comprises bending and shortening means adapted to transfer the elongate body from the delivery configuration to the remodelling configuration by reducing the distance between the first and second stent sections after the first and second stent sections have been positioned and fixed in the coronary sinus, thereby bending and shortening the elongate body,
wherein the elongate body, in the remodelling configuration, is bent such that the elongate body presses a portion of the coronary sinus against the mitral valve annulus in order to remodel the mitral valve annulus."

- IV. With his letter of 28 April 2008, the present representative announced that he took over representation in the present case. A corresponding authorisation was filed on 23 July 2008.
- V. With the annex to the summons to oral proceedings posted on 17 March 2009 the Board indicated that according to its provisional opinion claim 1 on file contravened Article 123(2) EPC, as in the originally filed documents only an implant with 3 stent sections connected by wires had been disclosed. An implant with two stent sections and without any specific connecting means as claimed in claim 1 had never been disclosed. The board however suggested that a claim with all the features of the third embodiment as originally filed would be clear and novel.
- VI. With its letter of 5 May 2009 the appellant filed a new main request and auxiliary requests 1 to 4 and requested that a patent be granted on the basis of one of these requests taken in the order in which they were numbered.

(a) Claim 1 according to the main request reads as follows:

"A device for treatment of mitral annulus dilatation without the need for cardiopulmonary bypass, comprising an elongate body (8; 8') made of memory metal which has a memory of an original shape, the elongate body having such dimensions as to be insertable through the venous system and into the coronary sinus (5) by a catheter technique and having two states, in a first of which the elongate body (8; 8') has a shape that is adaptable

to the shape of the coronary sinus (5), and to the second of which the elongate body (8; 8') is transferable from the said first state by returning toward the original shape and assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus (5) is reduced as well as the circumference of the mitral valve annulus (6), when the elongate body (8; 8') is positioned in the coronary sinus (5)."

(b) Claim 1 according to the first auxiliary request reads as follows:

"A device for treatment of mitral annulus dilatation without the need for cardiopulmonary bypass, comprising an elongate body (8; 8') comprising at least one memory metal string or a solid wire which has a memory of an original shape, the elongate body constructed to be temporarily forced into another shape having such dimensions as to be insertable through the venous system into the coronary sinus (5) by a catheter technique and having two states, in a first of which the elongate body (8; 8') has a shape that is adaptable to the shape of the coronary sinus (5), and to the second of which the elongate body (8; 8') is transferable from the said first state by returning toward the original shape and assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus (5) is reduced as well as the circumference of the mitral valve annulus (6), when the elongate body (8; 8') is positioned in the coronary sinus (5)."

(c) Claim 1 according to the second auxiliary request reads as follows:

"A device for treatment of mitral annulus dilatation without the need for cardiopulmonary bypass, comprising an elongate body (8; 8') which has a memory of an original shape, the elongate body comprising at least two memory metal strings or a solid wire, the elongate body having such dimensions as to be insertable through the venous system into the coronary sinus (5) by a catheter technique and having two states, in a first of which the elongate body (8; 8') has a shape that is adaptable to the shape of the coronary sinus (5), and to the second of which the elongate body (8; 8') is transferable from the said first state by means (9; 22) for the transfer of the elongate body (8; 8') to the second state by bending and/or shortening it from a larger radius of curvature to a smaller radius of curvature, whereby the radius of curvature of the coronary sinus (5) is reduced as well as the circumference of the mitral valve annulus (6), when the elongate body (8; 8') is positioned in the coronary sinus (5)."

(d) Claim 1 according to the third and fourth auxiliary requests correspond respectively to claim 1 of the first and second auxiliary requests but with the term "or a solid wire" deleted.

VII. On 5 June 2009 oral proceedings took place. The appellant maintained its requests set in point VI above.

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

The requests filed with the statement setting out the grounds of appeal were a reaction to the grounds for the decision of the examining division. The appeal was therefore admissible.

Article 13 RPBA generally provided the possibility to question the admissibility of requests filed after the filing of the statement setting out the grounds of appeal. This article however left it to the board's discretion to decide on such admissibility taking into account the current state of the proceedings, the complexity of the new subject-matter and the need for procedural economy.

After having received the provisional opinion of the Board the appellant was no longer interested in the embodiment with several stents as it was felt to be too restrictive, so that the present claims must be considered as a response to the communication of the Board.

Considering the current state of the proceedings it was to be noted that the present application entered the European phase in 2001. The decision of the examining division (against which an appeal was filed in 2006), was issued more than 3 years later and it was only now, in 2009, that the appeal was dealt with.

During the appeal phase the representative had changed.

The subject-matter of the present claims 1 of the various requests differed only slightly from that of the claim 1 according to the impugned decision. There were no more stent sections in the claim, as they had been replaced by an elongated body having a memory metal, and minor features describing the function had been introduced. Therefore, there was no unsearched subject-matter in present claims. It was believed that no major change or no complex change had taken place.

The subject-matter of present claims 1 was also clearly patentable so that it should be admitted into the proceedings.

It might have been a major problem if such claims had been filed at the oral proceedings, but in the present case this was not the case as these claims were filed one month before the oral proceedings. Furthermore no other party was involved which might have been surprised.

The board should also take into consideration that if the appellant were to file a divisional with claims corresponding to those presently on file, the same examining procedure might have begun again as the divisional application would probably be transmitted to and examined by the same examining division.

Reasons for the Decision

1. The appeal is admissible.

The new requests filed with the statement setting out the grounds of appeal are a reaction to the reasons of the decision. The jurisprudence of the boards admits appeals filed with such requests and considers them to form the basis for appeal proceedings.

2. *Admissibility of the requests on file*

New requests filed in appeal proceedings are only admissible if they comply with the criteria for exercising the discretionary power provided in Article 114(2) EPC as set out in Articles 12 and 13 RPBA.

- 2.1 Article 12 RPBA provides that the appeal proceedings shall be based on the notice of appeal, the statement setting out the grounds of appeal and on any communication sent by the board and any answer thereto. It further provides that the statement setting out the grounds of appeal shall contain a party's complete case.

According to Article 12(4) RPBA, submissions fulfilling these conditions shall be taken into account without prejudice to the power of the board to hold inadmissible requests which could have been presented in first instance proceedings.

- 2.2 The claims on file have been filed with the response to the provisional opinion annexed to the summons based on the set of claims filed with the statement setting out

the grounds of appeal. In this communication the Board raised objections under Article 123(2) EPC and Article 84 EPC and indicated that were these objections to be overcome, the subject-matter of the claims would be clear and novel.

Claim 1 according to present main request is far more general than claim 1 filed with the statement setting out the grounds of appeal, since the several stents and the bending and shortening means are no longer required, and is partly directed towards completely different subject-matter since claim 1 now requires the presence of an elongate body made of memory metal. In essence the subject-matter of claim 1 of the present main request is almost the same as that of originally filed claim 1.

The filing of this claim going back to claim 1 as originally filed cannot be considered to be a reaction to the provisional opinion expressed by the Board in the annex to the summons (see T 1282/05, not published in the OJ).

Additionally the appellant, upon questioning by the Board, stated that it had no good reasons why these requests were not filed in the first instance proceedings although this was possible.

- 2.3 The filing of the present requests with the letter of 5 May 2009 thus clearly does not comply with the provisions of Article 12 RPBA and can therefore not be admitted under this Article.

3. Article 13(1) RPBA rules that any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the board's discretion. It further provides that the discretion should be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

Pursuant to Article 13(3) RPBA, amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board cannot reasonably be expected to deal with without adjournment of the oral proceedings.

- 3.1 Article 13 RPBA in connection with Article 12 RPBA place emphasis on timely filing of the appeal case. One reason for this is to avoid late filings for reasons of procedural strategy of the parties. While late filing of amendments is not entirely excluded, such filings are discouraged by the growing probability of non-admittance as the proceedings draw to a close (see preparatory documents for the Administrative Council CA 133/02).

It is therefore in line with this principle to apply the criteria defined in Article 13(1) RPBA more strictly the closer to the end of the proceedings the amendments are filed. In particular filings after the date of oral proceedings has been arranged or during oral proceedings should be handled more restrictively.

It is further to be noted that while the criteria of "clear allowability" is not mentioned in Article 13(1) RPBA, in particular in ex-parte appeal cases such clear allowability of the amendments supports procedural economy.

- 3.2 The sets of claims presently on file are not clearly allowable. As already mentioned above the subject-matter of claim 1 according to present main request is quite different and more general than the subject-matter according to claim 1 filed with the statement setting out the grounds of appeal.
- In addition, over claim 1 as originally filed, claim 1 according to the main request includes numerous additions in the form of for instance indication of an aim "...without the need for cardiopulmonary bypass...", indication of a suitability, "...insertable through the venous system... by a catheter technique...", etc... and three new sub-claims with features taken from the description have been added.
- It is therefore far from clearly apparent that claim 1 and the sub-claims according to the main request are clear and supported by the originally filed documents.

The Board has never examined subject-matter corresponding to that of the present sets of claims, nor did the Board examine claim 1 as originally filed as it was neither the subject of the decision nor among the requests filed with the statement of the grounds of appeal. A new in-depth examination at a very late state of the proceedings would be necessary to examine these issues.

- 3.3 Because the requests were filed as late as after oral proceedings had been arranged and are not clearly allowable, and because the new subject-matter had not been examined by the Board these new requests do not serve procedural economy, pursuant to Article 13 RPBA, so that the Board decided that the requests on file were not admitted into the proceedings.
4. The appellant argued that there had been a change of representative and that the appellant changed its mind as regards the subject-matter it wished protection for after having received the communication of the Board.
- 4.1 A change of representative is a circumstance which is not inherent to the proceedings and cannot justify per se the filing of different claims. The board has to consider that all actions undertaken by the former representative were undertaken in agreement with the appellant, that these actions thus expressed the desires of the appellant.
- 4.2 While it is accepted that an applicant might change its mind as to what is worth protecting, such a change of the subject-matter is only possible under the conditions provided for in the EPC and its related provisions.
- 4.2.1 In examining proceedings Rule 137(3) EPC states that after receipt of the first communication from the examining division, the applicant may, of his own volition, amend once the description, claims and drawings, provided that the amendment is filed at the same time as the reply to the communication.

Any further amendment of its own volition requires the consent of the examining division.

4.2.2 In appeal proceedings, as explained above, Article 12 RPBA rules that the appeal proceedings shall be based on the notice of appeal and on the statement of the grounds of appeal which shall contain a party's complete case. This implies that the applicant-appellant might change the subject-matter for which protection is sought when starting the appeal proceedings. This is in line with the case law on the admissibility of an appeal, accepting as admissible the filing of new claims which render the attacked decision without object.

However any further change is then subject to the agreement of the Board pursuant to Article 13 RPBA.

4.2.3 These rules and Articles obviously aim at increasing the procedural efficiency and the legal security of third parties while maintaining fair amendment possibilities for the applicant or appellant-applicant.

It is to be noted in this context that notwithstanding the above cited provisions the applicant still has the possibility to file a divisional application for any subject-matter originally disclosed for which protection might be sought.

4.2.4 In the present case, when entering the appeal procedure, the appellant-applicant, in order to clearly render the lack of novelty objection of the decision without object, chose to limit the scope of its claims to the 3rd embodiment described in the patent application even if it was not obliged to do so to overcome the

objections in the impugned decision of the examining division. By doing so the appellant chose the case it considered important and wanted to form the basis of the appeal proceedings. To file an amended sets of claims of its own volition almost going back to the originally filed claim 1 and needing a new examination by the Board so late as one month before the date of the oral proceedings is precisely what Articles 12 and 13 RPBA are meant to avoid and obviously does not serve procedural economy.

- 4.3 It is to be noted that in the light of the fact that the above cited principles must be applied more strictly the closer to the end of the proceedings the amendment are filed (see point 3.1) the evaluation might have been different if the amendments had been filed earlier. The change of representative mentioned above took place almost one year before the sending out of the summons so that the appellant had ample time to file the requests now on file at an earlier stage of the proceedings before any Board's action.
5. Since auxiliary requests one to four, have a main claim along the same line as claim 1 according to the main request, the same reasoning applies to them.
6. Since the present requests are inadmissible and there are no other requests on file, the appeal is dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

M. Noël