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**Datasheet for the decision
of 5 November 2013**

Case Number: T 0174/12 - 3.2.08

Application Number: 06101425.4

Publication Number: 1690515

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
Cardiac-valve prosthesis

Patent Proprietor:
Sorin Group Italia S.r.l.

Opponent:
ATS Medical Inc.

Headword:

Relevant legal provisions:
EPC Art. 100(c), 100(a), 54, 56
RPBA Art. 13(1), 13(3)

Keyword:
Grounds for opposition - fresh ground for opposition
introduced by the opposition division
Amendments - added subject-matter (no)
Amendment to a party's case (admitted)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0174/12 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 5 November 2013

Appellant: ATS Medical Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 19 October 2011
rejecting the opposition filed against European
patent No. 1690515 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: M. Alvazzi Delfrate
D. T. Keeling

Summary of Facts and Submissions

- I. By its decision posted on 19 October 2011 the opposition division rejected the opposition against the European patent No. 1 690 515.
- II. The appellant (opponent) lodged an appeal against this decision on 28 December 2011, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 29 February 2012
- III. Oral proceedings before the Board of appeal took place on 5 November 2013.

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, in the alternative, that the patent be maintained on the basis of one of auxiliary requests 1 to 14 filed with letter of 17 September 2012 or on the basis of one of auxiliary requests 15 to 29 filed with letter of 4 July 2013.

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

"A cardiac-valve prosthesis (1), comprising:

- an armature (2) for anchorage of the valve prosthesis at an implantation site, said armature (2) defining a lumen for passage of the blood flow; and

- a set of prosthetic valve leaflets (3a, 3b, 3c), which are supported by said armature (2) and are able to move, under the action of the blood flow, in a

radially divaricated condition to enable the flow of the blood through said lumen in a first direction, and in a radially contracted condition, in which said valve leaflets (3a, 3b, 3c) cooperate with one another and block the flow of the blood through the prosthesis (2) in the direction opposite to said first direction, wherein said armature (2) comprises:

- two annular parts (20a, 20b) connected by connection formations (22), which extend as connection of said annular parts (20a, 20b), with the capacity of projecting radially with respect to the prosthesis (1); and

- supporting formations (24) for said set of leaflets (3), said formations being carried by at least one of said annular parts (20a, 20b) so as to leave substantially disengaged said lumen for passage of the blood,

characterized in that:

- said annular parts (20a, 20b) have a structure which can expand from a radially contracted condition of advance towards the site of implantation of the prosthesis to a radially expanded condition, in which the prosthesis (1) is withheld in the implantation site, and

- said connection formations (22) have an arched pattern arched towards the outside of the prosthesis (2), said connection formations constituting anchorage formations to ensure anchorage of the prosthesis at the implantation site."

The auxiliary requests are not relevant for the present decision.

V. The followings documents played a role for the present decision:

02: US -A- 2004/0260389; and

05: DE -A- 101 21 210.

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

Admissibility of the grounds of opposition under Article 100(a) in combination with Article 54 EPC and Article 100(c) EPC

The decision under appeal considered the grounds of opposition of lack of novelty and inadmissible extension of subject-matter. Therefore, contrary to the respondent's opinion, the consent of the respondent was not necessary in order to consider them also in the appeal proceedings. Indeed, since the appeal proceedings were directed to a review of the decision of the opposition division, there was no reason to disregard these grounds of opposition.

Article 100(c) EPC

The feature according to which the connection formations constitute anchorage formations to ensure anchorage of the prosthesis at the implantation site was not present in claim 1 as originally filed. This feature was disclosed in the description on paragraph [0044] solely for the case wherein these anchorage formations acted on the outside of the sinuses of Valsalva. As to paragraph [0052], it did not disclose

the anchorage of the prosthesis by means of anchorage formations, but rather as a result of the whole armature of the prosthesis. Hence, claim 1, which did not recite the feature that the anchorage formations extended into the sinuses of Valsalva, had been amended in a way which represented an unallowable intermediate generalisation. Therefore, the patent as granted extended beyond the content of the application as originally filed.

Admissibility of a new argument based on O5

It was clear to the person skilled in the art that the profile of the V-shaped part of the enlarged element shown in Figure 2 of document O5 was exactly the same as the profile of a human cardiac valve. Hence, it was implicit or at least obvious that such V-shaped part was to be used as a support element for the valve leaflets of the prosthesis of O5.

Although these considerations were put forward for the first time during the oral proceedings, they did not represent new facts or evidence, but merely arguments. Moreover, they did not constitute a fresh case, since throughout the proceedings it had been submitted that O5 disclosed a prosthesis with supporting formations in accordance with claim 1 or that it was at least obvious to provide these formations. Hence, there was no reason to disregard this line of argument.

Novelty

O5 disclosed a cardiac valve prosthesis in accordance with claim 1. In particular the enlarged parts shown in Figure 2 were arched towards the outside of the prosthesis and constituted anchorage formations to

ensure anchorage of the prosthesis at the implantation site. Moreover, as already explained, it was implicit for the person skilled in the art that the V-shaped part shown in Figure 2 was to be used as a supporting formation for the valve leaflets. This was not in contradiction to the disclosure in paragraphs [0034] and [0025] of the description, which stated that the leaflets were fixed to the ring element 17, since it was possible to stitch a part of the leaflets to this ring while supporting the rest by the V-shaped part. Hence, also supporting formations in accordance with claim 1 were implicitly disclosed in O5. Therefore, the subject-matter of claim 1 lacked novelty in view of O5.

O2 also related to a valve prosthesis. This valve, albeit indicated as venous valve, exhibited, in particular in the embodiment depicted in Figure 4, all the features of claim 1 of the patent in suit. Therefore, the prosthesis of O2 had to be considered also as a cardiac valve prosthesis. As a consequence, the subject-matter of claim 1 lacked novelty also in view of O2.

Inventive step

In the event that the subject-matter of claim 1 was considered to be novel over O5 by virtue of the supporting formations, it did not involve an inventive step.

Starting from O5 and faced with the object of providing a valve which reproduced as faithfully as possible the operation of a natural valve, the person skilled in the art would have immediately recognised that the profile of the V-shaped part of the prosthesis of O5 was the same as the profile of the leaflets of a natural valve,

which he knew from his common general knowledge. Therefore, it would have been obvious for him to fix the leaflets of the valve to this V-shaped part, which would thus act as a supporting formation. In this way he would have arrived in an obvious way at a prosthesis according to claim 1.

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

Admissibility of the grounds of opposition under Article 100(a) in combination with Article 54 EPC and Article 100(c) EPC

The grounds of opposition of lack of novelty and inadmissible extension of subject-matter were not raised in the notice of opposition but only at a later stage of the opposition proceedings. Moreover, they should have not been allowed in the opposition proceedings, since they were not relevant. Hence, they were to be considered as fresh grounds of opposition, whose introduction into appeal proceedings required the consent of the patent proprietor. Since the respondent denied this consent, these grounds of opposition had to be disregarded.

Article 100(c) EPC

It was clear that the anchorage formations defined in claim 1 as originally filed served to ensure anchorage of the prosthesis at the implantation site. This was also specified in paragraph [0052]. Since none of these passages specified that the anchorage took place in the sinuses of Valsalva it was not necessary, in order to comply with the requirements enshrined in Article 100(c) EPC, to mention it in present claim 1.

Admissibility of a new argument based on O5

The argument according to which the profile of the V-shaped part of the enlarged element shown in Figure 2 of document O5 was exactly the same as the profile of a human cardiac valve had been submitted for the first time during the oral proceedings. Hence, it represented an amendment of the appellant's case presented at a very late stage of the proceedings. Accordingly, this argument should be disregarded.

Novelty

In any event, even considering this new argument, O5 did not disclose a prosthesis with supporting formations according to claim 1. The drawing of Figure 2, like that of Figure 1, was of a mere schematic nature. Accordingly, it did not provide an accurate representation of the real geometry of the prosthesis or the anatomy of the patient. Therefore, the person skilled in the art had no reason to consider that the V-shaped part shown in Figure 2 corresponded to the anatomy of the natural valve leaflets. Hence, he had also no reason to use this part to support the leaflets of the prosthesis of O5, especially since this document explicitly taught that the valve leaflets were fixed to the annular ring. Therefore, O5 did not take away the novelty of claim 1.

O2 was less relevant because it related to a venous valve prosthesis. By contrast, claim 1 of the patent in suit was directed to a cardiac valve prosthesis. Since the hydrodynamic conditions in the veins were not the same to which a cardiac valve prosthesis was subjected the prosthesis of O2 could not be considered a cardiac

prosthesis. Hence, O2 did not take away the novelty of the claimed prosthesis either.

Inventive step

O5 could be considered as the most relevant prior art. Starting from this prior art, nothing prompted the person skilled in the art to depart from its teaching and fix the valve leaflets to the V-shaped part shown in Figure 2. Hence, it was not obvious to provide the prosthesis of O5 with support formations in accordance with claim 1. Therefore, the subject-matter of this claim involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. Admissibility of the grounds of opposition under Article 100(a) in combination with Article 54 EPC and Article 100(c) EPC

In the decision under appeal the opposition division admitted into the proceedings the new grounds for opposition based on extension of subject-matter (Article 100(c) EPC) and lack of novelty under Articles 100(a) and 54 EPC (see decision under appeal, points 1 and 4 of the Reasons). Hence, they are no fresh grounds introduced at the appeal stage, which can be introduced into the appeal proceedings only with the consent of the patent proprietor. On the contrary, since the decision of the opposition division addresses the objections based on these grounds (see points 3 and 5 of the Reasons), they are subject to the review of the Board of appeal when this decision is appealed.

Accordingly, there is no reason to disregard these grounds of opposition.

3. Article 100(c) EPC

Claim 1 of the main request comprises the wording according to which the connection formations constitute anchorage formations "to ensure anchorage of the prosthesis at the implantation site".

This wording was not present in claim 1 as originally filed, which merely referred to "anchorage formations" without specifying what is to be anchored and where. In other words the original claim 1, while disclosing that these formations perform an anchorage function, does not specify the nature of this function.

However, according to paragraph [0052] the annular parts, as well as the respective anchorage elements, substantially form the basic structure or armature of the prosthesis, designed to ensure positioning and anchorage in situ of the prosthesis itself. Accordingly, this passage discloses that the nature of the anchorage function is to ensure anchorage of the prosthesis at the implantation site, irrespective of whether this function is performed by the anchorage formations alone or in combination with other parts of the armature. Therefore, claim 1 and paragraph [0052] of the application as originally filed clearly disclose anchorage formations to ensure anchorage of the prosthesis at the implantation site.

Moreover, since these passages do not mention that the anchorage formations act on the outside of the sinuses of Valsalva the fact that this feature is not present in claim 1 as granted does not introduce subject-matter

which extends beyond the content of the application as originally filed.

Therefore, the objection under Article 100(c) EPC is not convincing.

4. Admissibility of a new argument based on O5

The appellant submitted for the first time during the oral proceedings that it was clear to the person skilled in the art that the profile of the V-shaped part of the enlarged element shown in Figure 2 of document O5 was exactly the same as the profile of a human cardiac valve. On the basis of this argument it questioned the novelty or at least the inventive step of the claimed prosthesis, arguing that O5 disclosed or at least rendered obvious the fixing of the valve leaflets at this part, which thus acted as a supporting formation.

It is true that this submission is neither a new fact nor new evidence, since both O5 and the attacks of lack of novelty and lack of inventive step based on this document were already present in the proceedings. However, these former attacks were completely different from the latter since they did not identify the supporting formation in this V-shaped part but in other elements. Therefore, the submission of this argument constitutes an amendment to the appellant's case after the filing of the grounds of appeal.

Admission and consideration of such amendments is subject to the Board's discretion. In particular, amendments sought to be made after oral proceedings have been arranged should not be admitted if they raise issues which the Board or the other party or parties

cannot reasonably be expected to deal with without adjournment of the oral proceedings (see Article 13(1) and (3) of Rules of Procedure of the Boards of Appeal).

Nonetheless, in the present case the Board considered that the nature of this amendment was not such as to require an adjournment of the oral proceedings. As a matter of fact the respondent itself, albeit objecting to the introduction of this new line of argument, did not request an interruption, let alone an adjournment, of the oral proceedings in order to consider it.

Under these circumstances the Board decided to admit into the proceedings and consider this new line of argument.

5. Novelty

Novelty has been put into question in view of each of O5 and O2.

According to established case law, it is a prerequisite for the acceptance of lack of novelty that the claimed subject-matter is "directly and unambiguously derivable from the prior art". In other words, it has to be beyond doubt - not merely probable - that the claimed subject-matter is disclosed in a prior art document (see Case law of the Boards of Appeal of the European Patent Office, 7th edition 2013, I.C.3.1).

- 5.1 O5 discloses a prosthesis which comprises: an armature (100) for anchorage of the valve prosthesis at an implantation site, said armature defining a lumen for passage of the blood flow; and a set of prosthetic valve leaflets ("Herzklappenersatz"), which are supported by said armature and are able to move, under

the action of the blood flow, in a radially divaricated condition to enable the flow of the blood through said lumen in a first direction, and in a radially contracted condition, in which said valve leaflets cooperate with one another and block the flow of the blood through the prosthesis in the direction opposite to said first direction. The armature comprises: two annular parts (indicated by references 30 and 17 in the reproduction of Figure 2 of 05 on page 16 of the appellant's letter of 29 February 2012) connected by connection formations ("Verankerungselemente" shown as expansions for the bulbi arteriae 13 and 14 in Figure 2), which extend as connection of said annular parts, with the capacity of projecting radially with respect to the prosthesis. The annular parts have a structure which can expand from a radially contracted condition of advance towards the site of implantation of the prosthesis to a radially expanded condition, in which the prosthesis is withheld in the implantation site (see claim 1). The connection formations are preferably adapted to the inner form of the bulbi (see paragraphs [0009] and [0034]). Hence, they have a pattern arched towards the outside of the prosthesis and constitute anchorage formations to ensure anchorage of the prosthesis at the implantation site (see paragraph [0010]).

However, neither the claims nor the description of document 05 disclose supporting formations for the valve leaflets, which formations are carried by at least one of the annular parts so as to leave substantially disengaged said lumen for passage of the blood. On the contrary, the parts of the description referring to the arrangement of the leaflets disclose that they are fixed by stitches to the ring element 17,

i.e. directly to one of the annular parts (see paragraphs [0034] and [0035]).

It is true that the prosthesis depicted in Figure 2 exhibits a V-shaped part whose profile may resemble that of the leaflets of a human cardiac valve. However, this drawing, which does not show the valve leaflets of the prosthesis, is merely schematic (see paragraph [0034]). Hence, it is not an exact representation of the geometry of the prosthesis and of its exact placement in the human body. This is corroborated by Figure 1, also schematic, which represents a section of the aorta, and shows a vessel which corresponds to the human anatomy only in a very approximate manner. Therefore, it cannot be clearly and unambiguously derived from O5 that the geometry of the V-shaped part shown in Figure 2 corresponds to that of natural valve leaflets. As a consequence, it is not implicit that the V-shaped part is to be used as a support element for the valve leaflets.

Therefore, the subject-matter of claim 1 is novel over O5.

5.2 As to O2, this document relates to a venous valve prosthesis (see paragraphs [0003] to [0006]).

By contrast, present claim 1 is directed to a cardiac valve prosthesis. This feature defines the prosthesis' capability of operating under the hydrodynamic conditions to be encountered in the heart. Since these conditions are not the same as those encountered in the veins, the prosthesis disclosed in O2 cannot be considered as a cardiac valve prosthesis.

Accordingly, the prosthesis of O2, in particular its embodiment depicted in Figure 4, does not exhibit all the features of claim 1 of the patent in suit.

Therefore, the subject-matter of claim 1 is also novel in view of O2.

6. Inventive step

6.1 It is common ground that O5, which like the patent in suit relates to a cardiac-valve prosthesis (see for instance the abstract), represents the most relevant prior art for assessing inventive step.

6.2 The object underlying the claimed product starting from this prior art is to provide a structure of prosthetic valve leaflets that can reproduce as faithfully as possible the operation of natural valve leaflets, this as regards minimization of the loss of head induced on the blood flow and as regards the possibility of preventing lines of flow of the blood through the prosthesis from being set up that might depart, as regards their pattern, from the pattern of the lines of flow characteristic of natural blood flow (see paragraph [0015]).

This object is achieved by a prosthesis in accordance with claim 1, which exhibits supporting formations for the set of leaflets, said formations being carried by at least one of the annular parts so as to leave substantially disengaged the lumen for passage of the blood.

6.3 In the appellant's opinion O5 itself, when considered in the light of the common general knowledge of human anatomy of the person skilled in the art, renders it

obvious to fix the valve leaflets to the V-shaped part depicted in Figure 2.

However, that V-shaped part belongs to an element which, according to the teaching of 05, is intended to anchor the prosthesis in place and not to support the valve leaflets (see paragraphs [0008], [0009] and [0034]). The description of 05 does not provide any hint that this part may perform the latter function. Nor does Figure 2 prompt the person skilled in the art in this direction since, as explained above, Figure 2 is merely schematic and cannot be assumed to correspond exactly to the arrangement of the prosthesis as implanted.

Therefore, 05 in combination with the common general knowledge of the person skilled in the art does not render it obvious to achieve the object above in accordance with claim 1. Accordingly, its subject-matter involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



V. Commare

T. Kriner

Decision electronically authenticated