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Datasheet for the decision of 13 September 2019

Case Number: T 0645/16 - 3.2.08

Application Number: 04744941.8

Publication Number: 1648339

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
IMPLANTABLE PROSTHETIC DEVICES PARTICULARLY FOR TRANSARTERIAL DELIVERY IN THE TREATMENT OF AORTIC STENOSIS, AND METHODS OF IMPLANTING SUCH DEVICES

Patent Proprietor:
Ventor Technologies Ltd.

Opponent:
isarpatent - Patent- und Rechtsanwälte Behnisch Barth Charles Hassa Peckmann und Partner mbB

Headword:

Relevant legal provisions:
EPC Art. 100(c), 84, 123(3), 123(2)
RPBA Art. 13(1)

Keyword:
Added subject-matter
Late-filed requests

Decisions cited:
G 0003/14

Catchword:

Europäisches Patentamt
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Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0645/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 13 September 2019

Appellant: (Patent Proprietor)	Ventor Technologies Ltd. 3 Ha Ta'asia Street Ra'anana 43654 (IL)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Appellant: (Opponent)	isarpatent - Patent- und Rechtsanwälte Behnisch Barth Charles Hassa Peckmann und Partner mbB Friedrichstrasse 31 80801 München (DE)
Representative:	Peterreins Schley Patent- und Rechtsanwälte Hermann-Sack-Strasse 3 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 January 2016 concerning maintenance of the European Patent No. 1648339 in amended form.**

Composition of the Board:

Chairman	C. Herberhold
Members:	M. Alvazzi Delfrate
	Y. Podbielski

Summary of Facts and Submissions

I. Subject of the proceedings are the appeals of the patent proprietor and of the opponent against the decision posted on 15 January 2016 in which the opposition division found that European patent No. 1648339, in amended form according to the first auxiliary request then on file, and the invention to which it related met the requirements of the EPC.

II. The opposition division was of the view that the claims of the main request satisfied the requirements of Article 83 EPC but not those of Article 123(2) EPC. The auxiliary request was found to comply with the requirements of Articles 83, 84, 123(2) and 123(3) EPC and to relate to subject-matter which was novel and involved an inventive step.

III. At the end of the oral proceedings before the Board of Appeal, held on 13 September 2019, the requests of the parties were as follows:

Appellant 1 (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted, or as an auxiliary measure and in that order: on the basis of one of new auxiliary request 1 or 2 filed during the oral proceedings before the Board, or on the basis of one of auxiliary requests 1a, 1b, 2a, 2b, 3a, 3b, 4, 5 and 6 filed with letter dated 18 July 2019.

Appellant 2 (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

IV. Claim 1 of the **main request** (patent as granted) reads as follows:

"A prosthetic device comprising:

two annular arrays of fingers (113, 114) engageable with a valve in a blood vessel and comprising a fluid inlet;
and a diverging conical section (111) that extends from the fluid inlet, the diverging conical section (111) comprising a proximal end (PE) near the fluid inlet and a distal end (DE) distanced from the proximal end (PE), at least a portion of the diverging conical section (111) being adapted to flex between an open orientation and a closed orientation, wherein in the open orientation a distal portion of the diverging conical section (111) has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof, and in the closed orientation the diverging conical section is closed for fluid flow therethrough."

Claim 1 of **new auxiliary request 1** reads as follows (differences in respect of the main request emphasised):

"A prosthetic device implantable in the aortic annulus comprising:
an expandable metal base (110) implantable in the aortic annulus and including two annular arrays of fingers (113, 114) engageable with a valve within the aortic annulus ~~in a blood vessel~~ and comprising a fluid inlet; and
a diverging conical section (111) that extends from the fluid inlet and that is an extension of an inner envelope lining the inner surface of the base (110), the diverging conical section (111) comprising a

proximal end (PE) near the fluid inlet and a distal end (DE) distanced from the proximal end (PE), at least a portion of the diverging conical section (111) being adapted to flex between an open orientation and a closed orientation, wherein in the open orientation a distal portion of the diverging conical section (111) has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof, and in the closed orientation the diverging conical section is closed for fluid flow therethrough."

Claim 1 of **new auxiliary request 2** reads as follows (differences in respect of the main request emphasised):

"A prosthetic device implantable in the aortic annulus comprising:
an expandable metal base (110) implantable in the aortic annulus and including two annular arrays of fingers (113, 114) engageable with a valve within the aortic annulus ~~in a blood vessel~~ and comprising a fluid inlet, wherein the two annular arrays of fingers are configured for engaging the opposite faces of the valve leaflets within the aortic annulus; and
a diverging conical section (111) that extends from the fluid inlet and that is an extension of an inner envelope lining the inner surface of the base (110), the diverging conical section (111) comprising a proximal end (PE) near the fluid inlet and a distal end (DE) distanced from the proximal end (PE), ~~at least a portion of~~ the diverging conical section (111) being adapted to flex between an open orientation and a closed orientation, wherein in the open orientation a distal portion of the diverging conical section (111) has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof, and in

the closed orientation the diverging conical section is closed for fluid flow therethrough
wherein the metal base (110) does not extend to or constitute a part of the diverging conical section."

V. The arguments of appellant 2 can be summarised as follows:

Main request - Article 100(c) EPC

Both the independent claims of the application as originally filed recited that the device comprised an "expandable metal base". This feature was omitted in claim 1 of the main request without any basis in the application as originally filed. Indeed, the feature was essential for the prosthetic device to be capable of transarterial delivery when in a compressed state. Hence, the feature that the base was an expandable metal base had to be included in claim 1, alongside with the fact that it could be in a compressed state for delivery.

The omission of the feature that the diverging conical configuration was such that during systole, the envelope opens and assumes a diverging conical configuration "so as to produce the non-turbulent blood flow" also represented added subject-matter. The passage on page 14 describing the embodiment of Figures 12-14, i.e. the basis for present claim 1, disclosed also this feature, which was presented as essential throughout the description. Moreover, present claim 1 did not recite that the diameter of the conical configuration "gradually increases", a feature also related to the effect of the shape of the conical section.

Furthermore, the "plurality of axially-extending struts", also disclosed on page 14, had been omitted in claim 1. All these omissions, together with further ones such as the particular configuration of the arrays of fingers, or of the fact that the base was not part of the conical section, represented added subject-matter.

The clamping function of the fingers, which was essential according to the originally filed application, had also been omitted from claim 1.

Moreover, present claim 1 stipulated that the proximal end of the conical section was "near the fluid inlet", in other words situated at a distance of said inlet. The application as originally filed did not mention any fluid inlet. Hence, while it was implicit that the device had some kind of fluid inlet, there was no disclosure that the respective positions of the fluid inlet and the proximal end of the conical section were as claimed.

Likewise not disclosed in the application as filed was the feature that the diverging conical section was "adapted to flex from an open orientation to a closed orientation". Instead, the application disclosed, on page 14, lines 11-14, that, during systole, the envelope opens and assumes the diverging conical configuration whereas, during diastole, it "collapses" to block the flow therethrough.

Therefore, claim 1 of the main request comprised subject-matter which extended beyond the content of the application as filed.

New auxiliary request 1

New auxiliary request 1 was filed at a very late stage of the proceedings without any good reason. It was not a reaction to the debate during the oral proceedings and was *prima facie* not allowable. In particular, it reintroduced several of the added subject-matter problems already discussed for the main request and overcome by the just discussed auxiliary request 3a. This was not procedurally efficient. Hence, the new auxiliary request 1 should not be admitted into the proceedings.

New auxiliary request 2

The new auxiliary request 2 met only some of the objections of added subject-matter brought forward in respect of the main request.

In addition, claim 1 had been rendered unclear by the amendments. The feature that the diverging conical section "is an extension of an inner envelope lining the inner surface of the base" was not consistent with the claimed position of the proximal end of the diverging conical section "near the fluid inlet".

Finally, claim 1 of new auxiliary request 2 defined that the diverging conical section extended from the envelope lining the base and thus from the fluid inlet. Thus, it could not be "near" the fluid inlet, as recited in granted claim 1. Hence, the new auxiliary request 2 was also in contravention of the requirements of Article 123(3) EPC.

VI. The arguments of appellant 1 can be summarised as follows:

Main request - Article 100(c) EPC

Claim 1 was not based only on the embodiments of Figures 12-14 described on page 14. The claims had to be considered, too. In this respect one was not limited to claims 13 and claim 28, disclosing a conical envelope opening and closing as claimed. Claim 12, which disclosed that the leaflets of the valve are integral with the inner envelope having a conical configuration was equally relevant. Taking this disclosure into account all the embodiments of the patent fell within the scope of claim 1.

The application as originally filed did not disclose an "expandable metal base" as essential for the invention, which was rather based on the conical section and its effect on the blood flow. Thus, the omission of this feature in claim 1 of the main request did not represent added subject-matter. In any event, an expandable metal base was an implicit feature of this type of device, like the wheels were always part of a car.

The omission of the feature that the conical section was such as to produce a "non-turbulent blood flow" did not result in added subject-matter either. Not only was it sufficient to merely reduce the turbulences of the flow but the combination of originally filed claims 17 and 19 did not mention this feature at all. As to the fact that the diameter of the conical configuration "gradually increases", this was a feature inherent in all conical configurations, so that it did not need to be explicitly recited in the claim. In respect of the "axially-extending struts" it was pointed out that they were not mentioned in claims 13 and 28.

It was true that the application as originally filed did not explicitly disclose that the proximal end of the conical section was "near" the fluid inlet. However, when this expression was interpreted in the context of claim 1 it was clear that it meant a conical section extending from the inlet comprised in the base, as disclosed throughout the application.

The term "flex" used in claim 1 was equivalent to the term "collapse" used on page 14. Moreover, the claims disclosed that the material of the envelope was flexible.

In summary the features of claim 1 were all disclosed in the originally filed application, so that no added subject-matter was present.

New auxiliary request 1

The new auxiliary request 1 was a reaction to the debate at the oral proceedings and it should thus be admitted into the proceedings.

New auxiliary request 2

New auxiliary request met all the objections under Article 123(2) EPC which applied to the main request.

It could not be objected to under Article 84 EPC because the alleged unclarity did not result from a post grant amendment. If anything, the geometry defined in claim 1 was now more clearly defined.

The requirements of Article 123(3) EPC were also satisfied because the claim had been amended to further

define a geometry which was already covered by claim 1 as granted.

Reasons for the Decision

1. Main request - Article 100(c) EPC

Both the independent claims of the application as originally filed (1 and 17) include the feature that the device comprises an "expandable metal base". The same applies to all the embodiments described in the description and depicted in the drawings. By contrast, claim 1 of the main request does not mention this feature. Nor can an expandable base be considered as inherent in the claimed device, as would possibly be the case for instance if the claim were directed to a prosthesis for percutaneous transaortic delivery. Hence, it must be assessed if the omission of an "expandable metal base" introduces added subject-matter.

It is true that the application as originally filed does not explicitly describe the expandable metal base as essential. However, this is not sufficient to clearly and unambiguously disclose that this feature can be omitted. Indeed, in the original application the possibility of omitting this feature is neither explicitly nor implicitly disclosed. On the contrary, the fact that the description discloses as one object of the invention the provision of a prosthetic device capable of transarterial delivery (requiring that the components are delivered in a compressed state) is for the person skilled in the art an indication of the need for expandable components.

Therefore the omission in claim 1 of an "expandable metal base" results in subject-matter which extends beyond the content of the application as filed. At least for this reason the patent cannot be maintained on the basis of the main request (Article 100(c) EPC).

2. New auxiliary request 1

The admittance of new auxiliary request 1, filed during the oral proceedings, was at the Board's discretion. In accordance with Article 13(1) RPBA this discretion shall 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.

New auxiliary request 1 was filed at a very late stage of the proceedings. Specifically, it was submitted after the discussion of auxiliary request 3a, which the Board considered to be not allowable solely in view of the replacement of the term "flex" used in granted claim 1 by the term "collapse" (this replacement was considered to be contrary to Article 123(3) EPC).

However, the new auxiliary request 1, in addition to reintroducing the term "flex", differs from auxiliary request 3a by a number of other amendments which had been present in the main request, but not in auxiliary request 3a. Said amendments had been objected to and had been discussed in connection with the main request.

Since the Board had not indicated that said other amendments were allowable, the submission of the new auxiliary request 1 cannot be regarded as a reaction to the debate in the oral proceedings. The new auxiliary request 1 was also diverging with regard to the previously discussed auxiliary request 3a and admitting

it would not have been conducive to an efficient procedure.

Under these circumstances the Board decided not to admit it into the proceedings.

3. New auxiliary request 2

3.1 Admittance

There was no objection to the admittance of the new auxiliary request 2 into the proceedings. The Board, considering that it was essentially based on auxiliary request 3a already into the proceedings with an amendment to take into account the course of the oral proceedings, decided to admit it into the proceedings.

3.2 Article 84 EPC

The feature that the diverging conical section "is an extension of an inner envelope lining the inner surface of the base" was not present in granted claim 1. The appellant argued that this added feature was not consistent with the claimed position of the proximal end of the diverging conical section being "near the fluid inlet" and rendered the claim unclear in this respect.

It is true that the wording "near the fluid inlet" may open the possibility that the proximal end is situated at a distance from the fluid inlet, while the feature added to the claim requires the conical section to be an extension of the liner of the surface of the base that comprises the fluid inlet, thus excluding said distance. However, these two possible interpretations of the claim were already present in claim 1 as

granted, which required that the diverging conical section "extends from the fluid inlet" and comprises "a proximal end (PE) near the fluid inlet".

Hence, the alleged lack of clarity does not result from a post-grant amendment. If anything, the wording of claim 1 of the new auxiliary request 2 is clearer than that of granted claim 1, since it further defines the geometry to be considered: an inner envelope that lines the inner surface of the base comprising the fluid inlet and a diverging conical section that extends from said envelope.

Since the alleged non-compliance with Article 84 EPC is not introduced by a post-grant amendment, claim 1 of auxiliary request 2 cannot be examined for compliance with the requirements of Article 84 EPC (see G 3/14, OJ 2015, 102, Order).

3.3 Article 123(3) EPC

Claim 1 as granted already defined that the diverging conical section extends from the fluid inlet comprised in the base. Hence, the possibility for this section to be an extension of the envelope lining said base was already encompassed in claim 1 as granted. Thus, the scope of protection of the new auxiliary request 2 now limited to this aspect is not extended in respect of that of claim 1 as granted and the requirements of Article 123(3) EPC are satisfied.

3.4 Article 123(2) EPC

3.4.1 In claim 1 of the new auxiliary request 2 the feature that the base is an "expandable metal base" has been added. Hence, the objection under Article 123(2) EPC

against the main request relating to this feature has been overcome.

Appellant 2 argued in this context that the claim should also recite that the device can exhibit a "compressed state" for delivery. However, the fact that the base is expandable necessarily implies that it can have a compressed and an expanded state. Hence, this feature is implicit in claim 1 of new auxiliary request 2 and no omission, let alone an omission resulting in an unallowable intermediate generalisation, can be seen in this respect.

3.4.2 Claim 1 relates to a device wherein at least a portion of the diverging conical section is adapted to flex between an open and a closed orientation. In the open orientation a distal portion of the diverging conical section has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof, while in the closed orientation the diverging conical section is closed for fluid flow therethrough.

Of the three embodiments shown in the drawings of the application as originally filed only the third one (Figures 12-14) exhibits a conical section which opens to allow fluid flow and closes to block it.

In the other two embodiments (Figures 4-8 and 9-11) this function is taken over by valve 16, mounted on the distal end of the conical section. This valve is not disclosed as having a conical section. Hence, these two other embodiments do not fall in the claimed scope and cannot provide a basis for present claim 1.

However, said basis can be provided not only by the embodiment of Figures 12-14, but also by the claims, in

particular claims 13 and 28, which also disclose an inner conical envelope with a configuration which permits fluid flow and a configuration which blocks fluid flow. By contrast claim 12, referred to by appellant 1, disclosing that the leaflets of the valve are integral with the inner envelope (having a conical configuration according to claim 1) but not specifying the geometry of said valve, cannot represent a basis for present claim 1.

3.4.3 It is undisputed that the original application discloses that the diverging conical section is an extension of an inner envelope lining the inner surface of the base (see for instance original claim 1 "... an inner envelope lining the inner surface of the metal base; characterized in that said inner envelope in the expanded state of the prosthetic device extends into the aorta and is of a diverging conical configuration ..."; claim 19 "... an inner envelope lining the inner surface of said metal base; said inner envelope, in the expanded state of the prosthetic device, being of a diverging conical configuration ..." or page 14, lines 20-23, "Envelope 111 lines the inner surface of metal base 110. It then extends outwardly of the metal base to define the diverging conical section of the prosthetic device ...").

However, as pointed out by appellant 2, the application as originally filed does not mention at all the fluid inlet. Hence, it does not disclose *expressis verbis* the feature of claim 1 that the proximal end of the conical section is "near the fluid inlet". It must thus be assessed whether this feature is implicitly disclosed. For doing so it must first be established what is the meaning of this feature in the context of claim 1. As already explained above claim 1 also recites that the

diverging conical section extends from the fluid inlet and is an extension of an inner envelope lining the inner surface of the base. Thus, the expression "near the fluid inlet" in the context of claim 1 cannot be taken to mean that a distance must be present between the proximal end of the diverging conical section and the fluid inlet but rather that they have to be situated in the same region of the device.

As acknowledged by appellant 2 themselves it is implicit that the device described in the application as filed comprises a fluid inlet. This inlet is situated in the region of the metal base (see for instance the schematic Figure 2), i.e. in the same region as the proximal end of the diverging conical section.

Therefore, the feature that the proximal end of the diverging conical is "near the fluid inlet" is disclosed in the application as originally filed.

3.4.4 Also the feature that the diverging conical section is "adapted to flex from an open orientation to a closed orientation" is not literally disclosed in the application as originally filed. Instead, the application discloses, on page 14, lines 11-14, that, during systole, "the envelope 111 opens and assumes the diverging conical configuration" whereas, during diastole, it "collapses" to block the flow therethrough. A similar disclosure is to be found in claims 13 and 28.

However, claims 14 and 29 (depending on claims 13 and 28) disclose that the envelope is made of a flexible pliable material. Hence, it is clear, albeit not literally disclosed, that the section that can collapse

from an open orientation to a closed orientation does so by flexing, as required by present claim 1. Thus, this feature is also disclosed in the application as filed.

3.4.5 Claim 1 of the new auxiliary request 2 does not mention the type of blood flow into the aorta resulting from the conical configuration of the envelope.

By contrast, claim 1 as originally filed (on which claim 13 indirectly depends) further defines the diverging conical configuration such "as to produce, during systole, a non-turbulent blood flow into the aorta with pressure recovery at the distal end of the plastic envelope". The passage in the description describing the embodiment of Figures 12-14 states likewise that "during systole, the envelope 111 opens and assumes the diverging conical configuration so as to produce the non-turbulent blood flow into the aorta with pressure recovery at the distal end of the envelope" (page 14, lines 11-13). However, the combination of originally filed claims 17 and 19, on which claim 28 indirectly depends, discloses a diverging conical configuration without any mention of the type of resulting blood flow. Hence, these claims directly and unambiguously disclose the geometry of the envelope as generalised in present claim 1.

The fact that, contrary to present claim 1, originally filed claim 19 further recites that the diameter of the conical configuration "gradually increases" cannot change this finding since in any conical configuration, comprising that of present claim 1, the diameter gradually increases, so that this feature does not need to be explicitly recited.

Equally immaterial is the fact that the importance of a laminar or non—turbulent flow is stressed throughout the description of the originally filed application. The test to be considered for Article 123(2) EPC is namely whether the claimed features are directly and unambiguously disclosed in the originally filed application and not whether all the essential features are present in the claim.

3.4.6 In order to comply with the requirements of Article 123(2) EPC it is also not necessary to explicitly include the clamping function of the base, which is recited in originally filed claim 5 or claim 7, since this feature is inherent in the fact that the arrays of fingers included in the base are "configured for engaging the opposite faces of the valve leaflets within the aortic annulus" as stipulated by present claim 1.

3.4.7 According to page 14, line 24 - page 15, line 1 the envelope forming the conical section further includes "a plurality of axially-extending struts" to permit the envelope to expand, during systole, to its open-valve condition and to collapse during diastole in order to effectively block the blood flow therethrough, and thereby to perform the function of a prosthetic valve. However, claims 13 and 28 describe the open and close function of the envelope without any reference to said struts.

Hence, no added subject-matter can be seen in the fact that the struts are not mentioned in claim 1.

3.4.8 The new auxiliary request 2 complies thus with the requirements of Article 123(2) EPC.

3.5 No other objections were raised against the new auxiliary request 2, in particular in respect of novelty, inventive step and sufficiency of disclosure. Furthermore, no objection was raised against the adapted description. Also in view of the findings in the appealed decision (points 2.2.1 and 2.3) the Board does not see any reason to doubt that these requirements are fulfilled.

4. Since the new auxiliary request 2 complies with the requirements of the EPC and the patent can be maintained on its base there is no need to consider the lower rankings auxiliary requests 1a, 1b, 2a, 2b, 3a, 3b, 4, 5 and 6.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in the following version:

   Claims 1-3 filed as auxiliary request 2 during the oral proceedings before the Board,

   Description: pages 1-18 filed during the oral proceedings before the Board,

   Figures 1a-17f of the patent specification.

The Registrar: The Chairman:

C. Moser C. Herberhold

Decision electronically authenticated