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**Datasheet for the decision  
of 28 November 2024**

**Case Number:** T 2259/22 - 3.2.02

**Application Number:** 17709795.3

**Publication Number:** 3402440

**IPC:** A61F2/24, A61F2/856

**Language of the proceedings:** EN

**Title of invention:**  
TREATMENT OF TRICUSPID INSUFFICIENCY

**Patent Proprietor:**  
Innoventric Ltd.

**Opponent:**  
MEDIRA GmbH

**Relevant legal provisions:**  
EPC Art. 54, 56, 111(1), 113(1)  
EPC R. 106  
RPBA 2020 Art. 11, 12(3), 12(5)

**Keyword:**

Novelty - (yes)

Inventive step - (yes)

Obligation to raise objections - objection dismissed

Statement of grounds of appeal - insufficient substantiation  
of objections (no) - objections admitted (yes)

Remittal - special reasons for remittal (no)



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0

Case Number: T 2259/22 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 28 November 2024**

**Appellant:** Innoventric Ltd.  
(Patent Proprietor) 3 Golda Meir  
Ness-Ziona (IL)

**Representative:** Nordmeyer, Philipp Werner  
Maucher Jenkins Patentanwälte & Rechtsanwälte  
Liebigstraße 39  
80538 München (DE)

**Appellant:** MEDIRA GmbH  
(Opponent) Ziegelwasen 4  
72336 Balingen (DE)

**Representative:** Witte, Weller & Partner Patentanwälte mbB  
Postfach 10 54 62  
70047 Stuttgart (DE)

**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
28 July 2022 concerning maintenance of the  
European Patent No. 3402440 in amended form.**

**Composition of the Board:**

**Chairman** M. Alvazzi Delfrate  
**Members:** S. Dennler  
C. Schmidt

## Summary of Facts and Submissions

I. Both the patent proprietor and the opponent filed an appeal against the interlocutory decision of the opposition division to maintain the contested patent as amended according to auxiliary request 3 then on file.

II. The opposition division held in the decision under appeal that the subject-matter of claim 1 of the main request was novel over D1 and D2 but not over D3, where D1, D2 and D3 are the following documents:

**D1** WO 2016/008526 A1  
**D2** US 2015/0282958 A1  
**D3** WO 2011/076408 A1

III. In their statements setting out the grounds of appeal, the appellants made the following requests.

The patent proprietor requested that the decision under appeal be set aside and that the contested patent be maintained as amended on the basis of one of the main request and auxiliary requests 1 to 5 filed together with the proprietor's statement setting out its grounds of appeal, the main request being identical to the main request on which the decision under appeal was based.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

In addition, the opponent requested that if claim 1 of the main request was found to be novel in view of D1, D2 and D3, the case be remitted to the opposition division for consideration of the following additional documents, which had been cited as novelty-destroying

in the notice of opposition but not discussed or otherwise addressed before the opposition division:

**D4** WO 2014/107748 A2  
**D5** US 2014/0358221 A1  
**D8** WO 2011/017123 A2

IV. In its communication under Article 15(1) RPBA dated 24 September 2024, the Board expressed the preliminary view, *inter alia*, that the subject-matter of claim 1 of the main request was not novel over D3.

V. In a letter dated 25 October 2024, filed in response to the Board's communication, the proprietor further argued why, in its view, the subject-matter of claim 1 of the main request was novel over D3 and filed a new auxiliary request 1a, which ranked between the pending auxiliary requests 1 and 2.

For some reason, as confirmed by the Registry after the oral proceedings, this letter was not forwarded to the opponent as it should have been. This issue only came to the attention of the Board and the parties during the oral proceedings before the Board, which took place on 28 November 2024 (see next point).

VI. At the beginning of the oral proceedings, the parties confirmed their requests as previously filed in writing, including explicitly, for the proprietor, auxiliary request 1a filed with the letter dated 25 October 2024.

Summarising the relevant facts of the case, the Chairman stated that even after considering the patent proprietor's latest submission, the Board maintained its preliminary opinion that the subject-matter of

claim 1 of the main request was not novel over D3. He further added that the Board intended to admit into the proceedings auxiliary request 1a filed with that submission and that the Board was of the preliminary opinion that the subject-matter of claim 1 of that request was novel over D3.

After the proprietor had presented its arguments in support of the novelty of the subject-matter of claim 1 of the main request in view of D3, the opponent stated that it had not received the proprietor's letter of 25 October 2024 and that it was not aware of the new auxiliary request 1a. The opponent then replied to the proprietor's arguments.

As the oral proceedings were interrupted for the deliberation of the Board on that issue, the proprietor handed over to the opponent a copy of its letter of 25 October 2024 and a copy of auxiliary request 1a.

After the Chairman had announced the Board's conclusion that the subject-matter of claim 1 of the main request was novel over D3 and that the Board was inclined to discuss the opponent's further objections during the ongoing oral proceedings, the opponent requested that the oral proceedings be postponed.

After the Chairman had announced the Board's decision not to grant this request, the opponent raised the following objection under Rule 106 EPC:

*"There was a violation of the opponent's right to be heard because arguments had been brought forward one month ago and the opponent did not have the possibility to prepare and address them."*

The Chairman announced the decision of the Board to reject the objection under Rule 106 EPC.

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

VII. **Claim 1 of the main request** ("claim 1"), which is identical to claim 1 as granted, reads as follows (with the feature numbering used by the parties in their submissions on appeal):

- 1.1 *"Apparatus comprising:  
a tricuspid insufficiency treatment device (10)  
comprising*
- 1.2 *a tubular vena cava member (12) implantable in a  
vena cava of a patient, said vena cava member  
(12) being formed*
- 1.3 *with at least one fenestration (14) formed in a  
side wall of said vena cava member (12) and  
further comprising*
- 1.4 *at least one corresponding blocking member (16),  
said or each blocking member (16) being arranged  
to block and unblock said or each respective  
fenestration (14), said at least one blocking  
member (16) comprising*
- 1.5 *at least one flap or cover pivoted to a portion  
of said vena cava member (12),*
- 1.6 *and wherein when said at least one blocking  
member (16) blocks said at least one fenestration  
(14), said tubular vena cava member (12) and said  
at least one blocking member (16) together have a  
closed cylindrical outer shape."*

VIII. The **patent proprietor's arguments** relevant for the present decision can be summarised as follows.

*Request for postponement of the oral proceedings*

There was no reason to postpone the ongoing oral proceedings before the Board since the arguments put forward in the proprietor's letter of 25 October 2024 were merely a refinement of the case previously made and had merely been repeated at the oral proceedings.

*Novelty in view of D3*

The subject-matter of claim 1 was novel in view of D3 because D3 at least did not disclose a tricuspid insufficiency treatment device (feature 1.1), i.e. a device *suitable* for treating tricuspid insufficiency.

Indeed, as argued by the proprietor during the oral proceedings before the Board, the suitability of the claimed device for the treatment of tricuspid regurgitation implied various requirements that the implant of D3, which was designed for a completely different purpose and environment, namely the treatment of stenoses and aneurysms in blood vessels, did not meet. In particular, the implant of D3, designed for use in blood vessels with a stable, constant geometry, would not be able to withstand the highly dynamic and mechanically challenging environment of the right atrium and the vena cava, the geometry of which changed significantly with each heartbeat and respiratory movements. Furthermore, given its homogeneous structure with flaps uniformly distributed along its length and its reliance on the support of the vessel walls to function properly, the implant of D3 would not be able to reliably and safely block blood backflow in the highly dynamic vascular environment of the heart, as expected of a tricuspid insufficiency treatment device.

*Admittance of the novelty objections in view of D1, D4, D5 and D8 and the inventive-step objections starting from D1, D2, D3, D5 or D8*

The opponent's further objections to claim 1, namely lack of novelty in view of D1, D4, D5 and D8 and lack of inventive step starting from D1, D2, D3, D5 and D8, were not substantiated as required by Article 12(3) RPBA and should therefore not be admitted pursuant to Article 12(5) RPBA. In any event, these objections were not convincing.

*Novelty in view of D1, D4, D5 and D8*

None of D1, D4, D5 and D8 disclosed an apparatus comprising all the features defined in claim 1. The subject-matter of claim 1 was therefore novel in view of all these documents.

Due to the biological heart valve 15 having a three-dimensional, tapered structure with a non-zero height, the implant of D1 did not have a closed cylindrical outer shape (feature 1.6).

The implants of D4, D5 and D8 were, like the implant of D3, not designed for the treatment of tricuspid insufficiency and were, for similar reasons as discussed for D3, unsuitable for this purpose (feature 1.1). In addition, the implant of D4 at least did not include a fenestration and a blocking member comprising a pivoting flap and arranged to block and unblock this fenestration (features 1.3 to 1.5). The implant of D8 did not comprise a vena cava member adapted to be implanted in a vena cava (feature 1.2).

*Inventive step starting from D1 or D2*

The subject-matter of claim 1 involved an inventive step starting from either D1 or D2.

Since the objective technical problem formulated by the opponent starting from D1 was solved in D1, the person skilled in the art would not have been motivated to look for further modifications of the device. In any event, the person skilled in the art starting from D1 would not have departed from a biological heart valve, which was at the core of the invention of D1, and would not have looked to D3, which disclosed implants with a completely different purpose and different construction. To facilitate the loading of the implant of D1 in a delivery catheter, the person skilled in the art would have modified the compressible stent-like vena cava member, as suggested in D1 itself (page 8, first paragraph, last sentence), or mounted the biological valve deeper in the lateral opening of the vena cava member to minimise the extent of its lateral protrusion. However, none of these measures would have led to feature 1.6.

A similar reasoning applied starting from D2, which disclosed an implant for treating tricuspid insufficiency having a similar construction to the implant of D1.

*Inventive step starting from D3, D5 or D8*

The subject-matter of claim 1 was also inventive starting from D3, D5 or D8. The devices disclosed in these documents did not have the same purpose of treating tricuspid insufficiency as the claimed device. Therefore, these documents could not qualify as the

closest prior art for assessing whether the subject-matter of claim 1 was inventive. These documents could not lead the person skilled in the art to the claimed invention in an obvious manner.

IX. The **opponent's arguments** relevant for the present decision can be summarised as follows.

*Request for postponement of the oral proceedings;  
objection under Rule 106 EPC*

The opponent had not received a copy of the proprietor's letter of 25 October 2024, in which the proprietor had set out further arguments on the key issue of novelty in view of D3, and a copy of the new auxiliary request 1a filed with that letter, prior to the oral proceedings before the Board, as should have been the case. Instead, the opponent was confronted with those documents for the first time at the oral proceedings. The opponent was not in a position to deal with this new matter - the letter was a full nine pages long - immediately on the very day of the oral proceedings. The oral proceedings should therefore have been postponed.

The Board's refusal to postpone the ongoing oral proceedings prevented the opponent from having a fair opportunity to address and prepare a response to the proprietor's letter and the new auxiliary request 1a. The opponent, unlike the Board and the proprietor which had filed it, had had no time to consider this matter prior to the oral proceedings. The opponent's right to be heard had thus been violated.

*Novelty in view of D3*

D3 disclosed, in particular in Figure 3, an implant comprising all the structural and functional features defined in claim 1. The subject-matter of claim 1 was therefore not novel in view of D3.

Like the apparatus of claim 1 (see paragraph [0009] of the contested patent), the implant of D3 was designed to prevent blood backflow from the outside of the implant to the inside by allowing the flaps 21 mounted on the tubular stent-like member 10 of the implant to pivot only outwards (page 31, first paragraph: "Rückströmung blockiert"; page 33, second paragraph) in response to a pressure gradient (page 4, second paragraph).

This implant was described as being implantable in coronary vessels (page 1, second paragraph). However, claim 1 and the contested patent in general did not limit the patient to a specific class of patients or the vena cava in which the vena cava member had to be implantable to have specific dimensions. In fact, the dimensions of the vena cava varied considerably even within a given class of patients, and the patient could be any mammal. Moreover, claim 1 did not define any specific feature to ensure proper anchoring of the implant and its stability once implanted. Rather, this simply resulted from the tubular structure of the implant, as with a stent implant in a blood vessel. Paragraph [0024] of the contested patent expressly disclosed that the vena cava member could be a self-expanding or balloon-expandable stent graft. This was expressly disclosed in D3 for the tubular stent-like member 10 (page 18, last paragraph: "Stabilität bzw. Kraft in radialer Richtung").

It followed that, although not mentioned in D3, the implant of D3 was suitable for implantation in a vena cava and at least to some extent suitable for treating tricuspid insufficiency, thus anticipating the apparatus of claim 1.

*Remittal of the case to the opposition division*

D4, D5 and D8 had been cited in the notice of opposition as novelty-destroying for claim 1 but had not been discussed or otherwise addressed before the opposition division. The case should therefore be remitted to the opposition division for consideration of these additional documents. At the oral proceedings before the Board, the opponent did not comment again on this request for remittal.

*Novelty in view of D1, D4, D5 and D8*

The subject-matter of claim 1 was also anticipated by each of D1, D4, D5 and D8.

D1 disclosed an implant specifically designed to treat tricuspid insufficiency (page 3, lines 24 to 26). It comprised (see figure) a tubular vena cava member 11 with a lateral opening 12 in which a biological heart valve 15 was arranged. The latter was not a prosthesis but a biological valve whose one or more leaflets formed flaps which were pivotally attached directly to the vena cava member, i.e. without the aid of a three-dimensional support structure. Consequently, the tubular vena cava member and the one or more flaps of the biological valve together had a closed cylindrical outer shape (feature 1.6). This feature was expressly disclosed in D1 (page 3, last paragraph; page 5, second paragraph). In any event, claim 1 did not require the

outer surface to be strictly flat. Even in the implants of the contested patent, some material protruded outwards from the outer surface of the tubular vena cava member, namely due to the non-zero thickness of the flaps. This was no different in the implant of D1.

D4 disclosed an implant comprising a tubular member (paragraphs [0011] and [0012]) suitable for implantation in the vena cava member (feature 1.2) and having flow channels, i.e. fenestrations, in its outer wall (feature 1.3) facilitating outward radial flow (Figure 2B, paragraph [0082]). The implant also included overlapping membranes which acted as blocking members or flaps which were pivotally attached to the tubular member and which were pressed onto the tubular member by external pressure, thus anticipating features 1.4 to 1.6 (Figure 2B, paragraphs [0080 to [0082]). This implant was suitable for treating tricuspid insufficiency for reasons similar to those discussed for D3.

D5 disclosed an implant similar to that of D3 (see in particular Figure 4C showing pivoting flaps 402 for blocking and unblocking corresponding fenestrations 408 formed in a side wall of the tubular implant and acting as a one-way valve, as disclosed in paragraph [0136]). This implant was suitable for treating tricuspid insufficiency for reasons similar to those discussed for D3 (paragraph [0002]).

D8 disclosed implants comprising a stent graft member having one or more openings and one or more flap members configured to selectively cover the one or more openings (paragraph [0013]). As shown in Figures 21 and 22, the stent graft member and the one or more flap members together had a closed cylindrical shape in the

blocking position. These implants were endoluminal vascular prostheses which could be used in blood vessels, such as the aorta (paragraph [0002]), and D8 disclosed that they could also be used in other fields or other parts of the body (paragraph [0010]). These implants were also suitable for treating tricuspid insufficiency.

*Inventive step starting from D1 or D2*

If feature 1.6 were to be considered novel over D1, this feature would in any event not render the subject-matter of claim 1 inventive over this document.

Feature 1.6 solved the objective technical problem of facilitating the sheathing and unsheathing of the device when loading and deploying the device on a delivery catheter.

Faced with this technical problem, the person skilled in the art would have consulted D3, which disclosed a device in which the valve function was achieved by means of flaps which, in the closed position, were in substantially complete contact with the tubular wall of the implant, hence resulting in a closed cylindrical shape (page 3, last paragraph). D3 explained that this configuration not only improved the valve function but also facilitated the crimping of the device, i.e. its loading onto a delivery catheter (page 19, third paragraph, seventh sentence). In the light of this teaching, it would have been obvious to the person skilled in the art to implement such a configuration in the implant of D1 in order to solve the technical problem. They would therefore have arrived at the subject-matter of claim 1 without exercising any inventive step.

It was irrelevant that the device of D3 was not disclosed for the treatment of tricuspid insufficiency since the objective technical problem formulated starting from D1 concerned only the loading of the implant on a delivery catheter, which was not related to the intended treatment itself.

A similar reasoning applied starting from D2, which disclosed a tricuspid insufficiency treatment device with a similar construction to that in D1.

*Inventive step starting from D3, D5 or D8*

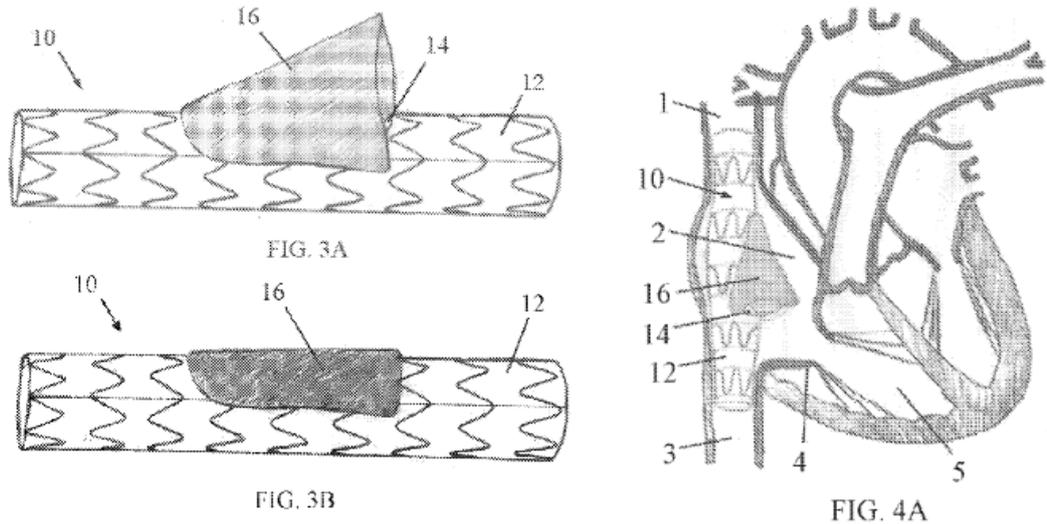
The subject-matter of claim 1 was also not inventive starting from D3, D5 or D8. It would have been obvious to the person skilled in the art faced with the technical problem of providing a device suitable for treating tricuspid insufficiency to use the devices disclosed in these documents for that purpose since they were suitable for implantation in blood vessels such as the vena cava.

## **Reasons for the Decision**

### **1. The subject-matter of the contested patent**

- 1.1 The contested patent relates to a stent-based implant for treating an incompetent or regurgitant tricuspid valve, i.e. a tricuspid valve that does not perform its normal function of preventing the backflow of blood from the right ventricle to the right atrium when it closes during ventricular systole and allowing blood to flow from the right atrium to the right ventricle when it opens during ventricular diastole (paragraphs [0001] to [0003] of the patent).

1.2 An example of an implant (10) according to claim 1 of the main request is shown in Figures 3A, 3B and 4A, reproduced below.



This implant comprises a tubular vena cava member (12) implantable in the superior vena cava (1) and the inferior vena cava (3) of a patient (see Figure 4A), with a fenestration (14) formed in a side wall of the vena cava member, and a blocking member (16) comprising a flap or cover pivoted to a portion of the vena cava member and arranged to block or unblock the fenestration. In the blocking configuration (see Figure 3B), the tubular vena cava member and the blocking member together have a closed cylindrical shape, as shown in Figure 3B. The implant can also comprise more than one fenestration and corresponding blocking member (see Figures 6 and 7). An overview of the functioning of the implant is given in paragraphs [0009] and [0010].

1.3 This implant provides an alternative to the complex and risky repair/replacement of the tricuspid valve (4) by open heart surgery (paragraphs [0004] and [0005]). For

this purpose, rather than mimicking the structure of the tricuspid valve, the implant aims to functionally replace a regurgitant tricuspid valve, while avoiding the complex anatomy of the right ventricle (5) and the valve itself (paragraphs [0007] and [0008]).

**2. Request for postponement of the oral proceedings;  
objection under Rule 106 EPC**

2.1 During the oral proceedings before the Board, the opponent stated that it had only become aware of the proprietor's letter of 25 October 2024, in which the proprietor had further discussed the issue of novelty of claim 1 in view of D3, and of the auxiliary request 1a filed with that letter, during the ongoing oral proceedings. The opponent therefore requested that the oral proceedings be postponed - i.e. more precisely, that they be adjourned - to give the opponent sufficient time to consider the proprietor's submissions and to prepare a reply.

2.2 An internal investigation by the Registry following the oral proceedings has indeed revealed that, for some reason, the proprietor's letter of 25 October 2024 was not forwarded to the opponent as would normally have been the case.

2.3 The Board recognises that this is regrettable. However, for the following reasons, the Board considered that this failure, however unfortunate, did not justify the adjournment of the oral proceedings.

The discussion at the oral proceedings did not turn on auxiliary request 1a filed with the letter of 25 October 2024 but was limited to the patentability of the main request. It is true that the letter of

25 October 2024 also comprised submissions on the novelty of the main request in view of D3. However, as discussed in detail in point 3. below, the Board's conclusion that the subject-matter of claim 1 is novel in view of D3 was not taken on the basis of those submissions but rather on the basis of the arguments put forward by the proprietor at the oral proceedings, which supported the view that the implant disclosed in D3 is unsuitable for treating tricuspid insufficiency. The opponent orally replied to these arguments. As can be seen from the minutes of the oral proceedings before the Board and as summarised in point VI. above, it was indeed only at the oral proceedings, after both parties had been heard by the Board on this issue, that the Board took the view that the subject-matter of claim 1 was novel over D3, thus departing from its preliminary opinion expressed in its communication under Article 15(1) RPBA and reiterated at the beginning of the oral proceedings, which was in favour of the opponent.

The issue of whether the implant of D3 is suitable for treating tricuspid insufficiency was of relevance throughout the opposition proceedings (see, for example, point 2 of the minutes of the oral proceedings before the opposition division) and was discussed in the decision under appeal itself (see points 2.3.2.1(i) and 2.3.2.2.1 of the Reasons). At the oral proceedings, the proprietor merely emphasised and refined some of the arguments already put forward on this issue in its statement of grounds of appeal (see in particular point II.2.a and b on pages 5 to 10). Therefore, the proprietor's submissions at the oral proceedings before the Board on this issue - which, moreover, were easily understandable - could not have surprised the opponent.

The fact that some of the arguments put forward by the proprietor at the oral proceedings before the Board may already have been set out in the letter of 25 October 2024 is irrelevant and did not prevent the opponent from commenting on and rebutting these arguments, something the opponent in fact did.

Furthermore, although reference was made to the proprietor's letter of 25 October 2024 and to auxiliary request 1a at the very beginning of the oral proceedings before the Board, i.e. before the actual discussion of novelty in view of D3, the opponent nevertheless made its request for postponement of the oral proceedings only after the Chairman had announced the Board's conclusion that the subject-matter of claim 1 was novel over D3. Up to that point, the opponent never complained that its right to be heard had been violated. Nor did it request an interruption of the oral proceedings to have more time to consider the arguments presented orally by the proprietor or indeed that the arguments be disregarded.

In these circumstances, the Board saw no reason to adjourn the oral proceedings and consequently did not grant the opponent's request to do so.

- 2.4 The opponent then raised an objection under Rule 106 EPC, claiming that the Board had violated its right to be heard by refusing to adjourn the oral proceedings.

As explained above, the Board's refusal to adjourn the oral proceedings did not prevent the opponent from having the opportunity to address and present its comments on the proprietor's arguments presented at the oral proceedings on the novelty of claim 1 in view of D3, on which the Board's conclusion, as discussed in

point 3. below, is based. It follows that, contrary to the opponent's contention, its right to be heard pursuant to Article 113(1) EPC was not infringed. The Board therefore rejected the opponent's objection under Rule 106 EPC.

### **3. Novelty in view of D3**

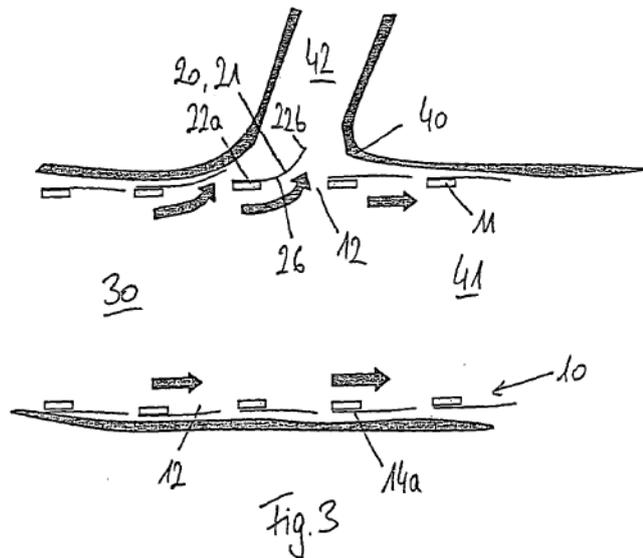
3.1 Contrary to the opponent's view, D3 does not disclose a device comprising feature 1.1, and the subject-matter of claim 1 is therefore novel in view of D3.

3.2 It is common ground that the expression "tricuspid insufficiency treatment device" in feature 1.1 means nothing other than a device *suitable* for treating tricuspid insufficiency. Accordingly, any prior-art device which, in addition to including the features expressly mentioned in claim 1, can be used for this purpose will take away novelty from the claimed device. This is irrespective of whether the prior art mentions the stated use or purpose or whether the stated use is obvious. This is because claim 1 is directed to the device and not to its use.

3.3 It is also common ground that D3 does not address the treatment of tricuspid insufficiency. Rather, D3 discloses implants primarily intended for implantation in blood vessels, in particular for treating stenoses or aneurysms. The question therefore arises as to whether the implants of D3 are *suitable* for treating tricuspid insufficiency.

3.4 As argued by the opponent, these implants, such as the implant shown in Figure 3 reproduced below, comprise, similar to the implant of claim 1, a tubular stent-like member 10 ("rohrförmige Wandung") on which flaps 21

("Klappen") are pivotally mounted so as to block and unblock multiple corresponding fenestrations 12 ("Zellen") defined in the side wall of the implant, in particular by the struts ("Stegen") 11 of the stent-like tubular member.



In the embodiment of Figure 3, the flaps are only allowed to pivot outwards, meaning that the implant, like the implant of claim 1, has a valve function in that it allows blood to flow from the inside of the implant to the outside, but not vice versa (page 31, first paragraph: "Rückströmung blockiert"; page 33, second paragraph), in response to corresponding pressure gradients (page 4, second paragraph). In this way, blood can flow from a main vessel 41 in which the implant is implanted into a branched secondary vessel 42, while blood backflow from the secondary vessel 42 into the main vessel 41 is prevented.

3.5 The opponent argued that that this implant could therefore be successfully implanted in a patient's vena cava for treating tricuspid insufficiency, at least to some extent.

The Board disagrees. As argued by the proprietor at the oral proceedings before the Board and as set out below, the suitability of the device of claim 1 for the treatment of tricuspid insufficiency implies various requirements that the implants of D3, which are designed for a completely different purpose and environment, such as the treatment of stenoses and aneurysms in blood vessels, do not meet. This applies even if, as set out above, these implants are designed to have a certain valve function.

It is true that claim 1 does not limit the patient to a specific class of patients or the vena cava in which the vena cava member of the implant must be implantable to have specific dimensions. Therefore, given the great variability of dimensions of the vena cava even within a class of patients, it is indeed conceivable that an implant of D3, such as that shown in Figure 3, may have a diameter suitable for implantation in the superior vena cava and the inferior vena cava of a patient, like the claimed implant shown in Figure 4A of the contested patent.

However, as argued by the proprietor, the implant of D3, especially when designed for use in blood vessels with a stable, constant geometry, would not as such be able to withstand the highly dynamic and mechanically challenging environment of the right atrium and the vena cava, the geometries of which, unlike that of a blood vessel, change significantly with each heartbeat and with each respiratory movement. Firstly, the Board is not convinced that this implant, without some *ad hoc* modification of its construction - which D3 neither discloses nor suggests - would be able to accommodate these constant variations in shape and withstand the resulting mechanical stresses without deteriorating, in

particular due to material fatigue. Secondly, it is also doubtful whether the implant would even remain in place in such a dynamic environment, with a substantial central part of the implant extending into the open space formed by the right atrium, thus leaving it without any support. In contrast, as argued by the proprietor, the implants of D3 are designed to maintain contact with the vessel walls and rely largely on the support of the vessel walls to function properly, with only a limited portion of the implant in the region of the branch left unsupported (see Figure 3).

Furthermore, as the proprietor also argued, the implant of D3, in particular because of its homogeneous structure with flaps uniformly distributed along its length, would not be able to reliably and safely block blood backflow in the highly dynamic vascular environment of the heart. This is because the constant deformation of the stent-like member 10 imposed by this environment would prevent the flaps from reliably blocking and unblocking the fenestrations primarily in response to blood pressure gradients between the vena cava and the right atrium, as expected of a device suitable for treating tricuspid insufficiency.

The Board therefore concludes, in agreement with the proprietor, that the implant of D3 is not suitable for treating tricuspid insufficiency as required by feature 1.1. Hence, the subject-matter of claim 1 is novel in view of D3.

**4. Substantiation and admittance of the novelty objections in view of D1, D4, D5 and D8 and the inventive-step objections starting from D1, D2, D3, D5 or D8**

Contrary to the proprietor's assertion, the Board does not consider the opponent's further objections to claim 1 to be unsubstantiated.

In point 2.4 of its statement of grounds of appeal, the opponent explained in detail why, in its opinion, "D1 disclose[d] each and every features of claim 1 as granted" (see fourth paragraph on page 6), in other words, why the subject-matter of claim 1 was not novel in view of D1.

It is true that the further novelty objections in view of D4, D5 and D8 and inventive-step objections starting from D1, D2, D3, D5 and D8 are not set out in detail in the opponent's statement of grounds of appeal (see points 2.6 and 2.7). However, for these objections, the opponent referred to specific passages of the notice of opposition, namely points III.A.4. to III.A.6. and III.B.1. to III.B.3., in which the opponent explained in detail why the subject-matter of claim 1 as granted, with which claim 1 is identical, was not novel or not inventive in view of these documents.

This enables the Board to understand without undue burden the reasons why the opponent requested that the decision under appeal concerning claim 1 be reversed or upheld regarding novelty and inventive step in respect of these documents. The Board thus considers that these further objections are substantiated as required by Article 12(3) RPBA, and there is therefore no reason for the Board not to admit them pursuant to Article 12(5) RPBA.

**5. Remittal of the case to the opposition division**

5.1 The opponent justified its conditional request for remittal of the case to the opposition division on the ground that D4, D5 and D8, which had been cited in the notice of opposition as prejudicial to the maintenance of the patent as granted, had not been considered by the opposition division. The opponent did not comment on this request again at the oral proceedings before the Board.

5.2 It is true that D4, D5 and D8 are not discussed in the decision under appeal. Indeed, as the opposition division found that the subject-matter of claim 1 as granted, with which claim 1 is identical, was not novel in view of another document, D3, there was no need to discuss the further objections to that claim based on D4, D5 and D8.

5.3 Nevertheless, the Board found it appropriate to exercise its discretion under Article 111(1) EPC to examine and decide on these objections itself.

The objections to claim 1 based on D4, D5 and D8 essentially depend on the suitability of an implant for treating tricuspid insufficiency (feature 1.1) and on what the person skilled in the art would consider to be a flap or cover pivoted to a portion of the vena cava member and a corresponding blocking member (features 1.4 and 1.5), i.e. similar issues to those considered in the decision under appeal, in particular as regards D3.

Furthermore, the objections based on D4, D5 and D8 were also addressed by the proprietor in its appeal submissions and by the Board in its communication under Article 15(1) RPBA.



the vena cava member and the one or more leaflets together have a closed "cylindrical" outer shape as required by feature 1.6.

D1 only discloses that the implant is tubular overall (page 3, last paragraph: "insgesamt rohrförmig"; page 5, second paragraph: "Rohrform"). In contrast, the term "cylindrical" in feature 1.6 requires that the outer shape of the vena cava member together with the one or more flaps is not merely as a whole tubular but also excludes protrusions from the stent graft body. This is in agreement with the description of the contested patent which stipulates "no element protruding towards or inwards from the stent graft body" (paragraph [0014]). The person skilled in the art would understand that this definition does not preclude that the flaps, due to their non-zero thickness, may slightly extend outwards from the outer surface of the tubular vena cava member, as long as they do not "protrude" inwards or outwards.

In the absence of any detailed description of the biological heart valve 15 in D1, the Board finds persuasive the proprietor's argument that, as a conventional biological heart valve, valve 15 may not be planar but instead seems to have a three-dimensional, tapered structure with a non-zero height to allow the leaflets (or parts of the single leaflet in the case of a monocuspid valve) to abut during coaptation, when the valve is closed. The valve therefore in this case constitutes an element which protrudes outwards from the vena cava member, meaning that the outer shape of the implant of D1 is not "cylindrical".

It follows that D1 at least does not directly and unambiguously disclose feature 1.6.

- 6.3 It is common ground that D4, D5 and D8 do not address the treatment of tricuspid insufficiency. Rather, like the implants of D3, the implants disclosed in these documents are primarily intended for the treatment of stenoses and aneurysms (see for example paragraph [0008] of D4; paragraphs [0004] to [0009] of D5; paragraph [0002] of D8).

Although these documents disclose that the implants might be used for other parts of the body, as argued by the opponent, the opponent's allegation that these implants are suitable for treating tricuspid insufficiency is not convincing. For reasons similar to those discussed for D3, the Board agrees with the proprietor that these implants could not be successfully used for this purpose without being specifically modified, something which D4, D5 and D8 neither disclose nor suggest. The opponent has not provided any convincing arguments to the contrary. It follows that D4, D5 and D8 do not disclose at least feature 1.1.

- 6.4 Furthermore, the implant of D4 shown in Figure 2B comprises a continuous helical stent member 280 and a continuous helical membranous covering 290 which together define the peripheral wall of a tunnel while allowing outward radial flow through this wall from the interior of the tunnel to the exterior. Contrary to the opponent's argument, this does not anticipate a blocking member comprising a flap or cover pivoted to a portion of the stent member, and adapted to block and unblock a corresponding fenestration formed in the side wall of the stent member (features 1.3 to 1.5).

The implant of D8 is designed for the treatment of type II endoleaks (paragraph [0002]). As shown in Figures 21 and 22, this implant is bifurcated and comprises two branch portions 185, 186, this making it unsuitable for implantation in a vena cava. D8 therefore does not disclose a vena cava member adapted to be implanted in a vena cava (feature 1.2).

**7. Inventive step starting from D1 or D2**

7.1 Contrary to the opponent's view and as set out below, the subject-matter of claim 1 involves an inventive step starting from D1 or D2.

7.2 As set out in point 6.2 above, the subject-matter of claim 1 differs from the implant of D1 at least by virtue of feature 1.6.

7.3 Similarly, it is common ground that D2 discloses (see Figures 2 and 3) a device for treating tricuspid insufficiency similar to the implant of D1, comprising a biological heart valve 40 laterally mounted on a tubular stented vena cava member 30 (see paragraph [0049]).

As the biological heart valve 40 projects outwards from the lateral surface of the vena cava member 30 (all the more so as the valve 40 is expressly a "stented" valve), these two parts together do not have a cylindrical outer shape as required by feature 1.6. It follows that the subject-matter of claim 1 also differs from the implant of D2 by virtue of feature 1.6.

7.4 Referring to paragraph [0030] of the contested patent, where the advantage of the closed cylindrical outer

shape of the claimed device resulting from this feature is emphasised, the opponent formulated the objective technical problem to be solved starting from D1 as facilitating the sheathing and unsheathing of the device when loading and deploying it on a delivery catheter.

- 7.5 Even assuming this objective technical problem - which is contested by the proprietor - the Board is not convinced that the person skilled in the art, starting from D1 or D2 and faced with this problem, would have implemented feature 1.6 in the implant of D1 or D2 in an obvious manner and without hindsight, even taking into account D3.

Firstly, it is already questionable whether, as the opponent argued, the person skilled in the art starting from D1 or D2 would have consulted D3 at all, which does not relate to the treatment of tricuspid insufficiency but discloses implants with a completely different purpose and different construction (see section 3. above).

Most importantly, the Board agrees with the proprietor that the person skilled in the art starting from D1 or D2 would in any event not have departed from a biological heart valve, which is consistently presented to be at the core of the inventions of D1 and D2. Consequently, the person skilled in the art would not have combined D1 or D2 with D3 as alleged by the opponent since this would have required replacing the biological heart valve with a different construction based on one or more flexible flaps as disclosed in D3.

Rather, the person skilled in the art seeking to facilitate the sheathing and unsheathing of the

implants of D1 or D2 in a delivery catheter would have modified the stent-like vena cava member to make it even more compressible, as indeed is suggested in D1 itself (page 8, first paragraph, last sentence), or would have mounted the biological heart valve deeper in the lateral opening of the vena cava member to minimise the extent of its lateral protrusion. However, none of these measures would have resulted in feature 1.6.

**8. Inventive step starting from D3, D5 or D8**

8.1 The opponent's inventive-step objections in respect of D3, D5 and D8 are based on the argument that the person skilled in the art, faced with the technical problem of providing a device suitable for treating tricuspid insufficiency, would naturally have considered using for this purpose the implants disclosed in these documents, even if the latter do not contain any indication to that effect.

8.2 The Board disagrees. As discussed in points 3.5 and 6.3 above, and contrary to the opponent's view, the implants disclosed in D3, D5 and D8 are not suitable to be implanted in a vena cava for the treatment of tricuspid insufficiency unless they are specifically modified for this purpose. In the absence of any disclosure or suggestion to that effect in these documents, the person skilled in the art starting from one of these documents would not, without the benefit of hindsight, have considered such modifications. For this reason alone, the opponent's objections are not convincing.

8.3 When looking for a device suitable for treating tricuspid insufficiency, the person skilled in the art would have instead chosen one of the implants disclosed in D1 or D2, not least because, in contrast to the implants of D3, D5 and D8, these implants are explicitly designed - and disclosed as such - as devices for treating tricuspid insufficiency. However, in doing so, the person skilled in the art would not have arrived at the subject-matter of claim 1, as set out in section 7. above.

8.4 The Board therefore agrees with the proprietor that the subject-matter of claim 1 involves an inventive step starting from D3, D5 and D8.

## **9. Conclusion**

It follows from the foregoing that none of the objections raised by the opponent prejudice the maintenance of the contested patent as amended on the basis of the main request, contrary to the finding in the decision under appeal.

## Order

### For these reasons it is decided that:

1. The decision is set aside.
2. The patent is maintained on the basis of the main request.

The Registrar:

The Chairman:



G. Magouliotis

M. Alvazzi Delfrate

Decision electronically authenticated