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**Datasheet for the decision
of 15 January 2025**

Case Number: T 2142/22 - 3.2.02

Application Number: 18181176.1

Publication Number: 3400908

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
ARTIFICIAL VALVE PROSTHESIS

Patent Proprietor:
Cook Medical Technologies LLC

Opponent:
(withdrawn)

Headword:

Relevant legal provisions:

EPC Art. 54
RPBA 2020 Art. 12(6)

Keyword:

Late-filed request - admitted in first-instance proceedings

(no) - admitted (yes)

Novelty - (yes)

Decisions cited:

T 0857/20

Catchword:



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Case Number: T 2142/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 January 2025

Appellant: Cook Medical Technologies LLC
(Patent Proprietor) 750 North Daniels Way
Bloomington, IN 47404 (US)

Representative: Mathys & Squire
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Respondent: (withdrawn)
(Opponent)

Representative:

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 6 July 2022
revoking European patent No. 3400908 pursuant to
Article 101(3) (b) EPC

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: D. Ceccarelli
C. Schmidt

Summary of Facts and Submissions

- I. The patent proprietor appealed against the Opposition Division's decision to revoke the European patent.
- II. The opposition to the patent was withdrawn.
- III. Oral proceedings took place on 15 January 2025.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of the first and second auxiliary requests, filed with the statement setting out the grounds of appeal dated 16 November 2022, and auxiliary requests 3 to 7, filed with letter dated 30 June 2023.

- IV. The following document is mentioned in this decision.

D7: US 2005/0137690 A1

- V. Claim 1 of the main request reads as follows.

"An artificial valve prosthesis for regulating fluid flow through a body vessel having a wall, comprising:
an outer frame (401) having a first, unexpanded configuration and a second, expanded configuration;
two or more support elements (406, 407), each of which is positioned within a lumen formed by the expanded outer frame, has a first end attached to the outer frame, and extends from said first end in a direction of antegrade fluid flow and into the lumen formed by the outer frame;
two or more valve leaflets (402, 403), each of which is supported by the outer frame and by one of

said support elements, at least a portion of a perimeter of the valve leaflet in question being attached to said one of the support elements wherein said at least a portion of the perimeter is positioned away from the vessel wall, and wherein the two or more valve leaflets are deformable between a first position allowing fluid flow in the first, antegrade direction and a second position restricting fluid flow in a second, retrograde direction;

for each of said two or more support elements, a respective element (408, 409) for providing additional support thereto; and

wherein the number of valve leaflets is the same as the number of support elements and a commissural point, where two of said valve leaflets are attached, is positioned on each of said support elements (406, 407) wherein the support elements are configured to accommodate limited radial movement of the commissural points with respect to the outer frame."

Claims 2 to 7 are dependent claims.

VI. The appellant's arguments, where relevant to this decision, may be summarised as follows.

The main request had to be admitted into the appeal proceedings. It had been filed during the oral proceedings at first instance, in response to an objection of added subject-matter raised during those oral proceedings. Formally, the Opposition Division decided not to admit it for *prima facie* lack of novelty; however, this decision was wrong in substance. Moreover, the decision had been taken after a lengthy discussion and a substantive examination during the oral proceedings. Hence, in practice, the request had been admitted.

The subject-matter of claim 1 of the main request was novel over D7. This document did not disclose support elements of an artificial valve prosthesis that were configured to accommodate limited radial movement of commissural points of valve leaflets with respect to an outer frame of the prosthesis, as claimed. D7 disclosed a valve prosthesis with support elements in the form of posts. However, in the expanded configuration of the valve prosthesis, these posts were locked and under a tensile load, as described in paragraph [0078] of D7. For this reason there was no direct and unambiguous disclosure in D7 that the posts could accommodate any radial movement at all.

This distinguishing feature addressed the objective technical problem of avoiding damage to the valve leaflets, as set out in paragraphs [0028] to [0030] of the patent, and was neither disclosed nor rendered obvious by the cited prior art.

Reasons for the Decision

1. The subject-matter of the patent

The patent relates to an artificial valve prosthesis for regulating fluid flow through a body vessel having a wall.

Valve prostheses are designed to replace or supplement malfunctioning natural valves, such as venous valves. The general field of application, however, includes any "blood vessels", "biliary ducts, ureteral passages and the alimentary canal" (paragraph [0026] of the patent).

An artificial valve prosthesis according to claim 1 of the main request is depicted in Figure 4 of the patent, reproduced below.

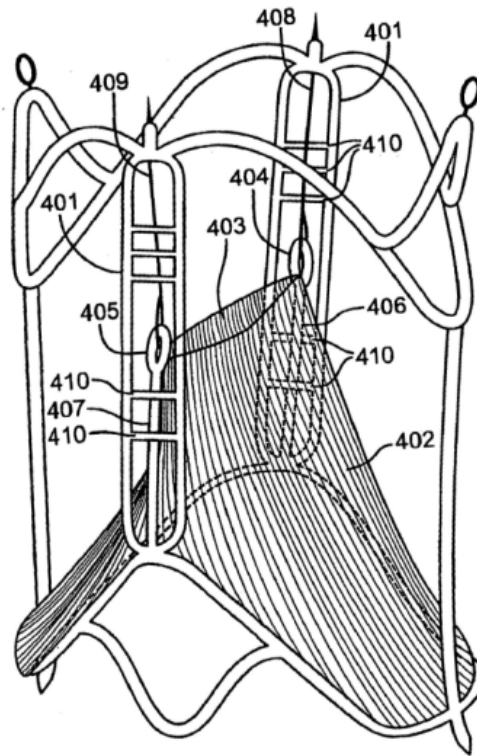


Fig.4

The prosthesis comprises an outer frame (401), such as a stent, having a first, unexpanded configuration and a second, expanded configuration. This allows the use of minimally invasive delivery devices for the placement of the valve (paragraph [0005] of the patent), such as catheter-based systems.

The prosthesis further comprises two or more support elements (406, 407), each of which is positioned within a lumen formed by the expanded outer frame, has a first end attached to the outer frame, and extends from the first end in a direction of antegrade fluid flow and into the lumen formed by the outer frame.

The prosthesis further comprises two or more valve leaflets (402, 403), each of which is supported by the outer frame and by one of the support elements, at least a portion of a perimeter of the valve leaflet in question being attached to one of the support elements, wherein the portion of the perimeter is positioned away from the vessel wall, and wherein the two or more valve leaflets are deformable between a first position allowing fluid flow in the first, antegrade direction and a second position restricting fluid flow in a second, retrograde direction. The support elements and the valve leaflets as defined may have the function of accommodating deployment of an oversized valve prosthesis within a vessel and still ensure proper sealing in the retrograde direction (paragraphs [0048] to [0050] of the patent).

For each of the two or more support elements there is a respective element (408, 409) for providing additional support. The number of valve leaflets is the same as the number of support elements. A commissural point, which is where two of the valve leaflets are attached, is positioned on each of the support elements. The support elements are configured to accommodate limited radial movement of the commissural points with respect to the outer frame.

2. Main request - admittance into the appeal proceedings

The main request was formally not admitted into the proceedings by the Opposition Division for *prima facie* lack of novelty over D7.

The appellant argued that the main request had to be admitted, as it had been filed in response to an

objection of added subject-matter raised during the oral proceedings. Moreover, this request had *de facto* been admitted by the Opposition Division, since it had been extensively examined.

Under Article 12(6) RPBA the Board must not admit requests which were not admitted in the proceedings leading to the decision under appeal, unless the decision not to admit them suffered from an error in the use of discretion or unless the circumstances of the appeal case justify their admittance.

The Board notes that, in the impugned decision, the Opposition Division explained in detail why auxiliary request 12, the current main request, did not include added subject-matter and met the requirements of sufficiency of disclosure and clarity. Moreover, it explained in detail why and where, in its opinion, the features that the "portion of the perimeter is positioned away from the vessel wall" and "the support elements are configured to accommodate limited radial movement of the commissural points with respect to the outer frame" were disclosed in D7 (points 12.3 and 12.4 of the Reasons). Only after this detailed analysis did the Opposition Division conclude that "the auxiliary request 12 therefore is *prima-facie* not novel".

However, the Board is compelled to conclude that, *de facto*, the Opposition Division did not carry out a *prima facie* assessment but fully considered the current main request, which was therefore implicitly admitted. The Board agrees with the conclusion drawn in a similar situation in T 847/20 (point 4.1 of the Reasons) that, by having implicitly admitted the current main request as a consequence of its extensive examination, the Opposition Division no longer had the discretion not to

admit it. Consequently, the Opposition Division wrongly exercised its discretion within the meaning of Article 12(6) RPBA. The Board also notes that it has all the elements it needs to review the substantive examination of the main request in a judicial manner, within the meaning of Article 12(2) RPBA.

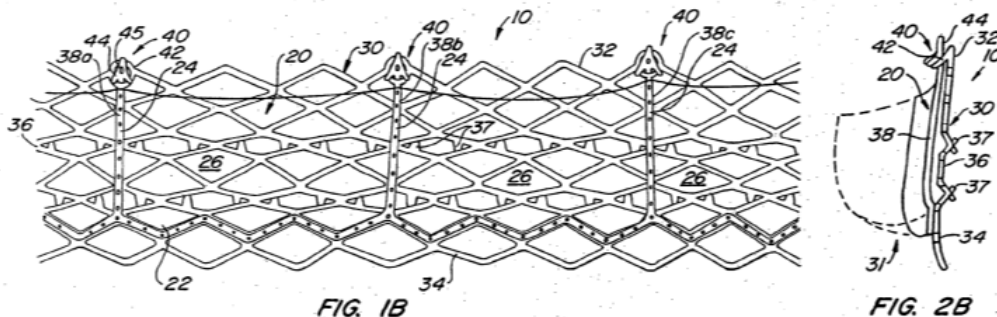
Moreover, as explained in the following, the main request can form a basis for the maintenance of the patent.

For these reasons, the main request is admitted into the appeal proceedings under Article 12(6) RPBA.

3. Main request - novelty and inventive step

3.1 The Opposition Division concluded that the subject-matter of claim 1 of the main request lacked novelty over D7.

D7 discloses an artificial valve prosthesis for regulating fluid flow through a body vessel having a wall (paragraph [0001]). Figures 1B and 2B of D7, reproduced below, depict such a valve prosthesis in plan views.



The artificial valve prosthesis comprises an outer frame (30), a plurality of support elements (38a to 38c in Figure 1B and 38 in Figure 2B) each having a first end attached to the outer frame, and a plurality of valve leaflets (26).

The outer frame has a first, unexpanded configuration and a second, expanded configuration (shown in Figures 1B and 2B; see also paragraph [0071], first sentence).

The Opposition Division concluded that the wording "limited radial movement" was broad, and that the inherent flexibility of support elements 38 of D7 and the fact that the commissural points of the valve leaflets had to be positioned on the support elements at some distance from where their male interlocking elements (44) cooperated with female interlocking elements (42) on the frame anticipated the feature of the support elements being configured to accommodate limited radial movement of the commissural points with respect to the outer frame.

The Board agrees that the claim wording may be considered broad, that support elements 38 are inherently flexible and that the commissural points of the valve leaflets cannot be positioned where the male and female interlocking members engage with one another.

However, for a feature to lack novelty there must be direct and unambiguous disclosure in the prior art. As the appellant pointed out, D7 discloses that in the expanded configuration of the outer frame, by virtue of the engagement with the frame created by the male and female interlocking elements, support elements 38 may be under a tensile load. Such a load is necessary to

expand the outer frame 30, while at the same time the length of the frame is decreased (D7, paragraph [0078]). Doubts therefore remain as to whether, in the conditions of normal use of the artificial valve prosthesis of D7 in the expanded configuration, the support elements could accommodate radial movement of the commissural points with respect to the outer frame at all. For the person skilled in the art, claim 1 of the main request specifies that the support elements must be configured to accommodate limited radial movement of the commissural points with respect to the outer frame under such a condition of normal use, because only under that condition would the accommodation of radial movement be technically meaningful.

It follows that the subject-matter of claim 1 of the main request is novel over D7 in respect of the feature of the support elements being configured to accommodate limited radial movement of the commissural points with respect to the outer frame.

3.2 It is possible to derive from paragraphs [0028] to [0030] of the patent, as argued by the appellant, and the common general knowledge that this distinguishing feature addresses the objective technical problem of avoiding damage to the valve leaflets when the artificial valve prosthesis is in its implanted and expanded configuration.

D7 does not teach the claimed solution to the objective technical problem. The Board also considers that none of the prior art cited in the opposition proceedings anticipates or renders obvious the distinguishing feature.

3.3 In conclusion, the subject-matter of claim 1 of the main request is novel (Article 54 EPC) and inventive (Article 56 EPC).

4. Main request - other issues

In the impugned decision, the Opposition Division concluded that claim 1 of the main request did not include added subject-matter and was clear, and that its subject-matter was sufficiently disclosed. The Board has no reason to question these findings, given also that the opposition has been withdrawn.

Hence, the patent can be maintained on the basis of the claims of the main request.

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 to 7 of the main request, filed with the statement setting out the grounds of appeal dated 16 November 2022, and
 - a description to be adapted.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated