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Datasheet for the decision of 31 July 2025

Case Number: T 0999/23 - 3.2.02

Application Number: 19191125.4

Publication Number: 3583922

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
PERIVALVULAR SEALING FOR TRANSCATHETER HEART VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Opponents:
MEDTRONIC INC.
Meril GmbH
Abbott Cardiovascular Systems, Inc.

Headword:

Relevant legal provisions:
EPC Art. 76(1), 83, 84, 111(1), 123(1)
RPBA 2020 Art. 12(2), 12(4)

Keyword:

Amendment to case - auxiliary request 3 - admitted (yes)
Amendments - added subject-matter - main request and auxiliary requests 1 and 2 (yes) - auxiliary request 3 (no)
Claims - clarity - (yes)
Sufficiency of disclosure - (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

T 0759/10, T 0879/18, T 1762/21

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0999/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 31 July 2025

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
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Respondent: (Opponent 3)	Abbott Cardiovascular Systems, Inc. 3200 Lakeside Drive Santa Clara, CA 95054 (US)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Decision under appeal:	**Decision of the opposition division of the European Patent Office posted on 10 May 2023 revoking European patent No. 3583922 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	N. Obrovski

Summary of Facts and Submissions

I. The patent proprietor appealed against the opposition division's decision to revoke European patent No. 3 583 922. The patent is derived from a divisional application of European application No. 15200039.4 (the parent application), which is itself a divisional of European application No. 12814795.6 (the grandparent application).

II. Oral proceedings took place on 31 July 2025.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request and auxiliary requests 1 to 87, filed with the statement setting out the grounds of appeal on 20 September 2023.

The respondents (opponents 2 and 3) requested that the appeal be dismissed.

III. **Claim 1 of the main request** reads as follows:

"A prosthetic heart valve (100) comprising:
a leaflet structure comprising a plurality of leaflets (104);
a sealing device in the form of a skirt (106); and
a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;
wherein each leaflet (104) has a scalloped lower edge portion (134), secured 10 to the frame (102) and/or the skirt (106) by sutures, and a tab portion (116) adjacent an upper free edge of the leaflet (104)

which is placed against another tab portion (116) of an adjacent leaflet to form a commissure (124);

and wherein the frame (102) comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114), the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells, wherein the plurality of rows of hexagonal cells are honeycomb shaped cells, wherein each of the hexagonal cells is defined by six struts (144, 146, 148), including:

two opposing side struts (144) extending parallel to a flow axis of the valve (100),

a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging to intersect with each other, and

a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging to intersect with each other,

wherein the frame comprises four rows (112a, 112b, 112c, 112d) of angled struts (114) forming three rows of hexagonal cells, wherein a first row (112a) of angled struts (114) is located at an inflow end (108) of the frame (102), a second row (112b) of angled struts (114) is located adjacent the first row (112a) of angled struts (114) in a flow direction, a third row (112c) of angled struts (114) is located adjacent the second row (112b) of angled struts (114) in the flow direction, and a fourth row (112d) of angled struts (114) is located at an outflow end (110) of the frame (102), the flow direction extending along the flow axis from the inflow end (108) to the outflow end (110)."

Claim 1 of auxiliary request 1 reads as claim 1 of the main request with the addition of the following wording after the first occurrence of "hexagonal cells":

", wherein the frame (102) is made up entirely of the hexagonal cells and does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end of the frame (102) or an outflow end of the frame (102) for mounting the frame (102) to the delivery apparatus"

and the replacement of the article "an" with the article "the" before the first occurrences (in claim 1 of the main request) of the expressions "inflow end (108)" and "outflow end (110)".

Claim 1 of auxiliary request 2 reads as claim 1 of the main request with the addition of the following wording after the first occurrence of "hexagonal cells":

", wherein the frame (102) is made up entirely of the hexagonal cells and does not include any struts that do not form part of one of the hexagonal cells"

Claim 1 of auxiliary request 3 reads as claim 1 of the main request with the addition of the following wording after the first occurrence of "hexagonal cells":

", wherein the frame (102) comprises a homogenous pattern of the hexagonal cells, meaning that the frame (102) is made up entirely of the hexagonal cells and does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end of the frame (102) or an outflow end of the frame (102) for mounting the frame (102) to the delivery apparatus"

and the replacement of the article "an" with the article "the" before the first occurrences (in claim 1

of the main request) of the expressions "inflow end (108)" and "outflow end (110)".

IV. The appellant's arguments relevant to this decision can be summarised as follows.

Main request and auxiliary requests 1 and 2 - extension of subject-matter

Claim 1 of the main request defined the plurality of rows of hexagonal cells as "honeycomb shaped cells". A basis for this wording could be found in paragraph [053] of the grandparent application as filed.

The features of the four rows of angled struts forming the three rows of hexagonal cells in claim 1 of the main request implied that all the cells of the frame were hexagonal and formed a homogeneous pattern as they defined the structure of the whole frame from the inflow to the outflow end, irrespective of the use of the open term "comprises". It followed that the claim mirrored the disclosure of paragraph [054] of the grandparent application as filed, with no omission of all the cells of the frame being hexagonal and forming a homogeneous pattern within the meaning of this paragraph. The same applied to the claims 1 of auxiliary requests 1 and 2.

Auxiliary request 3 - admittance

The filing of auxiliary request 3 had to be seen as a legitimate attempt to overcome the opposition division's objections in the impugned decision for not admitting the then pending auxiliary request 22.

The reasons given by the opposition division for not

admitting auxiliary request 22 were that the use of the word "comprises" meant that non-hexagonal cells could be present in the frame structure and that features of granted claim 3 inserted into claim 1 of auxiliary request 22 were redundant. This resulted in *prima facie* added subject-matter and a lack of clarity.

Claim 1 of auxiliary request 3 did not comprise the features of claim 3 of the patent as granted. Moreover, the conclusion that the use of the word "comprises" meant that non-hexagonal cells could be present in the frame structure was clearly wrong. The claim specified that "the frame (102) is made up entirely of the hexagonal cells".

Finally, claim 1 of auxiliary request 3 addressed the objection of added subject-matter prejudicing the maintenance of the patent on the basis of the main request and auxiliary requests 1 and 2 as it defined a frame structure as disclosed in paragraph [054] of the grandparent application as filed.

For these reasons, auxiliary request 3 should be admitted into the appeal proceedings.

Auxiliary request 3 - further objections

The objections of added subject-matter, lack of clarity and insufficiency of disclosure against claim 1 of auxiliary request 3 were not convincing.

Leaflet clips and commissure securement portions of the leaflet structure had been disclosed in the embodiment of Figures 5 to 14 of the grandparent application as filed. However, these features were not explained as essential and were not indispensable for the invention

as defined in claim 1 of auxiliary request 3. Paragraphs [056] and [060] respectively stated that the skirt could comprise a plurality of commissure securement portions and that a clip could hold together optional reinforcing strips and the tab portions of the leaflet structure. It followed that the leaflet clips and the commissure securement portions had been disclosed as optional in the grandparent application as filed. The leaflet structure was a valve member which was inherently collapsible and expandable as it was secured to the collapsible and expandable annular frame according to claim 1 of auxiliary request 3. Moreover, the allegedly omitted features of the leaflet structure were not inextricably linked to the claimed features.

Claim 1 of auxiliary request 3 recited a sealing device in the form of a skirt. Paragraph [052] of the grandparent application as filed introduced the "sealing device in the form a skirt" without further restrictions. Its position inside the claimed annular frame had been disclosed as optional in paragraph [056] of the grandparent application as filed, which stated that the skirt was desirably positioned on the inside of the frame. Moreover, the position of the skirt and the presence of excess material or slack between the upper and lower edges of the main body of the skirt were not inextricably linked with the claimed features.

Apices at the inflow and outflow ends of the annular frame were inherently formed by respective rows of hexagonal cells as defined in claim 1 of auxiliary request 3. No omission of such apices had been made in the claim.

Claim 1 of auxiliary request 3 defining a frame that comprised a homogenous pattern of hexagonal cells was

no different, in substance, from the disclosure of paragraph [054] of the grandparent application as filed which stated that the frame had such a pattern. Both the words "comprises" and "has" were open terms with the same meaning.

The expression "the plurality of rows of hexagonal cells are honeycomb shaped cells" was clear. It implied that all the hexagonal cells of the frame formed a honeycomb structure as in beehives.

The reference to struts extending axially away from "an" inflow end and "an" outflow end instead of "the" inflow end and "the" outflow end was clear. The indefinite article introduced the first occurrence of the expressions "inflow end" and "outflow end" but did not mean that the frame could have more than one inflow end and more than one outflow end.

The wording "except for any struts that extend axially away from an inflow end of the frame (102) or an outflow end of the frame (102) for mounting the frame (102) to the delivery apparatus" was clear. It meant that the frame could but did not have to have struts other than the ones forming the hexagonal cells as long as these struts extended axially away from either end of the frame and were for mounting the frame to a delivery apparatus. The wording did not result in a lack of sufficiency either as the person skilled in the art would have known how to make struts extend axially away from an end of a frame without the need of any further special teaching.

The board should remit the case to the opposition division if the question of novelty had to be

considered.

V. The respondents' arguments relevant to this decision can be summarised as follows.

Main request and auxiliary requests 1 and 2 - extension of subject-matter

Claim 1 of the main request defined the frame as comprising a plurality of rows of angled struts joined to each other to form a plurality of rows of hexagonal cells, the plurality of rows of hexagonal cells being honeycomb-shaped cells. This feature was an unallowable intermediate generalisation of the embodiment of Figures 5 to 14, described in detail starting from paragraph [052] of the grandparent application as filed. This embodiment was very specific and comprised a number of features inextricably linked with the claimed features, which had been omitted from the claim. For instance, the frame in the embodiment of Figures 5 to 14 was disclosed as having only hexagonal cells, in a homogeneous pattern, and being of the same shape and size. This cell pattern was not reflected in claim of the main request, or auxiliary requests 1 and 2, and had a function according to paragraph [055] of the grandparent application as filed.

Auxiliary request 3 - admittance

Auxiliary request 3 was part of a number of non-converging requests, and the objections that it attempted to address had been raised before the oral proceedings in the first-instance proceedings. Moreover, it did not address the issues discussed in the oral proceedings before the opposition division which led to the non-admittance of auxiliary

request 22. Claim 1 of auxiliary request 3 still did not mirror paragraphs [053] and [054] of the grandparent application as filed since it recited that "the frame comprises" instead of "the frame has" a homogeneous pattern of hexagonal cells and referred to struts extending axially away from "an" inflow end and "an" outflow end instead of "the" inflow end and "the" outflow end. If this request had been presented at the oral proceedings before the opposition division, it would have not been admitted. Moreover, admitting auxiliary request 3 would require a detailed analysis of the potential difference between the words "comprises" and "has" in view of, for example, the conclusions reached in decision T 759/10. For these reasons, auxiliary request 3 should not be admitted into the appeal proceedings under Article 12(4) and (6) RPBA.

Auxiliary request 3 - further objections

Claim 1 of auxiliary request 3 comprised added subject-matter.

Not all of the features described in the embodiment of Figures 5 to 14 of the grandparent application as filed had been included in the claim, although they were structurally and functionally linked to the claimed features. Therefore, as also concluded in decision T 879/18 in a similar situation, claim 1 constituted an inadmissible extension of subject-matter due to inadmissible intermediate generalisations.

The embodiment of Figures 5 to 14 was a prosthetic heart valve with a sealing mechanism to prevent or minimise perivalvular leakage. A number of omitted features of the valve leaflet structure, pertaining to

the claimed tab portions, contributed to this function. Tab portions were referenced in paragraph [059] of the grandparent application as filed. This paragraph and the following paragraphs [060] to [063] referred to securing the leaflet commissures to the frame via commissure securement portions without sutures using reinforcing strips and clips with the tabs. The omission of these features constituted an unallowable intermediate generalisation.

Moreover, all the independent claims of the grandparent application as filed required a "collapsible and expandable valve member mounted within the annular frame", meaning that this feature was mandatory. However, it was omitted from claim 1 of auxiliary request 3.

Also, features pertaining to the claimed annular frame, disclosed in the embodiment of Figures 5 to 14, had been omitted from claim 1 of auxiliary request 3 in an impermissible way. The claim did not recite apices at the inflow end and the outflow end of the annular frame; these apices defined how the struts of the frame were joined together.

Claim 1 of auxiliary request 3 recited a sealing device in the form of a skirt. The omission of the requirements for the sealing device to be positioned on the inside of the frame, having excess material or slack between its upper and lower edges and having securement portions for attaching the commissures of the leaflets, was a further unallowable intermediate generalisation. The omitted features contributed to the technical effect of reducing the crimping profile of the valve (as explained, for instance, in paragraph [058] of the grandparent application as

filed), and interacted with the claimed features of the annular frame for this purpose. The use of the term "desirably" in paragraph [056] of the grandparent application as filed did not imply that the position of the skirt on the inside of the frame was optional.

The definition of the frame and its hexagonal cells in claim 1 of auxiliary request 3, especially in view of the term "comprises", still did not reflect the pattern disclosed in Figures 5 to 14, this resulting in added subject-matter and a lack of clarity because of missing essential features.

The expression "the plurality of rows of hexagonal cells are honeycomb shaped cells" lacked clarity as it could not be established under what circumstances a row could be considered to be "honeycomb shaped cells". The expression could mean that the single cells were honeycomb shaped, which raised a separate question of how "honeycomb" was different from "hexagonal", or that the honeycomb shape defined the relationship between two adjacent rows or that the honeycomb shape was a property of the frame as a whole.

The reference to struts extending axially away from "an" inflow end and "an" outflow end instead of "the" inflow end and "the" outflow end was unclear as it conveyed the impression that the frame could have more than one inflow or outflow end.

The feature "except for any struts that extend axially away from an inflow end of the frame (102) or an outflow end of the frame (102) for mounting the frame (102) to the delivery apparatus" was unclear. The relative term "any struts" left the reader in doubt about whether it referred to struts extending axially

away to the inside of the frame or axially outwardly. Moreover, since the claim language only required these axial struts to be suitable for mounting the frame to a non-claimed delivery apparatus, the form of the axial struts to be excluded was not clear to the skilled person. The feature in question was not sufficiently disclosed either as no information could be drawn from the patent on how to put into practice an embodiment comprising the struts extending from an outflow or an inflow end for mounting the frame to the delivery apparatus.

Reasons for the Decision

1. Subject-matter of the patent

The patent is for a prosthetic heart valve.

Prosthetic heart valves are used for treating cardiac valvular disorders and are intended to replace defective native valves. A prosthetic heart valve as claimed is illustrated in Figures 5 and 6 of the patent, reproduced below.

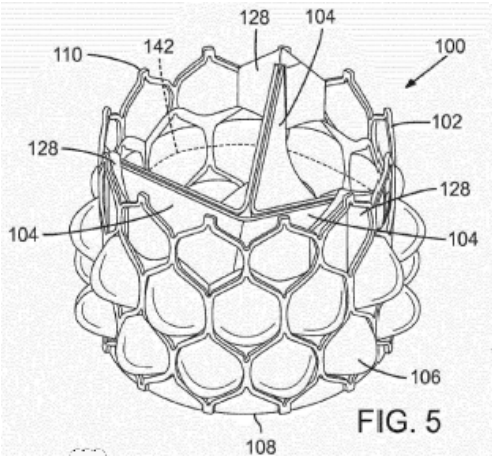

FIG. 5

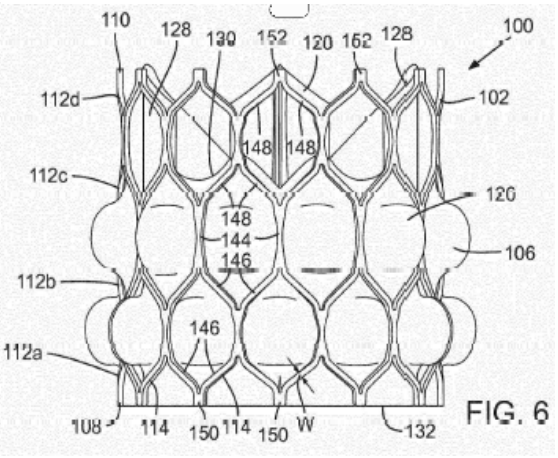

FIG. 6

The prosthetic heart valve (100) according to claim 1 of the main request comprises a leaflet structure with a plurality of leaflets (104), a sealing device in the form of a skirt (106), and a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body.

Such a valve is adapted to be deployed by a transvascular technique in which the valve is mounted in a crimped state on a catheter tip and advanced through a blood vessel of the patient until the prosthetic valve reaches the implantation site, i.e. the location of the defective native valve. The prosthetic valve at the catheter tip is then expanded to its functional size.

Each leaflet has a scalloped lower edge portion, secured to the frame and/or the skirt by sutures, and a tab portion adjacent an upper free edge of the leaflet which is placed against another tab portion of an adjacent leaflet to form a commissure.

The frame comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114). The angled struts are joined to each other to form a plurality of rows of hexagonal cells, the plurality of rows of hexagonal cells being honeycomb-shaped cells.

Each hexagonal cell is defined by six struts including two opposing side struts (144) extending parallel to a flow axis of the valve, a pair of lower angled struts (146) extending downwardly from respective lower ends of the side struts and converging to intersect with each other, and a pair of upper angled struts (148)

extending upwardly from respective upper ends of the side struts and converging to intersect with each other.

The frame comprises four rows of angled struts forming three rows of hexagonal cells. A first row of angled struts is located at an inflow end (108) of the frame, a second row of angled struts is located adjacent the first row of angled struts in a flow direction, a third row of angled struts is located adjacent the second row of angled struts in the flow direction, and a fourth row of angled struts is located at an outflow end (110) of the frame. The flow direction extends along the flow axis from the inflow end to the outflow end.

An aim of the claimed prosthetic heart valve is to keep a small overall crimp profile to facilitate its advancement through the femoral artery or vein (paragraph [0005] of the patent).

2. Main request and auxiliary requests 1 and 2 - extension of subject-matter

The respondents argued that the subject-matter of claim 1 of the main request was an unallowable intermediate generalisation of the embodiment according to Figures 5 to 14, described in paragraphs [052] to [055], of the grandparent application as filed. The opposition division, in the impugned decision, expressed the same view. For the following reasons, the board also shares this view.

The definition of the frame comprising four rows of angled struts forming three rows of hexagonal cells is derived from paragraph [053] of the grandparent application as filed, which relates to the embodiment

of Figures 5 to 14. Paragraph [054], which relates to the same embodiment, discloses:

"the frame 102 in the illustrated embodiment has what can be referred to as a 'homogenous' pattern of hexagonal cells, meaning that the frame is made up entirely of hexagonal cells and does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from the inflow end or outflow end for mounting the frame to a delivery apparatus"

Paragraph [055] goes on to explain the advantages of the "honeycomb structure of the frame" disclosed in the paragraphs before and in the figures. This structure "reduces the crimping profile of the valve, provides stability during crimping and subsequent expansion, is less sensitive to variations in strut width, and provides increased radial strength".

It follows that the grandparent application as filed teaches a pattern of hexagonal cells which provides several advantages, including the reduction of the crimping profile, which is necessary to satisfy the need put forward in paragraph [005] of the grandparent application as filed. This pattern is a homogeneous pattern of hexagonal cells, with the frame being made up entirely of hexagonal cells and not including any struts that do not form part of one of the hexagonal cells except for any struts that extend axially away from the inflow or outflow end for mounting the frame to a delivery apparatus, and with the hexagonal cells forming a honeycomb structure, implying, as the respondents pointed out, that the hexagonal cells are of the same shape and size (as also illustrated in Figures 5 and 6).

Claim 1 of the main request and auxiliary requests 1 and 2 omits some of the features of the pattern of hexagonal cells according to the embodiment of Figures 4 to 15 of the grandparent application as filed. These omissions teach the person skilled in the art that some features of the pattern of the hexagonal cells are merely optional, which contradicts, and thus extends beyond, the technical information in the grandparent application as filed according to which the pattern as originally disclosed is a measure for reducing the crimping profile of the prosthetic heart valve according to the embodiment of Figures 5 to 14.

The appellant argued, in substance, that claim 1 of the main request (and of auxiliary requests 1 and 2) defined all the features of the pattern of hexagonal cells according to the embodiment of Figures 4 to 15 of the grandparent application as filed. However, as the respondents pointed out, the claimed features of the frame do not exclude that there may be a non-homogeneous pattern of hexagonal cells, for example, with different honeycomb structures, i.e. with hexagonal cells of different dimensions.

In conclusion, the subject-matter of claim 1 of the main request and of auxiliary requests 1 and 2 extends beyond the content of the grandparent application as filed. Hence, the main request and auxiliary requests 1 and 2 are not allowable for lack of compliance with Article 76(1) EPC.

3. Auxiliary request 3 - admittance

Auxiliary request 3 was filed for the first time with the statement of grounds of appeal. Its admittance is

at the board's discretion under Article 12(4) RPBA. In accordance with this article, the board must exercise its discretion in view of, *inter alia*, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal and the need for procedural economy. In the current circumstances, which do not concern whether auxiliary request 3 was "admissibly raised" in the opposition proceedings within the meaning of Article 12(4) RPBA, it does not matter - contrary to the respondents' allegation - whether the opposition division would have admitted auxiliary request 3.

The board considers that the amendments in claim 1 of auxiliary request 3 are not complex and address the issues which led to the decision under appeal as, on a *prima facie* basis, they overcome the reasons for non-compliance with Article 76(1) EPC previously discussed for the higher-ranking requests by specifying the required properties of the frame. Claim 1 of auxiliary request 3 requires that the frame be made up entirely of hexagonal cells, with no struts that do not form part of one of the hexagonal cells except for any struts that extend axially away from the inflow or outflow end for mounting the frame to a delivery apparatus. The claim also requires the frame to comprise a homogeneous pattern of the hexagonal cells and to have the plurality of rows of hexagonal cells as honeycomb-shaped cells. These are the properties of the pattern of hexagonal cells disclosed in combination for the embodiment of Figures 4 to 15 of the grandparent application as filed. The amendments do not create any further non-compliance with the EPC and therefore satisfy the need for procedural economy.

The respondents' arguments that auxiliary request 3 was

part of a number of non-converging requests and that the objections it attempted to address had been raised before the oral proceedings in the first-instance proceedings are not convincing. Auxiliary request 3 is convergent with the higher-ranking requests as these requests are all concerned with the definition of the annular frame. While the board agrees with the respondents that the objections addressed by auxiliary request 3 were raised before the oral proceedings in the first-instance proceedings, the appellant was at the time faced with a high number of objections, which it tried to address with several auxiliary requests. Among these requests was auxiliary request 22, filed and discussed in the oral proceedings. Auxiliary request 22 was, although not admitted by the opposition division, an attempt which came close to overcoming the respondents' objections. The opposition division's reasoning which resulted in the non-admittance of auxiliary request 22 has in the appeal proceedings been addressed by the filing of current auxiliary request 3. Under these circumstances, the board does not consider that auxiliary request 3 should have been submitted in the proceedings leading to the decision under appeal within the meaning of Article 12(6) RPBA.

As to why, contrary to the respondents' view, auxiliary request 3 addresses the reasons given by the opposition division for not admitting the then pending auxiliary request 22, the board notes the following. The opposition division considered that claim 1 of auxiliary request 22 was unclear because some features from claim 3 as granted had been added. Claim 1 of auxiliary request 3 no longer comprises any such features of claim 3 as granted. The respondents' clarity objection to the indefinite article "an" in the expressions "an inflow end" and "an outflow end" was

not found convincing by the opposition division (and is not found convincing by the board as explained below). Finally, the opposition division considered that the use of the word "comprises" meant that non-hexagonal cells could be present in the frame structure according to claim 1 of auxiliary request 22. However, this conclusion was wrong as it disregarded the wording of the claim. Claim 1 of auxiliary request 22 (like claim 1 of current auxiliary request 3) expressly recites that "the frame is made up entirely of the hexagonal cells". Thus, in the case at hand, the meaning of the term "comprises" is expressly limited by further features in the claim. Hence, there is no need to establish the scope of the term "comprises" as such, i.e. irrespective of the context provided by the other claim features. The conclusions in T 759/10, which in any case do not concern the potential difference between the words "comprises" and "has", are therefore of no relevance for the current case either.

For these reasons, auxiliary request 3 is admitted into the appeal proceedings under Article 12(4) RPBA.

4. Auxiliary request 3 - further objections

4.1 The respondents argued, also with reference to decision T 879/18, that since not all the features described in the embodiment of Figures 5 to 14 of the grandparent application as filed had been included in claim 1 of auxiliary request 3, the claim comprised further unallowable intermediate generalisations because the omitted features were structurally and functionally linked to the claimed features.

For assessing an intermediate generalisation in an amended claim for compliance with Article 123(2) EPC,

it has to be established whether, because of this generalisation, the subject-matter of the claim extends beyond what was, explicitly or implicitly, directly and unambiguously disclosed to the person skilled in the art using common general knowledge in the application as filed. This is the gold standard for assessing any amendment for compliance with Article 123(2) EPC. If an amended claim comprises only some features of an originally disclosed combination, and the features left out of the claim are understood by the person skilled in the art to be inextricably linked to the claimed features, the claim contains subject-matter extending beyond the application as filed. This is the case if the person skilled in the art regards the omitted features to be necessary for achieving the effect associated with the added features. In such a situation, the amended claim conveys the technical teaching that the effect can be obtained with the claimed features alone, this being in contrast with and extending beyond the original disclosure that the whole combination of features was needed (T 1762/21, Reasons 2.4).

The expression "structurally and functionally linked" as used in T 879/18 reflects this concept in the board's view. An objection to an intermediate generalisation is therefore successful if it shows an inextricable link with the omitted features. In a mechanical system, merely showing some structural relationship between features added to a claim and omitted features is normally not sufficient to prove an inextricable link.

Many of the respondents' objections of added subject-matter to claim 1 of auxiliary request 3 do not address the issue of an inextricable link as they do not state

which technical effect the omitted features together with the added features are intended for or why the omitted features are necessary for such a technical effect.

4.2 The argument that the omission of a number of features of the leaflet structure as disclosed in the embodiment of Figures 5 to 14 constituted unallowable intermediate generalisations in view of the technical effect of preventing or minimising perivalvular leakage is not convincing. First, as explained above, claim 1 focuses on the features of the frame structure for reducing the crimping profile of the valve, providing stability during crimping and subsequent expansion, being less sensitive to variations in strut width, and providing increased radial strength (paragraph [055] of the grandparent application as filed). Second, it is not apparent, and the respondents have not convincingly explained, why the securement of the leaflet commissures to the frame via commissure securement portions without sutures using reinforcing strips and clips with the tabs were necessary, together with the claimed tab portions, to prevent or minimise perivalvular leakage.

4.3 As regards the alleged omission of a "collapsible and expandable valve member mounted within the annular frame", claim 1 of auxiliary request 3 recites a "collapsible and expandable annular frame". According to the claim, a leaflet structure, which provides the function of the valve and is therefore a valve member within the meaning of the grandparent application as filed, is secured to the annular frame and/or the skirt, all these elements being parts of the claimed prosthetic heart valve.

If the frame is collapsible and expandable, the leaflet structure must also be. Moreover, the leaflet structure must be within the annular frame to provide the functionality of a valve. It follows that claim 1 of auxiliary request 3 does not omit a collapsible and expandable valve member mounted within the annular frame.

4.4 The arguments on the alleged omission of apices at the inflow end and the outflow end of the annular frame are not convincing either. As the appellant pointed out, such apices are implied by the definition of the three rows of hexagonal cells in claim 1 of auxiliary request 3.

4.5 The objection against the general claim definition of the sealing device in the form of a skirt is not convincing either.

As the appellant pointed out, paragraph [052] of the grandparent application as filed introduces the "sealing device in the form a skirt" without further restrictions.

Irrespective of the meaning of the term "desirably" in paragraph [056] of the grandparent application as filed, the omitted features of the sealing device positioned on the inside of the frame, having excess material or slack between its upper and lower edges and having securement portions for attaching the commissures of the leaflets, were not recited in the independent claims of the grandparent application as filed and are not inextricably linked to the added features of the frame, on which claim 1 of auxiliary request 3 focuses.

Whether these omitted features may also have the technical effect of further reducing the crimping profile of the valve is not decisive. It is not because of their presence that the frame as defined in claim 1 of auxiliary request 3 "reduces the crimping profile of the valve, provides stability during crimping and subsequent expansion, is less sensitive to variations in strut width, and provides increased radial strength" (paragraph [055] of the grandparent application as filed), according to the disclosure of the grandparent application as filed.

4.6 Contrary to the respondents' arguments, the definition of the frame in claim 1 of auxiliary request 3 does reflect the pattern of hexagonal cells disclosed in the embodiment of Figures 5 to 14.

Claim 1 recites not only that "the frame comprises a homogeneous pattern of the hexagonal cells" but also that "the frame is made up entirely of the hexagonal cells and does not include any struts that do not form part of one of the hexagonal cells except for any struts that extend axially away from the inflow end or outflow end for mounting the frame to a delivery apparatus". Given this context, the use of the expression "comprises a homogeneous pattern of the hexagonal cells" cannot mean that non-hexagonal cells may be present. Moreover, the claim requires that the plurality of rows of hexagonal cells (which make up the entire frame) are honeycomb-shaped cells. Since the term "honeycomb" cannot relate to a single cell as a honeycomb in nature is made up of a plurality of cells and since the hexagonal cells must form a homogeneous pattern, this definition requires a homogeneous honeycomb structure made up of the hexagonal cells of the rows, which in turn means that the hexagonal cells

are of the same shape and size.

4.7 Given the technically sensible interpretation of the expression "honeycomb shaped cells" as just explained, the clarity objection against this expression is also without merit.

The clarity objection to the expressions "an inflow end" and "an outflow end" is not convincing either. The indefinite article is simply used to introduce the first occurrence of "inflow end" and "outflow end". It does not convey the impression that the frame may have more than one inflow or outflow end. This is further supported by the fact that the frame is defined as being annular.

The expression "except for any struts that extend axially away from an inflow end of the frame (102) or an outflow end of the frame (102) for mounting the frame (102) to the delivery apparatus" is clear too. It opens up the possibility that struts not forming part of the hexagonal cells, extending axially (i.e. in the axial direction) away from the frame, starting from the inflow or outflow end and serving to mount the frame to the delivery apparatus, are present. The frame according to the claim may comprise such struts but does not have to. These optional struts must comprise some means for mounting the frame to a delivery apparatus. The fact that the exact form of such a means is not claimed does not create any lack of clarity and is, at most, a matter of claim breadth. The person skilled in the art would be able to devise such a means on struts extending axially away for the inflow end and/or the outflow end in view of the delivery apparatuses commonly used to deliver prosthetic heart

valves. Hence, no lack of sufficiency arises either.

4.8 In conclusion, the objections of added subject-matter under Articles 76(1) and 123(2) raised by the respondents against claim 1 of auxiliary request 3 are not successful (the parent application and the application as filed comprise the description, the claims and the drawings of the grandparent application as filed).

Claim 1 is also clear (Article 84 EPC), and its subject-matter is sufficiently disclosed (Article 83 EPC).

5. Remittal to the opposition division

The opposition division revoked the patent holding that claim 1 of the requests admitted into the proceedings comprised added subject-matter. It also considered lack of clarity when not admitting some of the appellant's requests. The findings of the opposition division have been reviewed by the board for auxiliary request 3. However, the respondents raised further objections relevant to auxiliary request 3, including objections to some dependent claims, which still need to be considered for the first time.

As the primary purpose of the appeal proceedings is to review the decision under appeal in a judicial manner (Article 12(2) RPBA), there are special reasons within the meaning of Article 11 RPBA for remitting the case to the opposition division for further prosecution under Article 111(1) EPC. In the oral proceedings before the board, all parties agreed with this course of action.

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 for further prosecution.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated