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Datasheet for the decision of 23 September 2024

Case Number: T 1552/22 - 3.2.01

Application Number: 17168875.7

Publication Number: 3395296

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
ANNULOPLASTY IMPLANT

Patent Proprietor:
HVR Cardio Oy

Opponent:
Edwards Lifesciences Corporation

Headword:

Relevant legal provisions:
EPC Art. 83, 100(b), 53(c), 54, 100(a)
RPBA Art. 11 (2007), 12(3) (2007), 12(5) (2007), 13(2) (2007)
EPC R. 106

Keyword:
Main and auxiliary request - Sufficiency of disclosure - (yes)
Main and auxiliary request - Exceptions to patentability - (no)
Main request - Novelty - (no)
Remital (no)
amendment after communication under Article 15(1) admitted (no)
objection sufficiently substantiated (no)

Decisions cited:
T 1731/12, T 0775/97, T 0339/05, T 0123/06, T 0633/19

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

Boards of Appeal

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Case Number: T 1552/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 23 September 2024

Appellant: (Opponent)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Somerville, Andrew Edward Somerville Associates Dunston Innovation Centre Dunston Road Chesterfield S41 8NG (GB)
Respondent: (Patent Proprietor)	HVR Cardio Oy Upseerinkatu 1-3, Tower 1 02600 Espoo (FI)
Representative:	Cohausz & Florack Patent- & Rechtsanwälte Partnerschaftsgesellschaft mbB Bleichstraße 14 40211 Düsseldorf (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 8 April 2022 concerning maintenance of the European Patent No. 3395296 in amended form.**

Composition of the Board:

Chairman	G. Pricolo
Members:	S. Mangin
	S. Fernández de Córdoba

Summary of Facts and Submissions

I. The appeal was filed by the appellant (opponent) against the interlocutory decision of the opposition division finding that, on the basis of the main request filed on 15 February 2021, the patent in suit (hereinafter "the patent") met the requirements of the EPC.

II. In particular, the opposition division held that

(1) the patent, on the basis of this request, disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art,

(2) the subject-matter of the claims of this request did not extend beyond the content of the application as filed,

(3) the patent fulfilled the requirements of Article 53(c) EPC, and

(4) the subject-matter of this request was novel over: E6: EP 3 269 330 A1
E10: WO 2013/001339 A2
E3: US 2004/0225353 A1
E8: US 2015/0230921 A1
E2: US 2017/00074.02 A1
E9a: US 2013/0204311 A1

and involved an inventive step starting from E2 in combination with E12 (US 2017/0000608 A1) or E14 (US 2012/0071970 A1).

III. Oral proceedings were held before the Board on 23 September 2024.

IV. The appellant requested that the decision under appeal be set aside and that the patent be revoked. The appellant further raised an objection under Rule 106 EPC during oral proceedings.

The respondent (patent proprietor) requested that the appeal be dismissed (main request) or in the alternative that the patent be maintained on the basis of one of the auxiliary requests 1-3.

V. The subject-matter of claim 1, with the numbering used in the appealed decision, reads as follows:

1. An annuloplasty implant (100) comprising:
2. a first support member (101) and
3. a second support member (102),
4. wherein said implant comprises a shape memory material
4.1 and has an elongated delivery configuration for advancement in a catheter,
4.2 and an implanted shape in a coiled configuration, assuming a predefined configuration of said shape memory material for positioning at an annulus of a heart valve,
5. wherein the first and second support members are arranged as a coil in said coiled configuration around a central axis (103),
6. with two free ends (104, 105) on opposite sides of native heart valve leaflets of said heart valve,
7. wherein, when in said coiled configuration, said two free ends are displaced from each other with a peripheral off-set distance (106) extending in a coil plane (107),

8. said coil plane being substantially parallel to an annular periphery (108) of said coil and perpendicular to said central axis,
9. wherein said off-set distance corresponds to a determined circle sector (109) of said annular periphery by which said two free ends are separated.
10. said annuloplasty implant comprising at least one posterior bow (110, 110') adapted to conform to a posterior aspect of said heart valve, and
11. at least one anterior side (111, 111') adapted to conform to an anterior aspect of said heart valve, and
12. wherein said determined circle sector overlaps with said at least one anterior side, when in said coiled configuration, and
13. wherein the length of said off-set distance is between 50-100% of the length of said anterior side (111, 111').

VI. The subject-matter of claim 1 of auxiliary request 1 corresponds to the subject-matter of claim 1 of the main request with the following additional features:

"wherein said first support member is adapted to be arranged on a ventricular side of said heart valve, and said second support member is adapted to be arranged on an atrial side of said heart valve, and wherein said first support member assumes an annular ring-shape of substantially 360 degrees on said ventricular side, when in said coiled configuration, and wherein said second support member assumes an annular ring-shape of 360 degrees less said peripheral off-set distance on said atrial side, when in said coiled configuration".

VII. In the present decision, reference is also made to the following document:
E7a: US 2016/0199177 A1

Reasons for the Decision

1. Main request - Sufficiency of disclosure (Article 100(b) and 83 EPC)

The subject-matter of claim 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

1.1 The appellant (opponent) argued that either the main request was non-limiting over a standard prior art annuloplasty helical coil, or it lacked sufficiency of disclosure because no teaching was presented in the opposed patent concerning:
(a) determining the claimed determined circle sector, and
(b) facilitating the claimed off-set when implanted, which would depend upon e.g. highly variable human anatomy and fixation particulars associated with a particular surgical procedure.

1.1.1 First, trying to account for each patient's unique anatomy in the context of a pre-programmed shape memory coil before implanting the coil would be far from trivial.
Second, given the extensive variation between human anatomies, it could not be assessed whether the (anatomy dependent) off-set limitation of the claimed invention was satisfied in respect of any particular nitinol-based annuloplasty implant.

The appellant (opponent) referred to figures 9A to 9C and paragraph [0135] of E7a, which described the position of the ends 30a and 30b of helical anchor 30,

where the extent of the off-set depends on the forces acting on the helical coil.

Paragraph [0027] of the patent defined the length of the claimed anterior side as the length between native anterior and posterior commissures 301 and 301'. Thus the additional characterisation in the main request conferred a dependence upon a particular human anatomy.

The skilled person would need to have in mind a particular anatomy (as part of a surgical procedure), and then attempt to account for the inevitable force balance that would arise between that particular anatomy and the particular implant in question, which all had an impact upon the implanted shape of the implant and hence the offset between the free ends. But, as identified in paragraphs [0003], [0006] and [0022] of the patent, the use of imaging, pinching and fixation in addition to the above-described interplay between the implant and particular human anatomy, was necessary.

For the nitinol-based implant in question, there were further factors that would influence the off-set in the implanted position such as the pre-programmed shape absent any external loading, the extent of loading relative to that pre-programmed shape, any doping and other shape memory characteristics.
Thus, designing the implant to provide a final off-set in the implanted position was not merely a case of setting a particular shape-memory shape; the situation was significantly more complicated as acknowledged in paragraph [0022] of the patent.

1.1.2 Furthermore, claim 1 of the main request required an off-set distance "extending in a coil plane". However,

the patent only taught how to provide an arrangement in which the free ends extended on axially separated planes and not in a common coil plane.

1.1.3 The patent provided no teaching as to how to reproduce the claimed invention, disclosing only well-known properties associated with prior art nitinol-based shape memory coils, and therefore the skilled person would have to undertake a research programme in order to carry out the claimed invention.

Indeed, to carry out the claimed invention, the skilled person had to design and manufacture an annuloplasty implant with the claimed "determined circle sector" and "off-set" being present:
1. after having tailored the implant to the native anatomy (see paragraph [0023]) e.g. using imaging techniques (end portion paragraph [0022] from column 5, line 16);
2. after having implanted it following the shape memory transition (see paragraph [0028] from column 7, line 16);
3. after having reshaped the native annulus with it from the diseased state to the repaired state; and
4. after having fixed it to the anatomy using fastening devices and pinching of the native annulus (see paragraph [0022] from column 4, lines 22 to 33 and paragraph [0030]).

But to design and manufacture the claimed implant, the skilled person would be faced with a multitude of options and a vast number of undisclosed procedural parameters that would need to be resolved to carry out the claimed invention at its 2017 priority date including:

- using imaging procedures to model the pre-existing particular physiology of the diseased native heart valve in the diseased shape before the shape of the native annulus is modified from the diseased shape to the repaired shape using the implant;
- tailoring the implant to that modelled anatomy including determining the claimed circle sector which means determining a specific shape for the shape memory coil without any method disclosed for determining the claimed circle sector presumably taking place in the implanted state when the implant is already in the body;
- determining a myriad of structural particulars of the shape memory coil including the length and thickness of the coil, pre-programmed memory shape, rigidity, etc., these needing to work with the imaged diseased native heart valve, remodel it to its new shape, and then provide the claimed offset in the implanted state when the shape has been modified, the implant pinched the reshaped annulus to its final state, and post fixation between the implant and annulus.

So, the highly schematic construct of figure 1 could not be a sufficient disclosure of how to carry out the claimed invention. A coil with a certain length, a certain thickness and a certain axial offset between the ends was shown, however, the length, the thickness and the axial offset between the free ends were not known. All of these factors would play a significant role in the final peripheral off-set distance in the implanted state.
The opposed patent merely disclosed well-known properties relating to shape memory implants generally, not how to provide a specific structure capable of transitioning from the elongated delivery configuration to the implanted shape whereupon it provided the

claimed offset distance. In other words, the opposed patent described a goal in the form of the claimed off-set distance but did not provide any new technical information about how to achieve this goal. It was simply relying on the pre-existing information already available to a person of skill in the art.

This situation was very similar to T 0633/19 (revoked for lack of sufficiency given absence of a detailed description of how to work the claimed invention).

Furthermore, the question whether or not the parameter could be reliably determined played a role (T 339/05). In T 123/06 the board found that the functional definition of the device was no more than an invitation to perform a research program, the skilled person only being able to establish through trial and error whether the claimed device was achieved. This amounted to an undue burden.

1.2 The Board is not convinced by the arguments of the appellant (opponent).

1.2.1 The Board is of the opinion that features 7-9 and 13 in combination with figure 1 give sufficient information to the skilled person to carry out the invention. The "determined circle sector of said annular periphery" enables the "peripheral off-set distance 106" to be defined as a length in the coil plane (perpendicular to the central axis 103) along the periphery of the implant which corresponds to an angular off-set between two free ends (reference is also made to paragraph [0023] and the end of paragraphs [0039] of the patent).

As mentioned by the respondent (patent proprietor), the free ends 104, 105 of a coil are axially offset from

one another along the central axis 103 but the skilled person understands that the off-set distance 106, as defined in claim 1, is the distance between the two free ends 104, 105 as measured in the coil plane 107 along the periphery of the implant which, in the embodiment of figure 1 falls into a straight portion of the periphery of the anterior side 111 of the implant.

The Board notes that the length of the off-set distance is defined in claim 1 only in relation to the implant itself i.e. the length of the anterior side of the implant and is not defined in relation to the anatomy of the patient.

1.2.2 Moreover, the skilled person knows how to select a generally appropriate size range for a given patient age/size, requiring imaging the patient's heart to construct an annuloplasty implant as claimed so that it can achieve the claimed off-set distance range when implanted.

The use of imaging procedure is disclosed at the end of paragraph [0022]:
"Although the anatomy is investigated with various imaging procedures, the complexity of the actual valve and the dynamics of the movement thereof will always pose a significant factor when the implant 100 is being positioned and fixated at the target site".

While this passage notes the complexity of the implantation and fixation of the valve in the heart, it cannot be concluded from this passage that the skilled person will not be able to execute the claimed annuloplasty implant.

1.2.3 The appellant (opponent) refers to figures 9A-9C of E7a, which show helical anchor 30 with different distances between their free ends as the diameter of the coil is increased. The cited figures from E7a relate to a helical anchor which is expanded by a balloon 140. As the balloon 140 expands, the diameter of the helical anchor 30 increases and the opposite ends 30a, 30b of the helical anchor move to accommodate the expansion. This is however a different approach to the one of the present invention where the coil is made of memory shape material.

1.2.4 The annuloplasty implant of claim 1 is characterised by the off-set distance between the two free ends of the coil arrangement on the annular periphery of the annuloplasty implant. The skilled person is able to carry out an annuloplasty implant with such a configuration. Indeed, as argued by the respondent, annuloplasty implants are manufactured and then an appropriate one selected before its implantation based on imaging of the patient's heart. The coiled shaped annuloplasty implant made of shape memory material is placed in the delivery device and implanted, returning once implanted to its initial configuration. While there may be some small variations in the resulting off-set distance between the two ends of the annuloplasty implant when implanted, the off-set distance range claimed is broad enough to enable these small variations to occur while remaining in the claimed range.

1.2.5 The appellant (opponent) referred to case T 633/19, where the patent EP2806829 was revoked on the basis of insufficiency of disclosure.
Claim 1 of the European patent comprised the features F6 and F7:

F6: *"wherein a circumference of said loop-shaped support (41) is substantially larger than a circumference of said prosthetic heart valve (70)"* and *F7: "wherein said loop-shaped support (41) is radially downsizeable to fit tightly around said prosthetic heart valve (70) so as to seal the area between said prosthetic heart valve (70) and said loop-shaped support (41)"*
In this case, the Board noted that claim 1 specified an arrangement including a loop-shaped support in an intermediate state in which the support was helically loop shaped and had not yet reached its final memorised shape having a smaller diameter. The patent did not disclose the means necessary to achieve this intermediate state nor were these means part of the common general knowledge of the skilled person. Therefore, the subject-matter of claim 1 of the main request was not disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art.

The issue in the present case is very different since claim 1 does not require an intermediate size of the annuloplasty implant being subsequently downsized. The present invention requires an off-set distance of the free ends between 50-100% of the length of the anterior side of the annuloplasty implant in its final state.

1.2.6 The appellant also referred to T 339/05 and T 123/06. In these two cases, claim 1 was defined by parameters. However, the patents did not give enough information for the skilled person to reproduce the invention with undue burden. In the present case, the off-set distance between the two free ends of the coil is clearly defined. The skilled person shapes the annuloplasty ring before its implantation. The off-set distance can

thereby be easily adjusted by the skilled person. In the present case, no research program is necessary for configuring the annuloplasty ring.

2. Main request - Subject-matter excluded from patentability - Articles 100(a) and 53(c) EPC

The appellant (opponent) argued that the opposed patent defined the off-set relative to a specific anatomy. Claim 1 referred to the length of said anterior side and the patent defined in at least paragraph [0027] the anterior side as the space between native commissures 301 and 301' as depicted in Figure 2 of the opposed patent.

Mindful of the enormous variation in human anatomy, if claim 1 meant creating a structure such that it would reach the proper configuration in the implanted shape then it could only do so with respect to a particular anatomy as part of a particular surgical procedure. If it was not interpreted in this way, then the off-set feature was non-limiting because one could claim that for any coiled annuloplasty implant there would always be some anatomy that would cause the claimed offset.

If working claim 1 of the main request for a particular anatomy required implantation into that particular anatomy it contravened the excluded subject-matter provisions of the EPO in the light of at least T 1731/12 and T 775/97 and the additional legal provisions and case law designed to preclude patents interfering with restoring human health.

2.1 The Board is not convinced by the arguments of the appellant (opponent).

Article 53(c) EPC excludes from patentability:
"methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods".

In the present case, claim 1 defines the implant in terms of its structural features and configuration. Claim 1 is directed to a product that does not require a surgical step to manufacture the claimed annuloplasty implant.

As disclosed at the end of paragraph [0022] of the patent, imaging is used to view and measure the heart valve of the patient in order to select the annuloplasty implant size and to subsequently position and fixate the implant in the patient's heart.
As mentioned above, the last sentence of paragraph [0022] is not to be interpreted as meaning that the imaging procedure is not sufficient to produce an implant tailored to the patient's anatomy in particular wherein the length of said off-set distance is between 50-100% of the length of said anterior side, and that surgery is necessary to design the annuloplasty implant of claim 1.
The end of paragraph [0022] teaches that the complexity of the valve and its movement requires, despite the use of various imaging procedures, an implant that provides better adaptability and tolerances for the variations.

In both cases cited by the appellant (opponent), T 1731/12 and T 775/97 surgical steps were required to reproduce the invention such that the competent Board

concluded that the apparatus/the device of claim 1 was excluded from patentability.

However, in the present case no surgical step is required to reproduce the annuloplasty implant of claim 1. As argued by the respondent (patent proprietor), the size of annuloplasty implant will be chosen after investigating the heart valve of the patient using imaging procedure such that the length of the off-set distance between the two free ends is between 50-100% of the length of the anterior side of the annuloplasty implant. While there may be some variations when implanted, the claimed range is rather large enough to enable the provision the claimed implant.

3. Main request - Novelty over E6 - Articles 100(a) and 54 EPC

The subject-matter of claim 1 is not novel over E6.

3.1 The respondent (patent proprietor) argued that E6 did not disclose an annuloplasty implant but a docking station or an anchor for a prosthetic valve (see paragraphs [0021] and [0022]) and referred to the definition of an annuloplasty in the Merriam-Webster Online dictionary:
"surgical treatment of a ringlike anatomical part specifically: surgical repair of a heart valve that typically involves reducing the diameter of the valve's fibrous ring".

The respondent further referred to paragraph [0021] of the patent and noted that it indicated that the term "cardiac valve implants" included "annuloplasty rings". The second sentence of paragraph [0021] then provided examples of "other annuloplasty implants and cardiac

valve implants" – the specific examples provided in that second sentence were annuloplasty implants and/or cardiac valve implants. Therefore, paragraph [0021] did not indicate that "replacement valves, and other medical implantable devices" fell within the scope of the term "annuloplasty implants".

The skilled person reading the patent would also be guided by discussions of reshaping/remodeling the annulus in paragraphs [0022] and [0027] and would understand that the term "annuloplasty implant" was limited to an implant that reshapes/remodels the annulus of the heart valve. They would not consider an implant that merely provided support or any piece of wire having an appropriate length as constituting "an annuloplasty implant".

Figures 18A-18C of E6 and the corresponding description in paragraphs [0092]-[0093] of E6 did not mention, or suggest, any pinching that would cause reshaping of the annulus.

The "alternative helical anchor" 650 depicted in figures 34J-34L of E6 had at least one turn 652 positioned above a mitral valve 44, which compressed against the atrial wall 46a, while two other turns 654, 656 sat under the leaflets and pressed upward against the leaflets to bring the anterior and posterior leaflets 38, 42 together to close the commissures 80, (paragraph [0157] of E6). Thus, the embodiment of figures 34J-34L of E6 did not reshape the annulus through direct contact.
Instead, the loop 650 pressed against the atrial wall 46a while loops 654, 656 lifted the leaflets 38, 42 to close the commissures.

Furthermore, the use of shape memory material (feature 4) was not disclosed in relation to the embodiments of figures 5, 18A-18C and 34J-34L of E6, alleged by the appellant to prejudice novelty in relation to feature 4. Therefore, E6 did not teach an annuloplasty implant comprising shape memory material as claimed and recited in feature 4.

Therefore, the annuloplasty implant of claim 1 was novel with respect to E6, at least by way of features 1 and 4.

3.2 The Board is not convinced by the arguments of the respondent (patent proprietor).

Paragraph [0002] of the patent reads:
"Mitral and tricuspid valve replacement and repair are frequently performed with aid of an annuloplasty ring, used to reduce the diameter of the annulus, or modify the geometry of the annulus in any other way, or aid as a generally supporting structure during the valve replacement or repair procedure".

Furthermore paragraph [0021] of the patent reads:
"The following description focuses on an embodiment of the present invention applicable to cardiac valve implants such as annuloplasty rings. However, it will be appreciated that the invention is not limited to this application but may be applied to many other annuloplasty implants and cardiac valve implants including for example replacement valves, and other medical implantable devices".

Furthermore, the patent does not disclose the reduction of the diameter of the annulus in any other passage of

the description and the claims are silent about the fixation of the implant to the annulus.

According to the above, the annuloplasty implant cannot be interpreted narrowly as suggested by the respondent (patent proprietor) and the opposition division under 15.3.1 of the appealed decision:
"an annuloplasty implant [being] an implant that reshapes the annulus of the heart valve through direct contact with the annulus. Devices or implants that attempt to reshape the annulus indirectly, i.e. by interaction with the heart valves or cordae, are not considered to be annuloplasty implants".

E6, figures 34J, K, L and related paragraphs [0157] disclose the annuloplasty implant comprising the features of claim 1 and paragraph [0150] discloses the use of Nitinol, a shape memory material for the helical anchors of the invention.

As described in paragraph [0157] and figures 34 K and 34L, the helical anchor 650 has a turn 652 above the mitral valve 44 where it compresses against the atrial wall 46a close to the valve 44 and two turns 654 and 656 sit under the leaflets 38, 42 to close the commissure 80. The leaflets are in the continuity of the annulus of the heart valve. The position of the helical anchor above and below the annulus as described above will inevitably reshape the annulus of the valve. Therefore, even with a narrower interpretation of the annuloplasty ring made by the respondent (patent proprietor), the helical anchor of figures 34J to 34L anticipates the subject-matter of claim 1.

4. Auxiliary request 1

4.1 Remittal to the opposition division - Article 11 RPBA

Both the appellant (opponent) and the respondent (patent proprietor) requested the remittal of the case to the opposition division. However, the Board could not recognise any special reasons that would require the remittal of the case to the opposition division. Therefore, the case was not remitted to the opposition division.

4.1.1 The appellant (opponent) argued that auxiliary request 1 had not been discussed during the oral proceedings in opposition. The interpretation of the "annuloplasty implant" by the Board being different to the one of the opposition division new documents became relevant and required the case to be remitted to the opposition division.

4.1.2 The respondent (patent proprietor) argued that the opposition division did not take position on auxiliary request 1. Therefore, it would be more appropriate that the opposition division first reviewed this request to have the issue considered and decided at two instances.

4.1.3 Under Article 11 RPBA 2020 the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

Auxiliary request 1 corresponds to auxiliary request 2 filed with the reply to the notice of opposition. The subject-matter of claim 1 of auxiliary request 1 corresponds to the combination of the subject-matter of claims 1 and 3 of the main request.

Therefore, the Board and the parties have had enough time to consider auxiliary request 1 and should be prepared to discuss it during the oral proceedings.

The Board notes that the interpretation of the term "annuloplasty implant" corresponds to the broader interpretation submitted by the appellant (opponent). Therefore, the appellant should be prepared to address claims directed to "annuloplasty implant" following their own interpretation.

Furthermore, the Board notes that there is no absolute right to have each and every matter examined at two instances.

4.2 Admittance of the objections related to auxiliary request 1

The Board admits in the appeal proceedings the objections relating to insufficiency of disclosure and exclusion of patentability, but does not admit:
- the novelty and the inventive step objections raised with the grounds of appeal as they were not substantiated, and
- the new interpretation of claim 1 of the auxiliary request 1 as well as the novelty and inventive step attacks further elaborated during oral proceedings in appeal.

4.2.1 The respondent (patent proprietor) requested all the objections against auxiliary request 1 not to be admitted as they were confronted for the first time during oral proceedings in appeal with these objections.

The respondent (patent proprietor) held that the objections against auxiliary request 1, corresponding to auxiliary request 2 submitted on page 40 of the statement of grounds of appeal were not sufficiently substantiated. Substantiating these objections at the time of the oral proceedings constituted an amendment to the appellant's (opponent's) case made after the notification of the Board's communication under Article 15(1) RPBA and should not be taken into account. There were no exceptional circumstances as auxiliary request 1 (corresponding to auxiliary request 2 in opposition proceedings) was already filed in opposition proceedings on 15 February 2021. Furthermore, claim 1 of auxiliary request 1 was a combination of granted claims.

4.2.2 The appellant (opponent) argued that objections against auxiliary request 1 were raised with the statement of grounds of appeal.

For the objections of insufficiency of disclosure and exclusion of patentability, the appellant argued that the objections were the same as for the main request. The added features to claim 1 of auxiliary request 1 made the claimed helical coil even more dependent upon the human physiology in contravention of the excluded matter and sufficiency provisions of the EPO as identified for claim 1 of the main request.

For the objection of novelty and inventive step against claim 1 of auxiliary request 1, the appellant (opponent) argued that claim 1 of auxiliary request 1 required that the annuloplasty implant comprised a first support member and a second support member. The use of the term "comprising" in claim 1 meant that there could be other support members between the first

and the second support members such that the features added to claim 1 did not limit the claim. Therefore, all the objections raised against claim 1 of the main request applied to claim 1 of auxiliary request 1.

The appellant (opponent) further argued that in their statement of grounds of appeal they specifically referred to E2 and E10 and argued that adjusting the extent of rotation was obvious.

4.2.3 The Board admits the objections of insufficiency of disclosure and exclusion of patentability as they are, in accordance with the appellant's (opponent's) submissions, the same as the objections raised for the main request. Indeed, there is no amendment to the appellant's (opponent's) case as the objections remain in the framework of the main request's objections. However, the Board does not admit the objections of lack of novelty and inventive step against claim 1 of auxiliary request 1.

The objections related to novelty and inventive step on page 40 of the statement of grounds of appeal read: *"Auxiliary Request 2 [corresponding to auxiliary request 1 in appeal] does not confer novelty and/or inventive step over the citations identified herein mindful that the extent of coiling above and below the annulus hinges upon the anatomy and the way the coil is fastened during surgery. E2 discloses approximately two full rotations and most, if not all of the documents such as E10 disclose variable integer and non-integer numbers of turns. Adjusting the extent of rotation is obvious anyway".*

The Board judges that the novelty and inventive step objections are not sufficiently substantiated (Article

12(3) and (5) RPBA). Two documents, E2 and E10 are specifically cited. However, the appellant (opponent) does not explain the differences between claim 1 and the teaching of these documents and does not give any explanation why it would be obvious to arrive at the subject-matter of claim 1. The objection is a vague allegation which puts the burden on the respondent (patent proprietor) and the Board to speculate how and why starting from E2 and E10 the skilled person would obviously arrive at the subject-matter of claim 1. Substantiating at the day of the oral proceedings these objections represents an amendment to the appellant's (opponent's) appeal case, which should not be taken into account unless there are exceptional circumstances justified with cogent reasons by the appellant (opponent).

Furthermore, the new interpretation of claim 1 by the appellant (opponent) based on features 1-3 that were already in the main request during oral proceedings was made for the first time during the oral proceedings in appeal. In the course of the appeal, prior to the oral proceedings such an interpretation was never submitted. The interpretation of claim 1 of auxiliary request 1 represents an amendment to the appellant's (opponent's) case made after the notification of a communication under Article 15(1) RPBA which should not be taken into account unless exceptional circumstances, which have been justified with cogent reasons by the appellant (opponent) have been put forth (Article 13(2) RPBA). In the present case the appellant (opponent) did not provide any exceptional circumstances that could justify the new interpretation.

4.3 Insufficiency of disclosure and subject-matter excluded from patentability

For the same reasons as for the main request, auxiliary request 1 discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and its subject-matter is not to be excluded from patentability under Article 53(c) EPC.

4.3.1 The appellant (opponent) argued that the limitation made to claim 1 of auxiliary request 1 rendered the claimed helical coil even more dependent upon human physiology (in contravention with the excluded matter and sufficiency provisions of the EPO as identified above) given the additional explicit requirements that portions of the helical coil were to be tailored to fit the specific heart valve to be treated.

4.3.2 The Board cannot follow the arguments of the appellant (opponent).
The added feature requires that:
(a)- said first support member is adapted to be arranged on a ventricular side of said heart valve and said second support member is adapted to be arranged on an atrial side of said heart valve, and
(b) wherein said first support member assumes an annular ring-shape of substantially 360 degrees on said ventricular side, when in said coiled configuration, and wherein said second support member assumes an annular ring-shape of 360 degrees less said peripheral off-set distance on said atrial side when in said coiled configuration.

The specified localisation of the first support member on a ventricular side and the second support member on the atrial side of the valve does not require any surgical steps to be undertaken by a surgeon. The

manufacture of annuloplasty implants and the selection of an appropriate implant is made as for claim 1 of the main request before its implantation with the help of imaging but without having to undertake any surgical steps.

Furthermore, the first support member limited to a ring of 360 degrees and the second member limited to a ring of 360 degree minus the peripheral offset distance on the atrial side, does not require further measurement compared to claim 1 of the main request which could include further turns.

Compared to the main request, the number of helical or portion of helical turns of the annuloplasty ring is defined. This does not increase the complexity thereof, and thus a person skilled in the art would still be able to reproduce the annuloplasty ring without undue burden.

4.3.3 To conclude, the added features do not prevent the skilled person from carrying out the invention and do not require surgical steps.

5. Objection under Rule 106 EPC

The Board dismissed the objection under Rule 106 EPC.

The appellant (opponent) raised the following objection under Rule 106 EPC during oral proceedings:

"The Opponent hereby objects in respect of the oral proceedings dated September 23, 2024 that there is contemplated a violation in respect of its right to be heard, and namely that whereas novelty and inventive-step objections have been raised against the now-

pending First Auxiliary Request (c.f. at least Grounds of Appeal, page 40), and maintained during the Oral Proceedings, including the presenting of new argumentation at the oral proceedings, the Board contemplates not admitting any novelty or inventive step objections against the same. Not admitting these objections would be considered a violation of the Opponent's right to be heard".

The procedural defect (Rule 106 EPC and Article 112a(c) EPC invoked by the appellant (opponent) is thus a violation of the right to be heard (Article 113(1) EPC) because the objection of novelty and inventive step against the auxiliary request 1 were not admitted. However, the issue of admissibility was duly discussed during the oral proceedings (see page 2 of the minutes of the oral proceedings). In particular, the appellant was given the opportunity to comment the respondent's objection that these objections were not substantiated and were therefore inadmissible in appeal (see above point 4.2). The Board thus considers that the right to be heard has been respected.

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 with claims 1 to 12 according to the auxiliary request 1 submitted with the reply to the statement of grounds of appeal and a description to be adapted thereto.

3. The objection under Rule 106 EPC is dismissed.

The Registrar: The Chairman:

H. Jenney G. Pricolo

Decision electronically authenticated