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Datasheet for the decision of 23 October 2025

Case Number: T 1324/23 - 3.2.02

Application Number: 11820608.5

Publication Number: 2670349

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
REPOSITIONING OF PROSTHETIC HEART VALVE AND DEPLOYMENT

Patent Proprietor:
St. Jude Medical, Cardiology Division, Inc. D/B/A St. Jude Medical, Cardiovascular Division

Opponent:
Medtronic Vascular, Inc.

Relevant legal provisions:
EPC Art. 54, 83, 84, 99(1), 111(1), 113(1), 123(2)
EPC R. 103(1)(a), 111(2)
RPBA 2020 Art. 11, 12(6), 13(2)

Keyword:
Novelty - main request (no) - auxiliary request (yes) - new objection - admitted (no)
Clarity - auxiliary request - new objection - admitted (no)
Sufficiency of disclosure - auxiliary request (yes)
Amendments - extension beyond the content of the application as filed - auxiliary request (no) - new objection - admitted (no)
Reimbursement of appeal fee (yes) - substantial procedural violation (yes)
Remittal - (yes)

Decisions cited:
G 0003/14, T 1776/18, T 1639/23

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Case Number: T 1324/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 23 October 2025

Appellant: (Patent Proprietor)	St. Jude Medical, Cardiology Division, Inc. D/B/A St. Jude Medical, Cardiovascular Division 177 East County Road B St. Paul, MN 55117 (US)
Representative:	Valea AB Box 1098 405 23 Göteborg (SE)
Appellant: (Opponent)	Medtronic Vascular, Inc. 3576 Unocal Place Santa Rosa CA 95403 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 19 May 2023 concerning maintenance of the European Patent No. 2670349 in amended form.**

Composition of the Board:

Chairman	A. Martinez Möller
Members:	S. Dennler
	N. Obrovski

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent filed an appeal against the opposition division's interlocutory decision to maintain the patent in suit as amended on the basis of auxiliary request 2.

II. Auxiliary request 2 had been filed by the patent proprietor during the oral proceedings before the opposition division. In its decision, the opposition division held, *inter alia*, that claim 1 of that request did not contain added subject-matter (see Reasons 11 to 11.2) and that its subject-matter was novel in view of D1, D3, D4 and D5/D5a (see Reasons 12 to 12.4.2) and involved an inventive step when starting from D1 (see Reasons 14 to 14.5.4).

D1, D3, D4 and D5/D5a are the following documents:

D1 E. Grube *et al.*, "Percutaneous Aortic Valve Replacement for Severe Aortic Stenosis in High-Risk Patients Using the Second- and Current Third-Generation Self-Expanding CoreValve Prosthesis", Journal of the American College of Cardiology 50(1), 2007, 69-76

D3 WO 01/49213 A2

D4 WO 2009/045338 A1

D5 CN 101953725 A

D5a English translation of D5

In addition, the opposition division decided not to admit the following document, which the opponent had filed in response to the summons to oral proceedings and on the basis of which it wanted to raise a novelty

objection against claim 1 of auxiliary request 2 (see Reasons 13 to 13.2):

D16 WO 2012/039753 A2

III. The **appellant-patent proprietor** requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, as amended on the basis of one of auxiliary requests 1 and 2 as underlying the decision under appeal or auxiliary request 3 as filed with the patent proprietor's reply to the opponent's statement of grounds of appeal.

IV. The **appellant-opponent** requested that the decision under appeal be set aside and that the patent be revoked. In addition, the opponent requested the reimbursement of the appeal fee on the ground that the opposition division had committed several substantial procedural violations.

V. The Board summoned the parties to oral proceedings and provided its preliminary opinion in its communication under Article 15(1) RPBA. It indicated, *inter alia*, that D16 appeared to be *prima facie* relevant, in particular in view of the strong similarities between Figure 2 of the patent in suit and Figure 5 of D16.

VI. In response to the Board's communication, the patent proprietor filed, with its submission of 22 September 2025, the following document - the US application from which D16 claims the priority - and argued that D16 should not be admitted because it was not *prima facie* relevant due to the claimed priority being invalid:

D16a US application 61/384,553

VII. Oral proceedings before the Board were held on 23 October 2025, at the end of which the present decision was announced.

VIII. The present decision also refers to the following document:

D2 US 2006/0259136 A1

IX. Claim 1 of the **main request** (claim 1 as granted) reads as follows (with the feature numbering used by the parties):

F1 "*A prosthetic heart valve (100; 200), comprising:*

F2 *a collapsible and expandable stent (102; 202) having a proximal end (230), a distal end (232),*

F2.1 *an annulus section (110; 240) adjacent the proximal end,*

F2.2 *an aortic section (242) adjacent the distal end,*

F2.3 *a transition section (241) between the aortic section and the annulus section, and*

F2.4 *a plurality of cells (112; 212) connected to one another in annular rows around the stent from the proximal end to the distal end,*

F2.5 *each of the cells having a diamond shape formed by a plurality of struts (114),*

F2.6 *the annulus section having a first expanded cross-section, the aortic section having a second expanded cross-section larger than the first expanded cross-section, and*

F2.7 *the transition section having an expanded cross-section which transitions from the first expanded cross-section to the second expanded cross-section;*

F3 *a plurality of commissure points (116; 216) disposed at a juncture between the annulus section and the transition section; and*

F4 *a collapsible and expandable valve assembly (104; 204) disposed entirely within the annulus section between the proximal end of the stent and the plurality of commissure points,*

F5 *the valve assembly including a plurality of leaflets (108; 208) connected to the plurality of commissure points;*

F6 *the plurality of commissure points being spaced from the distal end of the stent by a selected distance such that the prosthetic valve can be partially deployed from a delivery device (1010) at a target site by withdrawing a portion of a sheath (1024) of the delivery device from around the prosthetic valve, and*

F7 *the valve assembly can function as intended while the distal end of the stent is held within the sheath of the delivery device in a manner that enables resheathing.*"

X. Claim 1 of **auxiliary request 1** differs from claim 1 of the main request in that feature F2.5 has been amended to feature F2.5* as follows (amendment highlighted by the Board):

F2.5* "*each of the cells having a diamond shape formed by a plurality of struts (114) <u>when the</u>*

prosthetic heart valve (100; 200) is in an expanded condition,"

XI. Claim 1 of **auxiliary request 2** differs from claim 1 of auxiliary request 1 in that feature F6 has been amended to feature F6* as follows (amendment highlighted by the Board):

F6* "*the plurality of commissure points being spaced from the distal end of the stent by a selected distance such that the prosthetic valve can be partially deployed from a delivery device (1010) at a target site by withdrawing a portion of a sheath (1024) of the delivery device from around the prosthetic valve, whereby the annulus section (110; 240) is deployed so that the entirety of the valve leaflets (108; 208), up to and including the commissure points (116; 216) is deployed and fully operational, and*"

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

Main request and auxiliary request 1 - novelty in view of D1

The subject-matter of claim 1 as granted and claim 1 of auxiliary request 1 was novel in view of D1. D1 did not disclose any of features F3, F6 and F7.

D1 did not disclose commissure "points", as required by feature F3, for attaching the leaflets to the stent, but only commissure "cells", as shown in Figure 1, which was different.

In any event, an annulus section could not be arbitrarily read onto the stent of D1. The annulus section was indeed the section of the stent intended to contact the native annulus after the valve had been implanted. Therefore, in D1, the commissure cells or points were disposed in the transition section of the stent, and not at a juncture between the annulus section and the transition section, as required by feature F3. This difference was explicitly discussed in paragraph [0054] with reference to Figure 4A of the patent in suit, which specifically related to the valve device of D1 and compared it to the valve of claim 1 as granted. This part of the description could not be ignored when interpreting claim 1 of the patent.

Since no commissure points were used in D1, feature F6 was not disclosed in D1 either.

As apparent e.g. from paragraphs [0008], [0036] and [0046] of the patent, the expression "as intended" in feature F7 referred to the manner in which the valve functioned after it had been fully deployed and released from the delivery device, i.e. when the valve was fully operating. In contrast, D1 disclosed only that the valve was "sufficiently functioning" in the partially deployed configuration shown in Figure 2A, i.e. that it was merely functioning to a limited extent. This could not anticipate feature F7. This further difference was also emphasised in paragraph [0054] of the patent.

Auxiliary request 2

Clarity

The limitation in feature F6* that the leaflets were "fully operational", to which the opponent had objected as being unclear in the opposition proceedings, had the clear definite meaning that the leaflets were functioning to their full extent. The opposition division had correctly considered the term "fully operational" to be clear.

The clarity objection raised by the opponent on appeal, namely that the structural limitations imposed by feature F6* on the claimed valve were unclear, differed from this earlier clarity objection and should therefore not be admitted. The opponent - which had itself requested seven minutes to study auxiliary request 2, according to the minutes - could and should have raised this further objection in the opposition proceedings. In addition, this objection was *prima facie* unconvincing. In fact, it already applied to feature F6 of claim 1 as granted, and was therefore not open to examination under Article 84 EPC by the Board pursuant to G 3/14.

Sufficiency of disclosure

The invention as claimed in auxiliary request 2 was sufficiently disclosed. The person skilled in the art would have no difficulty in constructing a valve as claimed that fulfilled the suitability criterion defined by features F6 and F7* for the sheath of a given delivery device.

Added subject-matter

Auxiliary request 2 did not contain added subject-matter. The opponent's added subject-matter objections newly filed on appeal in respect of the "commissure

points" in feature F6* and the drawings of the patent as granted could and should have been raised in the opposition proceedings and should therefore not be admitted. In any case, they were not convincing. With regard to claim 8, there was a basis in paragraphs [0112] ff. The combination of the delivery device and the valve was also supported by paragraph [0068] and the link between Figures 1 and 2 provided by the first sentence of paragraph [0070]. Original claim 29 also provided support for a system with a valve and a delivery device without any further limitations to the delivery device.

Novelty in view of D1

The subject-matter of claim 1 of auxiliary request 2 was novel in view of D1. The limitation introduced in feature F6* tightened the requirement already imposed on the claimed valve by features F6 and F7 by requiring the valve assembly not merely to function to some extent, but for the valve leaflets to be "fully operational", even if the valve was not fully deployed and released from the sheath of the delivery device. D1 did not directly and unambiguously disclose this. In Figure 2A of D1, it was clearly visible that the valve leaflets, though deployed out of the sheath, were not "fully operational".

Admittance of D16

The opposition division had correctly exercised its discretion in not admitting D16. In any case, D16 and the novelty objection based on it should not be admitted on appeal. It would be inappropriate to decide on the admittance of D16 without first assessing whether the relevant subject-matter of this document

had an effective date before the effective date of the patent in suit, i.e. whether this subject-matter could be directly and unambiguously derived from D16a, the US application from which D16 claimed priority. Only in that case could this subject-matter be relevant when assessing the novelty of claim 1 of auxiliary request 2. However, the comparison of D16 with D16a readily revealed that the passages of D16 on which the opponent relied in its novelty objection were absent from D16a. It followed that D16 was *prima facie* irrelevant and should therefore not be admitted.

This argument should be taken into account by the Board. Since the opposition division was not inclined to admit D16 - and indeed did not do so - the patent proprietor did not feel the need to carry out such an assessment in the opposition proceedings. On appeal, the patent proprietor provided this argument as soon as it became aware of it.

Novelty in view of D2

The opposition division had not committed a procedural violation in not addressing in the decision under appeal whether the subject-matter of claim 1 of auxiliary request 2 was novel in view of D2. The novelty objection in view of D2 raised by the opponent against claim 1 as granted did not automatically apply to claim 1 of auxiliary request 2, which was more limited. It was the opponent's responsibility to reiterate this objection against auxiliary request 2, something it did not do. In these circumstances, there was no reason to admit this objection on appeal either.

Remittal to the opposition division

The opposition division had not committed a substantial procedural violation either in not dealing with some of the opponent's added subject-matter objections to auxiliary request 2. It was also the opponent's responsibility to inform the opposition division that the added subject-matter objections it had raised against the patent as granted also applied to auxiliary request 2. Moreover, given the opposition division's decision to maintain the patent as amended on the basis of auxiliary request 2, these objections could also be considered to have been implicitly taken into account but deemed unconvincing by the opposition division. The absence of reasoning on these objections in the decision under appeal could therefore not justify the remittal of the case to the opposition division.

Even if the Board were inclined to remit the case to the opposition division, it would nevertheless be appropriate to deal with the issue of inventive step starting from D1 for auxiliary request 2 in these appeal proceedings since the Board had taken a decision on novelty in view of that document.

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

Main request and auxiliary request 1 - novelty in view of D1

The subject-matter of claim 1 as granted and claim 1 of auxiliary request 1 lacked novelty in view of D1. D1 disclosed features F3, F6 and F7.

The wording of claim 1 as granted was broad enough to read feature F3 onto the valve of D1. The description of the patent could not serve to arbitrarily limit the

claim with features which were not claimed. The description actually supported a broad interpretation of claim 1 in disclosing that the various stent sections could be significantly different from those of the valve in Figure 2, which was only a particular embodiment.

The fact that the valve of D1 was "sufficiently functioning" when partially deployed as shown in Figure 2A anticipated its functioning "as intended", as required by features F6 and F7.

Auxiliary request 2

Clarity

Claim 1 of auxiliary request 2 was unclear. It was unclear if and how the amendment made in feature F6* influenced the "selected distance" and, therefore, which structural limitations, if any, this amendment introduced into the valve. The scope of protection sought by the claim was therefore unclear.

The opponent had only become aware of this lack of clarity during the oral proceedings before the opposition division after the latter found amended feature F6*, in contrast to feature F6, to be novel over D1. However, at that stage, clarity had already been decided upon by the opposition division. Therefore, these appeal proceedings were the first opportunity for the opponent to raise this clarity objection, which it had done as early as possible, namely in its statement of grounds of appeal. Furthermore, auxiliary request 2 had been filed during the oral proceedings before the opposition division, the amendment in feature F6* was based on the patent

specification, and the opponent had had only seven minutes to study the new request. These circumstances had rendered it even more difficult for the opponent to spot this deficiency before the novelty discussion took place.

Sufficiency of disclosure

The invention as claimed in auxiliary request 2 was insufficiently disclosed for it to be carried out by a person skilled in the art over the full scope of claim 1. The "selected distance" in features F6* and F7 was defined on the basis of a degree of partial deployment and the delivery system used. However, both aspects were left open in claim 1, so that the "selected distance" as claimed was practically arbitrary and, thus, could not be selected by the person skilled in the art in a meaningful way and without undue burden. Notably, a valve with a given "selected distance" might implement features F6* and F7 with a certain delivery system and/or a certain degree of partial deployment, whereas the same valve might not for another delivery system and/or another degree of partial deployment. In addition, not only the "selected distance" but also many other parameters, such as stent elasticity, enabled the valve to function although only partially deployed. The patent was silent on these further parameters. The person skilled in the art was required to undertake a research programme to carry out the claimed invention.

Added subject-matter

Auxiliary request 2 contained added subject-matter contrary to Article 123(2) EPC.

a) Contrary to the opposition division's finding in the decision under appeal, a cell structure with a diamond shape as defined by features F2.4 and F2.5* was not disclosed in the application as originally filed in combination with the other features of claim 1 of auxiliary request 2.

Claim 1 of auxiliary request 2 was in essence directed to the valve of Figure 2. However, contrary to the opposition division's view, the original application did not disclose a cell structure with a diamond shape for the valve of Figure 2. Such a diamond shape was only disclosed in paragraph [0059] of the original application. However, this paragraph related to the valve of Figure 1, which was a different embodiment. In particular, it did not comprise a transition section, as required by claim 1. The original application did not contain any indication that the disclosure of paragraph [0059] for Figure 1 also applied to the valve of Figure 2. In any event, contrary to the opposition division's view, the cells of the lowest row of the valve of Figure 2 had no such diamond shape but a hexagonal one as they were formed by six struts. Indeed, due to a shift resulting from the presence of additional vertical struts, the struts of the valve of Figure 2 that might correspond to struts 114b and 114c in Figure 1 were not connected diagonally to each other in an end-to-end manner as originally disclosed in paragraph [0063] for the valve of Figure 1.

In addition, there was no basis in the original application for system claim 8, contrary to the opposition division's finding in the decision under appeal. Paragraphs [0112] ff. could not provide a basis for this claim since they did not disclose a delivery device for a prosthetic heart valve having those

features defined in claims 1 to 7, as required by claim 8. In any case, claim 8 failed to specify several features of the delivery device disclosed in those paragraphs which were required to achieve a controlled partial deployment of the valve. Therefore, claim 8 was at least based on an unallowable intermediate generalisation of that disclosure.

b) Furthermore, the decision under appeal failed to address several other added subject-matter objections which the opponent had raised in the opposition proceedings and never withdrawn which also applied to claim 1 of auxiliary request 2 (the omission from claim 1 of several features originally disclosed in combination with and inextricably linked to the subject-matter of the claim, this resulting in an inadmissible intermediate generalisation of the original disclosure; objections to claims 2, 4 and 7 as granted, to which claims 2, 4 and 7 of auxiliary request 2 were identical). The statement in the decision under appeal in Reasons 5.2 that the opponent did not have any further added subject-matter objection against claim 1 of auxiliary request 2 was therefore incorrect. This lack of reasoning constituted a substantial procedural violation.

c) Additionally, auxiliary request 2 contained added subject-matter for several other reasons, which the opponent conceded constituted new objections filed for the first time on appeal.

The amendment in feature F6* referred to the entirety of the valve leaflets up to and including the "commissure points". However, paragraph [0069] of the original application, which was alleged to form the basis for this amendment, referred not to "commissure

points" but to "commissures". Although minor in appearance, this difference in terminology implied substantial differences in meaning, which added matter. This new added subject-matter objection should be admitted because of its low complexity and in view of the short time the opponent had during the oral proceedings before the opposition division to study the then newly filed auxiliary request 2.

Furthermore, several of the drawings of the patent as granted, such as Figures 1 and 4B, differed from those originally filed. This also added matter.

Novelty in view of D1

The subject-matter of claim 1 of auxiliary request 2 was not novel in view of D1.

As was apparent from the comparison of Figure 2A with Figure 1 of D1, the commissure points of the valve of D1 were clearly out of the delivery sheath when the valve was in the partially deployed configuration of Figure 2A, meaning that the entirety of the valve leaflets was deployed in that configuration. In addition, the expressions "fully operational" and "as intended" were congruent. Consequently, since D1 disclosed features F6 and F7, it also disclosed feature F6*.

In any case, features F6* and F7 merely described some suitability of the valve to function in a certain manner when it was partially deployed from a delivery device. However, the delivery device was not part of the claim; nor was the degree of partial deployment specified in the claim. Therefore, almost any "selected distance" was sufficient to implement the functions

defined in features F6* and F7, provided that the delivery device and/or the degree of partial deployment were chosen in an *ad hoc* manner. This made the claimed "selected distance" arbitrary in practice, with the consequence that features F6* and F7 could not render the subject-matter of claim 1 novel in view of the valve of D1.

The opposition division's reasoning on novelty in view of D1 for auxiliary request 2 was hard to follow and did not address all the opponent's arguments. This constituted a substantial procedural violation.

Admission of D16

The opposition division had no discretion to disregard D16 since the subject of the proceedings had changed with the filing of auxiliary request 2. In any event, D16 had been filed before the final date set under Rule 116(1) EPC and was *prima facie* relevant, in particular in view of the strong structural similarities between the valves shown in Figure 2 of the patent in suit and Figure 5 of D16, which both appeared to have comparable dimensions, with their commissure points being spaced from the distal end of the stent by the same "selected distance". In addition, paragraph [0006] referred to the "sufficient operability of the valve leaflets during partial deployment" and paragraph [0060] to "applications such as partial deployment of the heart valve, for example, for testing"; both of these passages suggested features F6/F6* and F7. The Board should therefore overturn the opposition division's decision and admit D16 on appeal.

The patent proprietor's argument that the priority claimed by D16 was invalid had been filed well after the notification of the Board's communication under Article 15(1) RPBA and should therefore not be admitted under Article 13(2) RPBA. Moreover, it could and should have been raised in the opposition proceedings, in particular since D16 had always been presented as prior art under Article 54(3) EPC, for which assessing the validity of priority rights was common. In any event, this argument should not be taken into account in deciding whether to admit D16 because assessing the validity of a priority claim was a complex issue and should not form part of the *prima facie* assessment of the relevance of D16. In addition, this argument was unconvincing since Figure 3 of D16a substantially showed the lower part of Figure 5 of D16, which spoke in favour of the validity of the claimed priority.

Novelty in view of D2

The decision under appeal failed to address whether the subject-matter of claim 1 of auxiliary request 2 was novel in view of D2. This constituted a further substantial procedural violation.

D2, which disclosed a valve substantially similar to that of D1, had been presented as novelty-destroying from the outset of the opposition proceedings by the opponent. This had been acknowledged by the opposition division, as was apparent from the minutes, e.g. from Minutes 10.1. The opponent never withdrew the novelty objection in view of D2 originally raised against claim 1 as granted, and the fact that the novelty objection in view of D1 against claim 1 of auxiliary request 2 had been deemed unconvincing by the opposition division did not imply that the same

conclusion also applied to the corresponding novelty objection based on D2.

This novelty objection in view of D2 against claim 1 of auxiliary request 2 should be taken into account by the Board.

Novelty in view of D3, D4 and D5/D5a

While the novelty objections in view of D3, D4 and D5/ D5a against claim 1 of auxiliary request 2 were addressed in the decision under appeal (see Reasons 12.2 to 12.4.2), the decision failed to properly reason why the opponent's arguments in support of these objections were found unconvincing. This lack of reasoning constituted a further substantial procedural violation.

Reimbursement of the appeal fee; remittal of the case to the opposition division

The procedural violations committed by the opposition division were substantial, and at least some of them had a bearing on the outcome of the opposition proceedings. This justified the reimbursement of the appeal fee paid by the opponent and the remittal of the case to the opposition division.

Inventive step should not be dealt with in these appeal proceedings, even when starting from D1, but rather by the opposition division in the subsequent opposition proceedings, following remittal of the case. Indeed, claim 1 might well be amended in the subsequent proceedings, e.g. following the discussion of the added subject-matter objections not addressed in the decision under appeal. Therefore, any decision on inventive step

for claim 1 of auxiliary request 2 taken in these appeal proceedings might turn out to be moot and thus unnecessary.

Reasons for the Decision

1. Subject-matter of the patent in suit

1.1 The patent in suit relates to a prosthetic heart valve suitable for implantation by a minimally invasive technique at the native aortic valve region of the heart, which can be repositioned while allowing its functioning to be assessed during the deployment procedure (see paragraphs [0002], [0003], [0007] and [0008] of the patent specification).

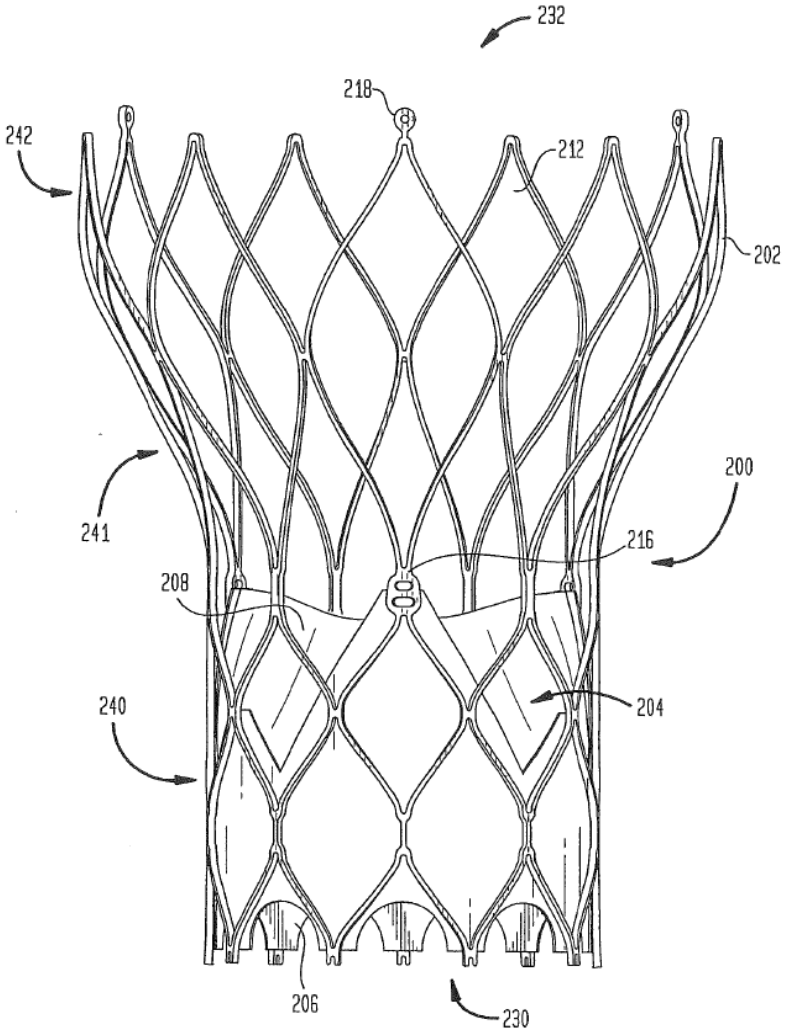
1.2 Figure 2 of the patent, reproduced below, shows an example of such a valve (200).

As defined in claim 1 as granted, the valve comprises a collapsible and expandable stent (202) having an annulus section (240) adjacent the proximal end (230), an aortic section (242) adjacent the distal end (232), and a transition section (241) between the aortic section and the annulus section (features F2 to F2.3). The annulus section has a first expanded cross-section, the aortic section has a second expanded cross-section larger than the first expanded cross-section, and the transition section has an expanded cross-section which transitions from the first expanded cross-section to the second expanded cross-section (features F2.6 and F2.7).

The valve further comprises a collapsible and expandable valve assembly (204) disposed within the stent and including a plurality of leaflets (208)

connected to the stent at a plurality of commissure points (216), the valve assembly being disposed entirely within the annulus section (240) between the proximal end (230) of the stent and the plurality of commissure points (features F3 to F5).

FIG. 2



1.3 As defined in features F3 and F6/F7, the plurality of commissure points (216) are disposed at a juncture between the annulus section (240) and the transition section (241) (feature F3), and are spaced from the distal end (232) of the stent by a selected distance such that the prosthetic valve can be partially deployed from a delivery device at a target site by

withdrawing a portion of a sheath of the delivery device from around the prosthetic valve (feature F6), and the valve assembly can function "as intended" while the distal end of the stent is held within the sheath of the delivery device in a manner that enables resheathing (feature F7).

The advantages of such a configuration are explained, *inter alia*, in paragraphs [0036], [0044] to [0047] and [0049] to [0051] with reference to Figures 3A and 3B, reproduced below.

FIG. 3A

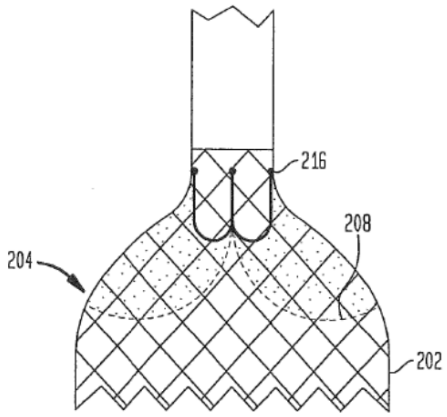
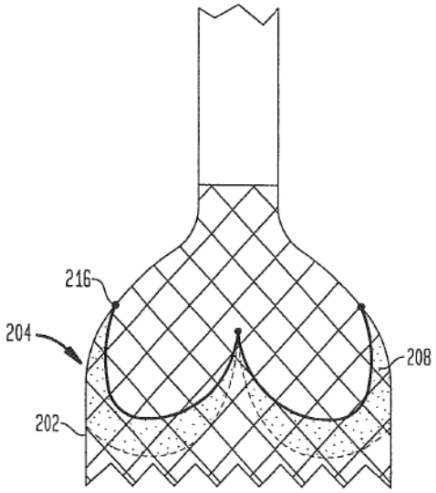


FIG. 3B

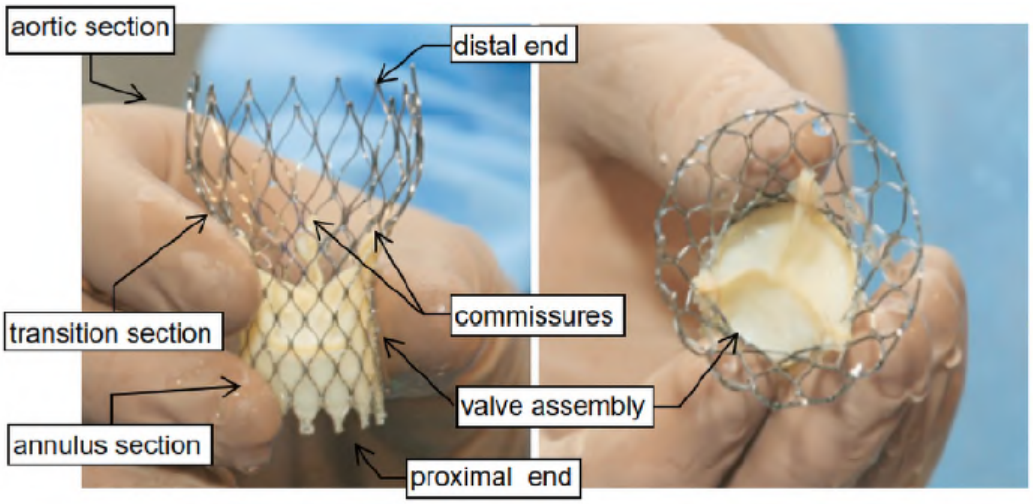


As shown in Figure 3A, the high placement of the valve assembly (204) relative to the stent - not in accordance with claim 1 - prevents the valve assembly from being fully deployed when the valve is only partially deployed, as shown in that figure. This affects the function of the leaflets and prevents the valve from being tested during partial deployment. In contrast, as shown in Figure 3B, the low placement of the valve assembly (204), consistent with claim 1, enables it to be fully deployed even when the valve is only partially deployed. This allows for a better assessment of the functioning of the valve during the

deployment procedure, meaning that it can be resheathed and repositioned if it appears that it needs to be moved.

2. Main request - novelty in view of D1

2.1 The subject-matter of claim 1 as granted is not novel in view of D1 (see the annotated copy of Figure 1 of D1 provided by the opponent on page 47 of its statement of grounds of appeal, reproduced below).



2.2 Contrary to the patent proprietor's argument, D1 discloses features F3, F6 and F7.

2.2.1 Feature F3

As set out in the Board's communication under Article 15(1) RPBA (see point 4.2) and as also considered by the opposition division (see Reasons 8.3.3), a "commissure point" is, in the context of the patent in suit, nothing more than a point of the stent at which a commissure between two adjacent leaflets is attached (see paragraph [0040] of the patent).

Therefore, the valve disclosed in D1 comprises such commissure points.

At the oral proceedings before the Board, the patent proprietor no longer disputed this interpretation but argued that in D1 the commissure points were disposed in the transition section of the stent joining its annulus section and its aortic section, and not at a juncture between the annulus section and such a transition section, as required by feature F3.

The Board is not convinced by this argument. While it is correct that the person skilled in the art understands the annulus section to be a section of the stent intended to contact the native annulus after implantation - which is the case for the bottom section of the valve stent of D1 as shown in Figure 1 - the wording of claim 1 as granted does not define any clear and unambiguous boundaries between the annulus, aortic and transition sections of the stent. In particular, features F2.6 and F2.7 do not restrict the annulus section to a section of the stent having a substantially uniform diameter. This is also supported by paragraph [0038] of the patent, according to which an annulus section in the form of a cylinder with a substantially uniform diameter along its length is described merely as an optional feature ("Preferably"). Accordingly, as submitted by the opponent and considered by the opposition division, the commissure points of the valve of D1 can be regarded as being disposed at a juncture between the annulus section and the transition section of the stent, as required by feature F3.

The patent proprietor argued that the patent in suit itself compares the valve of claim 1 with the valve of

D1, stating explicitly in paragraph [0054] that the valve of D1 ("the CoreValve device") has "commissure supports that extend up into the transition or sinus region of the device" - i.e. that it is not in accordance with feature F3. According to the patent proprietor, this statement could not be disregarded when interpreting claim 1 and assessing its novelty in view of D1, thus ruling out the opponent's above interpretation.

This is also unconvincing. The fact that the description of the patent in suit proposes its own interpretation of the annulus, transition and aortic sections of the valve of D1 does not change the Board's interpretation of claim 1 as set out above, nor can it determine or in any way limit the Board's own assessment of what D1 discloses. The argument put forward by the patent proprietor essentially amounts to an attempt to indirectly, by referring to prior-art disclosure allegedly not falling under the claim, read limitations into the claim which are not reflected in its features.

2.2.2 Feature F6

The patent proprietor's argument in the written proceedings that D1 did not disclose feature F6 was based on the contention that D1 did not disclose commissure "points" but only commissure "cells". In view of the interpretation adopted above, this argument is not convincing.

D1 discloses, with reference to Figure 2A, that the prosthetic valve can be partially released from a delivery sheath, in particular with the distal two thirds of the prosthesis being deployed (page 74,

right-hand column, first full paragraph). This disclosure anticipates feature F6. The patent proprietor did not contest this at the oral proceedings.

2.2.3 Feature F7

D1 discloses that when the valve is partially deployed from the delivery sheath as shown in Figure 2A, the valve is "already sufficiently functioning" (page 74, right-hand column, first full paragraph). The parties disagree on whether this disclosure anticipates feature F7, which requires that the valve assembly "function as intended".

The Board does not accept the patent proprietor's view that the expression "function as intended" necessarily implies that the valve assembly must function in the same manner as it would after full deployment and release from the delivery device, i.e. once expanded to its full operating size (see paragraph [0005] of the patent).

In the description of the patent in suit, the expression "as intended" is not used in isolation but is consistently supplemented by additional qualifications, such as that the valve assembly is "fully deployed" (see paragraphs [0008], [0015] and [0016]), more particularly that "the entirety of the valve leaflets, up to and including the commissures, is deployed and fully operational" (paragraph [0036]), or that it provides "adequate coaptation" by the leaflets in the closed condition (see paragraph [0017]). However, these additional qualifications are not reflected in the wording of claim 1 as granted.

In the absence of such limitations in the claim, the person skilled in the art understands the expression "function as intended" in feature F7 broadly, encompassing the expected operation of the valve assembly when it is only partially deployed, namely that the valve leaflets perform their intended valve function by opening and closing, albeit to a limited extent.

The Board therefore agrees with the opponent that the disclosure in D1 that the valve is "sufficiently functioning" when partially deployed implies that its valve assembly functions "as intended", at least to the extent that can be expected for such a degree of partial deployment. It follows that D1 discloses feature F7.

2.3 The Board agrees with the opponent that D1 also discloses the remaining features of claim 1. The patent proprietor did not contest this.

2.4 It follows that the subject-matter of claim 1 as granted lacks novelty in view of D1. Consequently, the main request is not allowable.

3. Auxiliary request 1 - novelty in view of D1

Claim 1 of auxiliary request 1 differs from claim 1 as granted only on account of amended feature F2.5*.

It is common ground that D1 discloses feature F2.5* (see the diamond-shaped cells formed by the struts in Figure 1 of D1, reproduced above). Consequently, as far as novelty in view of D1 is concerned, the same considerations as for claim 1 as granted apply to

claim 1 of auxiliary request 1. The patent proprietor did not contest this.

It follows that the subject-matter of claim 1 of auxiliary request 1 also lacks novelty in view of D1. Auxiliary request 1 is therefore not allowable either.

4. Auxiliary request 2

4.1 Compared to claim 1 of auxiliary request 1, claim 1 of auxiliary request 2 additionally specifies in amended feature F6* that the plurality of commissure points are spaced from the distal end of the stent by a selected distance such that the prosthetic valve can be partially deployed from a delivery device at a target site by withdrawing a portion of a sheath of the delivery device from around the prosthetic valve, "whereby the annulus section is deployed so that the entirety of the valve leaflets, up to and including the commissure points is deployed and fully operational".

4.2 Clarity

4.2.1 On appeal, the opponent did not reiterate its earlier objection, which the opposition division had found unconvincing (see Reasons 10 to 10.2 of the decision under appeal), that the term "fully operational" was unclear in itself. The Board concurs with the opposition division that this term is clear. In the context of the patent in suit, it means that the valve leaflets open and close to their full extent, i.e. in the same manner as if the entire valve had been fully deployed and expanded (see paragraph [0005]: "re-expanded to full operating size" and paragraph [0044]: "such that the leaflets can operate substantially as they would when the valve is fully deployed, even

though enough of the stent is still retained within the delivery device or sheath to permit resheathing").

4.2.2 Rather, the opponent contended on appeal that it was unclear if and how the amendment made in feature F6* influenced the "selected distance" and, consequently, which structural limitations, if any, this amendment introduced into the valve. According to the opponent, the scope of protection sought by claim 1 was therefore unclear.

As conceded by the opponent (see page 14, first two lines, of its statement of grounds of appeal), this objection was raised for the first time in the appeal proceedings.

Pursuant to Article 12(6) RPBA, second sentence, first alternative, a board must not admit objections which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

The opponent argued that it could not have raised this new objection earlier. The Board is not convinced by this argument. The objection could and should been raised in the opposition proceedings, in particular during the discussion of auxiliary request 2 at the oral proceedings before the opposition division, which largely focused on feature F6*, including the meaning of the term "fully operational", as is apparent from the minutes (see Minutes 15.1 and 15.2). Although auxiliary request 2 was filed during the oral proceedings, the minutes show that the opponent was given the time it had requested to study the request and prepare its objections (see Minutes 13.2 to 14).

Furthermore, the lack of clarity alleged by the opponent is in fact not open for examination under the principles set out in G 3/14. Indeed, features F6 and F7 define the "selected distance" by which the commissure points are spaced from the distal end of the stent - i.e. a structural feature of the claimed valve - by reference to the suitability of the valve assembly to function "as intended" when the valve is partially deployed while the distal end of the stent is held within the sheath of a delivery device in a manner that enables resheathing. The amendment from feature F6 to feature F6* merely tightens this suitability criterion already imposed on the claimed valve by features F6 and F7, without changing the nature of the alleged unclarity, by requiring that the leaflets of the valve assembly be not only able to function "as intended" but that they be "fully operational" during partial deployment. The question of which structural limitations of the valve, if any, follow from this suitability criterion therefore already arises for claim 1 as granted and is not introduced by the amendment from feature F6 to feature F6*.

In view of these circumstances, the Board decided not to admit the new clarity objection pursuant to Article 12(6) RPBA.

4.3 Sufficiency of disclosure

4.3.1 The invention as defined in claim 1 of auxiliary request 2 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4.3.2 The opponent's arguments to the contrary are not convincing.

The patent discloses, in a detailed and technically coherent manner, how a prosthetic heart valve can be designed such that when it is partially deployed from a delivery device, its valve assembly – including the leaflets up to and including the commissure points – is sufficiently released from the sheath to be deployed and fully operational, while the distal end of the stent remains constrained within the sheath of the delivery device to permit resheathing (see e.g. paragraph [0036] and the explanations given with reference to Figures 3A and 3B).

It is true, as argued by the opponent, that the design of a valve according to claim 1 depends not only, as expressed in the claim, on the "selected distance" by which the commissure points are spaced from the distal end of the stent, but also, implicitly, on other parameters, such as the elasticity of the stent and the mechanical behaviour of the valve assembly, which likewise play a role in determining whether the valve assembly will be fully operational when the valve is only partially deployed.

However, even if the patent in suit does not explicitly specify these other parameters, the person skilled in the art seeking to design such a valve would, on the basis of the information contained in the patent and common general knowledge, routinely take these parameters into account when implementing the claimed invention, without undue burden and without having to engage in a research programme.

Furthermore, the fact that claim 1 does not specify a particular delivery device or a specific degree of partial deployment does not prevent the person skilled

in the art from carrying out the invention. Rather, it reflects the fact that the claimed prosthetic valve is suitable for use with different suitable delivery systems and deployment conditions. For a given delivery device and a given partial deployment configuration, the person skilled in the art would have no difficulty, on the basis of the teaching of the patent and routine technical considerations concerning, *inter alia*, the elasticity of the stent and the mechanical behaviour of the valve assembly, in designing a prosthetic valve with a "selected distance" that fulfils the functional requirements set out in features F6* and F7.

4.3.3 The opponent's objection therefore, in substance, relates to the lack of precision with which the functional requirements set out in features F6* and F7 translate into structural features of the valve, in the absence of a particular delivery device or a specific degree of partial deployment specified in the claim. This, however, is a matter of clarity under Article 84 EPC rather than of sufficiency of disclosure. As indicated in point 4.2.2 above, this lack of clarity already arises for claim 1 as granted. It is therefore not open to examination in these proceedings under the principles set out in G 3/14.

4.4 Added subject-matter

4.4.1 Auxiliary request 2 does not contain added subject-matter contrary to Article 123(2) EPC.

The opponent raised several added subject-matter objections, which the Board addresses in turn.

4.4.2 Claim 1 - cell structure with a diamond shape

The opponent argued that, contrary to the opposition division's finding in the decision under appeal (see Reasons 4.1.3), a cell structure with a diamond shape as defined by features F2.4 and F2.5/F2.5*, i.e. for "each of the cells" of the stent "from the proximal end to the distal end", was not disclosed in the application as originally filed in combination with the other features of claim 1 of auxiliary request 2, with the consequence that claim 1 contained added subject-matter.

This is not convincing.

It is correct that the application as originally filed discloses a diamond-shaped cell structure in words only in paragraph [0059], in relation to the valve shown in Figure 1. In this regard, contrary to the opponent's argument, the person skilled in the art understands from that paragraph that the disclosure of a generally diamond-shaped cell structure is not restricted to a specific section of the stent but applies to the cells 112 of the stent as a whole. The person skilled in the art clearly recognises such a diamond shape, formed by four struts, in the cell structure depicted in Figure 1, in particular through the diagonal, substantially end-to-end connection of struts 114a, 114b and 114c along successive cells 112, as explicitly disclosed in paragraph [0063]. The Board acknowledges that a vertical shift between struts 114b and 114c can be observed, just as also pointed out by the opponent in relation to Figure 2. However, this shift does not result from the presence of additional vertical struts, as asserted by the opponent, which would be contrary to the explicit teaching of paragraph [0063], but from the geometry of the junctions at which the struts are diagonally connected to each other.

However, in view of the similarities between the cell structures of the valves shown in Figures 1 and 2 of the original application, the person skilled in the art recognises that the cells 212 of the stent in Figure 2, to which claim 1 of auxiliary request 2 is in substance directed, have the same generally diamond-shaped configuration as the cells 112 in Figure 1, and not a hexagonal one, for the reasons given above for Figure 1. As submitted by the patent proprietor, this understanding is corroborated by paragraph [0070], which suggests that Figure 2 primarily illustrates further, in more detail, the advantageous placement of the valve assembly within the stent already mentioned for the valve of Figure 1 in the preceding paragraphs, and not a different stent structure. This indicates that the cells 212 of the stent shown in Figure 2 are not substantially different from the cells 112 of the stent shown in Figure 1. For a similar reason, it is irrelevant that the stent of Figure 2 is described to include a transition section, whereas the original application contains no such explicit disclosure for the stent of Figure 1. The same conclusion is also supported by the schematic representations in Figures 3A and 3B, which are used in the application to explain the advantages of such a low placement of the valve assembly (see paragraphs [0082] to [0084]), and likewise show a diamond-shaped cell pattern extending along the stent.

The Board therefore concludes that the combination of features F2.4 and F2.5* in claim 1 of auxiliary request 2 does not add matter.

4.4.3 System claim 8

The opponent further argued that there was no basis in the application as filed for system claim 8, contrary to the opposition division's finding in the decision under appeal (see Reasons 6 to 6.2), in particular because paragraphs [0112] ff. did not disclose a delivery device for a prosthetic heart valve having the features defined in claims 1 to 7.

The Board does not share this view.

Paragraphs [0112] to [0121] and Figures 10 to 12 of the original application disclose a delivery system comprising a catheter assembly 1016 having an inner shaft 1026, a valve-receiving compartment 1023 defined around the inner shaft, and a slidable sheath 1024 configured to retain and release the prosthetic heart valve in a controlled manner (see paragraph [0112]), this corresponding to the delivery device defined in claim 8.

The person skilled in the art would recognise that these passages describe a delivery device for use with the prosthetic heart valves described in the preceding parts of the application, including the valve disclosed in relation to Figure 2 on which claims 1 to 7 of auxiliary request 2 are based (see also paragraphs [0068] and [0111] as well as the first sentence of paragraph [0070]).

Moreover, the person skilled in the art would also understand, as an implicit teaching of the application, that to achieve the functional effects defined in features F6* and F7, the valve and the delivery device must be configured such that the valve assembly is free to operate as intended in the portion of the stent not retained by the sheath when the sheath only partially

covers the stent, while normal valve operation is prevented when the sheath substantially completely covers the stent.

The opponent further argued that claim 8 was based on an unallowable intermediate generalisation because it omitted features allegedly necessary for a controlled partial deployment of the valve.

This is also unconvincing. The opponent has not convincingly identified any originally disclosed feature that is inextricably linked to the delivery system now claimed and that is omitted from claim 8, nor does the Board see any. The features invoked by the opponent (such as the delivery device being a transfemoral delivery device, an operating handle for controlling deployment of the valve from the catheter assembly, a retainer affixed to the inner shaft and a resheathing lock for preventing a user from accidentally completing the deployment of the valve) are merely additional features of a particular embodiment of the system and are not indispensable for achieving a controlled partial deployment of the valve, contrary to the opponent's argument. Just for completeness, the Board further notes that these features are not included in original claim 29, which disclosed a similar system comprising a prosthetic heart valve and a delivery device both configured, like those of claim 8, to allow for a controlled partial deployment of the valve. Since the prosthetic heart valve defined in claim 8 is more limited than the valve defined in original claim 29, the person skilled in the art would, *a fortiori*, understand that the additional features referred to by the opponent, absent from original claim 29, are not inextricably linked to the subject-matter of claim 8.

In summary, the added-matter objection against claim 8 of auxiliary request 2 is unconvincing.

4.4.4 Objections raised in the opposition proceedings not dealt with by the opposition division

The opponent submitted that the decision under appeal failed to address several other added subject-matter objections raised against claims 1, 2, 4 and 7 as granted in the opposition proceedings and never withdrawn, which, in its view, also applied to the corresponding claims of auxiliary request 2.

The objection to claim 1 as granted was essentially based on the argument that several features originally disclosed in combination with and inextricably linked to the subject-matter of claim 1 as granted had been improperly omitted from this claim, thus resulting in an inadmissible intermediate generalisation of the original disclosure. The omitted features referred to by the opponent included, *inter alia*, the design of various sections of the stent and the "selected length" of two thirds of the stent's overall length, which were disclosed in the application as originally filed in combination with the features of claim 1 as granted (see point II.1 of the notice of opposition). The opponent also referred to the features of dependent claims 2, 4 and 7 as granted, arguing that these features were not presented as optional in the original application and could therefore not be omitted from claim 1 as granted either (see points II.2 to II.4 of the notice of opposition). These objections likewise apply to claim 1 of auxiliary request 2, which is limited compared to claim 1 as granted but similarly does not include the features allegedly improperly

omitted. The added subject-matter objections to claims 2, 4 and 7 as granted raised in the notice of opposition also apply to the corresponding claims of auxiliary request 2, which are identical.

As put forward by the opponent, neither the decision under appeal nor the minutes of the oral proceedings before the opposition division indicate that these objections or lines of argument were withdrawn. The statement in the decision under appeal in Reasons 5.2 that the opponent did not have any further added subject-matter objection against claim 1 of auxiliary request 2 is therefore incorrect.

The Board agrees with the opponent that the decision under appeal is deficient in this respect. Since these objections might have had a bearing on the outcome of the opposition proceedings, this deficiency constitutes a substantial procedural violation (see also point 4.9 below in this regard).

4.4.5 Objections newly filed on appeal

The opponent further argued that auxiliary request 2 contained added subject-matter for several additional reasons, namely that feature F6* referred to "commissure points" whereas paragraph [0069] of the original application referred to "commissures", and that some drawings of the patent as granted differed from those originally filed.

As conceded by the opponent, these objections were filed for the first time on appeal. The Board agrees with the patent proprietor that these objections could and should have been raised in the opposition proceedings, in particular since, as noted in

point 4.2.2 above, the opponent was given the time it had requested to study auxiliary request 2 and prepare its objections.

Accordingly, the Board decided not to admit these objections, pursuant to Article 12(6) RPBA, in line with the Board's preliminary opinion indicated in the communication under Article 15(1) RPBA.

4.5 Novelty in view of D1

4.5.1 The subject-matter of claim 1 of auxiliary request 2 is novel in view of D1.

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that feature F6 has been amended to feature F6* to require that, when the prosthetic valve is partially deployed from the delivery device, the annulus section in which the valve assembly is disposed is deployed such that the entirety of the valve leaflets, up to and including the commissure points, is not only deployed but also "fully operational".

The opponent argued that this amendment did not introduce any distinguishing technical limitation over D1. It submitted that in the partially deployed configuration of Figure 2A of D1, the commissure points are already released from the sheath and the entirety of the leaflets is deployed, and that the expressions "fully operational" and "as intended" were equivalent. It further argued that features F6* and F7 merely defined a suitability of the valve to function in a certain way during partial deployment, without imposing any real structural limitation.

The Board does not agree.

As explained in the assessment of clarity (see point 4.2 above), the term "fully operational" has, in the context of the patent in suit, a clear technical meaning, namely that the valve leaflets open and close to their full extent, in substantially the same manner as when the valve is fully deployed and expanded. Feature F6* therefore requires that, already in the partially deployed configuration, the valve assembly be capable of operating in this fully functional manner, even though the distal end of the stent is still retained within the sheath of the delivery device.

D1 does not disclose such a situation. In D1, when the valve is partially deployed as shown in Figure 2A, the valve is described as being "already sufficiently functioning" (page 74, right-hand column, first full paragraph). This disclosure indicates that the valve has begun to function to some extent, but it does not amount to a direct and unambiguous disclosure that the valve leaflets are fully operational as required by feature F6*. Neither the description nor Figure 2A of D1 shows or implies that the leaflets open and close to their full extent in the partially deployed configuration as they do in the completely released configuration shown in Figure 2B.

The Board is also not convinced by the opponent's argument that features F6* and F7 merely define an arbitrary suitability of the valve which could be achieved for almost any "selected distance" by appropriately choosing the delivery device or the degree of partial deployment. Claim 1 of auxiliary request 2 defines a structural relationship between the position of the commissure points and the distal end of the stent which ensures that, upon partial deployment,

the valve assembly is already fully operational while resheathing remains possible. While this requirement might indeed be met for a range of "selected distances", depending, *inter alia*, on the diameter of the delivery sheath used, it is not directly and unambiguously disclosed for the valve of D1.

Consequently, D1 does not disclose feature F6* in combination with the other features of claim 1. It follows that the subject-matter of claim 1 of auxiliary request 2 is novel in view of D1.

4.5.2 Although the opposition division's reasoning in Reasons 12.1.1 and 12.1.2 is rather succinct, the Board understands from the decision under appeal that the opposition division applied the same distinction between "as intended" and "fully operational" as it did when dealing with the clarity objection in Reasons 10.2. In particular, it considered that "sufficiently functioning" as disclosed in D1 anticipates "function as intended" but not "fully operational" (see Reasons 8.3.3).

Accordingly, the opposition division concluded that even if the opponent's argument were accepted that the cell rows could be counted in the figures of D1 and that the commissure points were already outside the sheath in the partially deployed configuration (as summarised in Reasons 12.1.1), D1 did not disclose that the entirety of the leaflets was "deployed and fully operational" as required by feature F6*, but only that it was "sufficiently functioning". This corresponds to the proprietor's submissions as recorded in the minutes (see Minutes 17.2).

In these circumstances, and notwithstanding the brevity of the reasoning, the Board considers that the opposition division's reasoning on novelty in view of D1 for claim 1 of auxiliary request 2 is sufficient. Consequently, there is no procedural violation in this respect, contrary to the opponent's contention.

4.6 Admittance of D16

4.6.1 D16 had been filed by the opponent in response to the summons to oral proceedings issued by the opposition division, before the final date set under Rule 116(1) EPC for making final submissions. During the oral proceedings before the opposition division, in which auxiliary request 2 had been filed, the opponent relied on that document to raise a novelty objection against claim 1 of that request. As set out in Reasons 13.1 and 13.2 of the decision under appeal, the opposition division decided not to admit D16.

The opponent submitted that the opposition division should have admitted D16 and requested that this document be taken into account on appeal.

4.6.2 It is true, as argued by the opponent during the oral proceedings (see Minutes 19.1), that the subject of the proceedings had changed with the filing of auxiliary request 2 during the oral proceedings since claim 1 of that request incorporated an amendment (namely the change from feature F6 to feature F6*) originating from the description that intended to restore novelty over D1 (see Minutes 13.1).

However, contrary to the opponent's assertion, such a change in the subject of the proceedings did not mean that the opposition division had no discretion as to

the admittance of D16. As that document was filed after the end of the opposition period under Article 99(1) EPC, this was the case regardless of whether it was filed before the date set under Rule 116(1) EPC (see T 1776/18, Reasons 4.6.4 and T 1639/23, Reasons 1.5 with further references).

4.6.3 As is apparent from Reasons 13.1 and 13.2 of the decision under appeal, the opposition division based its decision not to admit D16 on the ground that it considered this document to be *prima facie* irrelevant since it did not directly and unambiguously disclose features F6/F6* and F7.

D16 was relied upon by the opponent as prior art under Article 54(3) EPC. Its relevance therefore depends, *inter alia*, on whether the subject-matter relied upon in the opponent's novelty objection, allegedly anticipating features F6/F6* and F7, is entitled to the priority claimed by D16 from the earlier application D16a.

The patent proprietor submitted, admittedly at a very late stage of the appeal proceedings, that the passages of D16 on which the opponent relied in its novelty objection were not directly and unambiguously disclosed in D16a and therefore were not entitled to the claimed priority. Although this argument was submitted after notification of the Board's communication under Article 15(1) RPBA, the Board considered it appropriate to take it into account for reasons of procedural economy. As argued by the patent proprietor, it would indeed serve no useful purpose to admit D16 into the proceedings if the parts of that document relied upon in the novelty objection were, in any event, not

entitled to a valid priority and therefore could not constitute relevant prior art under Article 54(3) EPC.

The opponent could not demonstrate in a convincing manner at the oral proceedings before the Board that the disclosure of D16 relied upon in its novelty objection and alleged to anticipate features F6/F6* and F7 was directly and unambiguously derivable from D16a. It is immediately apparent that paragraphs [0006] and [0060] of D16 are not present in D16a. Furthermore, the mere resemblance of Figure 3 of D16a to the lower part of Figure 5 of D16 - which itself is not present in D16a - does not amount to disclosure of features F6/F6* and F7, not even on a mere *prima facie* assessment.

Consequently, it could not be established, not even on a *prima facie* basis, that the relevant subject-matter of D16 alleged to anticipate features F6/F6* and F7 was entitled to the claimed priority.

In these circumstances, D16 cannot be regarded as *prima facie* relevant prior art under Article 54(3) EPC, with the result that the novelty objection based on D16 is itself not *prima facie* relevant either.

4.6.4 In its communication under Article 15(1) RPBA, the Board had indicated that the opposition division may not have addressed the opponent's arguments in favour of admittance in a sufficient manner when deciding not to admit D16 into the opposition proceedings. However, even if that were the case, the Board still has discretion under Article 12(4) and (6) RPBA not to admit this document into the appeal proceedings for lack of *prima facie* relevance.

Accordingly, following the discussion at the oral proceedings, the Board did not admit D16 into the appeal proceedings.

4.7 Novelty in view of D2

4.7.1 The opponent argued that the decision under appeal failed to address whether the subject-matter of claim 1 of auxiliary request 2 was novel in view of D2 and that this constituted a substantial procedural violation. It further requested that this novelty objection be examined in the current appeal proceedings.

4.7.2 The Board does not agree.

It is undisputed that the opponent raised a novelty objection in view of D2 against claim 1 as granted during the opposition proceedings (see point IV.4 of the notice of opposition).

However, claim 1 of auxiliary request 2 is more limited than claim 1 as granted, in particular by the amendment from feature F6 to feature F6*, which additionally requires that, when the prosthetic valve is partially deployed, the valve leaflets up to and including the commissure points be "fully operational". As argued by the patent proprietor upon filing auxiliary request 2 in the oral proceedings before the opposition division, this amendment was meant to distinguish the subject-matter of claim 1 from D1 (see Minutes 13.1).

When a patent proprietor files an amended claim which is more limited by way of the amendment and substantiates why this amendment overcomes the objection it intends to address, it is for the opponent to substantiate, if it wishes to maintain a novelty

objection, why the more limited claim is also not novel in view of the prior art relied upon. In the case at hand, this required the opponent to explain why D2 disclosed not only the features of claim 1 as granted but also the additional limitation introduced by feature F6* of auxiliary request 2.

However, the opponent did not do so during the opposition proceedings. As is apparent from the minutes of the oral proceedings before the opposition division, the opponent only disputed the novelty of the subject-matter of claim 1 of auxiliary request 2 in view of D1 (see Minutes 17), D16 (see Minutes 19) and D3 to D5 (see Minutes 20).

In these circumstances, the opposition division had no obligation to examine, of its own motion, whether the subject-matter of claim 1 of auxiliary request 2 was also novel in view of D2. The fact that a novelty objection in view of D2 had been raised against the broader claim 1 as granted did not automatically mean that the same objection applied to the more limited claim 1 of auxiliary request 2.

Accordingly, the omission in the decision under appeal to address novelty in view of D2 for auxiliary request 2 does not constitute a procedural violation, contrary to the opponent's assertion.

4.7.3 The substantiation as to why the subject-matter of claim 1 of auxiliary request 2 allegedly lacks novelty over document D2 was only made in the appeal proceedings (see point VI.4 of the opponent's statement of grounds of appeal). As this should have been submitted in the opposition proceedings, the Board did

not admit this objection into the appeal proceedings under Article 12(6), second sentence, RPBA.

4.8 Novelty in view of D3, D4 and D5/D5a

The opponent submitted that the decision under appeal (see Reasons 12.2 to 12.4) failed to properly reason why the novelty objections raised against claim 1 of auxiliary request 2 in view of D3, D4 and D5/D5a were unconvincing and that this constituted a substantial procedural violation.

The Board agrees.

In the decision under appeal, the opposition division addressed the novelty objections based on D3, D4 and D5/D5a in Reasons 12.2 to 12.4.2. However, these passages of the decision do not contain a complete and reasoned analysis of the opponent's arguments. Rather, the decision merely presents an unclear copy of a figure from each document annotated by the opponent and states that at least some features of claim 1 of auxiliary request 2 are not disclosed, without providing any explanation as to why the opponent's arguments to the contrary were unconvincing.

A mere statement of a conclusion, without addressing the decisive arguments put forward by a party, does not meet the requirements of Rule 111(2) EPC. The parties must be in a position to understand why their main lines of argument did not succeed, and the Board must be able to review the correctness of the opposition division's reasoning.

The Board therefore agrees with the opponent that the reasoning in the decision under appeal on the novelty

objections based on D3, D4 and D5/D5a is deficient and that this deficiency amounts to a substantial procedural violation.

4.9 Reimbursement of the appeal fee; remittal of the case to the opposition division

4.9.1 As set out above, the Board has identified deficiencies in the opposition proceedings, in particular that the opposition division failed to take into account several added subject-matter objections against auxiliary request 2 and failed to provide a sufficiently reasoned decision on the novelty objections based on D3, D4 and D5/D5a against claim 1 of that request.

These deficiencies deprived the opponent of its right to have its arguments properly considered and reasoned upon by the opposition division. The Board therefore agrees with the opponent that breaches of Article 113(1) EPC and Rule 111(2) EPC occurred.

Moreover, these breaches are not merely formal but concern issues which may have had a bearing on the outcome of the case. They therefore constitute substantial procedural violations within the meaning of Rule 103(1)(a) EPC which justify the reimbursement of the appeal fee paid by the opponent.

4.9.2 Furthermore, the substantial procedural violations in this case are fundamental deficiencies which constitute 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. The opposition division will have to re-examine, on the basis of auxiliary request 2, the objections that were not properly dealt with in the decision under appeal,

and, if appropriate, further issues such as inventive step.

4.9.3 The Board considers it neither necessary nor appropriate to decide on inventive step in the current appeal proceedings, including starting from D1. As argued by the patent proprietor, any such decision could be rendered moot by amendments to the claims or the outcome of the renewed examination before the opposition division. Furthermore, one of the inventive-step objections discussed in the decision (see Reasons 14) is based on D5, i.e. one of the documents in respect of which a novelty objection raised by the opponent was not properly addressed in the decision under appeal, which, as stated above, justifies the remittal of the case to the opposition division. Dealing with this inventive-step objection in the current appeal proceedings would require the Board to interpret D5, which would amount to pre-empting the opposition division's own assessment of that document in the subsequent proceedings following remittal.

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.

3. The appeal fee paid by the opponent is reimbursed.

The Registrar: The Chairman:

D. Grundner A. Martinez Möller

Decision electronically authenticated