Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 25 January 2023

Case Number: T 0148/20 - 3.2.01

Application Number: 11275139.1

Publication Number: 2489331

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
Stent structures for use with valve replacement

Patent Proprietor:
Cook Medical Technologies LLC

Opponents:
BIOTRONIK AG
St. Jude Med,LLC/Abbott Med GmbH/St. Jude Med UK Ltd/SJM Int. Inc./SJM Coordination Center BVBA/ St. Jude Med S. C. Inc.

Headword:

Relevant legal provisions:
EPC Art. 100(c), 100(a), 87(1), 54, 56, 54(3)
RPBA Art. 13(2)

Keyword:

Grounds for opposition - subject-matter extends beyond content of earlier application (no)
Priority - validity of priority date (yes)
Novelty - main request (yes)
Inventive step - main request (yes)
Late-filed objections not admitted - amendments after arrangement of oral proceedings

Decisions cited:

T 0748/91

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0148/20 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 25 January 2023

Appellant: (Opponent 2)	St. Jude Med,LLC/Abbott Med GmbH/St. Jude Med UK Ltd/SJM Int. Inc./SJM Coordination Center BVBA/ St. Jude Med S. C. Inc. 1 St. Jude Med Dr./Helfmann Pk 7/Banbury Rd/ 1 St. Jude Med Dr./Da Vincilaan 11/Bee Cave Rd/ St. Paul MN 55117/65760 Eschborn/Stratford CV37 7GX/St. Paul MN 55117/1935 Zaventem Austin, TX 78746 (US)
Representative:	LKGLOBAL Lorenz & Kopf PartG mbB Patentanwälte Brienner Straße 11 80333 München (DE)
Respondent: (Patent Proprietor)	Cook Medical Technologies LLC 750 North Daniels Way Bloomington, IN 47404 (US)
Representative:	Jehan, Robert Williams Powell 5 Chancery Lane London WC2A 1LG (GB)
Party as of right: (Opponent 1)	BIOTRONIK AG Ackerstrasse 6 8180 Bülach (CH)
Representative:	Biotronik Corporate Services SE Corporate Intellectual Property Sieversufer 7-9 12359 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 November 2019 rejecting the opposition filed against**

European patent No. 2489331 pursuant to Article 101(2) EPC.

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 2) against the decision of the opposition division to reject the oppositions filed against the patent in suit (hereinafter "the patent").

II. The opposition division held that:
- the patent did not extend beyond the application as originally filed (Article 100(c) EPC),
- the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person (Article 100(b) EPC), and
- the subject-matter of claim 1 was novel and involved an inventive step (Article 100(a) EPC).

III. Oral proceedings were held before the Board on 25 January 2023 in the absence of opponent 1, party as of right, as announced by letter of 16 January 2023.

IV. The appellant (opponent 2) requested that the decision under appeal be set aside and that the European patent be revoked.

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 1-11 filed with the reply to the statement of grounds of appeal.
The respondent further submitted the following: "Should the Board of Appeal be minded not to maintain the patent with the drawings as granted, the respondent requests that the patent be maintained in amended form, with the drawings substituted for the enclosed drawings entitled Auxiliary Request A. Should the Board of

Appeal maintain objections both to the drawings and to the claims as granted, we request that the patent be maintained in amended form, with the drawings substituted for the enclosed drawings entitled Auxiliary Request A and the claims substituted for one of the enclosed claim sets entitled Auxiliary Request X, the order of preference being the numerical order of X".

The party as of right (opponent 1) did not file requests or submissions on the substance in appeal proceedings.

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

M1 A medical device for implantation in a patient, the medical device including:
M1.1 a stent including:
M1.2 a proximal region (30) comprising a cylindrical shape having a first outer diameter when the stent is in an expanded state;
M1.3 a distal region (70) comprising a cylindrical shape having a second outer diameter when the stent is in the expanded state,
M1.4 wherein the second outer diameter is greater than the first outer diameter;
M1.5 a tapered region (50) disposed between the proximal and distal regions, wherein the tapered region transitions the stent from the first diameter to the second diameter; and
M1.6 a valve (120) coupled to at least a portion of the stent, the valve (120) having proximal (130) and distal (170) regions,
M1.7 characterised in that the proximal region (130) of the valve (120) is at least partially positioned within the proximal region of the stent; and

M1.8 that there are a plurality of closed cells disposed around the perimeter of the proximal region (30) of the stent,
M1.9 and another plurality of closed cells disposed around the perimeter of the distal region (70) of the stent;
M1.10 wherein the tapered region (50) includes a plurality of closed cells,
M1.11 wherein an overall length of each of the closed cells of the tapered region (50) is greater than an overall length of each of the closed cells of the proximal region (30) of the stent and less than an overall length of each of the closed cells of the distal region (70) of the stent when the stent is in the expanded state.

VI. In the present decision, reference is made to the following documents:
D1a: US 61 /410540 (priority of patent in suit)
D1b: EP 2 489 331 A2 (application as filed)
E2: WO 2010/098857 A1
E10: WO 2006/124649 a2
E11/D11: "Percutaneous Implantation of the CoreValve Self-Expanding Valve Prosthesis in High-Risk Patients With Aortic Valve Disease", E. Grube et al., Circulation of the American Heart Association, S. 1616 ff., October 10, 2006
E14/D14: "Geometry and Degree of Apposition of the CoreValve ReValving System With Multislice Computed Tomography After Implantation in Patients With Aortic Stenosis", C.J. Schultz et al., Journal of the American College of Cardiology, Vol. 54, No. 10, S.911ff., September 1, 2009
E34: WO 01/49213 A2
E35: WO 2010/096176 A1
E36: WO 2010/099032 A2

E37: WO 2011/025945 A1
E41: US 6 773 454 B2

Reasons for the Decision

1. Main request - Article 100(c) EPC

The replacement of figures 1, 2, 8, 9 and 13 during the examination procedure does not extend the subject-matter of the patent beyond the content of the application as originally filed.

1.1 The appellant argued that figures 1, 2, 8, 9 and 13 of the patent showed barbs at the common strut of every distal cell whereas figures 1 and 2 as originally filed indicated only one barb, with the reference number 83, in the barbed region 80 without showing the actual structure of the barb.
The appellant further noted that while the description on page 12, lines 7-13 referred to "barbs" in the plural form, this was not a direct and unambiguous disclosure for the presence of a barb on each distal and proximal cell.
Finally original figure 3 had only one reference number 33 and one reference number 83, disclosing one barb on the distal cell and one barb on the proximal cell. No other barbs were referenced such that it could not be inferred that there were several barbs. And even if it were considered that several barbs were depicted in figure 3, figure 3 only showed a part of the stent such that there was no direct and unambiguous disclosure of barbs on every distal and proximal cells.

1.2 The Board does not agree with the appellant.

To assess whether the replaced figures extend beyond the content of the application as originally filed, the content of the application as whole must be considered. In the present case, the amended figures find basis in particular in the following parts of the application as originally filed:
- figure 3, depicting a pattern of the stent structure 20, in a flattened and collapsed state, whereby every represented proximal cell and distal cell has a barb,
- figure 4, depicting a barb structure 33,
- page 9, lines 21-24 of the application as filed, reading: *"Further, a barbed region 80 having a barb 83 is disposed between the angled strut segments, as shown in FIG. 1. The barb 83 of the barbed region 80 may be formed integrally in the same manner as the barb 33 of the proximal region 30, as shown in FIG. 4, but preferably faces in a proximal direction"*, and
- page 12, lines 7-13 of the application as originally filed, reading: *"Moreover, in order to reduce migration of the stent structure when implanted at a target site, it is preferred that the barbs 33 of the proximal region 30 are oriented in a distally-facing direction, whereas the barbs 83 of the distal region 70 are oriented in a proximally-facing direction".*

The above cited figures and passages of the application as filed, and in particular figure 3, directly and unambiguously disclose an embodiment where each proximal apex 31 comprises an end region 32 having an integral barb 33 formed therein as depicted on figure 4 and each distal cell comprises a barb region 80 having a barb 83 oriented in the opposite direction of the barb 33. While figure 3 only shows a part of the stent (i.e., one side, the other side of the stent not being visible due to the perspective), the skilled person understands that the other side of the stent is similar

to the visible side of the stent and comprises barbs at each proximal and distal cell. Without any specific indication in the description, the skilled person would not envisage the stent having another configuration on its back side as alleged by the appellant.

2. Validity of claim 1's priority - Article 87(1) EPC

Claim 1 enjoys the right of priority as held by the opposition division (see point 12 of the appealed decision).
During oral proceedings, the parties referred to their written submissions.

2.1 The appellant held that paragraph [0059] of the priority document (D1a) provided three alternatives:
1. The distal region 170 of the aortic valve 120 extends within the tapered region 50 of the stent structure 20.
2. The distal region 170 of the aortic valve 120 extends within the distal region 70 of the stent structure 20.
3. The distal region 170 of the aortic valve 120 extends within the tapered region 50 and the distal region 70 of the stent structure 20.
The part of the sentence *"[...], although the exact positioning of distal region 170 of the aortic valve 120 relative to the stent structure 20 may be varied as needed"* in paragraph [0059] was a relative clause that related to the three alternatives mentioned immediately beforehand. The disclosure of paragraph [0059] thus required that the distal region of the aortic valve extended either (1) within the tapered region, or (2) within the distal region, or (3) within the tapered region and the distal region. No other extension of the distal region of the valve was disclosed and, thus, a

complete omission of this feature in claim 1 constituted an unallowable intermediate generalisation.

2.2 The Board does not agree with the appellant, especially with the interpretation of paragraph [0059] of the priority document. The preliminary opinion indicated in the communication according to Article 15(1) RPBA 2020 is confirmed.

Claim 1 of the patent is a combination of claims 1, 3 and 4 of the priority document with the omission that: *"the distal region of the valve is at least partially positioned within one of the tapered and distal regions of the stent".* However, paragraph [0059] of the priority document provides a basis for the generalisation of the position of the distal region of the valve.

The Board concurs with the opposition division that the passage of paragraph [0059] *" [...] although the exact positioning of distal region 170 of the aortic valve 120 relative to the stent structure 20 may be varied as needed"* is not restricted to the tapered region 50 and/or the distal region 70 of the stent structure as argued by the appellant but refers to the entire stent structure.

Furthermore, the use of the verb "may" in paragraph [0059] and the term "advantageously" at the beginning of paragraph [0060] (*"Advantageously, the distal region 170 of the aortic valve 120 is disposed within the tapered region 50 and/or the distal region 70 of the stent structure 20..."*) teaches the skilled person that these are non-limiting positions which are not required.

3. Novelty - Articles 100(a) and 54 EPC

The subject-matter of claim 1 is novel over E2, E10, E34 and E35. Feature 1.11 reading: *"wherein an overall length of each of the closed cells of the tapered region (50) is greater than an overall length of each of the closed cells of the proximal region (30) of the stent and less than an overall length of each of the closed cells of the distal region (70) of the stent when the stent is in the expanded state"* is not directly and unambiguously disclosed in these documents.

3.1 Firstly, the appellant noted that it was known that cells in an annulus section of a stent were smallest, that cells in an aortic section were largest, and that cells in a transition section had a size which was somewhere therebetween and reproduced the support frames of documents E1-E4, E6-E8, E10-E11, E14, E22, E25-E26, E35, E37 and E41.

The appellant further referred to the "Windkessel effect" and its principle described in Wikipedia and noted that while the native aortic annulus was formed of rather stiff fibrous tissue providing a non-flexible structure as basis for the leaflets allowing a reliably coaptation, the native ascending aorta was made of rather elastic tissue allowing for a back-pipe-function which was physiologically needed in the vasculature. The strong tissue in the annulus took more radial forces than the softer tissue in the ascending aorta and the aortic annulus was smaller in diameter than the ascending aorta.

The appellant indicated that the cells in all reproduced support frames were recognisably wider in

the aortic section than in the annulus section. Mechanically, wider and longer cells allowed for an expansion to a greater diameter with less force.

3.1.1 Secondly, the appellant referred to the 10th edition of the case law book II. E.1.1.13 "Disclosure in drawings" and in particular to the decision T748/91, where the Board reached the conclusion that size ratios could be inferred even from a schematic drawing as long as the delineation provided the relevant skilled person with discernible and reproducible technical teaching. The appellant insisted that in the present case no dimensions, no measurements, nor any specific values needed to be measured or otherwise obtained from prior art drawings, but merely required that a generic ratio (larger/smaller) could be derived from the prior art which was principally allowable in view of the case law, as clearly confirmed by T748/91.

3.1.2 Thirdly, the appellant focused on E10. Figures 1A and 1B, page 8, lines 30-32, page 12, lines 23-26, claims 19 and 46 taught that the frame comprised cells having sizes that vary along the length of the prosthesis. Page 13, lines 1-3 disclosed the technical function of the cell designs, namely to tailor *"compressibility, expansion characteristics, radia strength and so as to define a suitable contour for attachment of the valve body"* and figure 6 of E10 showed the implanted stent of figure 1.

The skilled person contemplating figure 1A, clearly recognised that the cell length got longer from the proximal region to the distal region, while having in mind to provide variation of cell size and pattern along the length of the stent according to the basic teachings of E10.

The appellant noted that figure 2A of E10, which showed a stent in the contracted delivery configuration, was irrelevant for the assessment of feature 1.11 which required the stent to be in its expanded state.

3.1.3 The appellant further referred to their written submissions regarding the novelty objections in view of E2, E34 and E35.

Figure 1 of E34, disclosed feature 1.11. Page 17, lines 13-14 taught to provide greater and thus longer cells in the distal anchor section 16. Therefore, the skilled person having in mind the importance of adapting the size of the cells, recognized from figure 1 of E34 that the delineation of the cell struts incorporates technical teaching.

Similarly, E2 (figure 10C) and E35 (figure 5) disclosed all the features of claim 1.

3.2 The Board does not agree with the appellant.

3.2.1 The schematic drawing of figure 1A of E10 does not allow for a comparison of the overall length of the tapered cells with the overall length of the distal cells and the proximal cells.

Firstly, in figure 1A, the overall length of the closed cells in the tapered region is not distinctively greater that the overall length of the closed cells of the proximal region. As the length difference between the tapered region's cells and the proximal region's cells is minimal, it requires measurements on the schematic drawing.

Secondly, the ratios in the figures of E10 are not respected as noted by the respondent and the opposition division. Indeed figure 2, which represents the stent in a non-extended state, shows an overall length of the cells being the same over the entire length of the stent and in figure 1A, the ratio of Do over D_I is over 2, while in table 1 of page 14 of E10, all the rations are below 2.

Thirdly, the technical function achieved through the overall length of the cells in the proximal, tapered and distal regions is not derivable from E10. The passage of E10 cited by the appellant (page 12, line 21 - page 13, line 3) does not refer to a technical effect of the different overall length of the cells but to a technical effect of the cell design and in particular the length of the zig-zag z_1 and z_2 (reference is made to figure 1B). Figure 6, showing the implanted stent with the valve, does not teach either the technical function of the varying sizes of the stent's closed cells.

To conclude the present case is different from the cited case T 748/91:
- The difference in the overall length of the closed cell of the tapered region and the closed cell of the proximal length is not evidently visible from figure 1A of E10.
- Figure 2 of E10 casts doubt about the overall length of the closed cells.
- The function of the overall length of the cells in the different regions is not derivable from E10.

3.2.2 As for documents E2, E34 and E35, the Board confirms its preliminary opinion stated in its communication according to Article 15(1) RPBA. Similarly to E10,

feature 1.11 cannot be directly and unambiguously derived from figure 10C of E2, figure 1 of E34 and figure 5 of E35 as the figures are schematic and no technical function can be derived from the overall length of the cells in the different regions.

4. Admissibility of the novelty objections in view of D11 and D14 - Article 13(2) RPBA 2020

The Board did not take into account the novelty objections based on documents D11 and D14 pursuant to Article 13(2) RPBA 2020.

4.1 With letter of 15 December 2022, the appellant raised two new novelty objections in view of D11 and D14. These two new novelty objections made after notification of a summons to oral proceedings represent an amendment to the appellant's appeal case which should not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

4.2 The Appellant argued that documents D11 and D14 were filed at the outset of the opposition procedure and were known to the parties. Furthermore, these two documents were prima facie relevant and would result in the revocation of the patent.
Finally, the appellant noted that they had referred to D11 and D14 on page 9 of their statement of grounds of appeal under point 2 "*lack of novelty (Article 100(a) and 54 EPC)*". While only feature 1.11 was discussed in the statement of grounds of appeals, it was clear that all the features of claim 1 were meant to be disclosed in D11 and D14.

4.3 The Board does not agree with the appellant: in their statement of grounds of appeal only four novelty objections were raised in view of E10 (under point 2.5), E34 (under point 2.6) and E2 and E35 (under point 2.7). The pictures of D11 and D14 under point 2.1 of the statement of grounds of appeal along with a figure of E1, E2, E3, E4, E6, E7, E8, E10, E11, E14, E22, E25, E26, E35, E37 and E41, respectively, were reproduced to illustrate that *"Support frames of prosthetic aortic valves which are designed so as to anchor the prosthesis both in the aortic annulus and in the ascending aorta, have smaller cells in the annulus section and larger cells in the aorta section (...)".* No concrete novelty objections were made in view of D11 and D14 or any of the other documents except for E10, E2, E34 and E35 in the statement of grounds of appeal such that neither the Board nor the respondent were expected to take position on the novelty of the subject-matter of claim 1 in view of each of the documents referred to under point 2.1 of the statement of grounds of appeal.

While all features of claim 1 did not have to be discussed in detail, at least the features that were found not to be disclosed in the documents D11 and D14 by the opposition division were expected to be discussed if the novelty of claim 1 was contested in view of D11 and D14. Indeed, the opposition division not only found that D11 and D14 did not disclose feature 1.11 but also feature 1.3 for document D11 and feature 1.2 for document D14.

Finally, there are no exceptional circumstances that justifies the amendment to the appellant's case. Prima facie relevance is not per se a criterion for assessing the admissibility of the new novelty objections at this late stage of the proceedings. The appellant has not provided any reasons that prevented

them from raising the novelty objection in view of D11 and D14 at an earlier stage of the appeal procedure.

5. Inventive step - Article 100(a) and 56 EPC

5.1 The subject-matter of claim 1 is not rendered obvious starting from E36 in combination with E41 or starting from E37 in combination with common general knowledge, E10, E41, E4 or E34.

5.2 The appellant referred to their submission in writing for the above mentioned inventive step objections.

5.2.1 In their view the assessment of documents E36 and E41 made by the opposition division was not correct since at least document E41 disclosed in figure 5 that the length of the cells of the tapered region was greater than the length of the cells in the proximal region and the length of the cells of the tapered region was less than the length of the cells of the distal region (feature 1.11). Furthermore E41, column 5, lines 6-15 explicitly stated the technical effect: *"When the frame 21 is in the expanded configuration, the frame 21 creates a sufficient outward radial force at its cephalic end (i.e., distal region) to ensure complete sealing against the vessel wall..."* and *"undulating metal structure of the frame 22 has a tighter and smaller pattern allowing for more strength"*
Feature 1.11 was therefore disclosed in E41, thereby solving the problem of improving the attachment at the implantation site taking into account the anatomy of the patient when starting from document E36.

5.2.2 Furthermore, the appellant considered that E37 constituted a prior art under Article 54(2) EPC since the priority of the opposed patent was not valid. E37

in combination with common general knowledge, E10, E41, E4 or E34 rendered the subject-matter of claim 1 obvious.

5.3 The Board does not agree and confirms its preliminary opinion provided in the communication under Article 15(1) RPBA.

5.3.1 As mentioned by the respondent, the skilled person would not combine the teaching of E36 with E41. Indeed, E36 deals with an aortic valve comprising a stent and a valve coupled to it, while E41 deals with endovascular stent graft for use in treating abdominal aortic aneurysm. In E36 the proximal portion of the stent is in contact with the aorta, while in E41 the proximal portion (caudal section) is not to be expanded against the wall of the aorta but must have sufficient inward radial strength to ensure a complete sealing against the modular stent graft 8.

But even if the skilled person would combine the teaching of E36 with E41, the skilled person would not arrive at the subject-matter of claim 1 as mentioned by the opposition division. Indeed, the relative dimensions of the overall length of the distal, tapered, and proximal closed cells and the technical effect is not directly and unambiguously derivable from E36 and E41.

In particular, the passage on column 5, lines 6-14 of E41 cited by the appellant does not clearly teach the force profile achieved by the relative overall length of the closed cells in the distal, tapered and proximal region (i.e., it does not disclose a higher outer radial force at the caudal section than in the cephalic end).

5.3.2 Furthermore, as assessed under 2., the priority of claim 1 dated 5 November 2010 is valid. E37, published on 3 March 2011 is not prior art under Article 54(2) EPC but under Article 54(3) EPC and thus cannot be used for inventive step.

6. Admissibility of the inventive step objection starting from E10 in combination with common general knowledge - Article 13(2) RPBA 2020

The Board did not take into consideration the inventive step objection starting from E10 in combination with common general knowledge raised for the first time during oral proceedings.

6.1 The appellant justified the late submissions by the fact that the Board considered only one distinguishing feature between claim 1 and E10. In their view this change of opinion of the board was an exceptional circumstance that justified the admissibility of the new inventive step objection.

6.2 It is firstly noted that neither in the written proceedings (see points 4 and 14.1 of the communication pursuant to Article 15(1) RPBA) nor at the oral proceedings did the Board issue a statement that the subject-matter of claim 1 only differed from E10 by feature 1.11, but simply that E10 did not disclose feature 1.11 whereby novelty was given. This was in accordance with the respondent's submissions in their reply to the statement of grounds of appeal (page 6) only focusing on feature 1.11. In any event, even if the discussion on novelty would have led to the conclusion that feature 1.11 would be the only difference over E10, still an inventive step objection

could and should have been raised with the statement of grounds of appeal, because also in the decision under appeal feature 1.11 was considered to be a distinguishing feature, together with feature 1.2 (see point 25 of the contested decision). Finally the Board notes that the appellant themselves in their statement of grounds of appeal (point 3 on page 22 and 23) formulated inventive step objections in the event "*that the Board of Appeal considers feature 1.11 as not being disclosed explicitly in the relevant prior art*" whereby "*the subject-matter of claim 1 lacks an inventive step in light of any one of the documents discussed above as novelty destroying*", thus including E10, but failed to substantiate any inventive step objections starting from E10. There is therefore no justification for the appellant seeking to introduce such objection at the oral proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Vottner G. Pricolo

Decision electronically authenticated