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Datasheet for the decision of 7 July 2022

Case Number: T 1810/18 - 3.2.08

Application Number: 07008364.7

Publication Number: 1900343

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
Stent valves

Patent Proprietor:
Cook Biotech Incorporated

Opponents:
Boston Scientific Corporation
St Jude Med,Inc/Abbott Med GmbH/St Jude Med UK Ltd /SJM Int, Inc./SJM Coord Center BVBA/St Jude Med S C Inc

Headword:

Relevant legal provisions:
RPBA 2020 Art. 15(2), 13(2)
EPC Art. 76(1), 123(2)

Keyword:
Change of date of oral proceedings (no)
Divisional application - added subject-matter (yes)
Amendments - added subject-matter (yes)
Amendment after summons - exceptional circumstances (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1810/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 7 July 2022

Appellant: (Patent Proprietor)	Cook Biotech Incorporated 3055 Kent Avenue West Lafayette, IN 47906 (US)
Representative:	Stafford, Jonathan Alan Lewis Marks & Clerk LLP 1 New York Street Manchester M1 4HD (GB)
Respondent 1: (Opponent 1)	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752-1234 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Strasse 3 80331 München (DE)
Respondent 2: (Opponent 2)	St Jude Med,Inc/Abbott Med GmbH/St Jude Med UK Ltd /SJM Int, Inc./SJM Coord Center BVBA/St Jude Med S C Inc 1 St Jude Med Dr/Helfmann Pk/Capulet House/1 St Jude Med Dr/Da Vincilaan/ 6300 Bee Cave Rd St Paul MN 55117/65760 Eschborn/S upon A 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)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 30 April 2018 revoking European patent No. 1900343 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: C. Vetter
C. Schmidt

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke the patent in suit.

II. The opposition division had decided that the subject-matter of the patent as granted and as amended during the opposition proceedings according to auxiliary request 1 extended beyond the content of the (earlier) application as filed (Articles 100(c), 76(1) and 123(2) EPC).

III. Oral proceedings were held by videoconference before the Board.

IV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, as an auxiliary measure, that the patent be maintained according to

- one of auxiliary requests 1 to 6, filed with the statement setting out the grounds of appeal dated 10 September 2018, wherein auxiliary request 1 should be treated as the 7th auxiliary request; or
- one of auxiliary requests 7a and 8, filed during oral proceedings.

It further requested that the proceedings before the Board be limited to Articles 100 c) and 123 (2) EPC and that the case be remitted to the opposition division for consideration of the other grounds of opposition.

With its letter of27 June 2022 the appellant also requested postponement of the oral proceedings. It

requested, as an auxiliary measure, that the oral proceedings be held by videoconference.

Respondent 1 (opponent 1) and respondent 2 (opponent 2) requested that the appeal be dismissed and the patent be revoked. They further requested that auxiliary requests 7a and 8 be rejected as inadmissible.

V. Claim 1 of the main request reads as follows (feature designation in square brackets added by the Board):

A stent valve device for delivery by catheter (100) to a vessel site (80) in the body, comprising:

[I] a radially expandable cylindrical stent (20), the radially expandable cylindrical stent having a collapsed configuration for delivery and an expanded configuration for deployment at the vessel site (80), the radially expandable cylindrical stent (20) having a proximal stent end (31), a distal stent end (33), a stent lumen (36), and a stent diameter (21) and a stent perimeter (34),
[II] a valve (41) located within the lumen (36) of the radially expandable cylindrical stent (20), the valve (41) comprising biocompatible material (38) and at least two leaflets, the valve (41) having a valve orifice (52) between the at least two leaflets, the valve orifice (52) extending substantially across the stent diameter (21), wherein
(a) the valve (41) has a proximal portion connected to a proximal portion (31) of the radially expandable cylindrical stent (20) and a distal portion connected to a distal portion (33) of the radially expandable cylindrical stent (20);
(b) at the locations between adjacent leaflets, the valve orifice (52) terminates 1 to 5 millimeters before

reaching the perimeter (34) of the radially expandable cylindrical stent (20);
(c) the valve material (38) is enclosed within the radially expandable cylindrical stent (20);
characterized in that
(d) reinforcement mechanisms (54) are located
[d-i] between the orifice perimeter and the stent (20) perimeter
[d-ii] at the locations between adjacent leaflets
[d-iii] at valve-stent-opening connection points;
thereby reinforcing said connection points against wear and tear due to opening and closing of the valve and permitting increased structural integrity of the stent valve device.

In claim 1 of auxiliary request 1, feature **(d)** has been amended to read (amendments underlined):

(d) reinforcement mechanisms (54) are located
[d-i] between the orifice perimeter and the stent (20) perimeter
[d-ii] at the locations between adjacent leaflets
[d-iii] at valve-stent-opening connection points, the reinforcement mechanisms provided by a reinforcement mechanism at each of the locations;
thereby reinforcing said connection points against wear and tear due to opening and closing of the valve and permitting increased structural integrity of the stent valve device.

In claim 1 of auxiliary request 2, feature **(a)** has been amended to read (amendments underlined):

(a) the valve (41) has a proximal portion connected to the stent perimeter (34) of a proximal portion (31) of the radially expandable cylindrical stent (20) and a

distal portion connected to a distal portion (33) of the radially expandable cylindrical stent (20), wherein the proximal portion of the valve (41) is connected to the portion of the stent at proximal valve-stent suture (44);

In claim 1 of auxiliary request 3, feature **(d)** has been amended to read (amendments underlined):

(d) reinforcement mechanisms (54), being reinforcement sutures sutured to the biocompatible material (38) of the valve (41), are located
[d-i] between the orifice perimeter and the stent (20) perimeter
[d-ii] at the locations between adjacent leaflets
[d-iii] at valve-stent-opening connection points;
thereby reinforcing said connection points against wear and tear due to opening and closing of the valve and permitting increased structural integrity of the stent valve device.

Auxiliary request 4, in essence, constitutes a combination of auxiliary requests 2 and 3.

In claim 1 of auxiliary request 5, feature **(d)** has been further amended to read (amendments underlined):

(d) reinforcement mechanisms (54), being reinforcement sutures sutured to the biocompatible material (38) of the valve (41) immediately inward of the perimeter (34) of the radially expandable stent (20), are located
[d-i] between the orifice perimeter and the stent (20) perimeter
[d-ii] at the locations between adjacent leaflets
[d-iii] at valve-stent-opening connection points;

thereby reinforcing said connection points against wear and tear due to opening and closing of the valve and permitting increased structural integrity of the stent valve device.

Auxiliary request 6, in essence, constitutes a combination of auxiliary requests 2 and 5.

In claim 1 of auxiliary request 7a, features **[II]** and **(d)** have been amended to read (amendments underlined):

[II] a valve (41) located within the lumen (36) of the radially expandable cylindrical stent (20), the valve (41) comprising biocompatible material (38) and at least two leaflets, the valve (41) having a valve orifice (52) between the at least two leaflets, the valve orifice (52) extending substantially across the stent diameter (21), the valve orifice (52) having a longitudinal valve orifice axis, wherein
(d) reinforcement mechanisms (54) are located
[d-i] between the orifice perimeter and the stent (20) perimeter [at the] longitudinal valve orifice axis
[d-ii] at the locations between adjacent leaflets
[d-iii] at valve-stent-opening connection points;
thereby reinforcing said connection points against wear and tear due to opening and closing of the valve and permitting increased structural integrity of the stent valve device.

Claim 1 of auxiliary request 8 differs from claim 1 of auxiliary request 7a in that feature **[II]** has been further amended to read (amendments underlined):

[II] a valve (41) located within the lumen (36) of the radially expandable cylindrical stent (20), the valve (41) comprising biocompatible material (38) and at

least two leaflets, the valve (41) having a valve orifice (52) between the at least two leaflets, the valve orifice (52) extending substantially across the stent diameter (21), the valve orifice (52) having a longitudinal valve orifice axis, wherein the leaflets are valve pockets, and wherein

VI. The appellant's arguments, as far as they are relevant to the present decision, can be summarised as follows:

Main request

The feature combination of claim 1 was supported by the (earlier) application as originally filed. The patent thus complied with the provisions of Articles 76(1) and 123(2) EPC.

Auxiliary requests 1 to 6

All these auxiliary requests limited the scope of protection so that the provisions of Article 123(3) EPC were fulfilled. Furthermore, all these requests complied with Article 123(2) EPC.

Auxiliary requests 7a and 8

The preliminary opinion of the Board had changed during the oral proceedings, resulting in the appellant being faced with exceptional circumstances which justified the filing of new requests.

VII. The respondents' arguments, as far as they are relevant to the present decision, can be summarised as follows:

Main request

Claim 1 combined features of different embodiments. However, the (earlier) application as originally filed did not disclose this combination. The patent thus contravened the requirements of Articles 76(1) and 123(2) EPC.

Auxiliary requests 1 to 6

The objections raised under Article 123(2) EPC against the main request could not be overcome without infringing Article 123(3) EPC. All these auxiliary requests were thus not allowable.

Auxiliary requests 7a and 8

The appellant did not demonstrate exceptional circumstances which could justify the late filing of these requests. They were thus to be rejected under Article 13(2) RPBA 2020.

Reasons for the Decision

1. Postponement of the oral proceedings

1.1 According to Article 15(2) RPBA 2020, a request of a party for a change of the date fixed for oral proceedings may be allowed if the party has put forward serious reasons which justify the fixing of a new date. If the party is represented, the serious reasons must relate to the representative.

1.2 The appellant requested by letter dated 27 June 2022 that the oral proceedings scheduled for 7 July 2022 be postponed until a later date. The reason given was that its representative's passport had been lost, with the result that the representative was unable to travel overseas to attend the oral proceedings. The representative declared that the fast-track passport replacement service offered by the UK government was unavailable due to lack of in-person appointments. Despite daily checks on the availability if appointments, it was impossible for the representative to obtain a replacement passport in time for the oral proceedings.

1.3 In assessing whether or not to reschedule oral proceedings, the Board considers the circumstances of the individual case.

1.4 In general, the difficulty in finding a new date for oral proceedings increases with the number of parties involved. In the case at hand, three parties are involved, meaning that the probability of one party not being available on the new date is already relatively high. Moreover, in the present case there is the

additional factor that the future availability of the appellant itself is uncertain. Indeed, in the time between the appellant's request for postponement and the date of the oral proceedings, its representative did not manage to obtain documents allowing him to travel. It is thus impossible for the Board to foresee when he would be able to attend oral proceedings.

Hence, there was a high probability that the oral proceedings, if rescheduled, would only be able to take place in the distant future.

1.5 However, time is a crucial factor in the present case. Firstly, the patent in suit had already expired. Secondly, there was a request for remittal of the case to the opposition division, which, if granted, would have further increased the duration of the proceedings. Therefore, a significant delay in the proceedings at this stage would not have been reasonable for the parties or the public.

1.6 For these reasons, the fixing of a new date for the oral proceedings was not justified by the overall circumstances of the present case. The appellant's request for a change of the date fixed for oral proceedings was therefore rejected.

1.7 In accordance with the appellant's auxiliary request and in view of both respondents' consent, the oral proceedings were conducted by videoconference.

2. Main request - amendments

2.1 The patent in suit is based upon a divisional application of an earlier application 01905265.3, which had been published as WO 01/54625 A1 and granted as EP 1 255 510 B1.

The text of the divisional application as filed corresponds, on a page-by-page and line-by-line basis, to that of the earlier application as filed. It follows that, whenever the requirements of Article 123(2) EPC are met, the requirements of Article 76(1) EPC are also met.

2.2 The patent had been revoked because the opposition division had considered the combination of features **(d)** and **(b)** to have no basis in the (earlier) application as originally filed.

2.3 The appellant argued that feature **(d)** was to be read in the context of the patent. While sub-feature **[d-i]** defined the location of the reinforcement mechanisms 54 in the radial direction, sub-feature **[d-ii]** gave their circumferential location. The "valve-stent-opening connection" of feature **[d-iii]** in turn described a region of 1 to 5 mm from the stent perimeter inwards, in accordance with features **[d-i]** and **(b)**.

2.4 Accordingly, claim 1 of the main request is construed to locate the reinforcement mechanisms 54 - in the radial direction - in a region of up to 5 mm from the stent perimeter inwards. This interpretation is in line with features **[d-i]** and **(b)**. Feature **[d-i]** locates the reinforcement mechanisms 54 between the orifice perimeter and the stent perimeter. The orifice perimeter is located where the valve orifice

terminates. Feature **(b)**, in turn, specifies that the valve orifice terminates 1 to 5 millimeters before reaching the perimeter of the stent.

2.5 It is undisputed that the only support for the reinforcement sutures 54 at the "valve-stent-opening connection" of feature **[d-iii]** can be found in the passage on page 10, line 29, to page 11, line 4, of the original description. This passage refers to the embodiment of figures 7 and 8 and reads as follows:

"Because of the opening and closing of the valve, there may be increased wear and tear at the valve-stent-opening connection. At this point, one embodiment of the present invention provides a reinforcement at this point. For example, this reinforcement can be a plurality of reinforcement sutures 54, adhesive, another material, or any other mechanism that permits increased structural integrity."

2.6 Figures 7 and 8, depicted below, show where said reinforcement sutures 54 at the "valve-stent-opening connection" are located in the radial direction, namely directly at the stent perimeter. This location is also in line with the wording of the description. The "point" of the "valve-stent-opening connection" cannot be at a distance from the stent.

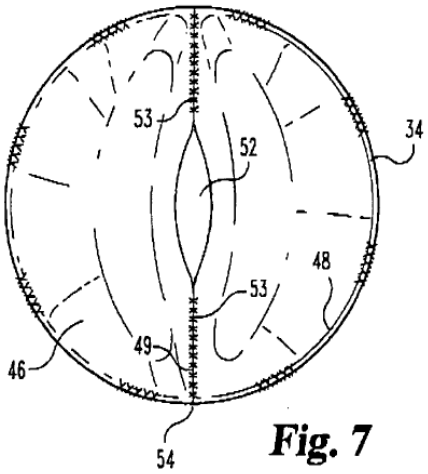

Fig. 7

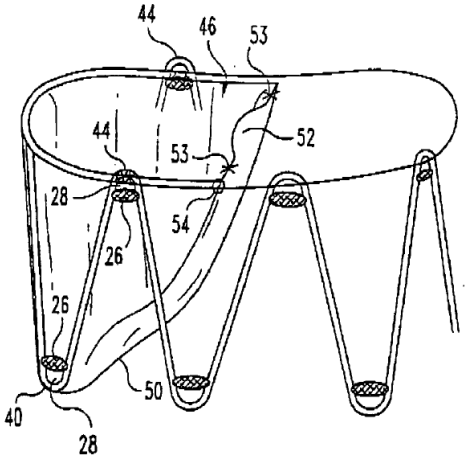

Fig. 8

2.7 It is not disclosed anywhere in the original application that the reinforcement sutures 54 at the "valve-stent-opening connection" could be located at a distance, such as up to 5 mm, from the stent perimeter inwards.

2.8 Figure 7 additionally shows an orifice reinforcement 53 which could be considered as being located in a region of up to 5 mm from the stent perimeter inwards in accordance with features **[d-i]** and **(b)**. However, as correctly stated by the appellant and as expressly disclosed in the original description on page 12, lines 6 to 12, the orifice reinforcement 53 represents another set of reinforcements. This set of reinforcements is not located at the "valve-stent-opening connection".

2.9 Consequently, the (earlier) application as originally filed does not directly and unambiguously disclose reinforcement mechanisms 54 at the "valve-stent-opening connection" which are located between the orifice perimeter and the stent perimeter in a region of up to 5 mm from the stent perimeter inwards according to

features **(d)** and **(b)**. Article 100(c) EPC, therefore, prejudices the maintenance of the patent.

3. Auxiliary requests - amendments

3.1 Claim 1 of auxiliary request 2 specifies in feature **(a)** the connection of the valve to the stent. The features which define the location of the reinforcement mechanisms 54, i.e. features **(d)** and **(b)**, have not been amended.

3.2 In claim 1 of auxiliary request 3, feature **(d)** has been amended to define the reinforcement mechanisms 54 as reinforcement sutures sutured to the biocompatible material 38 of the valve 41. This definition has no impact on the location of the reinforcement mechanisms 54.

3.3 Auxiliary request 4, in essence, is a combination of auxiliary requests 2 and 3.

3.4 Consequently, since none of the features inserted into auxiliary requests 2 to 4 affects the location of the reinforcement mechanisms 54, these requests are not allowable under Article 123(2) EPC for the reasons set out with respect to the main request (see point 2. above).

3.5 In claim 1 of auxiliary request 5, feature **(d)** has been further amended to define the reinforcement mechanisms 54 as being immediately inward of the perimeter 34 of the radially expandable stent 20.

3.6 Auxiliary request 6, in essence, is a combination of auxiliary requests 2 and 5.

3.7 Claim 1 of auxiliary request 1 specifies in feature **(d)** that the reinforcement mechanisms are provided by a reinforcement mechanism at each of the locations.

3.8 None of these amendments changes the location of the reinforcement mechanisms 54 to a location outside the range defined by the patent as granted. This also applies in particular to the vague wording "immediately inward of the perimeter" of auxiliary requests 5 and 6. Auxiliary request 1 in turn defines a plurality of "reinforcement mechanism[s] at each of the locations" without redefining the locations themselves. Auxiliary requests 5, 6 and 1 are thus also not allowable under Article 123(2) EPC for the reasons set out with respect to the main request (see point 2. above).

4. Auxiliary requests 7a and 8 - admittance

4.1 Auxiliary requests 7a and 8 were filed during oral proceedings and, hence, after notification of the summons to oral proceedings. According to Article 13(2) RPBA 2020 they therefore shall, in principle, 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 the preliminary opinion of the Board as expressed in its communication pursuant to Article 15(1) RPBA 2020 had changed during oral proceedings. While, in the preliminary opinion, features **[d-i]** and **[d-iii]** were not mentioned, they now seemed to be decisive. Therefore, the appellant was allegedly faced with exceptional circumstances which justified the filing of new requests.

4.3 A communication under Article 15(1) RPBA 2020 contains a preliminary assessment of the case, which is not binding on the Board (Article 17(2) RPBA 2020). It is intended to help the parties to concentrate on the essentials during the oral proceedings. The purpose of such a communication, therefore, is not to repeat all of the assertions exchanged in the written proceedings. It follows that, if the communication does not repeat a particular assertion made by a party, this does not necessarily mean that this assertion can be ignored.

4.4 In the present case, the Board's communication stated that during oral proceedings it would be discussed whether claim 1 of the main request fulfils the provisions of Articles 123(2) and 76(1) EPC. While the Board put particular emphasis on feature **[d-ii]** in its communication, it must have been clear to the appellant that the remaining objections under Articles 76(1) and 123(2) EPC extensively discussed by all parties in writing, and in particular those relating to feature **(d)**, would not be ignored. Therefore, the appellant could not have been taken by surprise when during oral proceedings the Board came to the conclusion that one or more of these objections prejudices the maintenance of the patent.

4.5 Since the appellant did not demonstrate exceptional circumstances which could justify the late filing of auxiliary requests 7a and 8, these requests were not admitted into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

B. ter Heijden P. Acton

Decision electronically authenticated