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Datasheet for the decision of 30 April 2025

Case Number: T 0622/23 - 3.2.02

Application Number: 11713597.0

Publication Number: 2558029

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
TRANSCATHETER PROSTHETIC HEART VALVE DELIVERY DEVICE WITH STABILITY TUBE

Patent Proprietor:
Medtronic Inc.

Opponents:
Abbott Cardiovascular Systems, Inc.
Boston Scientific Corporation

Headword:

Relevant legal provisions:
EPC Art. 54(3), 56, 83, 123(2)
RPBA 2020 Art. 12(2), 12(4), 13(2)

Keyword:

Novelty - auxiliary request 3 (no) - 5 (yes)
Inventive step - auxiliary request 5 (yes)
Sufficiency of disclosure - auxiliary request 5 (yes)
Amendments - added subject-matter - auxiliary request 5 (no)
Amendment to case - reordering of requests (yes) - admitted (no) - auxiliary request 5 (no) - admitted (yes)

Decisions cited:

T 2564/22, T 1192/22

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 0622/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 30 April 2025

Appellant: (Patent Proprietor)	Medtronic Inc. 710 Medtronic Parkway Minneapolis, MN 55432 (US)
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Appellant: (Opponent 2)	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)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 February 2023 concerning the maintenance of European Patent No. 2558029 in amended form**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor and both opponents appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings in accordance with the request then designated auxiliary request 2, the patent and the invention to which it related met the requirements of the EPC.

II. The Board summoned the parties to oral proceedings and provided its preliminary opinion in a communication under Article 15(1) RPBA, according to which auxiliary request 5 appeared to be allowable, while the higher-ranking requests did not.

III. In response to the Board's preliminary opinion, the appellant-proprietor ("the proprietor") requested, by letter dated 11 April 2025, reordering of the auxiliary requests already on file.

IV. Oral proceedings took place on 30 April 2025.

The proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of auxiliary requests 3, 6', 6, 7, 5 and 8, as filed with the proprietor's statement setting out the grounds of appeal and put in this order by letter dated 11 April 2025.

The appellant-opponents ("the opponents") requested that the decision under appeal be set aside and that the patent be revoked.

V. The following documents are mentioned in this decision:

D4: US 2005/0283223 A1
D11: WO 2011/126749 A1
D24: US 2006/0229561 A1

VI. **Claim 1 of auxiliary request 3** reads as follows:

"A system for restoring a defective heart valve of a patient, the system comprising:

a delivery device (40) for percutaneously delivering a stented prosthetic heart valve (30), the prosthetic heart valve (30) being radially self-expandable from a compressed arrangement to a normal, expanded arrangement, the delivery device (40) comprising:

a delivery sheath assembly (42) defining a lumen (62) and including a distal capsule (50) and a proximal shaft (60), wherein the capsule (50) is configured to compressively contain the prosthetic heart valve (30);

a handle (48) including:

a housing (180) defining a proximal side (190) and a distal side (192),

an actuator mechanism (182) maintained by the housing (180) and coupled to the shaft (60) such that the shaft (60) extends distal the distal side (192), wherein the actuator mechanism (182) is configured to selectively move the shaft (60) relative to the housing (180); and characterized in that

an outer stability tube (52) is coupled to the housing (180) and coaxially received over the shaft (60) such that the shaft (60) is slidable relative to the outer tube, wherein a distal end of the outer stability tube (52) is proximal the capsule (50) such that the capsule (50) does not contact a distal end (140) of the outer stability tube (52), or otherwise enter the outer stability tube (52), in transitioning from a delivery state to a deployed state;

wherein the outer stability tube (52) extends over at least a majority of a length of the shaft (60) in distal extension from the handle (48);

wherein the actuator mechanism (182) is operable to transition the delivery device (40) from the delivery state in which the capsule (50) encompasses the prosthetic heart valve (30) to the deployed state in which the capsule (50) is withdrawn from the prosthetic heart valve (30), the shaft (60) sliding relative to the outer stability tube (52) and transitioning from the delivery state to the deployed state;

a prosthetic heart valve (30) having a stent frame and a valve structure attached to the frame and forming at least two valve leaflets, the prosthetic heart valve (30) being self-expandable from a compressed arrangement to a natural arrangement; and

an introducer device including an introducer sheath and a valve, the introducer device configured to establish hemostasis with the outer stability tube (52), the outer stability tube (52) isolating the shaft (60) from

the introducer device;

wherein the system is configured to be transitionable from a loaded condition in which the prosthetic heart valve (30) is retained within the capsule (50) and deployed condition in which the capsule (50) is withdrawn from the prosthetic heart valve (30) to permit the prosthetic heart valve (30) to self-expand to the natural arrangement and release from the delivery device, the actuator mechanism (182) being configured to effectuate transitioning from the loaded condition to the deployed condition by sliding the delivery sheath assembly (42) relative to the prosthetic heart valve (30) and the stability tube (52)."

Claim 1 of auxiliary request 6' reads as follows:

"A system for restoring a defective heart valve of a patient, the system comprising:

a delivery device (40) for percutaneously delivering a stented prosthetic heart valve (30), the prosthetic heart valve (30) being radially self-expandable from a compressed arrangement to a normal, expanded arrangement, the delivery device (40) comprising:

a delivery sheath assembly (42) defining a lumen (62) and including a distal capsule (50) and a proximal shaft (60), wherein the capsule (50) is configured to compressively contain the prosthetic heart valve (30);

a handle (48) including:

a housing (180) defining a proximal side (190) and a distal side (192),

an actuator mechanism (182) maintained by the housing (180) and coupled to the shaft (60) such that the shaft (60) extends distal the distal side (192), wherein the actuator mechanism (182) is configured to selectively move the shaft (60) relative to the housing (180); and characterized in that

an outer stability tube (52) is coupled to the housing (180) and coaxially received over the shaft (60) such that the shaft (60) is slidable relative to the outer tube, wherein a distal end of the outer stability tube (52) is proximal the capsule (50); and

further comprising a flush port construction (132) maintained by the housing (180) and including tubing (170) fluidly connected to a region between an outer diameter of the delivery sheath assembly (42) and an inner diameter of the outer stability tube (52); the flush port construction (132) including a port connector (172), wherein the port connector (172) is a luer-lock type structure,

wherein the actuator mechanism (182) is operable to transition the delivery device (40) from the delivery state in which the capsule (50) encompasses the prosthetic heart valve (30) to the deployed state in which the capsule (50) is withdrawn from the prosthetic heart valve (30), the shaft (60) sliding relative to the outer stability tube (52) and transitioning from the

delivery state to the deployed state;

a prosthetic heart valve (30) having a stent frame and a valve structure attached to the frame and forming at least two valve leaflets, the prosthetic heart valve (30) being self-expandable from a compressed arrangement to a natural arrangement; and

an introducer device including an introducer sheath and a valve, the introducer device configured to establish hemostasis with the outer stability tube (52), the outer stability tube (52) isolating the shaft (60) from the introducer device;

wherein the system is configured to be transitionable from a loaded condition in which the prosthetic heart valve (30) is retained within the capsule (50) and deployed condition in which the capsule (50) is withdrawn from the prosthetic heart valve (30) to permit the prosthetic heart valve (30) to self-expand to the natural arrangement and release from the delivery device, the actuator mechanism (182) being configured to effectuate transitioning from the loaded condition to the deployed condition by sliding the delivery sheath assembly (42) relative to the prosthetic heart valve (30) and the stability tube (52)."

Claim 1 of auxiliary request 6 reads as claim 1 of auxiliary request 6', but with the addition of the following wording after "...luer-lock type structure,":

"wherein the outer stability tube (52) extends over at least a majority of a length of the shaft (60) in distal extension from the handle (48);"

Claim 1 of auxiliary request 7 reads as claim 1 of auxiliary request 6', but the word "and" after "proximal the capsule (50);" has been replaced by the following wording:

"wherein the outer stability tube (52) extends over at least 80% of a length of the shaft (60) in distal extension from the handle (48);"

Claim 1 of auxiliary request 5 reads as claim 1 of auxiliary request 3, but the wording

"wherein the outer stability tube (52) extends over at least a majority of a length of the shaft (60) in distal extension from the handle (48)"

has been replaced by the following wording:

"wherein an outer diameter of the capsule (50) is greater than an outer diameter of the shaft (60), the shaft (60) being affixed to the capsule at a connection point, and further wherein in the delivery state, the connection point is distal the distal end (140) of the stability tube (52) by a distance in the range of 3 - 13 cm".

Claims 2 to 6 of auxiliary request 5 are dependent claims.

VII. The proprietor's arguments, where relevant to this decision, can be summarised as follows.

Auxiliary request 3

D11 disclosed an embodiment of a transcatheter heart valve delivery system in Figures 6A and 6B. Figure 6C

illustrated, instead, a prior-art delivery system (paragraphs [19] to [21] of D11). The embodiment of Figures 6A and 6B and the system of Figure 6C could not be combined.

The prior-art system illustrated in Figure 6C did not comprise a number of features of claim 1 of auxiliary request 3.

As regards the embodiment of Figures 6A and 6B, there was no direct and unambiguous disclosure in D11 that this embodiment comprised a capsule that did not contact a distal end of an outer stability tube, or otherwise enter the outer stability tube, in transitioning from a delivery state to a deployed state.

Paragraph [44] of D11 described – with reference to Figures 6A and 6B – an optional outer stability tube 48, and compared this embodiment with the prior-art arrangement illustrated in Figure 6C. The embodiment of Figures 6A and 6B comprised a delivery sheath assembly with a capsule 50 having a distal segment 60, a proximal segment 62, and a distal end 56. Furthermore, it comprised a shaft 52 coupled to the distal segment 60 at a connection point 64. Paragraph [44] disclosed that the outer stability tube was sized to have as great a length/distal extension as possible for supporting the delivery sheath assembly and that the distal end of the outer stability tube was located along the shaft 52 (in the loaded state) at a proximal spacing from the distal end 56 by a distance that was less than twice the axial length of the capsule 50, and that the distal end of the outer stability tube could be located at a proximal spacing from the connection point 64 approximately equal to a

length of the distal segment 60, in the delivery state. This meant that by transitioning the device from the delivery state to the deployed state (i.e. withdrawing the capsule), the capsule had to enter the outer stability tube. Figures 6B and 8B confirmed this conclusion. Figure 8B showed proximal segment 62 arranged within the outer stability tube while transitioning from a delivery state to a deployed state.

Paragraph [42] of D11 reflected typical patent drafting, but could not be read in isolation. The text in this paragraph was connected to that of the subsequent paragraphs and referred to Figures 6A and 6B, as made clear by the expression "*as described in greater detail below*" in paragraph [42]. The last sentence of paragraph [44], i.e. "*a comparison of FIGS. 6B and 6C reveals that with the delivery system 40 of the present disclosure, the distal end 130 of the outer stability tube 48 can extend distally further as compared to prior delivery system arrangements*", clarified that the long stability tube and the withdrawal of the capsule into the stability tube were key features of the invention according to D11, and did not relate to a particular example only. If a shorter outer stability tube had been contemplated, this would have been reflected in the claims. However, while claim 12 of D11 was directed to a device with an outer stability tube which permitted the partial withdrawal of the capsule within its interior, there was no claim directed to a device with an outer stability tube which the capsule did not contact or otherwise enter in transitioning from a delivery state to a deployed state. In conclusion, all of the embodiments of D11 with an outer stability tube comprised a long outer stability tube, which permitted

the partial withdrawal of the capsule within its interior.

It followed that the subject-matter of claim 1 of auxiliary request 3 was novel over D11.

Reordering of requests

A number of auxiliary requests, having different distinguishing features, had been filed to address the opponents' objections of a lack of novelty over a document considered prior art according to Article 54(3) EPC. These requests had been grouped in accordance with the features added in comparison with the main request, such that converging requests had been numbered consecutively. This had been done to fulfil the requirement for the requests to be convergent, which was a difficult task when a novelty objection over a prior-art document according to Article 54(3) EPC had to be overcome. The numbering did not reflect an order of preference. The proprietor had established an order of preference of its claim requests only after the Board's preliminary opinion. The request for reordering of the requests, which were all admissible per se, was not a change of the proprietor's appeal case. Not admitting the request for reordering would amount to forcing the proprietor to accept a non-preferred request, which would go against the principle of party disposition.

There was not much case law relevant to requests for reordering. However, in all of the decisions in which such requests had been considered to be inadmissible amendments of the proprietor's appeal case, reordering had been regarded as a procedural abuse going against procedural fairness. For example, in one case,

reordering would have required remittal, which, in turn, would have delayed the proceedings in an unacceptable way. The current case was different since it did not involve any such procedural abuse. The proprietor had not requested remittal but a decision on all of the requests.

Auxiliary request 5

Auxiliary request 5 had already been filed during the first-instance proceedings. Claim 1 included the feature "*wherein an outer diameter of the capsule is greater than an outer diameter of the shaft, the shaft being affixed to the capsule at a connection point, and further wherein in the delivery state, the connection point is distal the distal end of the stability tube by a distance in the range of 3 – 13 cm*", which had a basis in claims 6 and 15 of the application as filed.

The subject-matter of claim 1 of this request was inventive when starting from D4. This document concerned a stent-graft deployment system. It did not relate to restoring a defective heart valve of a patient. Therefore, the person skilled in the art, starting from D4, may have arrived at an improved stent-graft delivery system, but not at a system for restoring a defective heart valve. The subject-matter of claim 1 was therefore inventive starting from D4 for this reason alone.

VIII. The opponents' arguments, where relevant to this decision, can be summarised as follows.

Auxiliary request 3

The subject-matter of claim 1 of auxiliary request 3

was not novel over D11. The embodiment of the transcatheter heart valve delivery system in Figures 6A and 6B, with an outer stability tube 48, a shaft 52, a capsule 50 and a handle 46, comprised all of the features of claim 1 of this request. Paragraph [42] was a general disclosure relating to this embodiment, whereas paragraph [44] disclosed preferred features. Paragraph [42] recited that the outer stability tube had a length "*selected to extend over a significant (e.g., at least a majority, and in other embodiments, at least 80%) of a length of the shaft 52 in distal extension from the handle 46*". Due to the lengths of the shaft and the capsule, if the outer stability tube extended over 80% of the shaft the capsule would not contact the distal end of the outer stability tube, or otherwise enter the outer stability tube, in transitioning from a delivery state to a deployed state.

Reordering of requests

The proprietor's request for reordering of its claim requests was an amendment of its appeal case. Under Article 13(2) RPBA, this request should not be admitted in the absence of exceptional circumstances. The proprietor had not put forward any such circumstances. Moreover, if the proprietor's request was admitted, claim features divergent from the preceding higher-ranking requests, on which the board had not expressed a preliminary opinion, would have to be discussed. This was detrimental to procedural economy.

Auxiliary request 5

The Opposition Division had not addressed auxiliary request 5 in its decision. The proprietor had made no

substantive arguments regarding the claims of auxiliary request 5 in its grounds of appeal, which should have contained the proprietor's complete appeal case. For these reasons, auxiliary request 5 should not be admitted into the appeal proceedings, as had been decided for a similar case in T 1192/22.

There was no basis in the application as filed for the wording "*such that the capsule does not contact the distal end of the outer stability tube, or otherwise enter the outer stability tube, in transitioning from a delivery state to a deployed state*" in claim 1 of auxiliary request 5 without specifying that a length of the outer stability tube in distal extension from the housing was selected to be at least slightly proximal to the capsule in the deployed state, as recited in paragraph [0066] of the application as filed. Hence, claim 1 of auxiliary request 5 included added subject-matter.

Where it was stated in the patent that the distal end of the outer stability tube was proximal to the capsule, the clarification "*in at least the delivery state*" was also present. Without this limitation, it was impossible for the person skilled in the art to identify and reproduce the relative location of the distal end of the outer tube with respect to the movable capsule, in all states. Due to the ambiguity of the term "proximal", claim 1 of auxiliary request 5 defined non-workable embodiments, with the result that the claimed invention was not sufficiently disclosed.

Moreover, the subject-matter of claim 1 of this request was not inventive over D4 in combination with common general knowledge or D24. D4 disclosed a device for intravascular insertion to deploy endoprostheses, with

an inner tube (corresponding to the claimed shaft), a primary sheath (corresponding to the claimed outer stability tube) and a secondary sheath (corresponding to the claimed capsule) affixed to the inner tube at a connection point. In view of common general knowledge or D24, the person skilled in the art would have positioned the primary sheath at a distance in the range of 3 to 13 cm from the connection point in an obvious way, so as to provide the inner tube with enough free space between the distal end of the primary sheath and the proximal end of the secondary sheath to allow for the more flexible secondary sheath to navigate tortuous bends near a targeted delivery site.

Reasons for the Decision

1. Subject-matter of the patent

The patent is concerned with restoring a defective heart valve of a patient by way of minimally invasive techniques, such as percutaneous transcatheter techniques, for the implantation of a valve prosthesis to replace the defective heart valve.

The system for restoring a defective heart valve according to claim 1 of auxiliary request 3 includes a delivery device, a prosthetic heart valve and an introducer device.

Figure 4 of the patent, reproduced below, is an exploded view of a delivery device as defined in this claim.

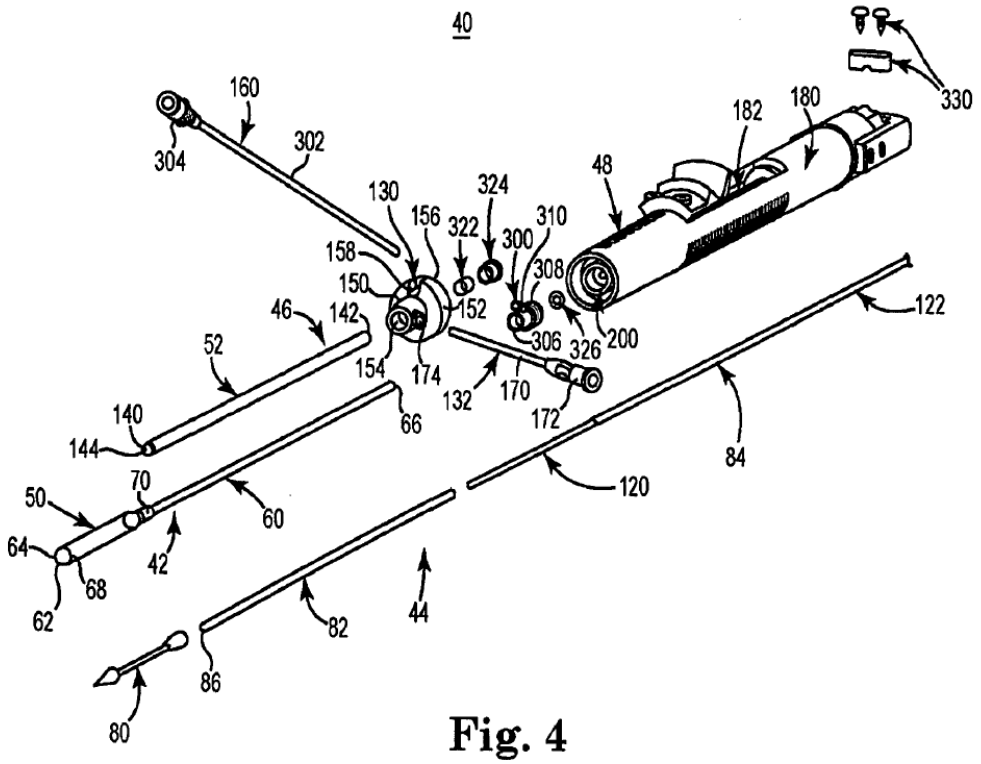

Fig. 4

The delivery device (40) is for percutaneously delivering a stented prosthetic heart valve radially self-expandable from a compressed arrangement to a normal, expanded arrangement. The delivery device comprises a delivery sheath assembly (42), a handle (48) and an outer stability tube (52).

The delivery sheath assembly (42) defines a lumen (62) and includes a distal capsule (50) and a proximal shaft (60). The capsule is configured to compressively contain the prosthetic heart valve.

The handle (48) includes a housing (180), defining a proximal side and a distal side, and an actuator mechanism (182) maintained by the housing and coupled to the shaft such that the shaft extends distal to the distal side. The actuator mechanism is configured to selectively move the shaft relative to the housing. The

actuator mechanism is operable to transition the delivery device from a delivery state in which the capsule encompasses the prosthetic heart valve to a deployed state in which the capsule is withdrawn from the prosthetic heart valve. This is achieved by the shaft sliding relative to the outer stability tube and transitioning from the delivery state to the deployed state.

The outer stability tube (52) is coupled to the housing and coaxially received over the shaft such that the shaft is slidable relative to the outer tube. A distal end of the outer stability tube is proximal to the capsule such that the capsule does not contact a distal end (140) of the outer stability tube, or otherwise enter the outer stability tube, in transitioning from the delivery state to the deployed state. The outer stability tube extends over a majority of a length of the shaft in distal extension from the handle.

The prosthetic heart valve has a stent frame and a valve structure attached to the frame and forming at least two valve leaflets. Moreover, the prosthetic heart valve is self-expandable from a compressed arrangement to a natural arrangement.

The introducer device includes an introducer sheath and a valve, and is configured to establish haemostasis with the outer stability tube, with the latter isolating the shaft from the introducer device.

The claimed system is configured to be transitionable from a loaded condition in which the prosthetic heart valve is retained within the capsule to a deployed condition in which the capsule is withdrawn from the prosthetic heart valve to permit the prosthetic heart

valve to self-expand to the natural arrangement and release from the delivery device. As stated above, the actuator mechanism is configured to effectuate transitioning from the loaded condition to the deployed condition by sliding the delivery sheath assembly relative to the prosthetic heart valve and the stability tube.

Additionally, according to claim 1 of auxiliary request 5, an outer diameter of the capsule is greater than an outer diameter of the shaft, with the shaft being affixed to the capsule at a connection point. In the delivery state, the connection point is distal to the distal end of the stability tube (52) by a distance in the range of 3 to 13 cm.

According to the patent, the provision of an outer stability tube as defined in the claims addresses the problems deriving from the friction between the delivery sheath assembly and the introducer device, which is typically used at the site of insertion of the delivery device into a patient (paragraphs [0007] and [0059] of the patent).

2. Auxiliary request 3

The opponents argued that the patent could not be maintained on the basis of auxiliary request 3 because the subject-matter of claim 1 thereof was not novel over D11.

It is common ground that D11 is prior art under Article 54(3) EPC, which is relevant for novelty only.

2.1 D11 discloses a system for restoring a defective heart valve, including a delivery device (40, Figure 3) for

percutaneously delivering a stented prosthetic heart valve, the prosthetic heart valve (paragraph [28]), and an introducer device ("conventional introducer device" in paragraph [30] or "introducer device 164" in paragraph [46]), as defined in claim 1 of auxiliary request 3.

The delivery device is shown in Figures 2, 3, 6A and 6B of D11, which illustrate one and the same "*delivery system in accordance with the principle of the present disclosure*" (paragraphs [14], [15], [19] and [20] of D11). Figure 3 of D11, which is very similar to Figure 4 of the patent, is reproduced below.

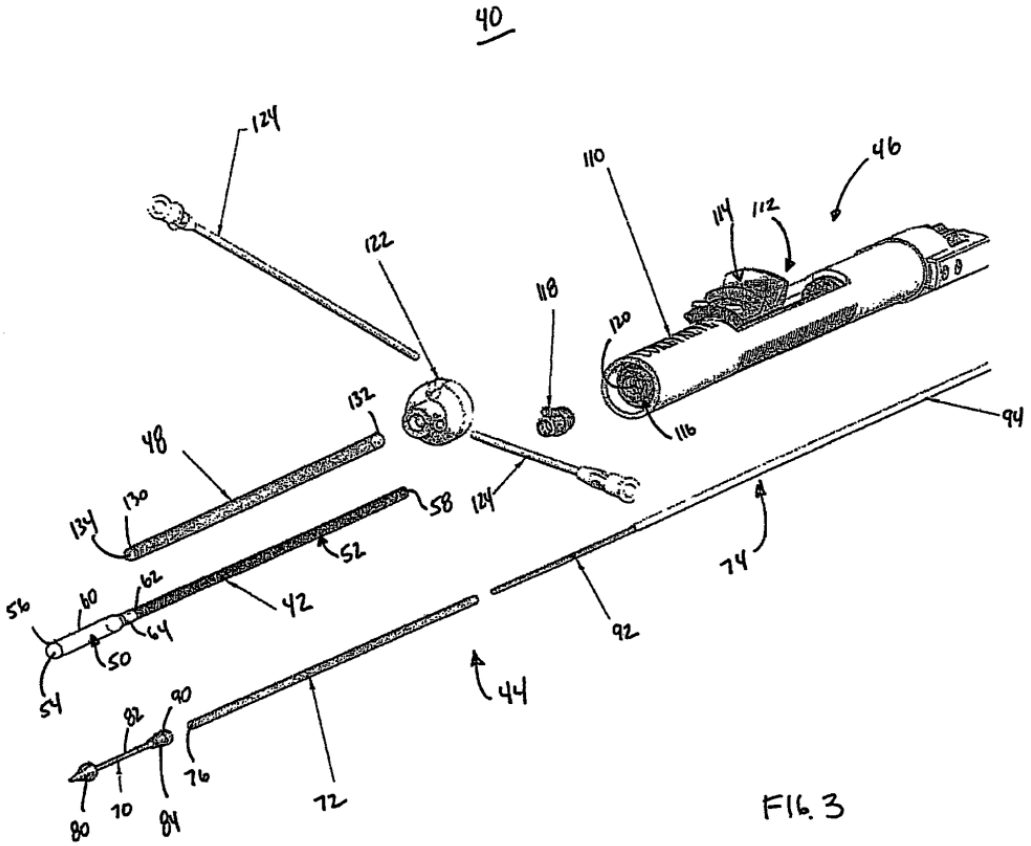

FIG. 3

This delivery device includes a delivery sheath assembly (42), defining a lumen (54) and including a distal capsule (50) and a proximal shaft (42), a

handle (46), including a housing (110) and an actuator mechanism (112), and an outer stability tube (48).

The system is configured to be transitionable from a loaded condition to a deployed condition (paragraph [30]), with the actuator mechanism being configured to effectuate transitioning from the loaded condition to the deployed condition by sliding the delivery sheath assembly relative to the prosthetic heart valve and the stability tube (paragraphs [30] and [41]).

2.2 The proprietor argued that D11 did not disclose in a direct and unambiguous way that the capsule in the system for restoring a defective heart valve shown in Figures 6A and 6B did not contact a distal end of the outer stability tube, or otherwise enter the outer stability tube, in transitioning from a delivery state to a deployed state.

This feature is, however, expressly disclosed in paragraph [42] of D11. In this paragraph, which relates to the delivery system shown in Figures 2, 3, 6A and 6B, it is stated that the outer stability tube extends over "*at least a majority*", preferably over "*at least 80%*", of a length of shaft 52. The end of the interval "*at least 80%*", which is 80% of the length of the shaft, is therefore explicitly disclosed. In view of the relative dimensions of the capsule and the shaft, which are necessary for the correct deployment of the stented prosthetic heart valve, the outer stability tube extending over 80% of the shaft inherently means that the distal end of the outer stability tube must be in a position such that the capsule does not contact a distal end of the outer stability tube, or otherwise enter the outer stability

tube, in transitioning from a delivery state to a deployed state.

As the proprietor submitted, paragraph [44] defines that the same delivery system may include an outer stability tube "*being sized to have as great a length/ distal extension as possible",* with the distal end of the outer stability tube being located at a distance from the distal end of the shaft "*that is less than twice the axial length of the capsule*". According to this paragraph, such an outer stability tube has the advantage of "*supporting the delivery sheath assembly*". This does not mean, however, that the disclosure of paragraph [42] should be ignored or interpreted such that D11 only contemplates an outer stability tube as disclosed in paragraph [44].

Paragraph [42] discloses more general features of the outer stability tube which, in a preferred construction, may have the features set out in paragraph [44]. The expression "as described in greater detail below" in paragraph [42] does not contradict the subsequent disclosure that the outer stability tube may extend over 80% of a length of the shaft. Moreover, paragraph [44] itself explains that the features of the outer stability tube expressly disclosed therein are optional, even if they are preferable and particularly advantageous over the prior art. This is made clear in the second sentence of paragraph [44], which begins with the following wording: "*in some constructions where the outer stability tube 48 is sized to have as great a length/distal extension as possible [...]*".

The proprietor's argument that the general disclosure of paragraph [42] was not reflected in any of the claims of D11 is not convincing either. The disclosure

content of a document is not limited to its claims.

In conclusion, auxiliary request 3 cannot be allowed for lack of novelty of the subject-matter of claim 1 thereof over D11 (Article 54(1) and (3) EPC).

3. Reordering of requests

3.1 In response to the Board's communication under Article 15(1) RPBA of 11 April 2025, which included the Board's preliminary opinion, the proprietor requested "*reordering of the Auxiliary Requests already on file*". It requested that auxiliary requests 6', 6 and 7, previously ranking lower than auxiliary request 5, now be ranked higher than auxiliary request 5.

3.2 The proprietor argued that the auxiliary requests presented with its statement setting out the grounds of appeal had actually not been ranked in accordance with the proprietor's preference.

The Board does not accept this argument. Not only did the proprietor number the auxiliary requests re-submitted with the statement setting out the grounds of appeal, but it also submitted further requests specifying an order in which the auxiliary requests were to be considered by the Board, i.e. an order of preference. Page 1, last sentence, of the statement setting out the grounds of appeal reads: "*as an additional auxiliary measure, it is requested to maintain the opposed patent on the basis of the claims according to Auxiliary Requests 6’ and 6a’, enclosed herewith. Auxiliary Requests 6’ and 6a’ are to be considered in case the Board of Appeal is of the opinion that the claims according to Auxiliary Request 5a are not allowable, i.e. between Auxiliary*

Requests 5a and 6". Moreover, the proprietor itself explicitly requested "*reordering*", which presupposes a previous order (of preference). The reasons why the proprietor originally ranked the requests as it did are of little relevance. The fact remains that the proprietor had ranked the auxiliary requests and that the proprietor requested a different ranking only after the communication under Article 15(1) RPBA, which included the Board's preliminary opinion.

3.3 The proprietor also argued that a request for reordering was not a change of its appeal case.

The Board has a different view. The term "*amendment*" of the appeal case is used generally in the RPBA, without being assigned any restricting interpretation. Article 13(1) and Article 13(2) RPBA expressly refer to "*any amendment of a party's appeal case*".

Moreover, there is consistent case law (T 2564/22 and the further decisions cited in point 2.1 of the Reasons thereof), with which the Board agrees, that has established that reordering claim requests in the appeal proceedings constitutes an amendment of the proprietor's appeal case.

3.4 It follows that Article 13(2) RPBA is applicable to the proprietor's request for reordering.

This article prescribes strict requirements for the admittance of any amendment to a party's appeal case made after notification of a communication under Article 15(1) RPBA. Such amendments must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

When the admittance of a set of requests (with a given order) is an issue, it is up to the Board to consider the admittance of the whole set or individual requests (or group of requests) in the order presented.

In the present case, auxiliary request 5 is an attempt to overcome the objection of a lack of novelty in view of D11 by defining the distance between the connection point and the distal end of the stability tube, whereas auxiliary requests 6, 6' and 7 are attempts to overcome the same objection in an alternative and unrelated approach, namely by introducing a flush port construction. In its preliminary opinion, the Board expressed the view that the approach of auxiliary request 5 was successful in overcoming the objection of a lack of novelty, and therefore there was no need to consider the lower-ranking requests. The whole set of requests expressed the proprietor's preference for the way the same objection was to be addressed. Changing this preference, as in the requested reordering, would have completely changed the procedure and, possibly, the outcome of the case. In view of these considerations, the Board is of the view that it is appropriate to consider the admittance of the whole set of requests 6', 6, 7 and 5.

3.4.1 In its letter dated 11 April 2025, the proprietor did not put forward any exceptional circumstances or cogent reasons for its request.

In the oral proceedings, the proprietor argued that the Board's preliminary opinion had triggered its request. However, the provision of a preliminary opinion by the Board is not an exceptional circumstance and could not justify any cogent reasons, as it was based on the

assessment of objections previously presented by the opponents.

3.4.2 The proprietor's argument that a request for reordering of claim requests should only be considered to be an inadmissible amendment of the proprietor's appeal case if the reordering could be seen as a procedural abuse going against procedural fairness, and that there was no such abuse in the current case, is not convincing either.

The Board agrees with the proprietor inasmuch as considerations about procedural economy may play a role in the Board's discretion to hold the request inadmissible. In the case at hand, however, the Board notes that the admittance of the request for reordering would have shifted the discussion from a first line of requests, focusing on the feature of the outer stability tube being such that that the capsule does not contact a distal end of the outer stability tube, or otherwise enter the outer stability tube, in transitioning from a delivery state to a deployed state, to requests which omit this feature and are instead concerned with features of a flush port construction. While the board provided a detailed preliminary opinion on the first line of requests, in the light of the positive preliminary conclusion on auxiliary request 5, it did not appear expedient to provide a detailed preliminary opinion on the lower-ranking requests concerned with a completely different technical aspect. This shift in the discussion caused by the proprietor's late request for reordering would certainly delay the proceedings and therefore have a negative impact on procedural economy.

3.4.3 The proprietor's argument that not admitting the request for reordering would go against the principle of party disposition is not accepted. The principle of party disposition is of no relevance for the application of the Board's discretion to hold requests inadmissible. Not admitting a request for reordering does not force the proprietor to accept a patent in a version it does not want; it simply puts a limit on what the proprietor may obtain. In the case at hand, the proprietor certainly had the option to withdraw auxiliary request 5, but it chose not to.

3.5 For these reasons, the Board has not admitted the proprietor's request for reordering its claim requests under Article 13(2) RPBA.

Considering the intention expressed by the proprietor to proceed with the requests in their original order in this eventuality, and given the fact that there was no objection to this by the opponents, the Board thus went on to consider auxiliary request 5.

4. Auxiliary request 5

As a preliminary remark, the Board notes that in the oral proceedings, the opponents, having received the Board's preliminary opinion, did not wish to discuss their objections against auxiliary request 5; instead, they merely referred to their written submissions.

4.1 The opponents argued that auxiliary request 5 should not be admitted into the appeal proceedings because the Opposition Division had not addressed it in its decision and the proprietor had not made substantive arguments on this request in its grounds of appeal.

Under Article 12(2) and (4) RPBA any request on which the decision under appeal was not based is to be regarded as an amendment, unless the proprietor demonstrates that it was admissibly raised and maintained in the proceedings leading to the decision under appeal. Any such amendment may be admitted only at the discretion of the Board.

Auxiliary request 5 was first filed during the first-instance opposition proceedings and the proprietor then indicated why the additional features of claim 1 of this request were inventive (points II.5 and II.9 of the letter dated 25 November 2022). Since the Opposition Division held allowable a higher-ranking request, it saw no need to discuss auxiliary request 5. For these reasons, the Board concludes that the proprietor did demonstrate that auxiliary request 5 had been admissibly raised and maintained in the proceedings before the Opposition Division.

On appeal, the opponents did not raise further objections to auxiliary request 5 that had not already been raised already before the Opposition Division. In this respect, the situation is different from that in case T 1192/22, to which the opponents referred.

For this reason, auxiliary request 5 is to form part of the appeal proceedings pursuant to Article 12(2) and (4) RPBA.

4.2 Claim 1 of auxiliary request 5 is based on claims 1, 10, 11 and 15, and paragraph [66], of the application as filed.

The opponents argued that there was no basis in the application as filed for the wording "*such that the*

capsule does not contact the distal end of the outer stability tube, or otherwise enter the outer stability tube, in transitioning from a delivery state to a deplo yed state" in claim 1 of auxiliary request 5 without specifying that a length of the outer stability tube in distal extension from the housing was selected to be at least slightly proximal to the capsule in the deployed state, as recited in paragraph [66] of the application as filed.

However, according to paragraph [66], fourteenth sentence, the additional feature of claim 1 of auxiliary request 5, i.e. "*wherein an outer diameter of the capsule (50) is greater than an outer diameter of the shaft (60), the shaft (60) being affixed to the capsule at a connection point, and further wherein in the delivery state, the connection point is distal the distal end (140) of the stability tube (52) by a distance in the range of 3 - 13 cm*", together with the feature "*the capsule (50) does not contact the distal end of the outer stability tube (52), or otherwise enter the outer stability tube (52), in transitioning from a delivery state to a deployed state*", result in a a length of the outer stability tube in distal extension from the housing being selected to be "*at least slightly proximal the capsule in the deployed state*" within the meaning of paragraph [66], tenth sentence.

In conclusion, the opponents' objection of added subject-matter (Article 123(2) EPC) does not prejudice the maintenance of the patent on the basis of auxiliary request 5.

4.3 The opponents argued that the invention as defined in claim 1 of auxiliary request 5 was not sufficiently

disclosed because the feature of the distal end of the outer stability tube being proximal to the capsule needed to be clarified by specifying that this was the case "*in at least the delivery state*".

However, this is specified in claim 1 of auxiliary request 5: "*in the delivery state, the connection point is distal the distal end (140) of the stability tube (52) by a distance in the range of 3 - 13 cm*".

Hence, the opponents' objection of a lack of sufficiency (Article 83 EPC) does not prejudice the maintenance of the patent on the basis of auxiliary request 5.

4.4 The additional feature of claim 1 of auxiliary request 5, i.e. "*wherein an outer diameter of the capsule (50) is greater than an outer diameter of the shaft (60), the shaft (60) being affixed to the capsule at a connection point, and further wherein in the delivery state, the connection point is distal the distal end (140) of the stability tube (52) by a distance in the range of 3 - 13 cm*", is not directly and unambiguously disclosed in D11. Hence, the subject-matter of claim 1 of auxiliary request 5 is novel (Article 54(1) and (3) EPC) over D11.

The opponents argued that the subject-matter of claim 1 of auxiliary request 5 was not inventive starting from D4 in combination with common general knowledge or D24.

As the opponents noted, D4 relates to a stent-graft deployment system. It does not disclose a system for restoring a defective heart valve of a patient, with a prosthetic heart valve retained within the capsule of a delivery device and a connection point of the capsule,

with a shaft being distal to the distal end of an outer stability tube of the delivery device by a distance in the range of 3 to 13 cm.

These distinguishing features have the technical effect of stabilising the delivery device during delivery of the heart valve to a patient. Hence, they address the objective technical problem of easier deployment of a particular stent (in the form of a heart valve).

Without any specific teaching of the solution to the objective technical problem, especially in relation to the delivery of a heart valve, common general knowledge cannot render obvious the distinguishing features of claim 1 of auxiliary request 5. Since neither D4 nor D24 discloses a heart valve, a combination of these documents does not render obvious the claimed subject-matter either.

Hence, the opponents' objections of a lack of inventive step (Article 56 EPC) do not prejudice the maintenance of the patent on the basis of auxiliary request 5.

4.5 The description has been adapted to the amended claims. The opponents had no objections to the adapted description.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent in the following version:

   - claims 1 to 6 of auxiliary request 5 as filed with the patent proprietor's statement setting out its grounds of appeal,
   - description: paragraphs [0001] to [0009], [0011] to [0050] and [0052] to [0068] of the patent specification, paragraph [0010] as filed during the oral proceedings before the Opposition Division on 25 January 2023, and paragraph [0051] as filed during the oral proceedings before the Board on 30 April 2025, and
   - the drawings of the patent specification.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated