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Datasheet for the decision of 7 May 2024

Case Number: T 1241/22 - 3.2.01

Application Number: 18152598.1

Publication Number: 3332743

IPC: A61F2/24, A61F2/95, A61F2/00

Language of the proceedings: EN

Title of invention:
METHOD AND APPARATUS FOR COMPRESSING/LOADING STENT-VALVES

Patent Proprietor:
Symetis SA

Opponent:
Edwards Lifesciences Corporation

Headword:

Relevant legal provisions:
EPC Art. 54(3), 76(1), 56
RPBA 2020 Art. 12(2), 12(4), 13(2)

Keyword:
primary object of appeal proceedings to review decision - appeal case directed to facts on which decision was based (yes)
Novelty - main request (no) - auxiliary request 1 (no)
Amendment after summons - taken into account (no)
Divisional application - subject-matter extends beyond content of earlier application (no)
Inventive step - auxiliary request 2 (yes) - non-obvious combination of known features

Decisions cited:
T 0161/09, T 0524/12

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1241/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 7 May 2024

Appellant: (Patent Proprietor)	Symetis SA Chemin de la Venoge 11 1024 Ecublens VD (CH)
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Appellant: (Opponent)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Somerville, Andrew Edward Somerville Associates Dunston Innovation Centre Dunston Road Chesterfield S41 8NG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 23 March 2022 concerning maintenance of the European Patent No. 3332743 in amended form.**

Composition of the Board:

Chairman	G. Pricolo
Members:	A. Wagner
	A. Jimenez

Summary of Facts and Submissions

I. The appeals by the opponent and the patent proprietor are directed against the decision of the opposition division to maintain European patent No. 3 332 743 in amended form on the basis of auxiliary request 2 filed during oral proceedings.

II. In its decision, the opposition division held among others that the patent as granted met the requirements of Article 100(c) EPC, but that the subject-matter of claim 1 and claim 11 as granted and of auxiliary request 1 did not meet the requirements of Article 54 EPC. With regard to auxiliary request 2, the opposition division found none of the inventive step attacks provided by the opponent convincing.

In order to come to these conclusions the opposition division considered, among others, the following documents:

E1: WO 2012/155130 A1
E4: WO 99/51167 A2
E9: EP 1 731 189 A1
E11: US 2009/0054976 A1
E13: WO 2011/051043 A1

III. Additionally, this decision refers to the following document filed during opposition proceedings:

X10: "Transcatheter Aortic Valve Implantation: Tips and Tricks to Avoid Failure", Patrick W. Serruys et al.

IV. Oral proceedings by videoconference were held before the Board on 7 May 2024.

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted, or, in the alternative, that the patent be maintained in amended form on the basis of one of the auxiliary requests 1 to 25 as submitted with the statement of grounds of appeal.

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

V. The patent as granted (main request) comprises two independent claims 1 and 11. **Claim 1** reads as follows (feature analysis added by the Board):

1. Apparatus comprising:
1.1 a stent-valve (10);

1.2 a delivery catheter for delivering the stent-valve to an implantation site within the body,

1.3 the delivery catheter having at least one translatable sheath (30) at a containment region (12a) for receiving the stent-valve (10) in a compressed form as a result of a loading operation for compressing and loading the stent-valve with respect to the delivery catheter;
characterized by

1.4 a packaging (120) containing the delivery catheter (12) prior to use,

1.5 the packaging (120) including a base (122)

supporting the delivery catheter in a storage position,

1.6 the base (122) having a liquid-tight trough (126),

1.7 the trough (126) having a depth suitable for use to hold liquid within which the containment region (12a) of the catheter (12) may be immersed during the loading operation.

Claim 11 reads as follows:

11. A method of preparing a stent-valve (10) and a delivery catheter (12) for use, the method comprising:

(a) providing a closed packaging (40) containing the delivery catheter (12), the packaging (40) including a base (122) supporting the delivery catheter (12) in a storage position, the base (122) having a liquid-tight trough (126);

(b) opening the closed packaging (40);

(c) introducing liquid into the trough (126)of the base (122);

(d) loading the stent-valve (10) into a containment region (12a) of the delivery catheter (12) while at least the containment region (12a) is immersed in the liquid in the trough (126).

In claim 1 of **auxiliary request 1** feature 1.1 is amended as follows:

1.1[1] a stent-valve comprising a stent component (14), a valve component (16), and an inner skirt and/or an

outer skirt covering at least partly a respective inner or outer surface portion of the stent component (14),

Method claim 11 is amended accordingly by adding feature 1.1^1 after step (d).

Auxiliary request 2 is based on auxiliary request 1, wherein feature 1.1^1 is amended as follows:

1.1^2 a stent-valve comprising a stent component (14), a valve component (16), and an inner skirt and an outer skirt covering at least partly a respective inner and outer surface portion of the stent component (14)

Method claim 11 is amended accordingly.

VI. The appellant's (patent proprietor's) arguments relevant to the present decision may be summarized as follows:

Admission of X10

X10 should not be admitted. X10 was late filed during opposition proceedings but not discussed at all. Also its admittance was not discussed.

Main request and auxiliary request 1 - novelty over E1 (Article 54(3) EPC)

E1 did not disclose feature 1.7. Contrary to the opposition division's opinion E1 neither explicitly nor implicitly disclosed an immersed loading operation (decision, point 16.2.3). The saline bath area 520 (figure 11) was not suitable to hold liquid such that the containment region of the catheter may be immersed.

Instead the saline bath might be used for different purpose, e.g. for rinsing or for crimping the heart valve.

The opposition division further wrongly assumed that the reference to the CoreValve in E1, paragraph [0027] implied full immersion. The CoreValve was not disclosed in the context of the packaging shown in figures 11 to 13. Instead, the packaging was only disclosed for "*a prosthetic heart valve*" (page 14, lines 1-2, 24) or "*a tissue heart valve*" (page 15, lines 21, 25-27, page 16, line 23, 25) in general.
Furthermore E1 did not specify the generation of the CoreValve.
With regard to feature 1.1^1 or 1.1^2, it was noted that E1 was a document under Article 54(3) EPC and no details at all about skirts of a heart valve prothesis were disclosed.

Added subject-matter

The findings of the opposition division (decision, point 16.1) with regard to the patent as granted were correct. These finding also applied to auxiliary request 2 in appeal.
Claim 1 was based on original claim 29 and page 20, last three lines of the parent application published as WO 2012/150290 A1.
Dependent claim 10 found basis on page 20, second paragraph.

Auxiliary request 2 - Admissibility of the novelty attack

The novelty attack over E1 against claim 1 of auxiliary request 2 was presented for the first time during

appeal's oral proceedings and fell under the provision of Article 13(2) RPBA. E1 had never been mentioned in relation to auxiliary request 2 before.

Auxiliary request 2 - Inventive step

The decision under appeal (points 19.3.1 to 19.3.3) was correct in acknowledging an inventive step starting from E4, E9 or E11 combined with E13.
During appeal's oral proceedings, the appellant (opponent) raised for the first time inventive step objections starting from E4, E9 or E11 combined with common general knowledge. These attacks should not be admitted.

Only E11 could be considered closest prior art as it was in the field of a packaging for transcatheter heart valves. Contrary to the appellant's (opponent's) opinion, claim 1 did not only differ in the heart valve comprising both an inner and outer skirt, but also in features 1.3, 1.5 and 1.7. As E13 or the common general knowledge was only cited for features 1.1^2 to 1.3, the combination of E11 with common general knowledge or with E13 did not obviously lead to the claimed subject-matter.

E4 referred to the technical field of embolic filters and was unrelated to the field of transcatheter heart valves. For this reason, the skilled person would not consider E4 as closest prior art. Even if E4 would be considered, the skilled person would neither simply replace the embolic filter by a heart valve because the delivery catheter for the embolic filter was not suitable for delivering a stent valve, nor use the packaging of E4 together with a delivery catheter and a heart valve according to features 1.1^2 to 1.3 as the

packaging was specifically adapted to the device disclosed in E4.

E9 was completely silent about a loading operation. The purpose of the tray shown e.g. in figure 1 was not presented as being the same as claimed.

VII. The appellant's (opponent's) arguments relevant to the present decision may be summarised as follows:

Admission of X10

X10 was filed in reaction to the auxiliary requests filed by the patent proprietor on the last day of the deadline for submissions before the first instance oral proceedings. X10 served as proof for the common general knowledge about the CoreValve mentioned in E1 and was not discussed because the opposition division did not dispute this common general knowledge.

Main Request and auxiliary request 1 - novelty over E1 (Article 54(3) EPC)

E1, paragraphs [0052] and [0055] explicitly disclosed that the bath area 520 shown in figure 11 was used during a heart valve loading process. Feature 1.7 was thus disclosed.

With regard to feature 1.1^1 of claim 1 of auxiliary request 1, the opposition division was right in finding that in paragraph [0027], the delivery catheter 10 and the packaging shown in figure 11 was disclosed together with the Medtronic CoreValve which is generally known as comprising feature 1.1^1 (decision, point 17). X10 gave proof of the features of the CoreValve and the necessity of an immersed loading.

Auxiliary request 2 - added subject-matter

Claim 1 introduced new technically relevant information when specifying an apparatus including a packaging containing the delivery catheter prior to use in a storage position together with a stent-valve without specifying
- that the packaging was closed and
- that the stent-valve was external to the closed packaging.

Claim 10 was a creation of an artificial hybrid, selecting arbitrarily optional features without any pointer in the disclosure to the specifically claimed feature combination and without any association with the claimed packaging. The combination of features selected by the patent proprietor did not emerge clearly and unambiguously from the content of the application as filed.

Auxiliary request 2 - Admissibility of the novelty attack

E1 was novelty destroying for the subject-matter of claim 1 of auxiliary request 2. The CoreValve mentioned therein had an inner skirt that was wrapped around from the inside to the outside at the inflow end of the frame as could be seen in figure 2 on e.g. page 96 of X10. This part of the inner skirt constituted an outer skirt.
The novelty attack against auxiliary request 2 was admissible according to T 0161/09 or
T 0524/12 (see also Case law of the BoA, 10th edition, chapter V.A.5.10.3) as the objection did not alter the legal or factual framework. The objection did not

substantially change the case and concerned the same features as already discussed.

Auxiliary request 2 - Inventive step

A delivery catheter and a heart valve according to features 1.1^2 to 1.3 were known from common general knowledge or from E13. Furthermore, the skilled person knew that some of these heart valves required an immersed loading process (e.g. X10).

E11 disclosed in figure 6 a storage container 50 constituting the fluid tight trough. Paragraph [0072] disclosed an additional exterior packaging in which the delivery catheter and the storage container 50 were included.
Claim 1 only differed from E11 in that the stent-valve additionally had an outer skirt.
The solution to the problem of providing an alternative stent-valve was trivial and it would be obvious to employ such a stent-valve known from the common general knowledge or known from E13.

E4 disclosed the packaging shown in figure 9 for medical devices and implants in general (claims 20, 21). The opposition division erred in concluding that the purpose of the bath 33 (figure 11) in E4 was different than the one of claim 1. The bath 33 not only had the purpose to exclude air from the catheter (E4, page 15, lines 4 to 6) but was explicitly used "*for submerged loading of the medical device into the catheter*" (page 7, fourth paragraph). Claim 1 and claim 11 only differed from E4 in that the medical device was a stent-valve with an inner and outer skirt (feature 1.1^2).

E9 disclosed a packaging 1 with two trays 2, 3 which could be filled with a saline to immerse a catheter before use. As in E4, the only difference was the kind of medical device. E9, paragraph [0003], explicitly mentioned a stent with delivery catheter.

In order to solve the objective technical problem to use the packaging of E4 or E9 with an alternative medical implant, it was obvious to use the packaging disclosed in E4 or E9 in combination with
- either the stent-valve of E13
- or the delivery device and the stent-valve of E13
- or a delivery device and a stent-valve according to features 1.1[2] to 1.3 known from common general knowledge.

Reasons for the Decision

1. Admission of X10

1.1 The Board considers X10 admissibly raised during first instance proceedings according to Article 12(4), first paragraph, RPBA. Therefore X10 constitutes part of the appeal proceedings according to Article 12(2) RPBA.

1.2 X10 was filed by the opponent in reaction to the filing of auxiliary requests 1 and 3 to 25 in response to the summons to oral proceedings. X10 is a textbook and was cited as proof for common general knowledge which was disputed by the patent proprietor. This common general knowledge only became relevant with the filing of the auxiliary requests, in particular in view of auxiliary request 1 underlying the impugned decision (filed as auxiliary request 6). As the opposition division acknowledged the common general knowledge without

further proof, no decision was taken upon the admission of X10 into the proceedings.

1.3 The Board considers the filing of X10 as an adequate reaction of the opponent to the course of the opposition proceedings. According to established case law, evidence of common general knowledge need to be submitted only if the latter's existence is disputed (Case Law of the Boards of Appeal of the EPO, 10th Edition, I.C.2.8.5). X10 was thus admissibly raised during opposition proceedings.

2. **Main Request and auxiliary request 1 - novelty over E1 (Article 54(3) EPC)**

2.1 The Board confirms the opposition division's findings that the subject-matter of claim 1 and of claim 11 of the main request and of auxiliary request 1 is not new over E1 (impugned decision, points 16.2.3 and 17.2).

2.2 The appellant (patent proprietor) disputed the disclosure of a trough having a depth suitable for use to hold liquid within which the containment region of the catheter may be immersed during the loading operation (feature 1.7). Neither the CoreValve mentioned in E1 nor the depth of the tray, which is indicated in figure 12 as being a "*~2.5" deep tray*", allowed any conclusion to be drawn about feature 1.7.

2.2.1 The Board is not convinced. E1 shows in figures 11 and 12 a packaging 500 containing a delivery catheter 10. The packaging comprises a saline bath 520 which is explicitly disclosed for a loading operation of a tissue heart valve. E1, paragraph [0052], recites: "*The bath area 520 can be formed in the second main tray 504 and can be filled with cold saline solution, as such*

solutions are well known for this purpose, which solution is used during a loading process of a tissue heart valve." Further on, the paragraph describes a strap 522 having the advantage that, during a tissue valve loading process, the catheter portion 12 is hold in place "*while collapsing a metal frame tissue valve onto the plunger 22 of the deployment portion 14 of a delivery system 10 in accordance with the present invention.*"
Additionally, paragraph [0055] describes that the position of the bath area 520 shown in figure 13 "*is advantageous for loading a tissue valve to the deployment portion 14 of the delivery system [...].*"

2.2.2 The description of E1 therefore provides an unambiguous disclosure of a loading operation with immersed containment region of the catheter. The depth of "~2.5" for the tray mentioned in figure 12, which is disputed as indicating the depth of the bath itself, is not relevant to conclude that feature 1.7 is disclosed in E1 or not.

2.2.3 Consequently feature 1.7 and therewith all features of claim 1 of the patent as granted are disclosed in E1. The same reasoning applies to claim 11 as granted.

2.3 Auxiliary request 1 in appeal is the same as auxiliary request 1 underlying the impugned decision. The Board shares the opinion of the opposition division, that contrary to the appellant's (patent proprietor's) arguments, E1 discloses the Medtronic CoreValve - which is generally known as a stent-valve comprising feature 1.1^1 - in the context of the packaging 500 shown in figure 11.

2.3.1 E1 describes in paragraphs [0049, 0050] the packaging 500 as being adapted to the delivery system 10. Furthermore, according to paragraph [0027], "*One preferably expandable valve that is desired to be delivered by the delivery system 10 of the present invention is the CoreValve aortic valve*". Consequently, the delivery system 10 shown in figure 11 is the same as the one used to deliver the CoreValve.

2.3.2 The appellant (patent proprietor) further argued that even if the CoreValve would be disclosed for the packaging, E1, paragraph [0027] only referred to the CoreValve in general "*as is commercially available from Medtronic*". No details were provided, in particular which generation of the CoreValve was meant. Therefore neither feature 1.1[1] nor the necessity of an immersed loading was directly derivable from E1.

2.3.3 The Board does not agree. X10 describes the third generation of the CoreValve which received a CE Mark in 2007 (page 94, last two lines of the first paragraph) and was worldwide used by the close of 2008 (page 99, lines 3, 4). The third generation of the CoreValve was thus generally known by 2011, the year of the priority date of E1.

2.3.4 X10 further shows that the CoreValve mentioned in E1 has an inner skirt and requires an immersed loading operation (see e.g. page 185, figure 2, for the inner skirt and page 98, chapter "Catheter-Loading System": "*While loading, the bioprosthesis and the tip of the delivery catheter must be kept submersed at alla times*").

2.3.5 Consequently E1 discloses all features of claim 1 of auxiliary request 1 in combination. The same reasoning applies to claim 11.

3. Auxiliary request 2 - added subject-matter

3.1 The Board confirms the decision of the opposition division (point 16.1) that the requirements of Articles 76(1) and 123(2) EPC are met. Although the opposition division's conclusion related to the main request (patent as granted), the reasoning also applies to auxiliary request 2 underlying the impugned decision which is the same as auxiliary request 2 in appeal.

3.2 The patent in suit is a divisional of the international application published as WO2012/150290 A1. The description of the A1-publication of the patent in suit and of the PCT-publication of the parent application is identical. The original claims of the parent application are added to the description of the A1-publication of the patent in suit (paragraph [0090]).

3.3 Claim 1

3.3.1 Claim 1 is based on claim 29 of the parent application with feature 1.1^2 and the wording "*supporting the delivery catheter in a storage position*" in feature 1.5 added. Additionally, the wording in feature 1.4 is amended from "*packaging for containing*" to "*packaging containing*".

3.3.2 Feature 1.1^2 is supported by the parent application, page 18, second paragraph, first two lines, and page 20, third last line, to page 21, first line. Further support is provided by figure 1, showing the stent-valve together with the delivery catheter.

The amendments in features 1.4 and 1.5 find basis e.g. in figure 14 and page 34, last paragraph.

3.3.3 The appellant (opponent) argued that the combination of features 1.4 and 1.5 was only disclosed in the context of a closed packaging as it was e.g. apparent from original claim 32 ("*the delivery catheter is positioned within the trough in a storage position prior to first opening of the packaging*"), from method claim 38 or page 14, 5th paragraph, defining the method step of "*providing a closed packaging containing the delivery catheter*".

Additionally an apparatus comprising the stent-valve and the packaging was only disclosed with the stent-valve being external to the closed packaging.

Finally, the features "*an inner skirt and an outer skirt*" were an arbitrary selection out of a list of optional features mentioned on page 18 to page 21 of the parent application without any pointer to this feature combination or any association with the claimed packaging.

3.3.4 The Board is not convinced.
Regarding features 1.4 and 1.5, the claim requires that the delivery catheter is contained in the packaging prior to use, and that the packaging includes a base supporting the delivery catheter in the storage position. These features are not linked to a closed or an open state of the packaging.
Furthermore, in the parent application, the storage position of the delivery catheter is not only disclosed with a closed packaging (claim 32) but also with an open packaging. On page 34, last 9 lines, of the parent application, it is stated that "*Optionally, the storage*

position and the loading position may be substantially the same as each other." The loading takes place after opening the package with the packaging containing the delivery catheter in a storage position.
Claim 38 as well as page 14, referred to by the appellant (opponent), do not refer to the apparatus, but describe the method as claimed in claim 11 of auxiliary request 2.

Concerning the location of the stent-valve - inside or external to the packaging - the Board agrees with the appellant (patent proprietor) that the parent application leaves it open where the stent-valve is prior to loading. Also method claim 11, corresponding literally to claim 38 of the parent application, leaves this open.

Also feature 1.1^2 does not add any new technical information to the original application. Figure 1 of the patent in suit shows the stent-valve having a valve component 16 and a stent component 14 with at least one skirt. The skirt has no reference sign but for the skilled person it is clearly shown by the light grey area. Page 20, last two lines, unambiguously discloses that additionally an outer skirt may be provided.

3.4 Claim 10

3.4.1 Dependent claim 10 finds basis in the parent application, page 20, second paragraph and third paragraph, lines 1 to 3.

3.4.2 Claim 10 refers to features of the valve component and of the stent component, all combined by "and/or":
(i) - porcine pericardium as valve component,
- bovine pericardium as valve component,

(ii)- an attachment portion at the stent for forming an interference fit with a complementary portion of a stent holder at the delivery catheter.

3.4.3 As for feature 1.1[2], the appellant (opponent) was of the opinion that claim 10 constitutes a list of features arbitrarily selected out of numerous optional features without any pointer to the specifically claimed combination of features and without any link to the claimed packaging. Furthermore page 20, second paragraph, described the attachment portions as geometrical openings or lugs which was missing in feature ii.

3.4.4 The Board does not agree. The material for the valve component (feature i) is disclosed as being one of the following options: porcine and/or bovine pericardium and/or harvested natural valve material (page 20, third paragraph). A skilled person wishing to put the claimed apparatus into practice has anyway to select a suitable material. Omitting one of the options does not extend the subject-matter as originally disclosed.

Feature ii is shown in the embodiment of figure 1. The stent valve has an attachment portion 26 and the delivery catheter comprises a stent holder 28. The shown embodiment of the stent-valve can thus be seen as a pointer to provide feature ii.
Furthermore the attachment portions are also described as being advantageous for the loading operation mentioned in claim 1. Page 20, second paragraph, with page 31, second paragraph to page 32, first paragraph, describe that for loading, the stent holder of the deliver catheter is coupled to the attachment portions to facilitate loading of the compressed valve on the catheter. Thus, the description comprises also a

pointer to select feature ii in combination with the apparatus of claim 1.

Contrary to the appellant's (opponent's) opinion, the attachment portion is not presented in a specific design. The skilled person understands the wording "*The attachment portion 26 may comprise one or more geometrical openings, or one or more lugs or other projections, for forming an interference (e.g. interlocking) fit*" (page 20, second paragraph), as an exemplary list of possible embodiments for the attachment portion.

4. Auxiliary request 2 - Admissibility of the novelty attack

4.1 The objection that claim 1 of auxiliary request 2 lacked novelty over E1 was raised for the first time during oral proceedings before the Board. As the appellant (opponent) did not bring forward any exceptional circumstances, the new objection was not taken into account pursuant to Article 13(2) RBPA.

4.2 The appellant (opponent) referred to T 0161/09, wherein the board exercised its discretion and admitted a new line of attack as it did not alter the legal and factual framework. Also in T 0524/12, a new line of attack was admitted as the arguments were largely those that had already been discussed. The same would apply in the present case.

4.3 However, contrary to the appellant's (opponent's) opinion, the novelty attack against auxiliary request 2 amends the opponent's appeal case in a substantial manner by introducing a new interpretation of the prior art that was never given before. In particular the

argument that the third generation of the CoreValve, as described in X10, comprised an outer skirt because a part of the inner skirt was wrapped to the outside at the inflow edge of the frame, was put forward for the first time at the oral proceedings before the Board. These would require a completely new discussion, contrary to the cases underlying the decisions cited by the appellant (opponent).

5. Auxiliary request 2 - Inventive step

5.1 Auxiliary request 2 corresponds to auxiliary request 2 underlying the impugned decision. The Board confirms the opposition division's decision (points 19.3.1 to 19.3.3) that auxiliary request 2 meets the requirements of Article 56 EPC.

5.2 The appellant (opponent) submitted attacks starting from E4, E9 or E11 as closest prior art, each document combined either with E13 or with common general knowledge.

5.3 While the attacks combining E13 were already raised during first instance proceedings, the attacks combining common general knowledge were presented for the first time during appeal's oral proceedings. As none of the attacks is convincing, the question of admittance of the new attacks - which was raised by the patent proprietor - can be left aside.

5.4 E11 with common general knowledge or with E13

5.4.1 E11, paragraph [0001], discloses a device that "*relates to a loading tool that may be used in crimping, loading, and delivery a stent-mounted valve or other expandable prosthetic device.*" According to paragraph

[0072], the stent-valve 20 is pre-mounted on a loading tool 30. Both parts are surrounded by a crimping tool 48. These components are all included within a wide-mouthed bottle storage container 50. The container 50 is filled with a sterile fluid (paragraph [0073]). Paragraph [0072] further discloses an additional exterior packaging without giving any further details.

5.4.2 The appellant (opponent) argued that claim 1 only differed from E11 in the stent-valve having an additional outer skirt.

5.4.3 The Board does not share this view. As brought forward by the appellant (patent proprietor), claim 1 not only differs in the outer skirt, but also in feature 1.3 (translatable sheath), feature 1.5 (base supporting the delivery catheter in a storage position) and feature and 1.7 (containment region of the catheter may be immersed).
The problem to be posed can thus not simply be seen in providing an alternative stent-valve as suggested by the appellant (opponent).
Instead, as formulated by the patent proprietor, the problem is to be seen in providing an apparatus for a transcatheter heart-valve implantation in which the implantation procedure can be performed more safely.

5.4.4 Starting from E11, the skilled person has many different options to improve the system of E11. The appellant (opponent) did not provide any problem-solution approach with regard to features 1.3 or 1.7. At least feature 1.7 establishes an inventive step starting from E11.

5.4.5 E11 does not include any pointer to feature 1.7. Even if the appellant's (opponent's) view would be followed

that in E11,
- the liquid-tight container 50 is seen as trough,
- providing an outer skirt to the stent-valve of E11 would be one out of several obvious options,
- feature 1.5 is to be understood broadly and disclosed or rendered obvious with the exterior packaging mentioned in paragraph [0072],
then E11 still does not disclose that the containment region of the delivery catheter may be immersed during the loading operation in liquid held in the storage container 50. Instead, E11 describes in paragraph [0074] that the crimping tool 48 is removed from the container 50 prior to the loading operation. After removal, the stent-valve is crimped in the crimping tool 48 and washed to remove the sterile fluid (figure 9, paragraph [0078]). Only then, the delivery catheter 66 is attached to the loading tool 30 at the outside of the crimping tool 48 (paragraph [0084], figure 10) and the loading tool 30 together with the crimped valve can be pulled out of the crimping tool and loaded into the catheter (figure 11).

5.4.6 Also E13 can not render feature 1.7 obvious as E13 is silent about any loading operation and does not mention at all that the disclosed stent-valve would need an immersed loading. E13 only discloses features 1.1^2 to 1.3 (paragraphs [0034, 0038], figures 12 to 14) - which is undisputed.
Furthermore even if an immersed loading might be known from common general knowledge (X10), E11 provides a specific solution for crimping and loading a stent-valve in a simple and reliable manner (E11, paragraph [0012]) without hinting the skilled person to the need of an immersed loading operation.

5.4.7 The delivery catheter of E11 additionally does not have a translatable sheath as required by feature 1.3. Instead, the heart valve is pulled into a hollow end section of the catheter tube which during loading (paragraph [0084]:"*Inner shaft (70) has the dual function of pulling the loading tool (30)/valve (20) into the catheter tube (68) and pushing the valve (20) out of the catheter tube (68) at implantation due to the relative motion between the inner shaft and the delivery tube.*").
As the delivery catheter of E11 matches the loading tool 30, it is not obvious to modify the catheter according to feature 1.3.

5.4.8 Finally, with regard to feature 1.5, it is noted that an exterior packaging in which the delivery catheter might be stored does not imply a base that is able to support the delivery catheter in a specific position.

5.4.9 Therefore, the subject-matter of claim 1 and of claim 11 involves an inventive step over E11 with E13 or common general knowledge.

5.5 E4 with common general knowledge or with E13

5.5.1 E4 discloses (figures 11 and 12) a packaging with a base ("*moulded plastic tray 30*") supporting a delivery catheter 1 in a storage position (page 7, fourth paragraph, and page 15, lines 2 to 4). The base 30 has a liquid-tight trough ("*bath 33*") with a depth suitable for use to hold liquid within which the containment region of the catheter is immersed during the loading operation (page 15, lines 5 to 19). In E4, the catheter is described as being suitable for transvascular deployment of expandable medical devices, e.g. an intravascular embolic filter device.

5.5.2 The Board can agree with the appellant (opponent) that E4 is not limited to embolic filters because claims 20, 21, 22 and 27 (with claim 1) are directed to a packaging for a medical catheter for transvascular deployment of an expandable medical device in general. It can further be agreed on that the purpose of the bath in E4 is the same as in claims 1 and 11 of the patent in suit. The bath 33 is explicitly used "*for submerged loading of the medical device into the catheter*" (page 7, fourth paragraph). Also claim 21 explicitly discloses that the packaging has a bath which has "*a depth sufficient to accommodate in a totally submerged state the distal end of the catheter and a medical device for submerged loading of the medical device into the catheter.*"

5.5.3 It is further undisputed that claim 1 and claim 11 differ from E4 at least in that the medical device is a stent-valve with an inner and outer skirt (feature 1.1^2).

5.5.4 According to the appellant (opponent) the objective technical problem was to use the packaging of E4 with an alternative medical implant.

5.5.5 In written proceedings, it was argued that it was obvious to use the stent-valve known from E13 with the apparatus of E4, thereby arriving at the claimed subject-matter.

However, assuming the delivery catheter would be suitable for the stent-valve of E13 - what is disputed by the appellant (patent proprietor) - and the skilled person would load the stent-valve of E13 to the delivery catheter of E4, the catheter of E4 does not have a translatable sheath but a pod 3, in which the

stent-valve would be pulled via the guide wire 6 (see figure 5, page 11, line 32 to page 12, line 7). Feature 1.3 would thus still be missing. Feature 1.3 is also not obvious as in E4 a catheter with a sheath is presented as being disadvantageous and to be avoided (page 3, lines 8 to 10 with page 4, lines 12 to 14, claim 1).

5.5.6 During oral proceedings the appellant (opponent) additionally argued that delivery catheters with a translatable sheath and respective stent-valves were known from common general knowledge or from E13 (paragraphs [0034, 0038], figures 12 to 14). It further belonged to common general knowledge that some of these stent-valves required a submersed loading process. e.g. the one known from X10.
It would thus be obvious to use only the packaging of E4 in combination with such a delivery catheter and the respective stent-valve.

The Board is not convinced. Even if features 1.1^2 to 1.3 are undisputedly known, be it from common general knowledge or from E13, their combination with E4 does not result obviously in the claimed subject-matter.

For the combination E4 with E13, it is noted that E13 does not include any hint that the heart valve disclosed therein requires an immersed loading process. There is thus no motivation for the skilled person to consider E13 when looking for an alternative medical device to be loaded in the packaging of E4.

Furthermore, in E4 (figures 11 and 12) all components are adapted to match each other. In particular the loading device 20 with the spigot 23 and the loading tube 24 located in the bath 33 match the delivery

catheter comprising a pod instead of a sheath. It is not obvious that the packaging with the loading device is suitable for delivery catheters with a translatable sheath - especially since the latter is explicitly avoided in E4. Further modifications would thus be necessary.

5.5.7 Consequently, E4 in combination with common general knowledge or with E13, can not render the subject-matter of claim 1 or 11 obvious.

5.6 E9 with common general knowledge or with E13

5.6.1 E9 discloses (figures 1 and 7) a packaging 1 with two trays 2, 3 which can be filled with a saline to immerse a catheter before use (paragraph [0018]: "*The devices to be introduced into a blood vessel such as a catheter, a sheath and a guide wire to be used must be immersed in physiological saline before use, for preventing from air bubbles interfusing into the blood vessel.*").
As an example, an angiography catheter 100 for the purpose of efficiently distributing an angiography contrast medium for obtaining the image of a blood vessel under fluoroscopy is disclosed (paragraphs [0019, 0033, 0034]).
A stent with delivery catheter is mentioned amongst numerous different medical devices in paragraph [0003] which refers to the background art.

5.6.2 As for E4, the appellant (opponent) argued that claim 1 only differed in the kind of medical device, i.e. the stent-valve. Therefore the same arguments applied for E9 as for E4, combined with common general knowledge or with E13.

5.6.3 The Board is not convinced for similar reasons as given under points 5.5.5 and 5.5.6 above.

5.6.4 The apparatus of E9 can not simply be used with a medical device being a stent-valve according to feature 1.1^2. The catheter of E9 (figure 7) is presented as an angiography catheter 100 which does not require any loading operation of a stent-like device and thus does not have a translatable sheath. The shown catheter is not suitable for delivering a stent-valve as required by feature 1.3.

5.6.5 Even under the assumption that the skilled person would use only the packaging of E9 and combine it with a delivery catheter and a respective stent-valve according to features 1.1^2 to 1.3 as known from the common general knowledge or E13, the skilled person does not get any hint to use the tray for a loading operation. E9 is completely silent about a loading operation but teaches to immerse a catheter before use to remove air bubbles. E13 also does not disclose that an immersed loading would be required. The combination with common general knowledge or E13 would simply lead to a trough in which the delivery catheter as such can be immersed before use.

5.6.6 Therefore, the subject-matter of claim 1 and of claim 11 also involves an inventive step over E9 with E13 or common general knowledge.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

M. Schalow G. Pricolo

Decision electronically authenticated