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Datasheet for the decision of 20 March 2025

Case Number: T 1268/23 - 3.2.02

Application Number: 19189544.0

Publication Number: 3590471

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
LOW PROFILE DELIVERY SYSTEM FOR TRANSCATHETER HEART VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Opponent:
Meril GmbH

Headword:

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

Keyword:
Divisional application - added subject-matter (yes)
Amendment after summons - exceptional circumstances (no)
- taken into account (no)

Decisions cited:

Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1268/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 March 2025

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Thum, Bernhard Thum & Partner Thum Mötsch Weickert Patentanwälte PartG mbB Siebertstr. 6 81675 München (DE)
Appellant: (Opponent)	Meril GmbH Bornheimer Straße 135-137 53119 Bonn (DE)
Representative:	Marks & Clerk LLP 15 Fetter Lane London EC4A 1BW (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 8 May 2023 concerning the maintenance of European Patent No. 3590471 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 the opponent 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 auxiliary request 7 then on file, the patent and the invention to which it related met the requirements of the EPC. The Opposition Division considered that the higher-ranking requests comprised added subject-matter.

II. The patent in suit is derived from European patent application EP 19189544.0, which is a divisional of European patent application EP 18210923.1 ("the parent application"), a divisional itself of European patent application EP 09743346.0 ("the grandparent application").

III. The Board summoned the parties to oral proceedings and provided its preliminary opinion by a communication under Article 15(1) RPBA dated 18 December 2024. None of the claim requests appeared allowable owing to added subject-matter.

IV. Oral proceedings took place on 20 March 2025.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of one of auxiliary requests 1 to 7, filed with the statement of grounds of appeal on 18 September 2023, 8 to 198, filed with the reply to the opponent's statement of grounds on 12 February 2024, and 199 to 201, filed with letter dated 21 February 2025.

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

V. **Claims 1 and 15 of the grandparent application as filed** read as follows (the crucial features for the assessment of added subject-matter are highlighted by the Board):

"1. An apparatus for delivering a prosthetic valve through the vasculature of a patient comprising:

a main catheter, the main catheter comprising an elongated shaft;

a balloon catheter comprising an elongated shaft and a balloon connected to a distal end portion of the shaft, **the shaft of the balloon catheter being capable of moving longitudinally within the shaft of the main catheter**; and

a valve carrying member, the valve carrying member having a mounting surface for receiving a crimped valve for insertion into the vasculature of the patient, the balloon being positioned distal or proximal to the mounting surface, the balloon being configured to be movable relative to the mounting surface, or vice versa, to position the balloon at a location extending through the crimped valve after the valve is inserted into the patient's vasculature."

"15. An apparatus for delivering a prosthetic valve through the vasculature of a patient comprising:

a main catheter, the main catheter comprising an elongated shaft; and

a balloon catheter comprising an elongated shaft, a balloon connected to a distal end portion of the

shaft, and **an extension portion, the balloon catheter being capable of moving longitudinally within the shaft of the main catheter;**

wherein **the extension portion of the balloon catheter is located between the balloon and the elongated shaft and is configured to receive a prosthetic valve in a crimped state on an outer surface of the extension portion.**"

VI. **Claim 1 of the main request** reads as follows:

"A delivery system for delivering a prosthetic aortic heart valve to a patient's native aortic valve, comprising:

a balloon catheter (16) comprising an elongated shaft (26) and an inflatable balloon (28) mounted at a distal end of the elongated shaft (26), and a flex indicating device (150) comprising:

a guide catheter (14) comprising a handle portion (158) and an elongated guide tube (152) extending distally from the handle portion (158), the elongated shaft (26) of the balloon catheter (16) extending coaxially through the elongated guide tube (152);
at least one pull wire (174) connected to a distal end portion (188) of the elongated guide tube (152); and
a slide member (192) connected to the at least one pull wire (174);
wherein the handle portion (158) comprises a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that manual adjustment of the flex activating member (154) causes the

distal end portion (188) of the elongated guide tube (152) to flex;
the flex indicating device (150) further comprising a flex indicating member (156) having an extending portion (166), wherein manual adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated guide tube (152)
wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) and an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive the extending portion (166) of the flex indicating member (156)."

In none of auxiliary requests 1 to 198 does claim 1 comprise all the highlighted features of claim 1 or of claim 15 of the grandparent application as filed.

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

Extension of subject-matter

Claim 1 of the main request related to aspects of a flex indicating device and found a basis in paragraphs [030], [031] and [0161] to [0175] (in relation to Figures 31 to 38B) of the grandparent application as filed. These paragraphs related to a flex indicating

device and focused on how to control the distal end of a catheter while navigating it into a patient's vasculature. They related to what happened outside the patient. The specific design of the balloon catheter and the guide, or main, catheter was not essential for flex indication and did not have to be included in the claim. The invention as defined in claim 1 of the main request was generally aimed at steering a delivery system through a patient’s vasculature, as indicated in paragraph [0161] of the grandparent application as filed. The core of the claimed invention was not the movability of the elongated shaft of the balloon catheter within the shaft of the main catheter, but the flexing of the catheters and the indication of the amount of flexing. The definition of the coaxial arrangement of the elongated guide tube of the guide catheter and the elongated shaft of the balloon catheter in claim 1 of the main request was sufficient to establish the specified flex activation and indication, irrespective of the relative longitudinal movability. Flexing the guide catheter would result in flexing the balloon catheter, whether the coaxially arranged shafts could move longitudinally or not.

Although there could have been a relationship between the relative longitudinal movability and the possibility of crimping the prosthetic aortic heart valve proximal or distal to the balloon, the grandparent application as filed was not limited to either off-balloon or on-balloon crimping, as apparent from paragraph [004]. In fact, the grandparent application as filed did not contain the expression "off-balloon crimping" at all. The invention as defined in claim 1 of the main request allowed for, and could even benefit from, crimping the prosthetic aortic heart valve proximal or distal to the balloon. However, this

was not necessary. Instead, the claimed invention related to flex indication, as per paragraph [030] of the grandparent application as filed, which disclosed an embodiment of an apparatus for indicating flex of a distal end of a catheter. Flex indication was beneficial and advantageous irrespective of how the valve was mounted.

In summary, for indicating flex neither relative movability of the shafts of the catheters in a longitudinal direction nor specific mounting of the prosthetic aortic heart valve were necessary.

Moreover, the relative movability of the catheter shafts was expressly described as an optional feature in paragraphs [033] and [034] of the grandparent application as filed: "*the shaft of the balloon catheter can be capable of moving longitudinally within the shaft of the main catheter*". Also paragraph [099] of the grandparent application as filed, referring to an illustrated embodiment, made it clear that the relative movability of the catheter shafts was optional.

Paragraph [004] of the grandparent application as filed described certain advantages resulting from off-balloon crimping. However, these advantages were not technically linked to flexing a catheter or to indicating the amount of flex. Paragraph [004] stated that only in certain embodiments was the balloon positioned either distal or proximal to the crimped prosthetic aortic heart valve, whereas the valve, traditionally, was crimped directly onto the balloon.

The grandparent application as filed even disclosed certain embodiments in which the prosthetic aortic

heart valve was crimped on a balloon. In the embodiment of Figure 18 the valve was crimped on a second, smaller, balloon 84 positioned inside the balloon intended to deploy the valve. It was irrelevant whether the smaller balloon could be considered a deployment balloon. Even two layers of balloon material would be underneath the valve in the embodiment of Figure 18, which made it clear that the advantages of having a smaller section of the catheter at the valve site were merely optional according to the grandparent application as filed.

According to paragraph [0132], in the embodiment of Figures 16 and 17 the balloon for deploying the valve could be moved to position it within the valve outside the patient's vasculature, which *de facto* meant that the valve was crimped on the balloon when it was navigated to the deployment site. In paragraph [0132] the reference to the configuration of Figure 18 was an obvious error and had to be read as the configuration of Figure 17, showing the balloon within the valve.

Moreover, a valve carrying member had been presented as optional in the grandparent application as filed, as the valve could be carried on an elongated shaft (paragraph [011]), which was defined in claim 1 of the main request. The claim did not have to specify that the balloon could be moved relative to the mounting surface of the valve, because it was contemplated, in the grandparent application as filed, that the valve itself could be movable.

Admissibility of auxiliary requests 199 to 201

Auxiliary requests 199 to 201 had been filed after the Board's preliminary opinion as a legitimate reaction to

a new objection raised by the Board in that opinion. This objection lead to exceptional circumstances according to Article 13(2) RPBA, which allowed an amendment to the proprietor's appeal case. Auxiliary requests 199 to 201 addressed the Board's new objection and should be admitted into the appeal proceedings.

The new objection was that claim 1 of the main request included added subject-matter because it did not "*define both a valve carrying member or structure positioned distal or proximal to the balloon and the capability of the balloon catheter of moving longitudinally within the main catheter*" (point 2.7 of the preliminary opinion). According to the case law, this objection was new as it at least substantially expanded (not simply built) upon the arguments presented by the opponent, who had only argued against the omission of the feature of the capability of the balloon catheter of moving longitudinally within the main catheter or, separately, the lack of the definition of the feature of a valve carrying member for off-balloon crimping. However, the opponent had not argued that the omission of both features simultaneously resulted in the addition of subject-matter. The Board had expanded upon the opponent's objections and formulated a better objection. In fact, the omission of a valve carrying member as such in claim 1 of the main request was not problematic, as the valve could be crimped on an extension portion of the balloon catheter according to the grandparent application as filed (claim 15). In the context of an intermediate-generalisation objection, the mere allegation that a certain feature was missing from the claim did not anticipate all the specific arguments. The objection had to involve concrete reasons as to why the allegedly inadmissibly omitted feature could not be

omitted and to which other features an inextricable link existed.

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

Extension of subject-matter

Claim 1 of the main request was not directed to a flex indicating device, but to a delivery system for delivering a prosthetic aortic heart valve. A basis in the grandparent application as filed should be sought in the disclosure of such a delivery system. Claim 1 and claim 15 of the grandparent application as filed were directed to such delivery systems. These claims and the rest of the grandparent application as filed only disclosed a delivery system for delivering a prosthetic aortic heart valve comprising a guide tube with a lumen sized to receive the shaft of the balloon catheter allowing the balloon catheter to slide longitudinally relative to the guide catheter. They did not disclose a delivery system in which the guide catheter and balloon catheter were parts of the same tube which could not be moved relative to each other. All the delivery devices disclosed in the grandparent application as filed related to off-balloon crimping of the prosthetic aortic heart valve and required the feature of relative movability of the elongated shaft of the balloon catheter and the elongated shaft of the guide catheter. Hence this feature was inextricably linked to the proper functioning of the prosthetic heart valve delivery system disclosed in the grandparent application as filed, as it was a requirement for off-balloon crimping to position the valve on the balloon before positioning it in the patient's native valve. In contrast to this disclosure,

claim 1 of the main request implied that a delivery device according to the invention did not require this feature, and therefore presented the person skilled in the art with new information over the grandparent application as filed.

Claim 1 of the main request also contained added subject-matter because the feature of off-balloon crimping was inadmissibly omitted. The main teaching of the grandparent application as filed was that the invention aimed at obtaining a low-profile delivery system. The technical effect of the feature stipulating that the balloon was positioned either distal or proximal to the crimped prosthetic aortic heart valve was, according to the grandparent application as filed, that the prosthetic aortic heart valve could be crimped to a smaller diameter, due to a reduced amount of balloon material being present in the valve during the delivery phase (paragraph [004] of the grandparent application as filed). Hence the feature was instead taught as being necessary to the solution to the problem at which the grandparent application as filed was aimed. The embodiment of Figure 18 was also designed to achieve the same technical effect, with the valve being crimped proximal to the balloon used to expand the valve to its functional size in the patient's body. This embodiment was in accordance with claim 15 of the grandparent application as filed. Paragraph [0132] of the grandparent application as filed, relating to the embodiment of Figures 16 and 17, explained the advantages of a nose piece attached to the balloon for deploying the valve. It did not teach crimping the prosthetic aortic heart valve on the balloon.

Admissibility of auxiliary requests 199 to 201

Auxiliary requests 199 to 201 should not be admitted into the appeal proceedings.

The opponent had raised several objections of added subject-matter, amongst which an objection to the omission of the relative movability of the elongated shaft of the balloon catheter and the elongated shaft of the guide catheter, and an objection to the omission that the balloon was positioned either distal or proximal to the crimped prosthetic aortic heart valve (i.e. off-balloon crimping). Objections to the omission of the feature of off-balloon crimping had been raised by the opponent prior to the Board's communication under Article 15(1) RPBA. In the preliminary opinion the Board had simply considered that some of the opponent's objections were convincing. The Board was not restricted to sticking to the same words used by the opponent in the communication of its opinion and had not formulated any new objection.

It followed that there were no exceptional circumstances for admittance of auxiliary requests 199 to 201 under Article 13(2) RPBA.

Reasons for the Decision

1. Subject-matter of the patent

The patent is concerned with a delivery system, an embodiment of which is illustrated schematically in Figure 1 reproduced below, for delivering a prosthetic aortic heart valve (12) to a patient's native aortic valve. Such valves are configured to replace the

function of a stenotic aortic valve in a human heart and are implanted within the stenotic region of the native aortic valve.

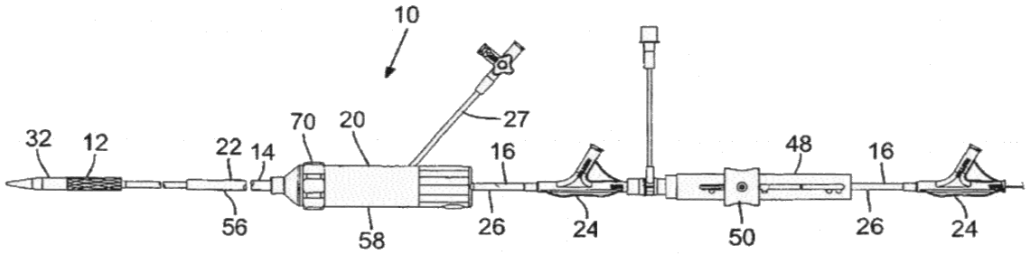

FIG. 1

The delivery system according to claim 1 of the patent as granted comprises a balloon catheter (16) with an elongated shaft (26) and an inflatable balloon mounted at a distal end of the elongated shaft, and a flex indicating device comprising a guide catheter (14) with an elongated guide tube.

The flex indicating device is for indicating the amount of flex of a distal end portion of the elongated guide tube.

The guide catheter further comprises a handle portion (20), the elongated guide tube extending distally from the handle portion and the elongated shaft of the balloon catheter extending coaxially through the elongated guide tube.

The flex indicating device further comprises a pull wire connected to the distal end portion of the elongated guide tube and a slide member connected to the pull wire. The handle portion comprises a flex activating member.

The flex activating member is coupled to the pull wire such that manual adjustment of the flex activating

member causes the distal end portion of the elongated guide tube to flex.

The flex indicating device further comprises a flex indicating member having an extending portion. Manual adjustment of the flex activating member causes the flex indicating member to move relative to the handle portion to indicate an amount of flex of the distal end portion of the elongated guide tube.

The flex activating member comprises a rotatable member which includes an internally threaded surface portion and an externally threaded surface portion.

The internally threaded surface portion is configured to receive the slide member and the externally threaded surface portion is configured to receive the extending portion of the flex indicating member.

Flexing the guide catheter may help a physician to effectively steer the delivery system to advance it through the femoral artery or vein to the heart.

2. Main request - extension of subject-matter

The opponent argued that the main request comprised added subject-matter *inter alia* because of the omission of the definition of the elongated shaft of the balloon catheter being capable of sliding longitudinally within the elongated guide tube of the guide catheter, and of the features relating to "off-balloon crimping" as explained below, which is technically related to the former omission.

By employing the expression "off-balloon crimping" the opponent means that the prosthetic aortic heart valve

is crimped distal or proximal to the balloon. It is irrelevant whether this expression is present in the grandparent application as filed.

The Board finds these objections by the opponent convincing.

2.1 The proprietor submitted that the subject-matter of claim 1 of the patent as granted was based on paragraphs [030] and [031] of the summary, and paragraphs [0161] to [0175] (in relation to Figures 31 to 38B) of the detailed description of the grandparent application as filed.

These paragraphs generally refer to an apparatus for indicating flex of a distal end of a catheter. It may be accepted that they focus on the control of the distal end of a catheter while navigating it into a patient's vasculature, and relate to what happened outside the patient, as the proprietor submitted. However, claim 1 of the main request is directed to a delivery system for delivering a prosthetic aortic heart valve to a patient's native aortic valve. It is not limited to an apparatus for indicating flex. What the grandparent application as filed presents as essential for the disclosed apparatus for indicating flex is not crucial in assessing what it presents as essential for a delivery system for delivering a prosthetic aortic heart valve to a patient's native aortic valve. This latter assessment is relevant to establish whether claim 1 of the main request contains added subject-matter.

2.2 The grandparent application as filed identifies "*an important design parameter*" of a transcatheter heart valve (THV), which corresponds to the prosthetic aortic

heart valve to be delivered by the claimed delivery system. This design parameter, which is strictly related to the delivery of the THV to a patient's native aortic valve, is "*the diameter of the folded or crimped profile*", which should be kept to a minimum "*because it directly influences the physician's ability to advance the THV through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety*" (paragraph [003]).

Accordingly, the grandparent application as filed discloses embodiments of delivery systems in which the balloon of a balloon catheter for radially expanding and deploying the heart valve within the patient's native aortic valve "*is positioned either distal or proximal to the crimped THV. This allows the THV to be crimped to a smaller diameter*" (paragraph [004]). Paragraph [004] explains that "*after the THV is advanced through narrow portions in a patient's vasculature (for example, the iliac artery which is typically the narrowest portion of the relevant vasculature), the THV is placed onto the balloon*" such that "*the balloon can be inflated to radially expand the THV within the native heart valve*". Paragraphs [0100], [0114], [0128], [0131], [0134] and [0139] stress the advantage of having the valve crimped distal or proximal to the balloon, and the capability of the balloon to be positioned under the valve for deployment.

2.3 In fact, all the specific embodiments of the delivery systems are configured for crimping the heart valve either distal or proximal to the balloon for radially expanding and deploying the heart valve within the patient's native aortic valve, i.e. the deployment

balloon.

Contrary to the proprietor's argument, paragraph [004] of the grandparent application as filed does not contemplate delivery systems according to the invention in which there is not a valve carrying member or a structure for receiving a crimped valve and positioned distal or proximal to the deployment balloon. It merely mentions that, traditionally, the valve was crimped directly onto the balloon, but such a configuration had disadvantages.

The proprietor's argument that the embodiment of Figure 18 included a valve that was crimped on a balloon, which implied that the advantages of having a smaller section of the catheter at the valve site were merely optional according to the grandparent application as filed, is not convincing. According to this embodiment a "*second smaller balloon*" is provided to "*partially expand valve 12 so that it is easier to move [deployment] balloon 28 in position within valve 12 for deployment of the valve at the treatment site*" (paragraph [0135] of the grandparent application as filed). However, according to paragraph [0134], "*because second balloon 84 is smaller in diameter than balloon 28, valve 12 can be crimped to a smaller diameter when crimped on second balloon 84 than when crimped on balloon 28*". Hence the "*important design parameter*" is still satisfied in the embodiment of Figure 18, irrespective of whether two layers of balloon material are underneath the crimped valve.

The proprietor's argument that the embodiment of Figures 16 and 17 of the grandparent application as filed included a valve crimped on the deployment balloon is not convincing either. According to this

embodiment a distal portion of the deployment balloon can be attached to a nose piece "*to provide a more efficient tracking profile*" (paragraph [0129]). Even accepting that paragraph [0132] relates to the configuration of Figure 17, this paragraph would disclose that the deployment balloon can be brought under the valve before insertion into the patient's vasculature, and in that configuration too, the nose piece would have some advantages. However, "*moving the apparatus into [that] configuration [...] while in the patient's vasculature allows for a smaller insertion profile, which is desirable to facilitate insertion*". Hence the embodiment of Figures 16 and 17 is still configured for crimping the valve proximal to the deployment balloon, which is advantageous. The mention of when and where the deployment balloon can be moved under the valve does not change the fact that the "*important design parameter*" is still satisfied by crimping the valve proximal to the deployment balloon.

2.4 Consistently, the independent claims (1 and 15) of the grandparent application as filed are directed to apparatuses for delivering a prosthetic valve through the vasculature of a patient comprising a main catheter, a balloon catheter and either a valve carrying member (claim 1) or an extension portion of the balloon catheter (claim 15) for receiving a crimped valve, located either distal or proximal to the (deployment) balloon. The balloon catheter (or its shaft) is capable of moving longitudinally within the shaft of the main catheter.

2.5 The capability of the movement of the balloon or its shaft with respect to the valve, or vice versa, is necessary to allow the deployment of the valve, irrespective of the wording "*the shaft of the balloon*

catheter can be capable of moving" used in paragraphs [033] and [034] and the embodiment referred to in paragraph [099] of the grandparent application as filed.

2.6 In summary, the grandparent application as filed is directed to and consistently stresses the advantages of apparatuses for delivering a prosthetic valve through the vasculature of a patient with a main catheter, a balloon catheter and a valve carrying member or structure, such as an extension portion of the balloon catheter, for receiving a crimped valve and positioned distal or proximal to the balloon, the balloon catheter being capable of moving longitudinally within the main catheter so as to be brought under the valve so as to be able to deploy it.

In claim 1 of the main request neither a valve carrying member or structure for receiving a crimped valve and positioned distal or proximal to the balloon nor the capability of the balloon catheter of moving longitudinally within the main catheter are defined. Consequently, the claim teaches a delivery system for delivering a prosthetic aortic heart valve to a patient's native aortic valve in which these features are merely optional. It is this technical information which is in contrast to and extends beyond the content of the grandparent application as filed, irrespective of the arguments relating to the so-called intermediate generalisations.

Hence the main request cannot be allowed for lack of compliance with Article 76(1) EPC.

3. Auxiliary requests 1 to 198 - extension of subject-matter

As also conceded by the proprietor during the oral proceedings, in none of auxiliary requests 1 to 198 does claim 1 define both a valve carrying member or structure for receiving a crimped valve and positioned distal or proximal to the balloon, and the capability of the balloon catheter of moving longitudinally within the main catheter.

It follows that auxiliary requests 1 to 198 cannot be allowed either, for lack of compliance with Article 76(1) EPC.

4. Admissibility of auxiliary requests 199 to 201

The filing of auxiliary requests 199 to 201 by the proprietor amounts to an amendment of the proprietor's appeal case made after notification of the communication under Article 15(1) RPBA. According to Article 13(2) RPBA such an amendment, in principle, must not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the proprietor.

The Board does not see any exceptional circumstances which might justify the amendment of the proprietor's case.

The proprietor argued that the Board's preliminary opinion contained a new objection, raised by the Board of its own motion, which was that claim 1 of the main request included added subject-matter because it did not "*define both a valve carrying member or structure positioned distal or proximal to the balloon and the*

capability of the balloon catheter of moving longitudinally within the main catheter" (point 2.7 of the preliminary opinion).

However, before notification of the communication under Article 15(1) RPBA the opponent had raised a number of objections of added subject-matter. These included one relating to the omission of the relative movability of the elongated shaft of the balloon catheter and the elongated shaft of the guide catheter, and one to the omission that the balloon was positioned either distal or proximal to the crimped prosthetic aortic heart valve. For example, section IV on page 18 of the opponent's statement of grounds of appeal is titled: "*Omission of the feature 'the elongated shaft of the balloon catheter is capable of sliding longitudinally within the elongated guide tube of the guide catheter'*". This section ends on page 22, point 4, with the conclusion: "*in summary, the omission of the limiting feature 'the elongated shaft of the balloon catheter is capable of moving longitudinally within the elongated guide tube of the guide catheter' into granted claim 1 of the opposed patent constitutes added subject matter for the followings* [sic] *reasons: 1) the [...grandparent application as filed] does not disclose a single embodiment of a delivery device wherein the elongated shaft of the balloon catheter is not capable of sliding longitudinally within the elongated guide tube of the guide catheter [...;] 2) The function of any heart prothesis* [sic] *delivery system disclosed in [... the grandparent application as filed] depends on the relative slidability of the balloon catheter to the guide catheter [...]".* Section II on page 10 of the opponent's statement of grounds of appeal is titled: "*Inadmissible omission of 'the valve is crimped distal or proximal to the balloon of the balloon catheter'*".

This section ends on page 14, point 4, with the conclusion "*there is no disclosure of a delivery apparatus without the valve being positioned distal or proximal to the balloon of the balloon catheter in the earlier application. Consequently, the lack of introduction of this feature into claim 1 constitutes added subject matter*".

It is irrelevant whether the opponent had argued that the two problematic omissions simultaneously resulted in the addition of subject-matter. In its preliminary opinion the Board considered the opponent's objections and found, among several, two convincing ones. This does not mean that a new objection was raised by the Board. It was merely the result of an evaluation of a series of objections raised by the opponent.

The fact that the Board considered the omission of either a valve carrying member or a structure positioned distal or proximal to the balloon (for receiving the crimped valve) problematic, and not the omission of the valve carrying member as such, does not amount to a new objection either. As explained above, the opponent had formulated a general objection relating to the omission that the balloon was positioned either distal or proximal to the crimped prosthetic aortic heart valve.
The explanation of why the opponent's objections were found convincing, in view of arguments raised by the opponent itself, does not amount to a new objection by the Board either.

It follows that the Board did not raise any new objections in its preliminary opinion. In view of this situation, any consideration on how far an objection can be "*expanded upon*" without becoming a new one is of

no relevance to the present case.

In conclusion, as the proprietor did not demonstrate that there were exceptional circumstances justified with cogent reasons for the amendment of its appeal case, auxiliary requests 199 to 201 are not admitted into the appeal proceedings under Article 13(2) RPBA.

5. In conclusion, none of the proprietor's requests in the appeal proceedings can form a basis for maintenance of the patent.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated