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Datasheet for the decision of 20 March 2025

Case Number: T 1176/22 - 3.2.02

Application Number: 18210923.1

Publication Number: 3494929

IPC: A61F2/24, A61F2/95

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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European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1176/22 - 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 1)	Meril GmbH Bornheimer Straße 135-137 53119 Bonn (DE)
Representative:	Marks & Clerk LLP 15 Fetter Lane London EC4A 1BW (GB)
Appellant: (Opponent 2)	(withdrawn)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 24 February 2022 concerning gthe maintenance of European Patent No. 3494929 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, opponent 1 and opponent 2 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 39 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 No. 18210923.1, which is a divisional of European patent application No. 09743346.0 ("the parent application").

III. Opponent 2 withdrew its opposition.

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

V. 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 I to XV, filed with the statement of grounds of appeal on 6 July 2022, auxiliary requests 16 to 75, filed with the reply to the opponents' statements of grounds on 22 November 2022, and auxiliary requests 76

to 79, filed with letter dated 21 February 2025.

The appellant/opponent 1 ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.

VI. **Claims 1 and 15 of the parent 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.**"

VII. **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);
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), 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 indicating device (150) further includes indicia (168) indicating the amount of flex of the distal end portion of the elongated guide tube (152), the indicia (168) being provided at the handle portion (158), and wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156)."

In none of auxiliary requests I to XV and 16 to 75 does claim 1 comprise all the highlighted features of claim 1 or claim 15 of the parent application as filed.

VIII. The proprietor's arguments 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 [175] (in relation to Figures 31 to 38B) of the parent 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 of the patient. The design of the balloon catheter and the guide, or main, catheter were 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 parent 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 proximally or distally to the balloon, the parent application as filed was not limited to either off-balloon or on-balloon crimping, as apparent from paragraph [004]. In fact, the parent application as filed did not contain the expression "off-balloon crimping". The invention as defined in claim 1 of the main request allowed for, and could even benefit from, crimping the prosthetic aortic heart valve proximally or distally to the balloon. However, this was not necessary. Instead, the claimed invention related to flex indication, in accordance with paragraph [030] of the parent application as filed, which disclosed an embodiment of an apparatus for indicating the 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 a relative movability of the shafts of the catheters in a longitudinal direction, nor a specific mounting of the prosthetic aortic heart valve was necessary.

Moreover, the relative movability of the catheter shafts was expressly described as an optional feature in paragraphs [033] and [034] of the parent 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 parent application as filed, referring to an illustrated embodiment, made clear that the relative movability of the catheter shafts was optional.

Paragraph [004] of the parent 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 distally or proximally to the crimped prosthetic aortic heart valve, whereas the valve, traditionally, was crimped directly onto the balloon.

The parent 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 clear that the advantages of having a smaller section of the catheter at the valve site were merely optional according to the parent 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 parent 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 parent application as filed, that the valve itself could be movable.

Admissibility of auxiliary requests 76 to 79

Auxiliary requests 76 to 79 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 under Article 13(2) RPBA, which allowed an amendment to the proprietor's appeal case. Auxiliary requests 76 to 79 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). In accordance with the case law, this objection was new as it at least substantially expanded (not simply built) upon the arguments presented by the opponent, which 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 parent application as filed (claim 15). In an intermediate-generalisation objection, the mere allegation that a certain feature was missing from the claim did not anticipate all specific arguments. The objection had to involve concrete reasons as to why the allegedly inadmissibly omitted feature could not be omitted and with which other features an inextricable link existed.

IX. The opponent's arguments 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. The basis in the parent application as filed had therefore to be found in the disclosure of such a delivery system. Claim 1 and claim 15 of the parent application as filed were directed to such delivery systems. These claims and the remaining parts of the parent 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 delivery devices disclosed in the parent application as filed related to off-balloon crimping of the prosthetic aortic heart valve and required the feature of the 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 parent 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 parent application as filed.

Claim 1 of the main request contained added subject-matter also because the feature of off-balloon crimping was inadmissibly omitted. The main teaching of the parent 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 distally or proximally to the crimped prosthetic aortic heart valve was, according to the parent 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 parent application as filed). Hence, the feature was instead taught as necessary for the solution to the problem at which the parent 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 parent application as filed. Paragraph [0132] of the parent 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 76 to 79

Auxiliary requests 76 to 79 should not be admitted into the appeal proceedings.

The opponent had raised several objections of added

subject-matter, including 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 distally or proximally 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 in the opponent's statement setting out the grounds of appeal, pages 12 and 14 and in its letter of 24 January 2024, page 4. In its statement setting out the grounds of appeal, page 22, the opponent had also argued that the feature of a valve carrying member having a mounting surface for receiving a crimped valve and the feature of the balloon being positioned distally or proximally to the mounting surface could not be omitted. 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 the admittance of auxiliary requests 76 to 79 under Article 13(2) RPBA.

Reasons for the Decision

1. The 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.

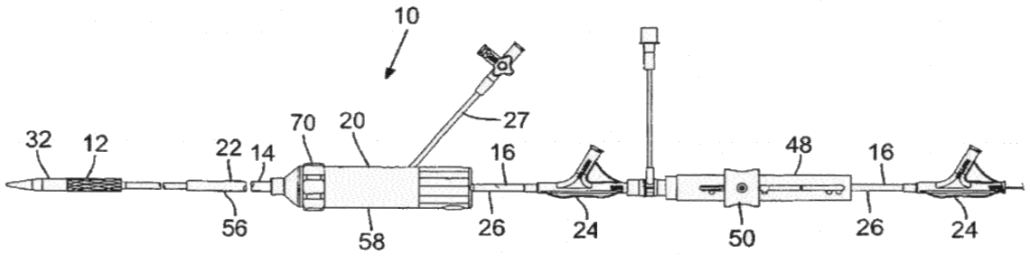

FIG. 1

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 flex indicating member. 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.

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 by means of indicia on the flex indicating device. The indicia are provided at the handle portion, which further comprises a slot for receiving a portion of the flex indicating member.

The indication of flexing of 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 Opposition Division considered that claim 1 of the main request extended beyond the content of the parent application as filed because it omitted the definition of the balloon catheter being capable of moving longitudinally within the guide tube.

The Board comes to the same conclusion.

Moreover, the omission of the features relating to "off-balloon crimping" as explained below, which is technically related to the former omission, also results in added subject-matter. By employing the expression "off-balloon crimping", the opponent means that the prosthetic aortic heart valve is crimped distally or proximally to the balloon. It is irrelevant whether this expression is present in the parent

application as filed.

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 [161] to [175] (in relation to Figures 31 to 38B) of the detailed description of the parent application as filed.

These paragraphs generally refer to an apparatus for indicating the 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 happens outside of 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 parent application as filed presents as essential for the disclosed apparatus for indicating flex is not decisive in the assessment of 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 parent 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 parent 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 [100], [114], [128], [131], [134] and [139] stress the advantage of having the valve crimped distally or proximally to the balloon and the capability of the balloon to be positioned under the valve for deployment.

2.3 In fact, all embodiments of the delivery systems are configured for crimping the heart valve either distally or proximally 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 parent 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 that is positioned distally

or proximally 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 parent 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 parent 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 parent 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

also in that configuration, 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 proximally to the deployment balloon, this being 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 proximally to the deployment balloon.

2.4 Consistently, the independent claims (1 and 15) of the parent 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 distally or proximally 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 movement of the balloon or its shaft with respect to the valve, or vice versa, is necessary for allowing 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 parent application as filed.

2.6 In summary, the parent application as filed is directed to, and consistently stresses the advantages of, apparatuses for delivering a prosthetic valve through

the patient's vasculature comprising 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 that is positioned distally or proximally to the balloon. The balloon catheter is capable of moving longitudinally within the main catheter to be brought under the valve to deploy it.

In claim 1 of the main request, neither a valve carrying member or structure for receiving a crimped valve that is positioned distally or proximally to the balloon, nor the capability of the balloon catheter of moving longitudinally within the main catheter is defined. As a consequence, 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 parent 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 I to XV and 16 to 75 - extension of subject-matter

As also conceded by the proprietor during the oral proceeding, in none of auxiliary requests I to XV and 16 to 75 does claim 1 define both a valve carrying member or structure for receiving a crimped valve that is positioned distally or proximally to the balloon and the capability of the balloon catheter of moving longitudinally within the main catheter.

It follows that auxiliary requests I to XV and 16 to 75 cannot be allowed either for lack of compliance with Article 76(1) EPC.

4. Admissibility of auxiliary requests 76 to 79

The filing of auxiliary requests 76 to 79 by the proprietor amounts to an amendment of the proprietor's appeal case made after notification of the communication under Article 15(1) RPBA. Under Article 13(2) RPBA, such an amendment, as a rule, must not be taken into account unless there are exceptional circumstances justified with cogent reasons by the proprietor.

The Board does not see any exceptional circumstances which could 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 on 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 include one to the omission of the relative movability of the elongated shaft of the balloon catheter and the elongated shaft of the guide catheter, which was found

convincing in relation to the main request by the Opposition Division in the impugned decision, and one to the omission that the balloon was positioned either distally or proximally to the crimped prosthetic aortic heart valve. For example, page 12, point 3 of the opponent's statement of grounds of appeal reads: "*the parent application as filed do[es] not explicitly or implicitly teach that the feature stipulating that the balloon is positioned either distal or proximal to the crimped THV can be omitted. It is submitted that this is a paradigm case in which the feature is actually taught as necessary to the solution to the problem at which [... the parent application as filed] is aimed*". Page 14, point 4.b) reads: "*The feature of off-balloon crimping cannot be omitted from the specific embodiment disclosed in paras. [0161] - [0167] (which, as we want to emphasize again, is the only embodiment which discloses indicia)".*

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 opponent.

The fact that the Board considered the omission of either a valve carrying member or a structure positioned distally or proximally 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. Although the opponent had formulated an objection to the omission of the valve carrying member (page 22 of its statement of

grounds of appeal), it had also formulated an objection to the more general omission of the off-balloon crimping on pages 12 and 14 of the statement of grounds, as explained above. The fact that the Board found this more general omission convincing, and not the specific one against the valve carrying member, is again the result of the Board's evaluation of the opponent's objections in their entirety.

The explanation 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 for the case at hand.

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 76 to 79 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 the 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