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**Datasheet for the decision  
of 16 June 2015**

**Case Number:** T 0565/14 - 3.2.08  
**Application Number:** 08016624.2  
**Publication Number:** 2000115  
**IPC:** A61F2/24, B60K37/06  
**Language of the proceedings:** EN  
**Title of invention:**  
A prosthetic valve assembly

**Patent Proprietor:**  
Edwards Lifesciences PVT, Inc.

**Opponents:**  
Boston Scientific Corporation (Respondent 01)  
Medtronic, Inc. US/Medtronic Vascular Galway [opposition  
withdrawn]  
Stolmár, Matthias (Respondent 02)

**Headword:**

**Relevant legal provisions:**  
EPC Art. 100(c), 123(2), 76(1)

**Keyword:**  
Divisional application - added subject-matter (no) -  
after amendment

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 0565/14 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 16 June 2015**

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**Decision under appeal:**      **Decision of the Opposition Division of the  
European Patent Office posted on 28 January 2014  
revoking European patent No. 2000115 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman**                    I. Beckedorf  
**Members:**                    C. Herberhold  
                                      M. Foulger

## **Summary of Facts and Submissions**

- I. By its decision posted on 28 January 2014 the Opposition Division revoked European patent EP-B-2000115 on the grounds of Article 100(c) EPC.
- II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. With letter dated 26 May 2014, opponent 02 withdrew the opposition.
- IV. Observations of a third party were received on 15 May 2015 relating to the ground of opposition under Article 100(c) EPC in respect of claim 1 of the patent as granted.
- V. Oral proceedings before the Board of Appeal took place on 16 June 2015.

As announced in the letter dated 12 May 2015 respondent 02 (opponent 03) did not attend the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA the proceedings were continued in their absence.

For the course taken by the proceedings, in particular the issues discussed with the parties and the parties' requests, reference is made to the minutes.

At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained as

granted or, in the alternative, that the patent be maintained in amended form on the basis of the set of claims filed as auxiliary request 1c with letter of 23 April 2015.

The respondent 01 (opponent 01) requested that the appeal be dismissed.

VI. Claim 1 as granted reads as follows:

"A prosthetic valve assembly for implantation in a stenotic native aortic valve, comprising:  
a metallic frame (10) having upper and lower extremities and wherein at least a portion of said frame has a concave profile between said upper and lower extremities, said frame being compressible to an external diameter capable of being introduced through an 18F (5,7mm) arterial introducer for advancing the prosthetic valve assembly through a patient's vasculature using a catheterization technique and said frame being expandable for implantation within said stenotic native aortic valve;  
a collapsible valvular structure (14) sewn to said frame between said upper and lower extremities, said valvular structure being formed of pericardial tissue for occluding blood flow in one direction; and  
an internal cover (19) made with the same tissue as the valvular structure, said internal cover having an upper end coupled to said valvular structure and a lower end attached to said lower extremity of said frame, said internal cover sewn to a wall of said frame and extending along an internal surface of said wall of said frame only between said valvular structure and said lower extremity of said frame for preventing regurgitation of blood through said wall of said frame below said valvular structure."

Claim 1 of **auxiliary request 1c** is based on claim 1 as granted with the following amendments (omissions are indicated by strike through, additions underlined):

"wherein ~~at least a portion of~~ said frame has a concave profile between said upper and lower extremities and wherein the extremities are projecting curved extremities (12)"

"said frame being expandable by balloon inflation for implantation within said stenotic native aortic valve"

VII. The following documents are relevant for the present decision:

D1d: WO-A-98/29057 (the grandparent application);  
BB1: US-A-5,411,552;  
D9: Textbook of interventional cardiology, Chapter 75: "Percutaneous Expandable Prosthetic Valves", by Steven R. Bailey, pp. 1268-1276 (1994).

VIII. The essential arguments of the appellant can be summarised as follows:

*Main request - Article 100(c) EPC*

The grandparent application disclosed several inventions in the field of catheter implantable valves, one of which - see in this respect page 5, lines 17,18, page 8, lines 28-30 and page 13, lines 4-15 - related to the prevention of fluid regurgitation through the wire frame of the implantable valve. Hence, claim 1 as granted, which defined an internal cover attached to the frame and which thus related to this particular

invention, only had to include the features essential for this invention.

In particular, there was no need for the frame to be defined as expandable by balloon inflation. While it was true that on page 13, lines 8-9, the description stated that the structures of the native valve were pushed aside by the inflated balloon, this passage related, however, to the pre-dilation, i.e. to the crushing of the valve before implantation and was therefore not in contradiction with a self-expandable frame being implanted thereafter. Although some recoil of the crushed valvular structure was to be expected, a self-expandable frame was well capable to overcome the recoil force and to be placed appropriately. On page 15, line 19, further reference was made to a metallic frame, which - for the person skilled in the art - evidently included self-expandable shape memory metals such as Nitinol. Moreover, expressions such as "dilated, for instance, by inflation of a balloon" on page 17, line 10-12, or "introduced by a catheterization technique" on page 25, line 4-7 clearly implied other implantation techniques as e.g. self-expansion of the valve. Documents BB1, column 2, line 56-60 and D9, page 1273, second sentence gave further evidence, that self-expandable frames were implicitly known to the person skilled in the art as alternative to balloon expandable frames.

Equally, there was no need for the frame to have projecting extremities. A comparison of D1d, Figure 2, which showed a cylindrical frame without projecting extremities, with Figure 3a, which showed a cylindrical frame with projecting extremities, illustrated that projecting extremities were an optional feature. Also from page 15, second paragraph and page 9, lines 19-21



it was evident that the features "concave" and "projecting extremities" were alternatives rather than functionally linked. Therefore, there was no need to claim the projecting extremities in addition to the concave shape.

The description further disclosed on page 15, lines 5-6 a frame "having ... a concave shape profile", a wording which did not require the complete frame to have a concave profile but included frames with at least a portion thereof having a concave profile. This was in accordance with the frame being a "substantially cylindrical structure" - see page 9, lines 7-9 - but more preferably having a "concave shape" - page 9, lines 19, 20 - which indicated that only the parts locking the device in the distorted aortic orifice, i.e. at least a part of the frame needed to be concave.

There was also no reason to include particular characteristics of the valvular structure, such as guiding means or the existence of a continuous surface, in the subject-matter of the claim. The description clarified on page 24, lines 9-10 that any type of valvular structure could be used and that - see page 26, lines 25, 26 - the valvular structure could have several types of designs and shapes.

Finally, there was support in D1d for an internal cover attached to the frame in the way as claimed. On page 8, lines 24-27 the description disclosed a valvular structure sewn to the frame and - see page 21, lines 29 to page 22, line 3 - an internal cover below the fastening line of the valvular structure and thus limited to the lower part of the frame. Obviously, in order to prevent regurgitation through the frame in case of inexact valve placement, such an internal cover

needed to be fixed to the wall and to the extremities of the frame, features which the description equally disclosed on page 20, lines 26-28 or page 24, lines 24-27.

To conclude, Article 100(c) EPC did not prejudice the maintenance of the patent as granted.

*Claim 1 auxiliary request 1c - Articles 123(2) and 76(1) EPC*

The amendments were based *inter alia* on page 9, lines 19, 20, and overcame all outstanding objections under Articles 76(1) and 123(2) EPC. The wording "more preferably" in line 19 made it clear that the disclosure of the projecting curved extremities was independent of the frame having the particular intercrossing bar structure defined in the preceding paragraph.

IX. The essential arguments of the respondent can be summarised as follows:

*Main request - Article 100(c) EPC*

The purpose of Articles 76(1) and 123(2) EPC was to protect third parties from being confronted with claims such as the ones granted, directed to a new, as yet undisclosed combination of features different from any embodiment disclosed, the features having been isolated out of the original disclosure in a multiple selection, cherry-picking approach. Indeed, claim 1 as granted did omit several features - in particular of the valve comprising a collapsible continuous structure with guiding means and the frame being strong enough to resist the recoil phenomenon of the fibrous tissue of

the diseased valve - which were part of the most general original definition of the invention on page 5, line 4 - page 6, line 17 of D1d and which were required to achieve the aims of the invention, see page 5, lines 22-27. These features had also to be considered essential in view of the statement in the description - see page 4, lines 8-13 and 13-15 - that conventional valve designs and conventional light stent structures were not suitable to be forcefully embedded into the aortic annulus.

It was true that - as pointed out in the Board's communication sent with the summons - the description on page 13, lines 4, 5 stated that "an implantable valve according to the invention essentially comprises a supple valvular structure supported by a strong frame". However, the wording "according to the invention" showed that this statement was nothing more than a back-reference to the invention as defined in the "summary of the invention" mentioned above, i.e. it referred to a valve having a continuous valvular structure with guiding means providing stiffness and to a strong frame.

There was furthermore no basis to omit the feature of the frame being expandable by balloon inflation. The technical problems solved by the invention as discussed on page 4, line 3 - page 5, line 2 all related to balloon expandable valves. Deployment of the frame by balloon expansion was also consistently mentioned in the grandparent application as filed, see e.g. page 17, lines 5, 6. This picture did not change when documents BB1 or D9 were taken into account. BB1 was a single patent document which - according to established case law - could not be considered to represent common general knowledge. D9 on the other hand dealt almost

exclusively with balloon expandable valve frames, making only passing reference to self-expandable valves on page 1273, second sentence. However, already in the following sentence, it was stated that "in order to be practical, some form of a balloon expandable system will probably be required". The document was furthermore directed to artificial valves implanted to treat valvular regurgitation rather than stenosis which did not have to overcome the strong recoil force of the latter.

With respect to the frame, the disclosure consistently showed a frame which as a whole was of concave form and which had either an opening out or projecting extremities. The comparison of Figures 2 and 3a - which showed cylindrical frames - could give no indication to omit the projecting extremities of a concave frame. There was no disclosure of a frame with only a portion thereof being concave. Furthermore, there was no basis for the frame being compressible to an external diameter capable of being introduced through an 18F arterial introducer - this was rather a property of the valve assembly.

Furthermore, as already discussed above, the invention required specific valvular structures which were able to withstand the strong forces upon insertion into the stenotic aortic valve. In this context, the valvular structure referred to on page 24, lines 9-10 or page 26, lines 25, 26 was clearly intended to mean a valvular structure having guiding means and a continuous surface as defined before, other valvular structures not being strong enough as discussed on page 4, lines 8-13.

Regarding the internal cover and its fixation to the frame as defined in the claim, there was no basis for all the claimed features in combination. In fact, the claim defined 4 different connections: the valvular structure needed to be sewn to the frame between the lower and upper extremities of the frame, the internal cover needed to be coupled to the valvular structure, attached to the lower extremity of the frame and sewn to a wall of the frame. Page 8, lines 24 - 30 disclosed a valvular structure sewn to the frame and an internal cover coupled therewith. However, the internal cover was - as also depicted in Figure 6b - placed between the valvular structure and the internal wall and thus did not extend along an internal surface of the wall of the frame only between the valvular structure and the lower extremity of the frame. There was thus no valvular structure directly coupled to the frame. Page 9, lines 3 - 6 disclosed a sleeve at least below the fastening of the valvular structure, albeit without indication that said sleeve was connected to the valvular structure, the wall of the frame and the lower extremity. Equally, page 24, third and fourth paragraphs as well as corresponding Figure 8 disclosed attachment of the internal cover to the frame on various parts of the internal surface as well as on the upper and lower extremities, however, only in the context of an internal cover extending from the lower to the upper extremities of the frame and with the valvular structure and the internal cover being one integrated structure. Consequently, none of the passages cited by the appellant disclosed the claimed features in combination.

The opposition grounds according to Article 100(c) thus prejudiced the maintenance of the patent as granted.

*Claim 1 auxiliary request 1c - Articles 123(2) and 76(1) EPC*

The amendment to claim 1 of auxiliary request 1c had to be considered an unallowable intermediate generalisation. The disclosure of a frame having projecting curved extremities and presenting a concave shape - see page 9, lines 19-21 - was made only in the context of the specific frame having intercrossing bars as defined in the preceding paragraph. These features stood in functional and structural relationship with the particular form now claimed and could thus not be omitted.

Consequently, claim 1 of auxiliary request 1c did not fulfil the requirements of Articles 76(1) and 123(2) EPC.

## **Reasons for the Decision**

1. Claim 1 as granted - Article 100(c) EPC

1.1 The disclosure

The patent (EP-B-2000115) had been filed as a divisional of EP05024006.8 (published as EP-A-1621162), which itself had been filed as a divisional of PCT application W098/29057 (D1d, which entered the European phase under the application number 97953935.0, published as EP-A-0967939).

The description and drawings of the three applications are identical. However, the claims of the parent applications have not remained in the respective divisional applications.

In accordance with G 1/05 (OJ EPO 2008, 271) and G 1/06 (OJ EPO 2008, 307), in order that the opposition ground of Article 100(c) EPC did not prejudice the maintenance of the patent, it is a necessary and sufficient condition that anything disclosed in the granted patent be directly and unambiguously derivable not only from the application on which the patent has been granted, but also from what was disclosed in each of the preceding applications as filed.

Therefore, in the present case, the maintenance of the patent can only be considered not to be prejudiced by the opposition ground under Article 100 (c) EPC, if the claimed subject-matter can be directly and unambiguously derived by the person skilled in the art from the description and drawings of the grandparent, of the parent and of the patent application as originally filed using common general knowledge.

Because all descriptions and drawings are identical it is sufficient that the claimed subject-matter is derivable from the description and drawings of the grandparent application (D1d, WO-A-98/29057) as filed. Thus, in the following, only the disclosure in this document will be discussed.

## 1.2 Main request - Article 100(c) EPC

On page 13, lines 4-15 (referred to as GD in the following), the description of D1d discloses: "An implantable valve according to the invention

essentially comprises a supple valvular structure supported by a strong frame." After having addressed the problem of regurgitation it is further stated that "any risk of regurgitation of blood is eliminated with the presence of an internal cover, as will be described below". The Board understands this passage as a general disclosure of what is essential to the invention. In fact, the first sentence stands on its own, without any indication of referring to a previous definition. If such a reference was intended, one would have expected the definite article (i.e. "the valve according to the invention" rather than "an expandable valve according to the invention").

- 1.2.1 The frame being not defined as balloon expandable, i.e. the claim encompassing self-expandable frames

GD states that "...the expanded frame has to be positioned exactly at the level of the native valvular leaflets of the native valve, the structures of which are pushed aside by the inflated balloon". The Board comes to the conclusion that "the pushing aside of the leaflets" mentioned in this passage refers to the placement of the valve rather than to the pre-dilation process. Firstly, the statement in the subordinate clause is made in the context of frame positioning, i.e. it relates to the pushing aside of the valve leaflets during valve insertion. If pre-dilation was indeed meant, one would have expected the past tense, i.e. "the structures of which have been pushed aside by the inflation balloon". Secondly, due to the strong recoil phenomenon - discussed repeatedly throughout the application - a pushing aside of the crushed leaflets will also be required after pre-dilation. Therefore, from the above cited passage the person skilled in the



art will understand the valve disclosed in GD to have a frame expandable by balloon inflation.

Also the further disclosure in D1d consistently refers to a balloon expandable frame. This is true for the problems discussed with respect to the prior art (page 4, line 3 - page 5, line 2), for the "summary of invention" (see page 5, line 7-10: structure which "is capable ... to stand the forceful balloon inflation performed to deploy the IV..."; page 6, line 25, 26: "forceful balloon inflation at the time of IV deployment") and for the implantation process (see Figures 13g-13j and 15 ; page 16, line 19-21: "When the frame has reached its maximal expanded shape under the push of a forcefully inflated balloon..."; page 17, line 4-6: "At time of the IV positioning, the frame is expanded again by balloon inflation to its maximal size in the aortic orifice"; page 17, line 14-16: "..., the shaft of the balloon catheter on which will be mounted the IV before introduction in the body..."; page 25, line 2,3: "to be able to be introduced via arterial introducer and finally expanded again by the balloon inflation").

On the other hand, a self-expandable valve, which is comprised in the subject-matter of claim 1 as granted, is not disclosed in D1d. In this context it does not matter whether self-expandable frames would at all be capable of overcoming the strong recoil. It is decisive that there is no disclosure of the valve frame being self-expandable.

The further passages cited by the appellant cannot change the above considerations: the generic disclosure of the frame being a metallic frame (page 15, line 19) does not clearly and unambiguously disclose more

specific, self-expandable frames, such as the ones made from Nitinol. Equally, the general reference to "a catheterization technique by a transcutaneous route in a peripheral artery" does not give any basis for a specific catheterization technique comprising a self-expandable frame. Finally, on page 17, lines 10-12, it is said that the frame is dilated, "for instance by balloon dilation". However, this passage refers to the building of the frame and not to its deployment. Furthermore, even if something else than a balloon was used for dilation, the dilation would still be actively enforced by an external mechanism, which is different from the self-expandable mechanism covered by claim 1 as granted.

The appellant was of the opinion that self-expandable frames were an evident and thus - as shown by documents BB1 and D9 - for the person skilled in the art an implicitly disclosed alternative to balloon expandable frames. However, self-expandable and balloon expandable frames being mentioned in parallel in a single prior art patent document (BB1) cannot establish that equivalence of both types of frames was part of the skilled person's general knowledge. Even D9 - which is a standard textbook in the field - does not disclose self-expandable frames in the context of a stenotic aortic valve but rather for aortic valve insufficiency (see D9, page 1273, right column, last sentence; page 1271, left column, penultimate paragraph). The original disclosure of the patent puts a particular focus on the strong recoil phenomenon of stenotic aortic valves which needs to be overcome upon valve placement. Even if - as argued by the appellant - it was in principle possible for a self-expanding frame to overcome the recoil, still there is no indication or proof that this was part of the general knowledge of the skilled person

at the time of filing. The Board thus comes to the conclusion that claim 1 as granted encompasses subject-matter as e.g. the valve having a self-expandable frame, which was neither originally disclosed nor part of the general knowledge of the skilled person at the time of filing.

Hence, the opposition ground under Article 100(c) EPC prejudices the maintenance of the patent as granted.

Further objections against claim 1 as granted which equally apply to claim 1 of auxiliary request 1c are discussed below in the context of that auxiliary request.

2. Claim 1 of auxiliary request 1c - Articles 123(2) and 76(1) EPC

2.1 Claim 1 of auxiliary request 1c defines a frame "expandable by balloon inflation for implantation within said stenotic native aortic valve".

It thus overcomes the unallowable broadening discussed in point 1.2.1 above.

Moreover, a frame being expandable by balloon inflation for implantation within the stenotic native aortic valve implicitly has to be a "strong frame" in the sense of GD. If a light stent structure as the one mentioned on page 4, lines 15 - 18 is too weak to allow forceful embedding into the aortic annulus, then it will not fall under the scope of claim 1.

2.2 The frame having a concave profile between said upper and lower extremities and wherein the extremities are projecting curved extremities.

Claim 1 of auxiliary request 1c defines a frame having a concave profile with projecting curved extremities.

This amendment is based on page 9, lines 19, 20, the wording "more preferably" clarifying that such a frame having projecting curved extremities and presenting a concave shape was a particular advantageous form of the frame having a "substantially cylindrical structure", as introduced on page 9, lines 7-9. In the paragraphs bridging the above cited passages the frame material and its detailed intercrossing bar structure are described, albeit as optional features ("preferably", "in a preferred embodiment"). The disclosure of the frame being concave and having projecting curved extremities is thus not inextricably linked with the disclosure of a particular intercrossing bar structure of the frame.

The further objections against claim 1 as granted based on the omission of the frame having projecting curved extremities or objecting to the broadened wording "at least a portion having a concave profile" do not apply to claim 1 of auxiliary request 1c.

### 2.3 The valvular structure

According to GD, the implantable valve according to the invention essentially comprises a supple valvular structure. Because pericardial tissue - as defined in claim 1 of auxiliary request 1c - is intrinsically supple, all features of the valvular structure disclosed in GD as essential are part of the claimed subject-matter.

With the frame - and the collapsible valvular structure sewn to the frame - being expandable by balloon inflation for implantation within said stenotic native aortic valve, a valve according to the definition of claim 1 needs to be suitable for this very purpose. If a valve cannot cope with such mechanical stresses, such as the semi-lunar leaflet design mentioned on page 4, lines 8-13 of the application, it will not be comprised in the claimed subject-matter.

Therefore, in view of the disclosure in GD, the omission of the more specific valve features - i.e. the valve having a collapsible continuous structure with guiding means providing stiffness - cannot be considered new technical information for the person skilled in the art.

- 2.3.1 The internal cover, the valvular structure and the connections of these entities with each other / to the frame.

GD discloses that for the implantable valve according to the invention, any risk of regurgitation of blood is eliminated with the presence of an internal cover.

From page 8, line 24-27 the person skilled in the art knows that the valvular structure may be fastened along a substantial portion of the expandable frame by sewing. Evidently, this fastening has to be between the upper and lower extremities of the frame.

Further information about the internal cover is disclosed on page 8, line 28 - page 9, line 6. In accordance with page 9, line 3 - 6 the internal cover makes a sort of "sleeve" at least below the fastening of the valvular structure. A sleeve "below" the

fastening line cannot - at the same time - be positioned "between" the frame and the valvular structure. Thus the person skilled in the art understands that the feature of the internal structure being placed between the valvular structure and the internal wall of the frame applies to a long sleeve (such as shown e.g. in Figure 6a), whereas for the short sleeve, extending below the fastening line of the valvular structure, the sleeve only starts below the fastening line of the valve and thus is not positioned between valvular structure and frame.

The reference to the "fastening of the valvular structure" again confirms that the valvular structure is fixed to the frame, a connection for which sewing is an explicitly disclosed possibility (page 8, line 25).

It is immediately clear and thus implicitly disclosed to the skilled person that a sleeve below the fastening of the valvular structure needs to be connected to the lower extremity of the frame and, at its end facing the fastening of the valvular structure, to the wall of the frame. Without these connections, the cover would be drawn into the lumen by the blood flow thus hindering cardiac output. It is furthermore immediately evident to the skilled person that, in order to prevent regurgitation, a passage of blood between valvular structure and internal cover needs to be prevented by coupling these structures together. As disclosed for connecting the valvular structure to the frame (page 8, line 25), sewing is one of the disclosed solutions for connecting pericardial tissue (of the internal cover) to the frame, sewing also being the classical, well-established surgical connection technique for soft tissue such as pericardial tissue.

The above discussed immediate understanding of the skilled person is further endorsed on page 24, lines 24 - 27, which disclose that the "fastening of the internal cover on the extremities can be reinforced by various points of attachment on various parts of the internal surface of the frame" and that it can be "fastened by sewing, molding or gluing". Although the statement is made with reference to the Figure 8 embodiment and thus in the context of a longer internal cover extending between the extremities of the frame, this passage still confirms -fully in accordance with what the skilled person already understands from common general knowledge - that an internal cover is to be connected to the frame on the extremities of the internal cover and in the parts extending there between.

- 2.4 The frame being compressible to an external diameter capable of being introduced through an 18F arterial introducer.

According to page 25, lines 4-11, the valve should be able to be introduced in the femoral artery through an arterial introducer, for which a diameter of 18 F was acceptable. Because the frame is the outermost part of the claimed valve, this passage discloses that in particular the frame is compressible to an external diameter capable of being introduced through an 18 F introducer.

- 2.5 To conclude, the subject-matter of claim 1 of auxiliary request 1c is clearly and unambiguously disclosed to the person skilled in the art, taking into account the general knowledge. Therefore, the claim is not objectionable under Articles 76(1) and 123(2) EPC.

3. None of the parties chose to address the third party submission of 15 May 2015. There is thus no need for the Board to comment thereon, in particular because its relevant points have been covered during the oral proceedings and are thus already taken into account in the present decision.

## Order

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution on the basis of claim 1 according to auxiliary request 1c, filed with letter of 23 April 2015.

The Registrar:

The Chairman:



V. Commare

I. Beckedorf

Decision electronically authenticated