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**Datasheet for the decision
of 5 June 2025**

Case Number: T 1011/23 - 3.2.02

Application Number: 18210741.7

Publication Number: 3485848

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
PROSTHETIC HEART VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Opponent:
Abbott Cardiovascular Systems, Inc.

Relevant legal provisions:
EPC Art. 76(1), 123(2)
RPBA 2020 Art. 12(3), 12(5)

Keyword:
Amendments - added subject-matter (no)
Discretion not to admit submission - requirements of Art.
12(3) RPBA 2020 met (no) - submission admitted (no)



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Case Number: T 1011/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 June 2025

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
17 March 2023 concerning maintenance of the
European Patent No. 3485848 in amended form.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Dennler
N. Obrovski

Summary of Facts and Submissions

- I. The patent proprietor appealed against the opposition division's interlocutory decision to maintain the contested patent as amended in accordance with the request then on file as auxiliary request 2.
- II. The patent had been granted from a divisional patent application ("the divisional application") derived from an earlier European patent application ("the parent application"), itself published as WO 2012/048035 A2.

In its decision, the opposition division had found, *inter alia*, that claims 1 and 14 as granted contained added subject-matter, in breach of Articles 76(1) and 123(2) EPC (see Reasons 14-16.6.5 and 17-17.1).
- III. The **appellant (patent proprietor)** requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, as amended on the basis of one of auxiliary requests 1 to 54 filed with the statement of grounds of appeal.
- IV. The **respondent (opponent)** requested that the appeal be dismissed.
- V. Oral proceedings were held before the Board on 5 June 2025, at the end of which the present decision was announced.
- VI. **Claim 1** of the main request, i.e. claim 1 as granted, reads as follows (with the feature numbering used in the decision under appeal):

1. *"A balloon-expandable prosthetic aortic heart valve with a radially collapsed state and radially expanded state, comprising:*
 - 1.1 *a balloon-expandable frame (12) comprising a nickel-cobalt-chromium-molybdenum alloy, the frame (12) comprising:*
 - 1.1.1 *an inflow row of openings (36) at an inflow end portion of the frame (12),*
 - 1.1.2 *an outflow row of openings (40) at an outflow end portion of the frame (12); and*
 - 1.1.3 *at least one intermediate row of openings (38) between the inflow row of openings (36) and outflow row of openings (40);*
 - 1.2 *wherein the inflow row of openings (36) is formed by*
 - 1.2.1 *a circumferentially extending lower row of angled struts (22) arranged end-to-end and a circumferentially extending first intermediate row of angled struts (24) arranged end-to-end,*
 - 1.2.2 *the lower and first intermediate rows of angled struts (22, 24) interconnected by a plurality of substantially straight, axially extending struts (34),*
 - 1.2.3 *wherein each axially extending strut (34) of the inflow row of openings (36) extends from a location defined by the convergence of the lower ends of two angled struts (24) of the first intermediate row of angled struts (24) to another location defined by the convergence of the upper ends of two angled struts (22) of the lower row of angled struts (22); and*

- 1.3 *wherein the outflow row of openings (40) is formed by*
 - 1.3.1 *a circumferentially extending upper row of angled struts (32) arranged end-to-end and a circumferentially extending second intermediate row of angled struts (28) arranged end-to-end,*
 - 1.3.2 *the upper and second intermediate rows of angled struts (28, 32) interconnected by a plurality of axially extending struts (31) and*
 - 1.3.3 *a plurality of angularly spaced, axially extending commissure window frame portions (30),*
 - 1.3.4 *each commissure window frame portion (30) comprising an enclosed opening (20) between first and second axially oriented side struts,*
 - 1.3.5 *wherein each axially extending strut (31) and each commissure window frame portion (30) of the outflow row of openings (40) extends from a location defined by the convergence of the lower ends of two angled struts (32) of the upper row of angled struts (32) to another location defined by the convergence of the upper ends of two angled struts (28) of the second intermediate row of angled struts (28),*

- 1.4 *the prosthetic aortic heart valve further comprising a leaflet structure (14), wherein each commissure window frame portion (30) is configured to mount a respective commissure of the leaflet structure (14)."*

VIII. **Claim 14** of the main request, i.e. claim 14 as granted, reads as follows:

"The prosthetic aortic heart valve of claim 13, wherein each pair of primary side tabs (116) extends radially

outwardly through a corresponding commissure window (30) to a location outside of the frame (12), the portions of the primary side tabs (116) located outside of the frame (12) extend circumferentially away from one another and along an exterior surface of the side struts, wherein the prosthetic aortic heart valve further comprises a plurality of wedges (126), each wedge (126) being positioned between the side struts of a commissure window (30) and separating the pair of primary side tabs (116) extending through the commissure window (30), the wedge (126) being urged radially inwardly against the primary side tabs (116)."

VIII. The **appellant's arguments**, where relevant to the present decision, can be summarised as follows.

Added subject-matter

Claims 1 and 14 as granted did not contain added subject-matter.

The person skilled in the art would understand that the features alleged by the respondent and the opposition division in the decision under appeal to have been improperly omitted from claim 1 as granted were either implicit in the claim, merely optional, or, in any case, not inextricably linked with the other features defined in the claim. Therefore their omission from claim 1 did not constitute an unallowable intermediate generalisation of the original disclosure.

The subject-matter of claim 14 as granted was disclosed in the parent application in relation to the embodiment shown in Figures 29-33 and described in paragraph [080], onto which the person skilled in the art would immediately map the disclosures of paragraph [021] and

original claim 26. Contrary to the respondent's view, there was no inconsistency between these two paragraphs.

Novelty and inventive step

The opposition division had concluded that the subject-matter of claim 1 of auxiliary request 2 underlying the decision under appeal was novel and inventive due to - in particular - feature 1.3.3. The same conclusion also applied to claim 1 as granted, since this claim also included feature 1.3.3.

IX. The **respondent's arguments**, where relevant to the present decision, can be summarised as follows.

Added subject-matter

Claims 1 and 14 as granted contained added subject-matter.

a) Claim 1 was based on the frame of Figure 5 of the parent application, the only embodiment originally disclosed that comprised the features defined in that claim. However, several features of this embodiment had been omitted from claim 1, constituting unallowable intermediate generalisations of the original disclosure.

Firstly, claim 1 did not specify that the frame was annular, although all the frames disclosed in the parent application were annular.

Secondly, the structural features of the frame of Figure 5 were interdependent and inextricably linked with each other; all these features collectively

contributed to the frame's overall function. The parent application provided no basis for isolating and omitting some of these features, such as the sizes of the openings of the inflow and outflow rows, or the number of two intermediate rows of openings.

This was particularly the case given that the larger size of the openings of the inflow row resulted from the axially extending struts specified in claim 1 as defining in part the openings of the inflow row. Moreover, the parent application did not disclose any frame with the claimed structure and only one intermediate row of openings.

In any case, it was not allowable to generalise the number of intermediate rows of openings beyond two without also including the feature that the openings of the inflow row were larger than those of the intermediate rows, as specifically disclosed in paragraph [061] for the embodiment of Figure 5. Moreover, paragraph [012] of the parent application, which had to be read in the context of the preceding paragraphs, related to other embodiments: it was not applicable to the embodiment of Figure 5. In any event, the person skilled in the art would not read the two sentences of paragraph [012] in isolation from each other, and the parent application did not disclose that the teaching of the first sentence could be applied to the specific embodiment of Figure 5 without also applying the teaching of the second sentence.

The size of the openings of the outflow row was inextricably linked to their function of allowing the leaflet structure to protrude or bulge into or through them when the valve was crimped, as described in

paragraph [056] of the parent application. This was essential to the described valve's function.

Thirdly, the inner skirt disclosed for the embodiment of Figure 5 was not optional: it was necessary in order to secure the leaflet structure to the frame and form a good seal between the prosthetic valve and the native annulus (paragraphs [063], [064] and [078]). The inner skirt was therefore indispensable for the heart valve to function as described, and necessary for it to fulfil its intended function.

b) The combination of paragraphs [021] and [080] of the parent application could not provide a supporting basis for claim 14. Firstly, paragraph [080] only disclosed tabs having specific upper and lower positions, not "primary" and "secondary" tabs as defined in claim 14. Secondly, there was no link in the parent application between the general embodiment of paragraph [021] and the specific embodiment shown in Figure 29 and discussed in paragraph [080]; therefore there was no reason to interpret the disclosures of paragraphs [021] and [080] together. Moreover, the general disclosure in paragraph [021] related to leaflets with two opposing side tabs and the pairs of side tabs in that paragraph referred to tabs of adjacent leaflets. This was inconsistent with the specific embodiment described in paragraph [080], relating to leaflets with two upper and two lower tab portions.

Novelty and inventive step

With regard to novelty and inventive step, the respondent's reply to the statement of grounds of appeal contains the following statement on page 12:

"For completeness, we refer the Board to [sic] Appeal to our novelty and inventive step arguments in the Annexes A and B. These are to be considered in the event that the Board is minded to set aside any part of the Decision."

Annexes A and B are earlier submissions made by the respondent in the opposition proceedings and attached as annexes to the reply (see page 1 of the reply).

Reasons for the Decision

1. Subject-matter of the contested patent

The contested patent relates to a prosthetic aortic heart valve as defined in claim 1 as granted. This valve comprises a balloon-expandable frame (12) to which a leaflet structure (14) is mounted.

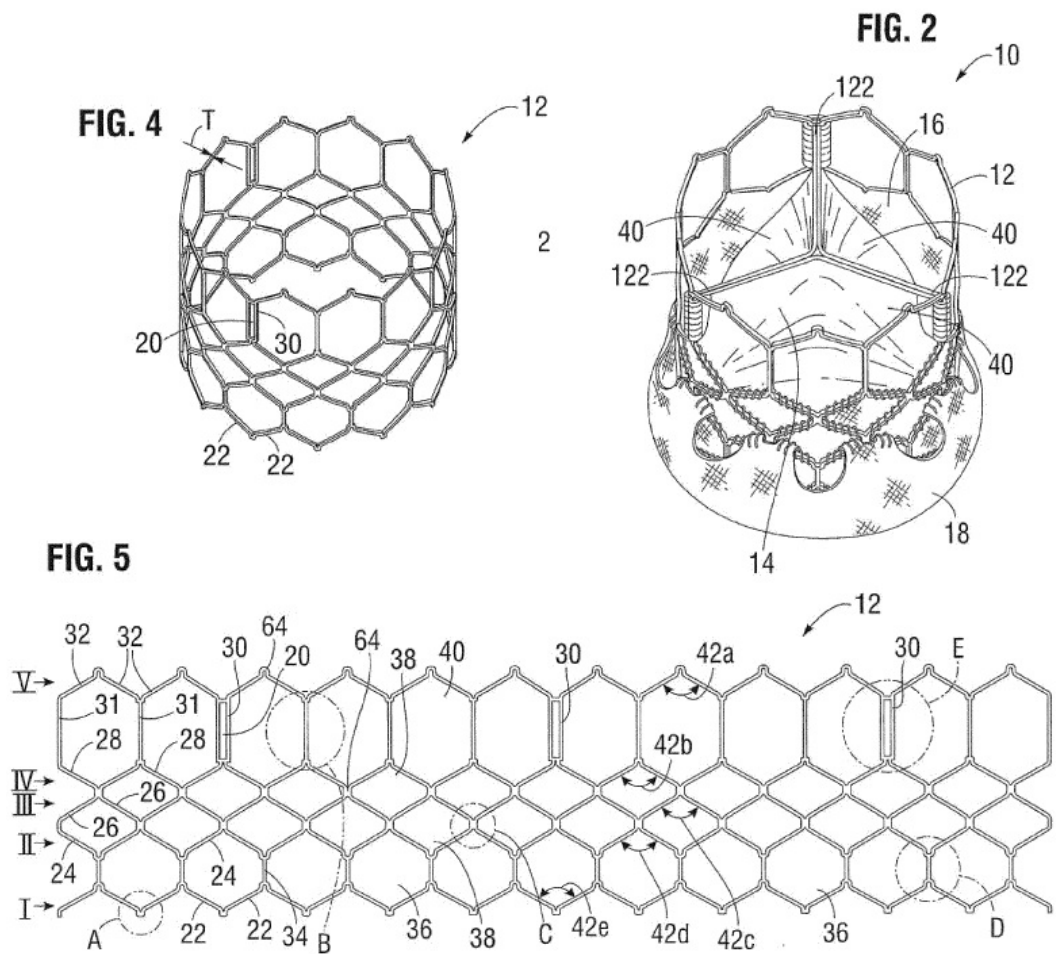
The frame comprises: an inflow row of openings (36) at an inflow end portion (feature 1.1.1); an outflow row of openings (40) at an outflow end portion (feature 1.1.2); and at least one intermediate row of openings (38) between the inflow and outflow rows (feature 1.1.3). Further structural details of the frame are defined in features 1.2 to 1.3.5.

Notably, the frame comprises a plurality of angularly spaced, axially extending commissure window frame portions (30), which define in part some of the openings of the outflow row (features 1.3.3 and 1.3.4) and are configured to mount corresponding commissures of the leaflet structure (feature 1.4). Each of these portions is secured at its upper and lower ends to adjacent rows of struts of the frame (feature 1.3.5). This configuration enhances the valve's fatigue

resistance under cyclic loading compared with known cantilevered struts for supporting the commissures of the leaflet structure (paragraph [0030]).

In addition, the inflow row of openings (36) is formed by two intermediate rows of angled struts (22, 24) interconnected by a plurality of substantially straight, axially extending struts (34) (features 1.2 to 1.2.3).

Figures 2, 4 and 5, reproduced below, show an example valve (10) with such a frame (12) comprising two intermediate rows of openings (paragraphs [0025] to [0029]).



Additionally, it is described in the patent (but not defined in claim 1 as granted) that the valve shown in Figure 2 further comprises an inner skirt (16) and an outer skirt (18) (paragraphs [0038] and [0059]).

2. Added subject-matter

- 2.1 The descriptions and drawings of the parent and divisional applications as filed are substantially identical, with the claims of the parent application being included as a list of embodiments in paragraph [0115] of the description of the divisional application. Consequently, the content of the parent application as filed is relevant to the assessment of added subject-matter under both Articles 76(1) and 123(2) EPC.
- 2.2 Contrary to the respondent's view, and as set out below, claims 1 and 14 as granted do not contain subject-matter which extends beyond the content of the parent application as filed. Therefore these claims comply with both Articles 76(1) and 123(2) EPC.
- 2.3 *Claim 1 as granted*
- 2.3.1 It is common ground, and the Board agrees, that the subject-matter of claim 1 as granted can be seen as an intermediate generalisation of the valve embodiments disclosed in the parent application as filed which comprise the specific frame 12 shown in Figure 5, such as the valve shown in Figure 2. Indeed, this frame 12 comprises, as defined in claim 1 as granted, an outflow row of openings with a plurality of commissure window frame portions (features 1.3-1.3.5), and an inflow row of openings formed by two rows of angled struts interconnected by a plurality of substantially

straight, axially extending struts (features 1.2-1.2.3).

2.3.2 The respondent objected that several features of such an embodiment had been omitted from claim 1 as granted even though it was apparent from the parent application as filed that they were inextricably linked with the features defined in claim 1, so this intermediate generalisation was not admissible. The Board disagrees, for the following reasons.

2.3.3 As set out in the Board's communication under Article 15(1) RPBA (see point 3.1.6), the fact that claim 1 as granted specifies that the frame is balloon-expandable (feature 1.1) and that it comprises rows of openings formed by circumferentially extending rows of angled struts (features 1.2.1 and 1.3.1) implies that the frame is annular, especially in the context of a prosthetic aortic heart valve as defined by claim 1. Therefore the fact that claim 1 does not explicitly define the frame as annular does not add subject-matter. The respondent did not comment on this issue at the oral proceedings before the Board; it merely referred to its written submissions.

2.3.4 It is true that, as submitted by the respondent, the structural and functional features of the frame of Figure 5, such as the size of the openings of the inflow and outflow rows and the particular number of two intermediate rows of openings connecting these rows, collectively contribute to the overall behaviour and function of the frame, and more generally to the overall behaviour and function of a valve comprising this frame. The same applies to the inner skirt in the valve of Figure 2, which assists in securing the

leaflet structure to the frame (paragraph [063] of the parent application).

However, this does not render the intermediate generalisation on which claim 1 as granted is based unallowable under Articles 76(1) or 123(2) EPC, since this generalisation remains within the limits of what the person skilled in the art would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the parent application as filed as a whole ("gold standard"). This conclusion partly deviates from the Board's preliminary opinion set out in the communication under Article 15(1) RPBA (see points 3.1.4 and 3.1.5), the Board being convinced by the appellant's arguments put forward at the oral proceedings.

2.3.5 As argued by the appellant, the person skilled in the art would recognise from the parent application as filed that, by integrating the commissure window frame portions in the outflow row of openings (features 1.3-1.3.5), the valve's fatigue resistance under cyclic loading is enhanced compared with the known cantilevered struts typically used to support the commissures of the leaflet structure (paragraph [055]). The person skilled in the art would understand that this effect is achieved independently and regardless of the number of intermediate rows of openings, the size of the inflow and outflow openings, or the presence of an inner skirt in the valve.

2.3.6 Designing the openings 40 of the outflow row as *"relatively large and [...] sized to allow portions of the leaflet structure 14 to protrude, or bulge, into and/or through the openings 40 when the frame 12 is*

crimped" is merely described in paragraph [056] as a way of minimising the crimping profile of the valve. The person skilled in the art would recognise this as an advantageous feature, albeit one not inextricably linked with the other features of the frame, contrary to the respondent's argument. Not sizing the outflow openings 40 as explained in paragraph [056] would just have resulted in a larger crimping profile. However, this would not have prevented, *inter alia*, the integration of the commissure window frame portions in the outflow row, as defined in claim 1.

- 2.3.7 The inner skirt 16 provided in the valve of Figure 2 is described in paragraph [063] as merely "assist[ing]" in securing the leaflet structure to the frame and forming a good seal between the valve and the native annulus. As put forward by the appellant, the person skilled in the art would see no inextricable link between the inner skirt and the features defined in claim 1 as granted, in particular given that the leaflet structure is already mounted to the frame via the commissure window frame portions as defined in feature 1.4.

This conclusion is supported by the fact that independent claims 9 and 16 of the parent application as filed both define a valve comprising a frame with a leaflet structure secured to it via "commissure windows" comprised in the frame, or "attachment portions of the frame" - similar to the commissure window frame portions defined in claim 1 as granted - but with no inner skirt. The absence of any reference to an inner skirt in claims 9 and 16 leaves it open whether the leaflet structure is additionally secured to the frame by other means, such as an inner skirt as in the valve of Figure 2. Therefore the person skilled in the art would derive that for such an embodiment an

inner skirt is merely an optional feature, not inextricably linked with the features of the frame or the leaflet structure.

- 2.3.8 The person skilled in the art would also understand from the parent application as filed that the number of intermediate rows of openings in the frame 12 of Figure 5, two, is merely exemplary.

The specific description of the frame 12 in paragraph [054] does not present this number as anything other than an example, with paragraph [054] merely describing "the illustrated embodiment" shown in Figure 5. Furthermore, the person skilled in the art would find in paragraph [012] the disclosure of a frame comprising, like the frame 12, an inflow row of openings and an outflow row of openings connected to each other by "at least one intermediate row of openings". Even assuming that paragraph [012] relates to embodiments different from those including the frame 12, as asserted by the respondent, the person skilled in the art would still derive from this disclosure that, similarly, the frame 12 of Figure 5 could also generally include "at least one intermediate row of openings" as defined in feature 1.1.3 of claim 1 as granted, even if this is not explicitly disclosed.

Contrary to the respondent's view, the fact that none of the drawings show a frame with a single intermediate row of openings between the inflow and outflow rows is irrelevant. The respondent's argument that the person skilled in the art might have difficulty in conceiving of such an embodiment relates to the question of whether the subject-matter defined in claim 1 as granted is sufficiently disclosed, which the respondent did not dispute.

2.3.9 That said, as the appellant further argued, neither paragraph [012] nor the description of the frame 12 establishes an inextricable link between the number of intermediate rows of openings (at least one according to paragraph [012], and exactly two in the frame 12) and the inflow openings being larger than the openings of the intermediate rows of openings.

Even if the second sentence of paragraph [012] clearly refers to "the" openings defined in the preceding sentence, as argued by the respondent, the person skilled in the art would not infer any such link from the mere juxtaposition of these two sentences.

Nor would they derive such a link from the specific disclosure in paragraph [061] that the inflow openings 36 are larger than the openings 38 of the two intermediate rows of openings. From this, they would merely conclude that designing the inflow openings to be larger than those of the intermediate rows enables the valve to adopt a tapered shape when crimped, making it easier to accommodate an outer skirt - which is not claimed in claim 1 as granted - at the inflow end of the valve, without increasing its overall crimp profile. The person skilled in the art would understand that this option is not inextricably linked with the remaining features of the frame 12.

2.3.10 The person skilled in the art would also understand that the feature of the inflow openings 36 being larger than the openings 38 of the intermediate rows of openings in the frame 12 is not inextricably linked with the axially extending struts 34 defining in part the inflow openings. Indeed, paragraph [061] merely describes an additional aspect of the frame 12 ("Also

[...]"), but does not link the larger size of the inflow openings to the presence of these struts. Conversely, these struts are described in paragraph [054] independently of any reference to the size of the inflow openings. As argued by the appellant, the presence of these struts merely limits the structure of the claimed valve.

For the sake of argument, the Board notes that, if the larger size of the inflow openings implicitly resulted from the fact that these openings were partly defined by the axially extending struts 34, as the respondent alleged, this would mean that the inflow openings of the valve of claim 1 as granted were in fact implicitly larger than the openings of the intermediate rows, since these struts are defined in features 1.2.2 and 1.2.3. Therefore the fact that claim 1 does not explicitly mention this would not constitute added subject-matter.

- 2.3.11 It follows that the features alleged by the respondent and the opposition division in the decision under appeal to have been improperly omitted from claim 1 as granted are either implicit in the claim or, in any case, not inextricably linked with the other features defined in the claim. Therefore their omission from claim 1 as granted does not constitute an unallowable intermediate generalisation of the original disclosure.

2.4 *Claim 14 as granted*

The Board agrees with the appellant that the subject-matter of claim 14 as granted is disclosed in Figures 29-33 and in the corresponding passages of the description of the parent application, particularly

Figure 29 and paragraph [080]. The respondent's arguments to the contrary are not convincing.

The person skilled in the art would recognise that the "primary side tabs" referred to in claim 14 and the "secondary side tabs" defined in claim 13, on which claim 14 depends, correspond to the lower and upper tab portions 116 and 112, respectively, referred to in paragraph [080]. Contrary to the respondent's argument, the Board sees no addition of subject-matter in the present context in the change of terminology from "lower"/"upper" to "primary"/"secondary". The vertical orientation of the valve does not affect the way in which the different tabs or tab portions fold and are used to mount the leaflet structure to the frame. Therefore these terms merely correspond to two equivalent ways of labelling the different types of tab portions or tabs provided in each leaflet.

In addition, even if the subject-matter of claim 14 is not literally disclosed in the parent application with regard to the specific embodiment shown in Figure 29, the person skilled in the art would directly and unambiguously read this subject-matter in this figure and its description in paragraph [080], with each "pair of primary side tabs" corresponding to a pair of two adjacent lower tab portions 116 of two adjacent leaflets 40 as depicted in Figure 29, and each of the claimed plurality of wedges corresponding to a wedge 126, as being illustrated in the same figure. For this reason alone, claim 14 as granted complies with Articles 76(1) and 123(2) EPC.

Contrary to the respondent's view, the fact that paragraph [021] and claim 26 of the parent application disclose features similar to those of claim 14, albeit

for "side tabs" instead of "primary side tabs", is irrelevant. Firstly, this disclosure does not prevent the person skilled in the art from reading the subject-matter of claim 14 in Figure 29, as stated above. Secondly, as the appellant argued, the person skilled in the art would in any event understand from the parent application that the general disclosure of paragraph [021] and original claim 26 also applies to the specific embodiment disclosed in Figure 29 and paragraph [080]. When mapping the language of paragraph [021] and claim 26 onto this embodiment, the person skilled in the art would recognise that each of the wedges described in paragraph [021] separates a pair of lower side tabs, i.e. a pair of primary side tabs, to use the terminology of claim 14.

3. Novelty and inventive step

- 3.1 In the decision under appeal (see Reasons 31.1-31.2 and 33.1-33.2), the opposition division held that the subject-matter of claim 1 of the request deemed allowable (request then on file as auxiliary request 2) was novel and inventive in view of the prior art relied on by the respondent due to - in particular - feature 1.3.3. As argued by the appellant, the same conclusion applies immediately to claim 1 as granted, since claim 1 also includes this feature.
- 3.2 Regarding novelty and inventive step, in its reply to the statement of grounds of appeal (see page 12) the respondent merely "refer[red] the Board [...] to [its] novelty and inventive step arguments" contained in two of its earlier written submissions made in the opposition proceedings, which the respondent had attached to the reply as annexes.

3.3 As set out in the Board's communication under Article 15(1) RPBA (see point 4.3), the respondent's general reference to these earlier submissions does not meet the requirement of Article 12(3) RPBA that the reply must set out the reasons why the decision under appeal should be upheld, and specify expressly all the facts, arguments and evidence relied on. Therefore the respondent's submission regarding novelty and inventive step in its reply to the statement of grounds of appeal does not substantiate any objections.

At the oral proceedings before the Board, the respondent did not provide any comments in this regard.

Consequently, in line with the Board's preliminary opinion set out in its communication, the Board decided to exercise its discretion under Article 12(5) RPBA, and disregarded the respondent's submission regarding novelty and inventive step in its reply.

4. Conclusion

It follows from the foregoing that none of the objections substantiated by the respondent prejudices maintenance of the contested patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated