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**Datasheet for the decision
of 25 April 2023**

Case Number: T 0621/20 - 3.2.01

Application Number: 10712101.4

Publication Number: 2413842

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
HEART VALVE PROSTHESIS

Patent Proprietor:
UCL Business PLC

Opponent:
Edwards Lifesciences Corporation

Headword:

Relevant legal provisions:
EPC Art. 54(2), 53(c), 123(2)
RPBA 2020 Art. 13(2)

Keyword:

Novelty - (no) - main and auxiliary requests 2-5
Exceptions to patentability - method for treatment by surgery
- auxiliary request 1
Amendments - allowable (no) - auxiliary requests 6, 7
Amendment after summons - exceptional circumstances (no) -
auxiliary request 8

Decisions cited:

G 0001/07

Catchword:



Beschwerdekammern

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Case Number: T 0621/20 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 25 April 2023

Appellant: UCL Business PLC
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
20 January 2020 concerning maintenance of the
European Patent No. 2413842 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: S. Mangin
P. Guntz

Summary of Facts and Submissions

- I. The appeals were filed by the appellant 1 (patent proprietor) and appellant 2 (opponent) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 2, the patent in suit (hereinafter "the patent") met the requirements of the EPC.
- II. The opposition division held that:
- The invention in accordance with the main request was sufficiently disclosed and the subject-matter of claim 1 did not extend beyond the content of the application as originally filed. However, the method claim 6 of the main request did not fulfil the requirements of Article 53(c) EPC.
 - The subject-matter of claim 1 of auxiliary request 1 was not novel over D7 (US 2008/0228263 A1).
 - The auxiliary request 2 met the requirements of clarity and sufficiency of disclosure. The subject-matter of claim 1 was novel over D1 (US 2004/0186563 A1), D6 (US 2008/0255661 A1), D7 and D16 (US 2008/0140189 A1) and involved an inventive step starting from D7 and starting from D6.
- III. Oral proceedings were held before the Board on 25 April 2023.
- IV. The appellant 1 (patent proprietor) 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 based on one of auxiliary requests 1 to 7, submitted with the reply to the statement of grounds of appeal dated 13 November 2020 or on the basis of auxiliary request

8, submitted during the oral proceedings at 14:30 as a further alternative.

The appellant 2 (opponent) requested that the decision under appeal be set aside and that the European patent be revoked.

V. The independent claims 1 and 6 of the main request read as follows:

Claim 1:

A heart valve prosthesis comprising:

a support structure (10) comprising a framework deformable between an expanded state and a compressed state and vice versa; and

a flow-control structure (12), supported by the support structure (10), for permitting blood flow in a first direction, defining an axial direction of the prosthesis, and for restricting blood flow in a direction opposite to the first direction,

wherein the flow-control structure (12) comprises at least one leaflet (16), and wherein the support structure comprises an integral rib (14), curved to match the profile of the radially outer edge of said leaflet (16), and to which the leaflet (16) is attached,

wherein at least one end of the support structure (10) comprises a plurality of apexes of the framework, and wherein the support structure (10) is collapsible from the fully expanded state into the compressed state by pulling on the apexes, to enable it to be drawn into a sheath in the compressed state, the sheath having an inner radial dimension smaller than the radial dimension of the support structure in the expanded state, and

wherein the support structure (10) comprises smoothly curved ribs (14),
wherein the support structure (10) comprises a first set of petal-like portions (14a) that protrude beyond the flow-control structure axially in the direction opposite to the first direction, and protrude radially further than the flow-control structure (12), and **characterized in that** the support structure (10) is at least one bent wire in the form of the framework.

Claim 6:

A method of collapsing a heart valve prosthesis,
the method comprising:
providing a prosthesis as defined in any preceding claim;
pulling on the apexes of the prosthesis when in the expanded state, to commence collapse into the compressed state; and
drawing the prosthesis into a sheath (44) having an inner radial dimension smaller than the radial dimension of the support structure (10) in the expanded state.

VI. Auxiliary request 1

Claim 1 of auxiliary request 1 corresponds to claim 1 of the main request with the addition of the following feature:

"wherein the at least one wire is bent to form the framework".

Claim 6 of auxiliary request 1 corresponds to claim 6 of the main request.

VII. Auxiliary request 2

Claim 1 of auxiliary request 2 is identical to claim 1 of the main request.

Claim 6 of auxiliary request 2 corresponds to claim 1 of the main request with the addition of the feature:
"wherein the method is performed on the heart valve prosthesis ex vivo"

VIII. Auxiliary request 3

Claim 1 of auxiliary request 3 corresponds to claim 1 of the main request with the addition of features referred (d) and (e) in the decision:

(d) *"wherein the support structure comprises a second set of petal-like portions (14b) that protrude beyond the flow-control structure radially further than the flow-control structure",*

(e) *"wherein the first set of petal-like portions and the second set of petal like portions are configured to clamp the structure in position".*

Claim 6 of auxiliary request 3 is identical to claim 6 of auxiliary request 2.

IX. Auxiliary request 4

Claim 1 of auxiliary request 4 corresponds to claim 1 of the main request with the addition of the above recited feature (d) only (without feature (e)).

Claim 6 of auxiliary request 4 is identical to claim 6 of auxiliary request 2.

X. Auxiliary request 5

Claim 1 of auxiliary request 5 corresponds to claim 1 of the main request with the addition of the following feature, referred as feature (f) in the decision:

(f) "wherein loops (40) are provided at the apexes for attaching members for pulling thereon for collapsing the heart valve"

Claim 6 of auxiliary request 5 is identical to claim 6 of auxiliary request 2.

XI. Auxiliary request 6

Claim 1 of auxiliary request 6 corresponds to claim 1 of auxiliary request 5 with the addition of the following feature, referred as feature (g) in the decision:

(g) "wherein the loops (40) are configured to act as torsion springs that reduce the bending stresses acting on the support structure when the valve is collapsed and assist in self-expanding the heart valve to its expanded state".

Claim 6 of auxiliary request 6 is identical to claim 6 of auxiliary request 2.

XII. Auxiliary request 7

Claim 1 of auxiliary request 7 corresponds to claim 1 of the main request with the addition of the following feature, referred as feature (h) in the decision:

(h) "wherein the support structure (10) is a single bent wire in the form of the framework"

Claim 6 of auxiliary request 7 is identical to claim 6 of auxiliary request 2.

XIII. Auxiliary request 8

Claim 1 of auxiliary request 8 corresponds to claim 1 of the main request with the following additional feature, referred as feature (i) in the decision:

(i) *"wherein the support structure (10) is formed from a single wire bent to form the framework"*.

Claim 6 of auxiliary request 8 is identical to claim 6 of auxiliary request 2.

Reasons for the Decision

1. Main request - Novelty over D7 - Article 100(a) and 54 EPC

The subject-matter of claim 1 is not novel over D7.

- 1.1 Appellant 1 argued that D7 did not disclose the following features of claim 1:

- 1.1.1 (a) *"at least one end of the support structure comprises a plurality of apexes of the framework, and wherein the support structure is collapsible from the fully expanded state into the compressed state by pulling on the apexes, to enable it to be drawn into a sheath in the compressed state, the sheath having an inner radial dimension smaller than the radial dimension of the support structure in the expanded state"*.

In particular, appellant 1 considered that there was no direct and unambiguous disclosure that the stent of figure 50 of D7 could be delivered with the delivery process and device of figures 22-28 of D7.

- 1.1.2 (b) *"the support structure is at least one bent wire in the form of the framework"*.

Appellant 1 argued that feature (b) limited the support structure to be manufactured using wires drawn and subsequently bent to form the framework. Stents manufactured by laser cutting out the wall of a tube were not covered by claim 1. Appellant 1 referred to paragraph [0019] of the patent, where the alternative of the support structure *"formed by laser-cutting out the wall of a tube and then forming into shape"* had been deleted to bring it in conformity with the support structure of claim 1 which was limited to *"at least one bent wire in the form of the framework"*.

The stent of figure 50 in D7 was made by laser cut out the wall of a tube as could be recognised from the seamless three-way joints. Therefore figure 50 did not anticipate feature (b).

- 1.1.3 (c) *"wherein the support structure comprises a first set of petal-like portions that protrude radially further than the flow-control structure"*.

D7 did not include any plan view of the embodiment shown in figure 50. Accordingly, there was no unambiguous disclosure that the lower flanges 450 extended radially further than the curved structures that connected the bottoms of the vertical members 452.

- 1.2 The Board holds that features (a), (b) and (c) are disclosed in D7:

- 1.2.1 In particular, figure 50 and the related paragraph [0121] disclose a stent 444 that *"includes upper connecting members 448 that can be used for engagement with a delivery system during the delivery and*

positioning process". While there is no reference to the specific delivery system of figures 22-28 in paragraph [0121], the stent structure delivered in figures 22-28 is similar to the stent structure represented on figure 50; in particular both stents comprise upper connecting members with grooves for engaging the delivery system. The skilled person would therefore directly and unambiguously derive that the delivery system used in figures 22-28 is suitable for the stent of figure 50.

Furthermore, figures 22-28 sequentially illustrate a delivery process for percutaneous delivery of a self-expanding type of stent into a prosthetic heart valve 320 and the related paragraph [0107] disclose that: *"Advantageously, after deployment of at least part of the stent 328, as shown in FIGS. 23-25, for example, the stent 328 can be retracted back into the delivery system 324 if desired or necessary, due to the continued engagement between the upper connecting members 334 and the engagement devices 340. That is, the delivery systems and stents of the invention advantageously provide opportunities for stent repositioning that are not typically available in the deployment of self-expanding stents", and the method claim 1 of D7 comprises the step of: "verifying the placement of the replacement valve; at least partially recompressing the replacement valve within the sheath of the delivery system; repositioning the delivery system with the compressed replacement valve relative to the implantation site". Feature (a) is thus anticipated by the teaching of D7.*

- 1.2.2 As for feature (b), the Board considers that this feature refers to the end shape of the support structure. The term "bent wire" recited in the claim for defining the end product "heart valve prosthesis"

does not necessarily require that it was made from a wire which was drawn and subsequently bent. The bent wires could also be made by cutting out a wall of a tube, the term "bent" simply refers to the form of the wire and not to the production process. Indeed, claim 1 does not limit the bent wire to be manufactured in any specific way. Therefore, the support structure of figure 50 is at least one bent wire in the form of a framework.

Moreover, the argument of appellant 1 that the description has been brought in conformity with the claims by deleting the support structure formed by laser-cutting out the wall of a tube is not convincing. Indeed, it is the claim wording itself that defines its scope, which is broad as explained herein above and cannot be construed as excluding a possible interpretation for the mere reason that there is no longer a corresponding embodiment in the description.

- 1.2.3 As for feature (c), should the stent 444 be made by laser cutting without any subsequent bending and the flanges be added subsequently as argued by appellant 1, then the upper and the lower connecting members extend radially to the same extent. The tissue structure 446 being attached to the interior of the stent, the upper and the lower connecting members will extend beyond the flow control structure made of the tissue structure in the closed state. The lower flanges 450 that are said to "serve as anchors with the native valve structure" in paragraph [0121] extend radially further away from the lower connecting members. This is confirmed by figure 50, where the two flanges' apex represented on each side of figure 50 extend beyond the ones of the lower connecting members. Therefore, the flanges extend unambiguously radially beyond the flow-control structure and anticipate feature (c).

2. Auxiliary request 1 - Article 53(c) EPC

2.1 The opposition division exercised its discretion to admit the late filed objection under Article 53(c) EPC regarding the method claim 6. The opposition division did so in a reasonable manner, in accordance with the right principles. The method claim 6 of collapsing a heart valve prosthesis was rightly considered by the opposition division as a method for treatment of the human body by surgery excluded from patentability pursuant Article 53(c) EPC.

2.1.1 Appellant 1 argued that the opposition division should not have admitted the new objection under Article 100(a) EPC in respect of Article 53 EPC.

The new objection under Article 100(a) in respect of Article 53 EPC was filed only two weeks before the scheduled date of the oral proceedings, well after the deadline for making written submissions (Article 116 EPC). Prior to that deadline, the opponent's representatives had filed two other submissions citing late filed documents but choosing to hold back the new objection under Article 100(a) in respect of Article 53 EPC until after the final date for making written submissions. There was no good reason for the new ground to be filed late.

The opposition division decided to admit the late filed ground into the proceedings based on a manifestly incorrect technical assumption. The assumption was that the skilled person reading claim 6 would unambiguously identify claim 6 as a surgical method. This technical assumption was incorrect because claim 6 did not specify any interaction with the human or animal body.

This incorrect assumption amounted to a misuse of discretionary power under Article 114(2) EPC. Accordingly, the Board of Appeal had the power to overrule the decision to admit the late filed ground.

- 2.1.2 Appellant 1 further argued that none of the steps of the method claims 6 comprised any surgical step:
- *"pulling on the apexes of the prosthesis when in the expanded state, to commence collapse into the compressed state"* related to an action (pulling) performed on part of the apparatus, and a respective reaction (collapse) of the apparatus. Such manipulation of an apparatus did not constitute a method step for treatment of a human or animal body by surgery.
 - *"drawing the prosthesis into a sheath having an inner radial dimension smaller than the radial dimension of the support structure in the expanded state"* related to the interaction between the prosthesis and another piece of apparatus, namely the sheath. Interaction between the prosthesis and the sheath of the delivery system did not constitute a method step for treatment of a human or animal body by surgery.
- Claim 6 did not specify any interaction between the claimed method and the human body.

Furthermore, there was no surgical nature of the method steps of claim 6 and no evidence (e.g. a risk matrix) was provided that could justify why health risks associated with the method of claim 6 were substantial. Furthermore, claim 6 of the patent as granted should not be excluded from patentability merely for the reason that it did not explicitly exclude the possibility of a surgical step being performed temporally at the same time as the claimed method.

Finally, it was not typically required for a claimed method to specify that it was performed ex vivo, regardless of whether or not the method could in theory be performed inside a human or animal body.

- 2.1.3 The Board judges that the late filed objection of exception to patentability under Article 53(c) EPC raised by the opponent on 19 November 2019, only two weeks before the date of the oral proceedings, regarding method claim 6 had been correctly admitted by the opposition division, using the right criteria. According to Article 53(c) EPC European patents shall not be granted in respect of methods for treatment of the human body by surgery on the human body. Following G1/07, the opposition division considered that claim 6, defining a method of collapsing a heart valve prosthesis in vivo is prima facie a method for treatment of the human body by surgery. Indeed, while dependent claim 10 limits the method on the heart valve to be performed ex vivo, claim 6 covers both performing the method in vivo and ex vivo. This interpretation is supported by paragraph [0031] of the description, which discloses the possible need of the heart valve to be repositioned during endovascular surgery.

The opposition division has correctly applied the criteria for considering whether a method claim is a method for treatment of the human body by surgery. Indeed, the method of claim 6 in which, when carried out in vivo, maintaining the life and health of the subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise, is excluded

from patentability as a method for treatment of the human or animal body by surgery pursuant to Article 53(c) EPC.

According to G 1/07, a method claim falls under the exclusion from patentability if it comprises or encompasses at least one feature defining a physical activity or action that constitutes a method step for the treatment of the human or animal body by surgery or therapy. In the present case, *"pulling on the apexes of the prosthesis in the expanded state"* in vivo, so when the prosthesis is located into the human body, is a surgical step. Indeed, there is an implicit direct interaction between the valve and the heart of the patient. Therefore, the opposition division has rightly concluded that the method of claim 6 was excluded from patentability pursuant Article 53(c) EPC

3. Auxiliary request 2 - novelty over D7 - Article 54 EPC

The subject-matter of claim 1 of auxiliary request 2 is identical to the one of claim 1 of the main request and is therefore not novel over D7 for the same reasons as for the reasons given above for the main request.

4. Auxiliary requests 3 - Novelty over D7 - Article 54 EPC

The subject-matter of claim 1 is not novel over D7.

4.1 Appellant 1 argued that D7 did not disclose the added features:

4.1.1 *(d) wherein the support structure comprises a second set of petal-like portions (14b) that protrude beyond the flow-control structure radially further than the flow-control structure.*

Appellant 1 pleaded that the radial position of the upper connecting members 448 in figure 50 of D7 matched the outer edge of the tissue structure 446 rather than radially protruding further than the tissue structure. There was no space in the radial direction between the upper connecting members and the tissue structure in figure 50. Appellant 1 further argued that when the tissue structure 446 expanded to its open position, the leaflet may expand radially further than the upper connecting member.

- 4.1.2 *(e) wherein the first set of petal-like portions and the second set of petal like portions are configured to clamp the structure in position.*

Appellant 1 argued that in figure 50, the connecting members 448 did not clamp the structure in position. Only the lower flanges served as anchors with the native valve structure.

- 4.2 The Board does not agree. Both features (d) and (e) are disclosed in the embodiment of figure 50 of D7.

- 4.2.1 Feature (d) requires that the petal like portions protrude radially further than the flow control, without specifying how much the petal like portions should radially extend beyond the flow control. Feature (d) does not define a radial gap between the flow control structure and the set of petals and encompasses a set where the petal like portions are just on the outside of the flow control structure. Therefore the upper connecting members which extend radially at the same distance as the lower connecting members which are attached to the outer edges of the flow-control structure extend radially further than the flow control

structure. Furthermore as mentioned by appellant 2, the leaflets are unlikely to extend radially beyond the support structure during opening of the flow control structure. But in any event feature (d) does not specify that the petal like portion should protrude radially beyond the flow control structure in its open position.

4.2.2 Feature (e) defines that the petal like portions are configured to clamp the structure in position. The Board notes that as long as the petal like portions can apply a certain pressure on the tissue where the heart valve prosthesis is to be implanted, the petal like portions are configured to clamp the structure in position. Indeed claim 1 does not specify the type of prosthetic valve (mitral valve, tricuspid valve, aortic valve or pulmonary valve) and does not indicate the anatomy of the site where the heart valve prosthesis is to be implanted. The upper connecting member 448 protruding just beyond the tissue structure and the lower flanges protruding further away, depending on the insertion site, can apply a radial pressure on the surrounding tissue and are therefore configured to clamp the structure in position.

5. Auxiliary request 4 - Novelty over D7 - Article 54 EPC

Claim 1 of auxiliary request 4 is broader than claim 1 of auxiliary request 3 as it corresponds to claim 1 of auxiliary request 3 without the above-mentioned feature (e). The subject-matter of claim 1 of auxiliary request 4 is therefore not novel over D7 for the same reasons as for auxiliary request 3.

6. Auxiliary request 5 - Novelty over D7 - Article 54 EPC

The subject-matter of claim 1 of auxiliary request 5 is not novel over D7.

- 6.1 Appellant 1 was of the opinion that feature (f):
"wherein loops (40) are provided at the apexes for attaching members for pulling thereon for collapsing the heart valve"
was not directly and unambiguously disclosed in D7 in relation with the embodiment of figure 50.

In their view, the disclosure in D7, paragraph [0121], of the connecting members having the shape of a coil did not imply that loops were provided at the apexes. Loops required that the wire, after being curved, came in contact with the wire again to close the open curve, or at least came very close to it. Whereas in coils after curving the wire, the wire did not usually come close to the wire again. A significant gap was present between the curves of the wire.

Furthermore, the disclosure of loops as an alternative connection feature to grooves disclosed in paragraph [0105] was made in relation with the embodiment of figures 22 to 27 and not in relation with the embodiment of figure 50.

- 6.2 The Board does not agree. Paragraph [0121] relating to the embodiment of figure 50 discloses that the connecting members can have a different structure than a simple curved structure that facilitates compression and expansion of the stent, for example, a coiled shape. Coils imply that loops are provided at the apexes of the connecting members that are suitable for pulling thereon for collapsing the heart valve. Indeed, coils are made of successive loops regardless of the gap between the curves of the wires. The Board notes

that claim 1 does not specify the loop and in particular that it is a closed or nearly closed loop.

In any case, the disclosure of the loops as an alternative connection feature to the grooves in paragraph [0105] relating formally to figures 22-27, is a direct and unambiguous disclosure to the skilled person that loops, like grooves, are suitable engagement features. That suitability concerns all embodiments of D7 that comprise a similar upper connecting member, that is to be used for engagement with a delivery system. This is clearly the case for the embodiment of figure 50 comprising upper connecting members each with a groove at its apex for engagement with a delivery system (see paragraph [0121]).

7. Auxiliary request 6 - Added Subject-matter - Article 123(2) EPC.

The subject-matter of claim 1 of auxiliary request 6 is based on claim 1 of auxiliary request 5 with the addition of feature (g): *"wherein the loops (40) are configured to act as torsion springs that reduce the bending stresses acting on the support structure when the valve is collapsed and assist in self-expanding the heart valve to its expanded state"*.

The added feature (g) extends beyond the content of the application as originally filed.

- 7.1 Appellant 1 referred to page 7, lines 22-25 of the application as filed for the basis of feature (g): *"These loops 40 have several functions. One is to enable a filiform material to be attached securely to pull on the device to enable it to be collapsed and/or retrieved, as will be described further below. Another function is that when the support structure is formed*

from bent wire as illustrated in Fig. 4, then the loops 40 act as torsion springs that reduce the bending stresses acting on the support structure when the valve is collapsed and assist in self-expanding the heart valve to its expanded state".

- 7.2 As argued by appellant 2, feature (g) added to the subject-matter of claim 1 leads to an unallowable intermediate generalisation. Page 7, lines 22-25 of the application as filed discloses the torsion spring's function of the loops in the context of figures 4 and 5, which are support structures formed from wires which have been bent to form the framework. The embodiment of figure 9 also comprises loops acting as a torsion spring in a structure which is made from wires that are subsequently bent to form the framework. However, claim 1 does not define that the support structure is formed from bent wires, but that the support structure is at least one bent wire, thus not excluding that the support structure is obtained by laser-cutting out the wall of a tube ("bent wire", see above, main request) or that the structure is only formed in part by bent wires. However, the function of the loops acting as torsion springs is described on page 7 in connection with figures 4 and 5 in relation with the whole support structure being formed from bent wires. The torsion springs indeed provide a reduction of the bending stresses acting on the support structure when the valve is collapsed and assist in self-expanding the heart valve to its expanded state, whereby the whole support structure formed by bent wires is affected by and reacts to the elastic forces generated by the torsion springs.

8. Auxiliary request 7 - Added subject-matter - Article 123(2) EPC

The subject-matter of claim 1 is a combination of claim 1 of the main request with feature (h) "wherein the support structure (10) is a single bent wire in the form of the framework".

8.1 According to appellant 1, basis for the added feature was original claim 4 and page 5, lines 1-7 of the application as filed.

8.2 The Board however follows the view of appellant 2 that neither original claim 4, nor page 5, lines 1-7 can form the basis for feature (h). Indeed a single bent wire in the form of a framework encompasses framework made of a single drawn wire which is subsequently bent and a wire which is obtained by laser cutting out the wall of a tube. However, in the application as filed, the single bent wire is only disclosed for a wire which is bent to form the framework.

The Board notes that the subject-matter of claim 1 is not a combination of claim 1 of the main request with original claim 4. Indeed the wording added to claim 1 is different from the wording of original claim 4. While original claim 4 reads: "*A prosthesis according to claim 1, 2 or 3, wherein the support structure is formed from a single wire bent to form a framework*", the feature added to claim 1 reads: "*wherein the support structure (10) is a single bent wire in the form of the framework*", which does not make the distinction whether the framework is made from a single wire which is subsequently bent or from a single wire having a bent shape and obtained by laser cutting out of a wall of a tube.

Similarly the passage on page 5, lines 1-7 reading: "*In fact, as illustrated, the entire support structure 10 can be made from a single wire that is bent into the*

appropriate shape. The starting wire could be a loop or could be a straight wire; if a straight wire, the two free ends may optionally be joined together", clearly refers to a single wire which is subsequently bent and does not encompass wires made by laser cutting out the wall of a tube.

9. Auxiliary request 8 - Admissibility - Article 13(2) RPBA 2020

Appellant 1 filed auxiliary request 8 during the oral proceedings. The subject-matter of claim 1 being a combination of claim 1 of the main request with original claim 4 (using the wording of original claim 4).

The Board does not take into account auxiliary request 8 pursuant Article 13(2) RPBA 2020 as it constitutes an amendment to appellant 1's appeal case in the absence of exceptional circumstances justified with cogent reasons.

9.1 Appellant 1 argued that the auxiliary requests submitted with their reply to the statement of grounds of appeal were designed to provide a small number of them. The auxiliary requests were designed to address some of the foreseeable eventualities. However, not every eventuality was foreseeable and therefore appellant 1 requested to be allowed to amend the auxiliary requests in an appropriate manner during the proceedings. For example, by combining auxiliary requests in the light of decisions on certain grounds or introduce new requests, for example, if new facts or arguments were put forward by the appellant 1.

They held that auxiliary request 8 used a similar wording as the one used in auxiliary request 1 to limit the claim to wires that are bent to form the framework, thereby distinguishing it from the framework made by laser cutting out of the wall of a tube. Auxiliary request 8 was a direct response to the findings of the Board that auxiliary request 7 did not meet the requirement of Article 123(2) EPC.

- 9.2 The Board considers that there are no exceptional circumstances for admitting auxiliary request 8 filed during oral proceedings, representing an amendment to appellant 1's appeal case. Indeed the issue with the wording of a *"bent wire in the form of the framework"* encompassing both wires drawn that are subsequently bent and bent wires resulting from the cutting out of the wall of a tube was raised by appellant 1 at the outset of the opposition proceedings and reiterated in the statement of grounds of appeal. The objection of added subject-matter regarding feature (h) was raised in appellant 2's statement of grounds of appeal (reference is made to page 57 of appellant 2's statement of grounds of appeal) in relation with the seventh auxiliary request filed in opposition not pursued by appellant 1 in appeal.

The Board notes that each party to the appeal proceedings had to present their own case at the outset rather than after the Board confronted them with an unfavourable opinion. According to the Rules of Procedure of the Boards of Appeal 2020, a party's complete case, including all auxiliary requests, should be filed with the statement of grounds of appeal and the reply.

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. Vottner

G. Pricolo

Decision electronically authenticated