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Datasheet for the decision of 4 April 2022

Case Number: T 2514/18 - 3.2.02

Application Number: 14806770.5

Publication Number: 3043735

IPC: A61B18/14, A61B5/00, A61B17/00, A61B90/00

Language of the proceedings: EN

Title of invention:
MEDICAL DEVICE WITH CONTACT FORCE SENSING TIP

Applicant:
St. Jude Medical, Cardiology Division, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - (no)
Amendment after summons - exceptional circumstances (no)
- taken into account (no)

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Decisions cited:

Catchword:

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Case Number: T 2514/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 4 April 2022

Appellant: (Applicant)	St. Jude Medical, Cardiology Division, Inc. 177 East County Road B St. Paul, MN 55117 (US)
Representative:	Kramer Barske Schmidtchen Patentanwälte PartG mbB European Patent Attorneys Landsberger Strasse 300 80687 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 25 May 2018 refusing European patent application No. 14806770.5 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The applicant has appealed against the Examining Division's decision, posted on 25 May 2018, to refuse European patent application No. 14 806 770.5 for lack of inventive step of the subject-matter of claim 1 of the main request and of auxiliary request 1.

II. The Board summoned the appellant to oral proceedings and sent its preliminary opinion in a communication dated 20 January 2022. In the communication the Board expressed the view that the subject-matter of claim 1 of all the requests lacked inventive step.

III. Oral proceedings took place on 4 April 2022.

The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request, filed by letter dated 26 July 2017, or alternatively on that of auxiliary request 1, filed by letter dated 10 April 2018, auxiliary request 2, filed by letter dated 25 September 2018, auxiliary request 3, filed by letter dated 3 March 2022, or auxiliary request 4, filed by letter dated 4 April 2022.

IV. The following documents are mentioned in this decision:

D2: US 2009/0138007 A1
D4: EP 2 641 555 A1
D6: WO 01/70117 A2

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

"A medical device (16) for the treatment or diagnosis of tissue (12) within a body, comprising:

an elongate, tubular shaft (36) configured to be received within the body, said shaft (36) having a proximal portion (68) and a distal portion (70) configured for movement relative to a distal end (72) of the proximal portion (68) including by movement towards and away from the distal end (72) of the proximal portion (68) along a longitudinal axis of said shaft (36) and by deflection from the longitudinal axis;

a flexible member (76) disposed between the proximal and distal portions (68, 70) of said shaft (36), said flexible member (76) having a predetermined stiffness;

a first electromagnetic coil (44) which is adapted for creating a magnetic field and which is disposed within said shaft (36); and,

a first electrically passive element (50, 79, 94, 98) disposed within said shaft (36), said first electrically passive element (50, 79, 94, 98) comprising a material effecting [sic] an electrical characteristic of said first electromagnetic coil (44),

wherein one of said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98) is configured for movement with the distal portion (70) of the shaft (36) and relative to the other of said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98), relative movement between said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98) in response to contact of the distal portion (70) with the tissue (12) and deformation of said flexible member (76) causing a change in the

electrical characteristic in said first electromagnetic coil (44), the change indicative of said deformation of said flexible member (76) and at-least a contact force magnitude between the distal portion (70) and the tissue (12)."

Claim 1 of auxiliary request 1 reads as follows (amendments over claim 1 of the main request highlighted by the Board):

"A medical device (16) for the treatment or diagnosis of tissue (12) within a body, comprising:

an elongate, tubular shaft (36) configured to be received within the body, said shaft (36) having a proximal portion (68) and a distal portion (70) configured for movement relative to a distal end (72) of the proximal portion (68) including by movement towards and away from the distal end (72) of the proximal portion (68) along a longitudinal axis of said shaft (36) and by deflection from the longitudinal axis;

a flexible member (76) disposed between the proximal and distal portions (68, 70) of said shaft (36), said flexible member (76) having a predetermined stiffness;

a first electromagnetic coil (44) which is adapted for creating a magnetic field and which is disposed within the proximal portion (68) of said shaft (36); and,

a first electrically passive element (50, 79, 94, 98) disposed within the distal portion (68) of said shaft (36), said first electrically passive element (50, 79, 94, 98) comprising a material effecting [sic] an electrical characteristic of said first electromagnetic coil (44),

wherein ~~one of said first electromagnetic coil (44) and~~ said first electrically passive element (50, 79, 94, 98) is configured for movement with the distal portion (70) of the shaft (36) and relative to the ~~other of said~~ first electromagnetic coil (44) ~~and said first electrically passive element (50, 79, 94, 98)~~, relative movement between said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98) in response to contact of the distal portion (70) with the tissue (12) and deformation of said flexible member (76) causing a change in the electrical characteristic in said first electromagnetic coil (44), the change indicative of said deformation of said flexible member (76) and at_-least a contact force magnitude between the distal portion (70) and the tissue (12)."

Claim 1 of auxiliary request 2 reads as follows (amendments over claim 1 of auxiliary request 1 highlighted by the Board):

"A medical device (16) for the treatment or diagnosis of tissue (12) within a body, comprising:

an elongate, tubular shaft (36) configured to be received within the body, said shaft (36) having a proximal portion (68) and a distal portion (70) configured for movement relative to a distal end (72) of the proximal portion (68) including by movement towards and away from the distal end (72) of the proximal portion (68) along a longitudinal axis of said shaft (36) and by deflection from the longitudinal axis;

a flexible member (76) disposed between the proximal and distal portions (68, 70) of said shaft (36), said flexible member (76) having a predetermined stiffness;

a first electromagnetic coil (44) which is adapted for creating a magnetic field and which is disposed entirely within the proximal portion (68) of said shaft (36); and,

a first electrically passive element (50, 79, 94, 98) disposed within the distal portion (68) of said shaft (36), said first electrically passive element (50, 79, 94, 98) comprising a material effecting [sic] an electrical characteristic of said first electromagnetic coil (44),

wherein said first electrically passive element (50, 79, 94, 98) is configured for movement with the distal portion (70) of the shaft (36) and relative to the first electromagnetic coil (44), relative movement between said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98) in response to contact of the distal portion (70) with the tissue (12) and deformation of said flexible member (76) causing a change in the electrical characteristic in said first electromagnetic coil (44), the change indicative of said deformation of said flexible member (76) and at least a contact force magnitude between the distal portion (70) and the tissue (12)."

Claim 1 of auxiliary request 3 reads as follows (amendments over claim 1 of the main request highlighted by the Board):

"A medical device (16) for the treatment or diagnosis of tissue (12) within a body, comprising:

an elongate, tubular shaft (36) configured to be received within the body, said shaft (36) having a proximal portion (68) and a distal portion (70) configured for movement relative to a distal end (72) of the proximal portion (68) including by movement towards and away from the distal end (72) of the

proximal portion (68) along a longitudinal axis of said shaft (36) and by deflection from the longitudinal axis;

a flexible member (76) disposed between the proximal and distal portions (68, 70) of said shaft (36), said flexible member (76) having a predetermined stiffness;

a first electromagnetic coil (44) which is adapted for being both electrically excited and transmitting electrical signals ~~creating a magnetic field~~ and which is disposed within said shaft (36); and,

a first electrically passive element (50, 79, 94, 98) disposed within said shaft (36), said first electrically passive element (50, 79, 94, 98) comprising a material effecting [sic] an electrical characteristic of said first electromagnetic coil (44),

wherein one of said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98) is configured for movement with the distal portion (70) of the shaft (36) and relative to the other of said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98), relative movement between said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98) in response to contact of the distal portion (70) with the tissue (12) and deformation of said flexible member (76) causing a change in the electrical characteristic in said first electromagnetic coil (44), the change indicative of said deformation of said flexible member (76) and at-least a contact force magnitude between the distal portion (70) and the tissue (12)."

Claim 1 of auxiliary request 4 reads as follows (amendments over claim 1 of the main request

highlighted by the Board):

"A system for the treatment or diagnosis of tissue within a body, comprising a medical device (16) for the treatment or diagnosis of tissue (12) within a body, comprising:

an elongate, tubular shaft (36) configured to be received within the body, said shaft (36) having a proximal portion (68) and a distal portion (70) configured for movement relative to a distal end (72) of the proximal portion (68) including by movement towards and away from the distal end (72) of the proximal portion (68) along a longitudinal axis of said shaft (36) and by deflection from the longitudinal axis;

a flexible member (76) disposed between the proximal and distal portions (68, 70) of said shaft (36), said flexible member (76) having a predetermined stiffness;

a first electromagnetic coil (44) which is adapted for being both electrically excited and transmitting electrical signals ~~creating a magnetic field~~ and which is disposed within said shaft (36); and,

a first electrically passive element (50, 79, 94, 98) disposed within said shaft (36), said first electrically passive element (50, 79, 94, 98) comprising a material effecting [sic] an electrical characteristic of said first electromagnetic coil (44),

wherein one of said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98) is configured for movement with the distal portion (70) of the shaft (36) and relative to the other of said first electromagnetic coil (44) and said first electrically passive element (50, 79, 94, 98), relative movement between said first electromagnetic coil (44) and said first electrically passive element

(50, 79, 94, 98) in response to contact of the distal portion (70) with the tissue (12) and deformation of said flexible member (76) causing a change in the electrical characteristic in said first electromagnetic coil (44), the change indicative of said deformation of said flexible member (76) and at-least a contact force magnitude between the distal portion (70) and the tissue (12); and,

an electronic control unit (24) configured to determine a specific contact force magnitude responsive to a signal generated by said first electromagnetic coil (44, 46, 48) indicative of the change in the electrical characteristic of said first electromagnetic coil (44, 46, 48), wherein the electronic control unit (24) itself excites the first electromagnetic coil (44) and measures the change in the electrical characteristic on the first electromagnetic coil (44) during operation of the system."

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

The subject-matter of claim 1 of the main request and of auxiliary requests 1 and 2 differed from the disclosure of D2 not only in the definition of an electrically passive element, but also in that the device of D2 comprised a first electromagnetic coil and an electrically active element both disposed within a flexible member, not within a proximal or distal portion of a shaft. The whole element 60 (Figure 3) of the device of D2 was a flexible member within the meaning of claim 1 of the appellant's requests, since the whole element 60 was flexible. Such a flexible element with a first electromagnetic coil and an electrically active element both disposed in its interior was also disclosed in D4. Hence it was a

technically viable solution.

Moreover, D2 did not disclose that the first electromagnetic coil was adapted for creating a magnetic field. The coil was not supplied with any current other than the electric current induced by the movement of the electrically active element. According to the application, two magnetic fields rather than one were used for determining the contact force between the medical device and tissue to be treated.

The distinguishing features of the subject-matter of claim 1 of all the requests addressed the objective technical problem of constructing a device which caused fewer injuries and worked more reliably, in particular because the determination of the deformation of the flexible member and of the contact force between the distal portion and the tissue was improved.

D6 did not give any indication that it would be advantageous to arrange a first coil in a proximal portion of a catheter shaft and an electrically passive element in a distal portion of a catheter shaft in order to measure the contact force between the medical device and the tissue more accurately. There were many ways of improving the accuracy of the measurement, such as using other sensors or other materials for the catheter shaft portion. Moreover, the use of an electrically passive element in the form of a permanent magnet could also be regarded as a non-obvious alternative to the use of an electrically active element in the form of a coil, as disclosed in D2. For these reasons, the subject-matter of claim 1 of all the requests involved an inventive step.

Auxiliary requests 3 and 4 had been filed after the

summons to oral proceedings in response to the Board's preliminary opinion, which made the appellant change its mind and focus on a more precise definition of the first electromagnetic coil adapted for being both electrically excited (by an electronic control unit) and transmitting signals. That occurred in particular on the weekend before the oral proceedings, when the case was reviewed thoroughly. It had always been the appellant's intention to emphasise this feature, which was not known from the prior art. For these reasons auxiliary requests 3 and 4 should be admitted into the appeal proceedings.

Reasons for the Decision

1. The invention

The invention relates to a medical device for the treatment or diagnosis of tissue within a body.

The detailed description of the embodiments of the invention focuses on an ablation catheter for treating atrial fibrillation. Such a catheter is inserted into the heart and is used to deliver electrodes for electrophysiological mapping of the heart surface and to deliver ablative energy to the heart surface. The ablative energy forms lesions of the heart surface. The scar tissue helps break up anomalous electrical signals that cause irregular heartbeats.

A medical device according to claim 1 of all the requests comprises an elongate, tubular shaft with a proximal portion and a distal portion. A distal part of the medical device is depicted in Figure 3 of the application, reproduced below.

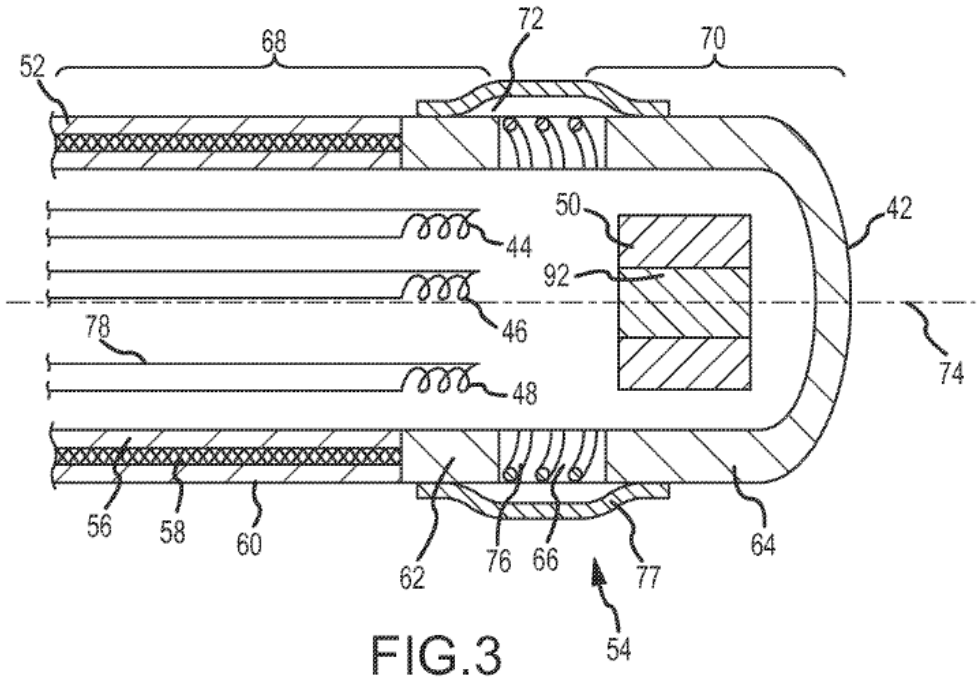

FIG.3

The elongate, tubular shaft has a proximal portion (68) and a distal portion (70).

A flexible member (76) is disposed between the proximal and the distal portions. The distal portion is configured for movement relative to a distal end (72) of the proximal portion. This movement is made possible in particular by the flexible member disposed between the two shaft portions.

An electromagnetic coil (44) and an electrically passive element (50) comprising a material affecting an electrical characteristic of the coil are disposed within the shaft. One of the two elements is configured for movement with the distal portion of the shaft relative to the other element. When the movement occurs, the flexible member is deformed and a change in the electrical characteristic of the coil takes place. This change is indicative of the deformation of the

flexible member and of a contact force magnitude between the distal portion and the tissue.

The electrically passive element is typically a magnet. Its relative movement with respect to the coil changes the magnetic field produced by the magnet at the location of the coil. By detecting and measuring this change in the magnetic field (by measuring the current generated in the coil by the change) the amount of movement, and hence the deformation of the flexible member which is indicative of a contact force with tissue, is quantified.

Ensuring sufficient contact with tissue is necessary to provide meaningful mapping of the heart and to effectively form ablative lesions in the tissue. The claimed medical device may be helpful in ensuring such sufficient contact.

2. Main request and auxiliary requests 1 and 2 - lack of inventive step

2.1 It is common ground that D2 can be considered the closest prior art for the subject-matter of claim 1 of the main request and of auxiliary requests 1 and 2.

D2 discloses a medical device for the treatment or diagnosis of tissue within a body (paragraph [0023] and Figures 1 and 2), in particular for cardiac catheterisation.

Figure 3 of D2, reproduced below, depicts a distal part of the medical device disclosed in the document.

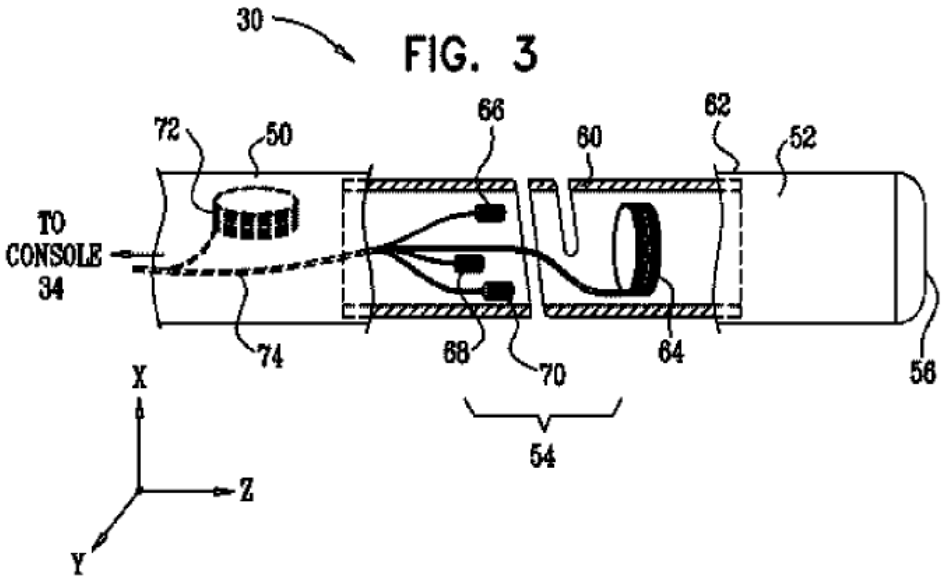

FIG. 3

The medical device comprises an elongate tubular shaft (distal part 30 of a catheter) configured to be received within the body.

The tubular shaft has a proximal portion (comprising insertion tube 50) and a distal portion (comprising distal tip 52), which are described in particular in paragraph [0028] of D2.

The distal portion is for movement relative to a distal end of the proximal portion including by movement towards and away from the distal end of the proximal portion along a longitudinal axis of said shaft ("compressions" mentioned in paragraph [0022]) and by deflection from the longitudinal axis ("deflections" also mentioned in paragraph [0022]).

The medical device further comprises a flexible member with a predetermined stiffness (that part of coupling member 60 provided with a helical cut along a portion of its length, see also paragraph [0031]) disposed between the proximal and distal portions of the shaft.

In this respect those parts of the shaft proximal and distal to the helical cut, including respective parts of coupling member 60 of elastic joint 54 (clearly depicted in Figure 2 as well), are considered the proximal portion and the distal portion within the meaning of the claims.

The medical device comprises a first electromagnetic coil (coil 66) which is adapted for creating a magnetic field, and a first electrical element (coil 64) affecting an electrical characteristic of the first electromagnetic coil. The interaction between coils 64 and 66 is described in detail in paragraphs [0033] and [0034].

In view of the interpretation explained above by reference to the helical cut, the first electromagnetic coil is disposed entirely within the proximal portion of the shaft, and the first electrical element is disposed within the distal portion of the shaft (see also paragraph [0034], first sentence).

The first electrical element is configured for movement with the distal portion of the shaft and relative to the first electromagnetic coil. The relative movement between the first electromagnetic coil and the first electrical element in response to contact of the distal portion with the tissue and the deformation of the flexible member cause a change in the electrical characteristic in said first electromagnetic coil, the change being indicative of the deformation of the flexible member and a contact force magnitude between the distal portion and the tissue (paragraphs [0032] and [0036]).

2.2 The appellant argued that in the device of D2 first electromagnetic coil 66 was not disposed, at least not entirely, within the proximal portion of the elongated shaft and that coil 64 was not disposed within the distal portion of the shaft.

As explained in the preliminary opinion and in the oral proceedings, the Board's view is that the helical member resulting from the helical cut in coupling member 60 can be regarded as the flexible member within the meaning of the claims. This helical member performs the function of a coil spring and is responsible for the relative movement between insertion tube 50 and distal tip 52 of the device of document D2. Considering those parts of the elongated tubular shaft proximal and distal to the helical member as the proximal and distal portions of the shaft within the meaning of claim 1, it is apparent from Figure 3 and paragraph [0034] of D2 that coil 66 is entirely disposed within the proximal portion and that coil 64 is disposed within the distal portion. Hence it is a matter of definition of a member which may be regarded as the flexible member within the meaning of claim 1. In this respect it is irrelevant whether the whole coupling member 60 is flexible. The elongated tubular shaft as a whole is flexible too. It is also irrelevant whether D4 discloses a flexible element with a first electromagnetic coil and an electrically active element both disposed in its interior, since the disclosure of D2 is decisive in this respect.

2.3 The appellant also argued that D2 did not disclose that the first electromagnetic coil was adapted for creating a magnetic field.

However, any coil is adapted for creating a magnetic

field if current flows thorough it. In the case of the device of D2, the fact that current must flow through the coil is even fundamental to its purpose, which is to measure the deformation of the flexible member and a contact force magnitude between the distal portion and the tissue. It is this current which is generated by and indicative of the movement of coil 64 relative to coil 66.

Whether coil 66 of the device of D2 may be supplied with current other than the electric current induced by the movement of coil 64 is irrelevant, as the subject-matter of claim 1 of the main request and auxiliary requests 1 and 2 is not limited to such a situation. In this respect it is also irrelevant whether the application describes two magnetic fields rather than one being used for determining the contact force. The claims, which normally generalise the specific disclosure of a patent application, define the matter for which protection is sought.

As a side remark, even if the supply of an additional current had been defined in the independent claims, the Board cannot see why, and the appellant could not explain how, such a supply would have resulted in an improvement of the measurement.

2.4 It follows that the subject-matter of claim 1 of the main request and auxiliary requests 1 and 2 differs from the disclosure of D2 only in that the first electrical element is an electrically passive element, e.g. a permanent magnet.

As also found by the Examining Division in the impugned decision, this feature addresses the objective technical problem of providing a less complex and more

compact sensor tip. This is in accordance with the application as filed, which states the problem of the invention in paragraph [0045].

The problem formulated by the appellant cannot be accepted, as avoiding injuries and working more reliably is in no apparent relation to the distinguishing feature.

It is common ground that the person skilled in the art, at the time of filing of the application, knew that a permanent magnet may be equivalent to a coil for the purpose of generating a constant magnetic field. This is also the kind of magnetic field needed for the sensor of D2.

Using such a magnet in a catheter tip for insertion into the heart was also specifically known from D6 (magnet 96, Figure 9; page 1, line 18 to page 2, line 13; and page 13, lines 12 to 27). Moreover, it would have been immediately clear to the person skilled in the art that using a permanent magnet would have reduced space requirements and complexity, since a permanent magnet does not require wiring for generating a constant magnetic field. Finally, D2 itself hints at the possibility of using different kinds of magnetic transducers (paragraph [0033], last sentence).

Hence the person skilled in the art would have combined the teaching of D2 and D6 to solve the objective technical problem. Therefore the subject-matter of claim 1 of the main request and auxiliary requests 1 and 2 would have been arrived at in an obvious way.

It follows that the main request and auxiliary requests 1 and 2 are not allowable for lack of

inventive step (Article 56 EPC).

3. Auxiliary requests 3 and 4 - non-admittance

Auxiliary requests 3 and 4 were filed after notification of the summons to oral proceedings.

According to Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The appellant has not presented any exceptional circumstances which might support the admittance of auxiliary requests 3 and 4 into the appeal proceedings.

In particular, receipt of the Board's preliminary opinion is not an exceptional circumstance as it is a foreseen and usual procedural step in the appeal proceedings. The content of the preliminary opinion could not give rise to exceptional circumstances either as the impugned decision was endorsed in substance. Whether the appellant changed its mind after having read the preliminary opinion is irrelevant for the purposes of Article 13(2) RPBA.

Hence under Article 13(2) RPBA auxiliary requests 3 and 4 are not admitted into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated