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Datasheet for the decision of 2 April 2025

Case Number: T 0896/23 - 3.2.02

Application Number: 14846348.2

Publication Number: 3047796

IPC: A61B5/026, A61B5/0265, A61B5/0275, A61B10/00, G01N21/64

Language of the proceedings: EN

Title of invention:

METHOD AND SYSTEM FOR IMAGE PROCESSING OF INTRAVASCULAR HEMODYNAMICS

Patent Proprietor:

Infocom Corporation

Opponent:

Leica Microsystems CMS GmbH

Relevant legal provisions:

EPC Art. 83, 84, 123(2)
RPBA 2020 Art. 12(3), 12(4), 12(5)

Keyword:

Amendment to case - reasons for submitting amendment in appeal proceedings (yes) - amendment admitted (yes)
Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Claims - lack of clarity no ground for opposition

Decisions cited:

G 0003/14

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Case Number: T 0896/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 2 April 2025

Appellant: (Opponent)	Leica Microsystems CMS GmbH Ernst-Leitz-Strasse 17-37 35578 Wetzlar (DE)
Representative:	2SPL Patentanwälte PartG mbB Landaubogen 3 81373 München (DE)
Respondent: (Patent Proprietor)	Infocom Corporation 2-34-17, Jingumae Shibuya-ku Tokyo 150-0001 (JP)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 30 March 2023 concerning maintenance of the European Patent No. 3047796 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. This appeal was filed by the opponent against the opposition division's interlocutory decision to maintain the contested patent as amended on the basis of the claims of the patent proprietor's alternate main request and an amended description of the patent.

II. At the end of the oral proceedings held before the Board on 2 April 2025, the **parties' final requests** were as follows.

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

The respondent (the patent proprietor) requested that the appeal be dismissed and that the patent be maintained on the basis of the claims of alternate main request c as filed with the reply, dated 12 December 2023, to the statement setting out the grounds of appeal, and the amended description of the patent as maintained by the opposition division; or, as auxiliary measures, that the patent be maintained on the basis of one of the other claim requests filed with the reply.

III. The independent claims of **alternative main request c**, claims 1 and 8, read as follows (with a feature numbering based on that used in the decision under appeal, and the amendments to claims 1 and 8 of the alternate main request underlying the decision - these latter claims being themselves identical to claims 1 and 10 as granted - highlighted by the Board):

Claim 1

M1.1 "*A method for image processing of intravascular hemodynamics, characterized by:*

M1.2 *shooting video using infrared light, wherein the object of shooting is a portion of a blood vessel injected with a standard amount of a fluorescent contrast agent;*

M1.3 *performing image analysis of a shape of a chronological change curve of intensity values of image outputs from the video shooting;*

M1.4 *calculating relative data for blood volume (rBV) and blood flow (rBF) based on results of the image analysis; and*

M1.5 *calculating quantitative data for blood volume (BV) or blood flow (BF) based on the relative data,*

M1.6 *wherein the relative data for blood volume (rBV) ~~or blood flow (rBF)~~ is calculated based on an integral value from the chronological change curve and the relative data for blood flow (rBF) is calculated based on the relative data for blood volume and based on a centroid of an area under the chronological change curve.*"

Claim 8

M1.1' "*A system for image processing of intravascular hemodynamics, characterized by comprising:*

M1.2' *an infrared imaging device (100) for shooting video images, using infrared light, of a portion of a blood vessel injected with a standard amount of a fluorescent contrast agent; and*

M1.3' *an image analysis device (104) for performing image analysis of a shape of a chronological change curve of intensity values of image outputs shot by the imaging device, and*

M1.4' *calculating relative data for blood volume (rBV) and blood flow (rBF) based on results of the image analysis;*

M1.5' *wherein the image analysis device (104) comprises an image analysis device that calculates quantitative data for blood volume (BV) or blood flow (BF) based on the relative data,*

M1.6' *wherein the image analysis device is configured to calculate relative data for blood volume (rBV) ~~or blood flow (rBF)~~ based on an integral value from the chronological change curve and to calculate the relative data for blood flow (rBF) based on the relative data for blood volume and based on a centroid of an area under the chronological change curve.*"

In the following, these claims are referred to as claim 1 and claim 8.

IV. The **appellant's arguments** relevant to this decision can be summarised as follows.

Admittance of alternate main request c

Alternate main request c should not be admitted. This request had been filed for the first time with the respondent's reply. However, it could have been filed in the opposition proceedings, and the reply provided no justification for its late filing on appeal. Moreover, this request was one of 74 auxiliary requests. This huge number of requests was

disproportionate, and for this reason alone, none of these requests, including alternate main request c, should be admitted. In addition, the reply failed to explain how alternate main request c overcame any of the objections raised by the appellant in the statement of grounds of appeal. In fact, claims 1 and 8 of this request still contained added subject-matter.

Added subject-matter

Claims 1 and 8 contained added subject-matter. Features M1.5 and M1.6 and the corresponding features of claim 8 represented inadmissible intermediate generalisations of the disclosure of the application as originally filed.

Feature M1.5

Original claim 2, on which the respondent alleged feature M1.5 was based, defined that quantitative data for blood volume or blood flow was calculated "instead of" the relative data, and not "based on" it, as defined in feature M1.5. This was different. Therefore, original claim 2 did not disclose feature M1.5.

In the original description, feature M1.5 was consistently disclosed in combination with the conversion coefficient Kbf, which was essential for converting the relative data into quantitative data in the first to third embodiments disclosed. The fourth embodiment, to which the Board had referred in its communication under Article 15(1) RPBA and in which the calculation of quantitative data was allegedly carried out "without using an electromagnetic blood flow meter" (paragraph [0094]), i.e. without using the conversion coefficient Kbf, was insufficiently

disclosed and thus non-enabling. This had been confirmed by the opposition division in the decision under appeal (Reasons 14.3). Therefore, this embodiment could not be relied upon as a basis for feature M1.5. Consequently, the omission of the conversion coefficient Kbf from feature M1.5 constituted an inadmissible intermediate generalisation of the original disclosure.

Feature M1.6

The calculation of the relative data for blood volume, rBV, and blood flow, rBF, from the chronological change curve as defined in feature M1.6 was only disclosed in the original application for a calculation scheme based on the formulas shown in Figures 3, 5 and 6 and described in the relevant sections of the description. However, these formulas were not defined in feature M1.6, and several parameters and features involved in the calculation scheme, such as mean transit time MTT, oMTT, arrival time AT and the coefficient Kbf derived from electromagnetic blood flow measurements, had been omitted from feature M1.6. Feature M1.6 also failed to define that the calculated rBV and rBF "[did] not depend on the timing of the injection", as disclosed in paragraph [0067] of the original description. These omissions also represented an inadmissible intermediate generalisation.

Sufficiency of disclosure

The invention as claimed in alternate main request c was insufficiently disclosed.

According to feature M1.3, an image analysis "of a shape of a chronological change curve" was performed.

This required an image of the chronological change curve to actually exist. However, the patent specification only described that an image analysis of the image output from the video shooting was performed to obtain the intensity values of the chronological change curve, which were then used to calculate rBV and rBF using the provided formulas. An image of the chronological change curve was never generated in the examples described in the specification. Therefore, feature M1.3 and the corresponding feature of claim 8 were not supported by the specification, with the result that the disclosure of the claimed invention was insufficient for a person skilled in the art to be able to carry it out.

Clarity

The "area under the chronological change curve" referred to in claims 1 and 8 was not clearly defined, rendering these claims unclear.

This objection had initially been raised against the auxiliary requests filed in the opposition proceedings (see point 2 of the appellant's submission of 25 October 2022, to which the appellant specifically referred on page 7 of the statement of grounds of appeal) but also applied to alternate main request c, which used the same wording.

V. The **respondent's arguments** relevant to this decision can be summarised as follows.

Admittance of alternate main request c

Alternate main request c should be admitted. This request had been filed with the respondent's reply in

response to the new added-matter objection to feature M1.6 raised by the appellant for the first time in the statement of grounds of appeal in case the Board considered admitting this objection. Therefore, this request could not have been filed earlier. In addition, the amendments made in this request clearly overcame the new objection, as detailed in the reply.

Added subject-matter

Claim 1, and claim 8 for similar reasons, did not contain added subject-matter.

Feature M1.5

The person skilled in the art would understand from the application as originally filed that the expression "instead of" in original claim 2, on which the wording of feature M1.5 was based, actually meant "based on". This was no different to the wording of original claim 5, which also used the expression "instead of" to mean "based on", by referring to generating a video "instead of" the image generated in a previous step, it being clear that a video implicitly included an image.

In any event, the original description disclosed that quantitative data for blood volume or blood flow was calculated from the previously determined relative data, and was thus "based on" this relative data, as claimed in feature M1.5. As the Board considered in its communication under Article 15(1) RPBA, this calculation did not necessarily involve the conversion coefficient Kbf derived from quantitative measurements made using an electromagnetic blood flow meter. Thus, the fact that feature M1.5 did not refer to Kbf was not an inadmissible intermediate generalisation.

Feature M1.6

The calculation of rBV and rBF as defined in feature M1.6 corresponded, at least implicitly, to the original disclosure in Figures 5 and 6 and in the corresponding parts of the disclosure, for example, paragraphs [0067] and [0069]. The person skilled in the art would understand that the part of the chronological change curve prior to the peak, i.e. the part of zero intensity, was irrelevant for determining rBV and rBF. They would therefore determine the claimed centroid relative to the left foot of the peak - this implying the definition of an AT depending on the system's sensitivity, as for any detection system - thus in accordance with the definition of MTT provided in the original disclosure, rather than relative to an arbitrary absolute time reference. Therefore, the omission from feature M1.6 of the parameters referred to by the appellant did not constitute an inadmissible intermediate generalisation.

In addition, the fact that the rBV and rBF determined by the claimed method "[did] not depend on the timing of the injection" was simply the consequence of determining rBV and rBF as defined in feature M1.6. Moreover, the original application contained many passages describing the calculation of rBV and rBF as claimed without referring to the timing of the injection. Therefore, the absence of a reference to this timing in feature M1.6 did not add matter either.

Sufficiency of disclosure

The invention as claimed in alternate main request c was sufficiently disclosed. The person skilled in the

art would understand that the image analysis referred to in feature M1.3 was performed on the image outputs from the video shootings to obtain the shape of a chronological change curve. As acknowledged by the appellant, this was exactly what the patent specification described.

Clarity

The mere reference to the appellant's submission of 25 October 2022 could not substantiate any objection, and therefore should not be taken into account. In any event, the objection raised in that submission asserting that the area under the chronological curve was not clearly defined was unconvincing.

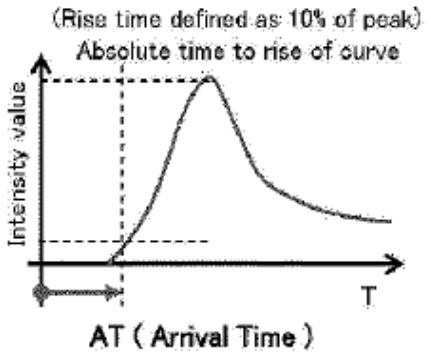
Reasons for the Decision

1. Subject-matter of the contested patent

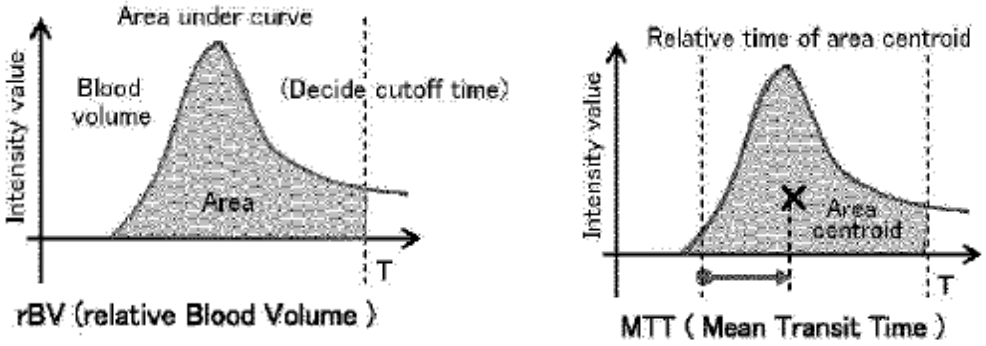
1.1 The contested patent relates to a method, and a system implementing this method, for analysing blood flow dynamics within a blood vessel, for example, during vascular surgery, as defined in independent claims 1 and 8 of alternate main request c.

1.2 As explained in the patent specification, for example, for the first embodiment described (see paragraphs [0046] ff), the method is based on analysing the fluorescence signal detected by an infrared imaging device (such as an infrared camera of a surgical microscope) at a portion of the blood vessel, following the administration of a bolus of fluorescent contrast agent (feature M1.2). Analysing the images from a video of the blood vessel (feature M1.3) allows the change in fluorescence signal intensity detected for a given

pixel or group of pixels to be monitored, resulting in a typical time-intensity curve (referred to as a "chronological change curve" in the claims), as shown in the cut-out of Figure 3 below, with the peak in the curve reflecting the arrival of the bolus of fluorescent contrast agent and its subsequent transport due to blood flow (see paragraph [0058]):



1.3 Relative data for blood volume (rBV) and blood flow (rBF) is then calculated by integrating this curve (features M1.4 and M1.6). As defined in feature M1.6 and shown in the two further cut-outs of Figure 3 below, rBV is calculated based on an integral of the curve (i.e. as an area under the curve), while rBF is calculated based on rBV and based on a centroid of an area under the curve (i.e. the first-moment integral or centre of gravity of this area). This is described in more detail in Figures 3, 5 and 6, where rBF is defined as rBF = rBV / MTT, with the MTT (mean transit time) being the time coordinate of the centroid relative to the arrival time (AT) of the peak (see paragraphs [0066] to [0068]).



1.4 Finally, quantitative data for blood volume (BV) or blood flow (BF) is calculated based on the relative data (feature M1.5). For this purpose, the patent specification describes that a conversion coefficient Kbf can be determined from quantitative measurements with an electromagnetic blood flow meter (see paragraphs [0060] to [0064]).

1.5 The system of claim 8 is designed to implement this method and, accordingly, comprises features which correspond substantially to those of claim 1. Therefore, the considerations made for claim 1 also apply to claim 8 and are not repeated here.

2. Admittance of alternate main request c

2.1 Alternate main request c was filed for the first time with the respondent's reply to the statement of grounds of appeal. Thus, pursuant to Article 12(4) RPBA, this request may be admitted only at the discretion of the Board.

2.2 The appellant requested that this request not be admitted. At the oral proceedings before the Board, it did not comment on this issue again, merely referring to its written submissions. The Board therefore saw no reason to deviate from the preliminary view set out in

its communication under Article 15(1) RPBA, which is reiterated below.

2.3 The respondent argued in the reply (see page 4, first paragraph) that alternate main request c had been filed in response to the added-matter objection raised in the statement of grounds of appeal for the first time (see page 4, first three paragraphs), asserting that feature M1.6 of claim 1 of the alternate main request and the corresponding feature of claim 8 contained added subject-matter in defining that the rBV was also calculated "based on a centroid of an area under the chronological change curve", should the Board decide to admit this objection - which the Board did at the oral proceedings.

As set out in the Board's communication (see points 3.2 and 2.1.3), this objection was indeed a new objection, different from the objections to feature M1.6 previously raised in the opposition proceedings (see point 3.2.2 below regarding these other objections). Therefore, contrary to the appellant's argument, the respondent had no reason to consider it necessary to file alternate main request c in the opposition proceedings. This was all the more so given that the opposition division was of the preliminary opinion that feature M1.6 did not contain added subject-matter, a view that the opposition division subsequently confirmed at the oral proceedings.

On appeal, alternate main request c was filed together with the respondent's reply to the statement of grounds of appeal, i.e. at the earliest possible stage of the appeal proceedings. Moreover, the amendments made to feature M1.6 and the corresponding feature of claim 8 are not complex and merely bring the definition of rBV

and rBF in line with their definitions originally disclosed, *inter alia*, in Figures 3, 5 and 6, removing the alternative that the rBV was also calculated "based on a centroid of an area under the chronological change curve". This immediately overcomes the appellant's new objection, which the appellant did not dispute. Hence, contrary to the appellant's argument, it is clear from the reply how this request addresses the appellant's objection, and the Board is satisfied that the requirements of Article 12(3) RPBA are met.

Furthermore, contrary to the appellant's view, the fact that alternate main request c was filed together with a large number of other lower-ranked claim requests is immaterial.

For these reasons, the Board decided to exercise its discretion and admit alternate main request c.

3. Added subject-matter

Contrary to the appellant's view, claim 1 of alternate main request c, and claim 8 for similar reasons, do not contain added subject-matter.

3.1 Feature M1.5

It is common ground that the original description discloses feature M1.5 by disclosing that, in a further method step, rBV and rBF, obtained by integrating the chronological change curve, are converted into corresponding quantitative data, BV and BF (see for example paragraph [0063]: "converting relative rBF images to quantitative BF images" and "converting relative rBV images to quantitative BV images").

The appellant's objection to feature M1.5 is based on the argument that in all embodiments disclosed in an enabling way in the original application (allegedly the first to third embodiments), the calculation of the quantitative data systematically involves a conversion coefficient Kbf derived from measurements using an electromagnetic flow meter (see, for example, the formulas in paragraph [0064]). Thus, according to the appellant, not mentioning the conversion coefficient Kbf in feature M1.5 constituted an inadmissible intermediate generalisation of the original disclosure.

The Board disagrees. As set out in the communication under Article 15(1) RPBA (point 4.1.2), the original application also discloses a fourth embodiment in which quantitative data for blood volume and blood flow is calculated "even without using an electromagnetic blood flow meter" (see paragraphs [0094] onwards). Regardless of whether this embodiment is sufficiently disclosed - which the appellant disputed and which was indeed held not to be the case in the decision under appeal, see the *obiter dictum* in Reasons III - the person skilled in the art would nevertheless understand from the original disclosure that converting the relative data into quantitative data using the conversion coefficient Kbf is merely one example of conversion and that this conversion could be performed using other techniques. Therefore, contrary to the appellant's argument, the fact that feature M1.5 does not specify that the calculation of the quantitative data is based on the conversion coefficient Kbf does not add matter.

3.2 Feature M1.6

3.2.1 As indicated in point 2.3 above, the amendments made to feature M1.6 overcome the appellant's new added-matter

objection to feature M1.6 as defined in the version maintained by the opposition division raised in the statement of grounds of appeal. This was not disputed by the appellant at the oral proceedings.

3.2.2 The other added-matter objections to feature M1.6 raised by the appellant also for alternate main request c were based on the argument that the calculation of rBV and rBF was only disclosed in the original application in the context of the calculation scheme illustrated in Figures 3, 5 and 6 and described in the relevant sections of the description, and that, by omitting the calculation or determination of several other parameters involved in this calculation scheme, such as MTT, oMTT, AT and Kbf, feature M1.6 was based on an inadmissible intermediate generalisation.

This is not convincing. As argued by the respondent, the calculation of rBV and rBF from the chronological change curve as defined in feature M1.6 corresponds to the original disclosure in Figures 5 and 6 and in the corresponding parts of the description, for example, paragraphs [0067] and [0069].

As to rBV

The "integral value from the chronological change curve" on which rBV is based according to feature M1.6 is mathematically the area under this curve, as originally disclosed in Figure 3 and paragraph [0069] of the original description. This also explicitly corresponds to the formulas in Figures 5 and 6, which both express rBV as an integral of the detected intensity. This was not disputed by the appellant.

As to rBF

The person skilled in the art would understand that the "centroid of an area under the chronological change curve" on which rBF is based according to feature M1.6 refers in fact to the time coordinate of this centroid, as also supported by Figures 3, 5 and 6 of the patent - identical to those of the original application - and paragraph [0070] of the patent. The appellant did not dispute this but objected that feature M1.6 should have defined MTT, oMTT and AT, all of which appear in the formulas provided in Figures 5 and 6 of the original application.

The Board does not accept this argument. As argued by the respondent, the person skilled in the art would understand that the part of the chronological change curve prior to the peak, i.e. the part of zero intensity, is irrelevant for determining rBV and rBF. The person skilled in the art would therefore determine the claimed centroid relative to an arrival time AT of the peak, i.e. in accordance with the definition of MTT provided in the original disclosure, rather than relative to an arbitrary absolute time reference. The definition of the centroid in feature M1.6 is therefore implicitly equivalent to the calculation of MTT originally disclosed, and the fact that feature M1.6 does not refer explicitly to the calculation of MTT is irrelevant.

Moreover, as further argued by the respondent, the person skilled in the art would also be aware that any detection system has a minimum level below which no detection is possible, depending on the system's sensitivity. Therefore, the fact that feature M1.6 does not define a specific AT is irrelevant.

In addition, as stated in the Board's communication under Article 15(1) RPBA (see point 4.1.3), defining MTT as the time coordinate of the centroid relative to the arrival time AT is mathematically equivalent to defining MTT as the difference between oMTT and AT. Thus, the fact that feature M1.6 does not mention oMTT is also irrelevant.

The appellant also objected that the coefficient Kbf was not mentioned in feature M1.6. However, Kbf is not involved in the calculation of rBV and rBF. It only plays a role in a possible conversion technique for calculating quantitative data based on the relative data (see point 3.1 above). Thus, the fact that feature M1.6 does not mention Kbf does not add matter either.

The appellant also objected that feature M1.6 did not specify that the blood volume and blood flow determined by the claimed method "do not depend on the timing of the injection", as disclosed in the second sentence of paragraph [0067] of the original application. However, the person skilled in the art would understand from this sentence not that the blood volume and blood flow have to be determined in such a way that they do not depend on the timing of the injection, as alleged by the appellant, but rather that they advantageously do not depend on that timing because their calculation is based on the determination of the integral value of the intensity curve and the centroid of the area, as defined in feature M1.6. Therefore, the independence of the blood volume and blood flow from the timing of the injection is in fact implicit in feature M1.6, and the fact that feature M1.6 does not explicitly mention this independence does not add matter.

4. Sufficiency of disclosure

4.1 Contrary to the appellant's view, the invention as claimed in alternate main request c is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

At the oral proceedings before the Board, the appellant did not comment on this issue again; it merely referred to its written submissions. The Board therefore sees no reason to deviate from its preliminary view set out in the communication under Article 15(1) RPBA, which is reiterated below.

4.1.1 Feature M1.6

The appellant's objection that feature M1.6 of the alternate main request was insufficiently disclosed raised in the statement of grounds of appeal (see pages 6 and 7) does not apply to feature M1.6 as amended in alternate main request c. This was not disputed by the appellant, which did not reiterate this objection against alternate main request c.

4.2 Feature M1.3

The appellant's objection to feature M1.3 is not convincing. As argued by the respondent, the person skilled in the art would not understand, as alleged by the appellant, that the image analysis referred to in feature M1.3 is performed on an image of the chronological change curve - which is indeed not disclosed in the patent - but rather that it is performed, as disclosed in the patent specification, on the image outputs from the video shootings to obtain the shape of a chronological change curve. The

construction of the chronological change curve is described in detail in the patent specification, and the person skilled in the art would not face an undue burden in implementing feature M1.3. The Board therefore agrees with the respondent that this feature is sufficiently disclosed in the patent.

5. Clarity

5.1 In point 2 of the appellant's submission of 25 October 2022, to which the appellant referred on page 7 of its statement of grounds of appeal, the appellant objected that the claimed feature "area under the chronological change curve" was not clearly defined, rendering the claimed subject-matter unclear.

At the oral proceedings, the appellant reiterated this clarity objection against alternate main request c, referring to its written submissions in this respect.

5.2 The respondent objected that the mere reference to an earlier submission could not substantiate any objection, and that the appellant's submission of 25 October 2022 should therefore not be taken into account pursuant to Article 12(5) RPBA.

5.3 It is true that claims 1 and 8 of alternate main request c define the same feature "area under the chronological change curve" objected to by the appellant. However, as set out in the Board's communication under Article 15(1) RPBA (see point 4.3), this feature is also defined in identical terms in claim 1 as granted. Consequently, in accordance with decision G 3/14 of the Enlarged Board of Appeal, this feature cannot be examined for compliance with

Article 84 EPC. The appellant's clarity objection is therefore inadmissible for this reason alone.

6. Conclusion

6.1 It follows from the foregoing that none of the objections raised by the appellant prejudice the maintenance of the contested patent on the basis of the claims of alternate main request c.

6.2 Furthermore, neither the appellant nor the Board had any objections to the amended description of the patent as maintained by the opposition division.

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 with the order to maintain the patent as amended in the following version:

- claims 1 to 10 of alternate main request c filed with the reply, dated 12 December 2023, to the statement setting out the grounds of appeal
- description: paragraphs [0001] to [0032] and [0034] to [0133] of the patent specification
- drawings: Figures 1 to 13 of the patent specification

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated