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**Datasheet for the decision  
of 26 May 2021**

**Case Number:** T 2994/18 - 3.4.02

**Application Number:** 10011398.4

**Publication Number:** 2270481

**IPC:** G01N27/00, G01N33/487

**Language of the proceedings:** EN

**Title of invention:**  
Glucose measuring instrument

**Patent Proprietor:**  
Roche Diagnostics Operations, Inc.

**Opponent:**  
James Poole Limited

**Relevant legal provisions:**

EPC Art. 76(1), 84, 100(c)  
EPC R. 103(1)(a), 111(2)  
RPBA Art. 12(4)  
RPBA 2020 Art. 13(2)

**Keyword:**

Subject-matter extending beyond the content of the earlier application as filed (yes: main request and auxiliary requests 5 to 14)

Clarity of claims (no: auxiliary request 4)

Admission of requests (no: auxiliary requests 1 to 3 and 4A)

**Decisions cited:**

T 1067/97, T 0714/00, T 0025/03



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Case Number: T 2994/18 - 3.4.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.02**  
**of 26 May 2021**

**Appellant:** Roche Diagnostics Operations, Inc.  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
5 October 2018 concerning maintenance of the  
European Patent No. 2270481 in amended form.**

**Composition of the Board:**

**Chairman** R. Bekkering  
**Members:** F. J. Narganes-Quijano  
G. Decker

## Summary of Facts and Submissions

- I. The patent proprietor and the opponent lodged an appeal against the interlocutory decision of the opposition division finding European patent No. 2270481 as amended according to the third auxiliary request then on file to meet the requirements of the EPC. The patent was based on a divisional application of the earlier European application No. 98962920.9 (published as WO 99/28736 A1).

The opposition filed by the appellant against the patent as a whole was based on the grounds for opposition of added subject-matter in respect of the application as filed (Article 100(c) EPC), insufficiency of disclosure (Article 100(b) EPC), and lack of novelty and of inventive step (Article 100(a) together with Articles 52(1), 54 and 56 EPC).

Subsequently, in the course of the first-instance proceedings, the ground for opposition under Article 100(c) EPC was also considered in respect of the earlier application as filed.

- II. In the decision under appeal the opposition division concluded, *inter alia*, as follows:
- the subject-matter of the patent as granted (main request) extended beyond the content of the earlier application as filed;
  - the first and the second auxiliary requests then on file were not admitted into the proceedings; and
  - the then third auxiliary request was allowable and, in particular, it complied with Articles 76(1), 123(2), 83 and 84 EPC, and the claimed subject-matter

was new and involved an inventive step over the documents considered by the opponent.

III. With its statement setting out the grounds of appeal the patent proprietor filed claims according to auxiliary requests "I" and "II" (subsequently relabelled by the board as auxiliary requests "1" and "2"), and a copy of the following document already referred to during the first-instance proceedings:

A1: Webster's Third New International Dictionary - Unabridged, 1993; front page and page 592.

IV. With its statement setting out the grounds of appeal the opponent submitted that the decision under appeal was tainted by a substantial procedural violation.

V. With the letter of reply dated 3 July 2019 the patent proprietor filed claims according to auxiliary requests 3 to 14.

VI. In a communication annexed to the summons to oral proceedings the board presented a preliminary assessment of the case.

VII. With the letter dated 26 March 2021 the patent proprietor filed claims according to auxiliary request 4A.

VIII. Oral proceedings before the board were held on 26 May 2021.

The patent proprietor requested as a main request that the decision under appeal be set aside and the opposition be rejected, i.e. that the patent be maintained as granted. Alternatively, it requested that

the patent be maintained in amended form on the basis of the claims of auxiliary requests 1 or 2 filed with the statement of grounds of appeal, or of auxiliary request 3 filed with the letter dated 3 July 2019. As auxiliary request 4, it requested that the appeal of the opponent be dismissed. Further alternatively, it requested that the patent be maintained in amended form on the basis of the claims of auxiliary request 4A filed with the letter dated 26 March 2021, or of one of auxiliary requests 5 to 14 filed with the letter dated 3 July 2019.

The opponent requested that the decision under appeal be set aside and that the patent be revoked. It further requested the reimbursement of the appeal fee.

At the end of the oral proceedings the chairman announced the decision of the board.

IX. Claim 1 of the main request (patent as granted) reads as follows:

"A hand held instrument (20) for determining the concentration of a medically significant component of a biological sample, the instrument including a controller (110), at least one key (54a, 54b, 54c) for the entry of information by a user, and a display (42) for displaying results of tests to determine the concentration of the medically significant component of a biological sample, **characterized in that** the controller (110) is coupled to the at least one key (54a, 54b, 54c) and to the display (42) and is arranged to permit the user to enter into the controller (110) a first user-defined range of values for the concentration of the medically significant component of the sample, the display (42) is arranged to display the

first user-defined range, and the controller (110) is arranged to produce an indication during a subsequent determination of the concentration whether the subsequently determined concentration falls within the first user-defined range."

The wording of claim 1 of auxiliary request 1 is not relevant for the present decision.

The wording of claim 1 of auxiliary request 2 differs from that of claim 1 of the main request in that

- the expression "at least one key" appearing twice in claim 1 of the main request is replaced by the expression "keys", and

- the feature "wherein the user may change a setting by pressing one of the keys until the correct setting appears on the display," is inserted before the expression "the display (42) is arranged to display the first user-defined range [...]".

The wording of claim 1 of auxiliary request 3 differs from that of claim 1 of the main request in that

- the expression "at least one key" appearing twice in claim 1 of the main request is replaced by the expression "keys"; and

- the feature "wherein the controller is arranged to let the user elect a 'set the glucose ranges' option, wherein a set glucose ranges screen is displayed on the display, wherein the user may change a setting by pressing one of the keys until the correct setting appears on the display," is inserted before the expression "the display (42) is arranged to display the first user-defined range [...]".

The wording of claim 1 of auxiliary request 4 differs from that of claim 1 of the main request in that the claim contains the two following amendments:

- amendment L1: the expression "at least one key" appearing twice in claim 1 of the main request is replaced by the expression "keys"; and

- amendment L2: the following feature is inserted before the expression "the display (42) is arranged to display the first user-defined range [...]":

"wherein the controller is arranged to let the user elect a 'set the glucose ranges' option, wherein a set glucose ranges screen is displayed on the display, wherein the controller further is arranged to permit the user to save the displayed settings by pressing a first one (54c) of the keys, wherein no other action will save these settings, wherein the controller further is arranged to let the user change these settings by pressing a second one (54a) of the keys, wherein the controller is arranged to show the set glucose ranges screen with a setting in a highlighted area, wherein the controller further is arranged to permit the user, if the setting in the highlighted area is the one the user wishes to change,

a) to change the setting to a desired setting by pressing one of the first key (54c) or the second key (54a) until the desired setting appears in the highlighted area,

b) to press a third one (54b) of the keys until the display returns to the set glucose ranges screen, and

c) to permit the user to save the desired setting by pressing the first key (54c), wherein the controller further is arranged to, if the setting in the highlighted area is not the one the user wishes to change, to permit the user to press the third key (54b) until the setting in the highlighted area is the one to be changed, and wherein the controller



further is arranged to then proceed by steps a) to c),".

The wording of claim 1 of auxiliary request 4A differs from that of claim 1 of auxiliary request 4 in that

- the feature "arranged to permit the user to enter into the controller (110)" is replaced by the feature "arranged to permit the user, by electing a 'set the glucose ranges' option, to enter into the controller (110)";

- the feature "arranged to let the user elect a 'set the glucose ranges' option, wherein a set glucose ranges screen is displayed on the display" is replaced by the feature "arranged to let the user elect the 'set the glucose ranges' option for viewing glucose settings and editing glucose settings, wherein the glucose settings comprise an upper limit, a lower limit and a hypoglycemic limit, wherein a set glucose ranges screen is displayed on the display displaying glucose settings", and

- in the subsequent wording of the claim, the terms "setting" and "settings" are respectively replaced by "glucose setting" and "glucose settings" in the following expressions: "the displayed settings", "save these settings", "change these settings", "with a setting", the first occurrence of the expression "if the setting", the two occurrences of the expression "the desired setting", and the expression "until the setting".

The wording of claim 1 of auxiliary requests 5 to 14 differs from that of claim 1 of the main request in that the respective claim 1 contains the following amendments:

- auxiliary request 5: amendment M1;
- auxiliary request 6: amendments M1 and M2;

- auxiliary request 7: amendment M3;
  - auxiliary request 8: amendments M1 and M3;
  - auxiliary request 9: amendments M2 and M4;
  - auxiliary request 10: amendments M1, M2 and M4;
  - auxiliary requests 11 and 12: amendments M1 and M5;
  - auxiliary request 13: amendments M1, M2 and M5;
- and
- auxiliary request 14: amendments M1 and M6;

wherein:

- the amendment M1 consists in the insertion of the feature "wherein the medically significant component is glucose," after the expression "[...] a medically significant component of a biological sample,";

- the amendment M2 consists in the insertion of the feature "wherein the first user-defined range is a first range entered by the user," before the expression "the display (42) is arranged to display the first user-defined range [...]";

- the amendment M3 consists in the insertion of the following feature at the end of the claim: ", wherein the controller (110) further is arranged to permit the user to enter into the controller (110) a second user-defined range of values for the concentration of the medically significant component of the sample, the display (42) is arranged to display the second user-defined range, and the controller (110) is arranged to produce an indication during a subsequent determination of the concentration whether the subsequently determined concentration falls within the second user-defined range";

- the amendment M4 consists in the insertion of the following feature at the end of the claim: ", wherein the controller (110) further is arranged to permit the user to enter into the controller (110) a second user-defined range of values for the concentration of

the medically significant component of the sample, wherein the second user-defined range is a second range entered by the user, the display (42) is arranged to display the second user-defined range, and the controller (110) is arranged to produce an indication during a subsequent determination of the concentration whether the subsequently determined concentration falls within the second user-defined range";

- the amendment M5 consists in the replacement of the expressions "a subsequent determination of the concentration" and "the subsequently determined concentration" by the expressions "a subsequent measurement of the concentration" and "the subsequently measured concentration", respectively; and

- the amendment M6 consists in the insertion of the following feature at the end of the claim: ", wherein the instrument (2) further comprises a strip (21) for dosing with the sample, the instrument (20) including a port (94) for receiving the strip (21) to enable the instrument (20) to determine the concentration of the medically significant component of the sample, wherein the medically significant component is glucose and the chemistry reacts with glucose to produce an indication of the glucose concentration of the sample".

While claim 1 of both auxiliary requests 11 and 12 include amendments M1 and M5 and are therefore identical to each other, according to the statements of the patent proprietor in the paragraph bridging pages 13 and 14 of the letter dated 3 July 2019 claim 1 of auxiliary request 11 only included amendment M5.

## Reasons for the Decision

1. The appeal of the patent proprietor and the appeal of the opponent are admissible.
2. *Main request (patent as granted) - Article 100(c) EPC in respect of the earlier application as filed*
  - 2.1 In its decision the opposition division held that the feature "first user-defined range of values" of claim 1 as granted constituted an unallowable generalisation of the content of the earlier application as filed (Article 100(c) EPC). According to the opposition division, the mentioned claimed feature implied that the user could freely determine the upper and lower limits of the range, and this feature could not be derived from the more general feature "permit the user to enter into a controller a first range of values" of independent claim 71 of the earlier application as filed. In addition, the mentioned claimed feature was disclosed in the paragraph bridging pages 42 and 43 of the description of the earlier application as filed and relating to Fig. 65A to 65C, but only in structural and functional connection with the features of the sequence of steps disclosed therein, and these features were not required by the claimed subject-matter.
  - 2.2 With the appeal the patent proprietor contested the opposition division's finding in this respect.
    - 2.2.1 The patent proprietor submitted that the term "defined" generally referred to "clearly outlined, characterized, or delimited" as shown in document A1 (page 592, entry "defined"), and that independent claim 71 and the

passage on page 11, lines 11 to 13 of the earlier application as filed disclosed the feature "to permit the user to enter into the controller a first range of values for the concentration [...]"; therefore, the range of values was not pre-installed or unchangeable, but could be specified and therefore "defined" by the user.

The board notes that, while the claimed feature "to permit the user to enter into the controller (110) a first user-defined range of values" of claim 1 as granted requires or at least encompasses that the user can freely determine or select the upper and the lower limits of the mentioned ranges, the feature "to permit the user to enter into the controller a first range of values for the concentration" defined in independent claim 71 and also recited in page 11, second paragraph, of the description of the earlier application as filed - and on which claim 1 as granted is based - is a more general expression that encompasses the free determination or selection by the user of the upper and the lower limits for the concentration and also other possibilities, such as - as submitted by the opponent - the selection of one of a series of pre-installed ranges of values already present in the instrument and among which the user can select, thus "enter[ing] into the controller a first range of values". Therefore, the board is of the opinion that, contrary to the submissions of the patent proprietor - including their arguments based on the definition of the term "defined" in document A1 -, the mentioned feature of claim 1 as granted is not directly and unambiguously derivable from independent claim 71 or from the corresponding passage on page 11, second paragraph, of the description of the earlier application as filed.

2.2.2 The patent proprietor also submitted that according to the passage on page 42, line 30, to page 43, line 8, together with Fig. 65A to 65C of the earlier application as filed the user could freely determine the upper and lower limits of the range, and that this feature was not disclosed as being functionally or structurally related to (*cf.* decisions T 1067/97 and T 25/03), or inextricably linked with (*cf.* decision T 714/00), the sequence of steps disclosed therein. Therefore, the mentioned claimed feature did not constitute an unallowable intermediate generalisation. More particularly, following the so-called "gold standard", the skilled person, using common general knowledge, would notice that the first used-defined range is not functionally and structurally related to the specific order of screens on the hand held device and to the specific sequence of pressing of specific keys disclosed in the mentioned passage.

The board notes that it is undisputed between the parties that the passage on page 42, line 30, to page 43, line 8, and Fig. 65A to 65C of the earlier application as filed discloses the free selection by the user of the upper and lower limits of the range of values of the concentration, and that the resulting range constitutes a "user-defined range of values" as claimed. However, the mentioned disclosure of the earlier application as filed discloses a - and in fact the sole - particular embodiment of independent claim 71. In addition, while independent claim 71 defines relatively broad means ("a controller" coupled to "at least one key for the entry of information by a user" and to "a display [...] displaying the first range" [*emphasis added by the board*]) enabling the user "to enter into the controller a first range of values for the concentration", the mentioned particular

embodiment involves the use of specific means having specific structural and functional features (three keys 54a, 54b and 54c arranged to be selectively pressed by the user in order to change and save settings, while corresponding information is being displayed on the display, see page 42, last line, to page 43, line 8) specifically enabling the user to freely select the upper and lower limits of the range of values, i.e. to enter a "user-defined range of values" as defined in claim 1 as granted. The skilled person would therefore understand that, while the relatively broad means defined in independent claim 71 would be sufficient to enable the user to enter into the controller a first range of values, according to the particular embodiment disclosed in the description it would be possible to enable the user to specifically enter a user-defined range of values, and that in this case more specific means, and in particular those disclosed in the mentioned paragraph, would be required. In addition, there is no indication in the earlier application as filed from which the skilled person could directly and unambiguously derive that the means defined in independent claim 71 ("at least one key", "a display [...] displaying the first range", etc.) would be sufficient to enable the user to specifically enter a user-defined range of values as claimed, and the general reference of the patent proprietor to the common general knowledge of the skilled person is not sufficient to conclude otherwise.

Therefore, the claimed feature under consideration is - as submitted by the opponent and as held by the opposition division in its decision - disclosed in the mentioned paragraph together with other features, and more specifically as being structurally and functionally related to, or inextricably linked with,

at least some of them within the meaning of decisions T 1067/97 (reasons, point 2.1.3), T 25/03 (reasons, point 3.3) and T 714/00 (reasons, point 3.3) cited by the patent proprietor, and in the board's opinion the omission of these features results in an unallowable intermediate generalisation of the content of the earlier application as filed.

- 2.2.3 During the oral proceedings the patent proprietor submitted that the feature relating to entering a range was always disclosed in the description of the earlier application as filed as referring to a freely selectable range of values and referred in this respect to the language used in the earlier application as filed and in particular, as an example, to the language used in the passage on page 36, second paragraph, relating to Fig. 40B and according to which "[t]he user's normal range can be entered [...] and, if entered will be indicated by dotted lines. Values within the user's range are illustrated by + symbols. [...]". According to the patent proprietor, a reading of the earlier application as filed excluded the selection of one range from among different pre-defined ranges, and the disclosure relating to the user "entering" a range of values was disclosed as synonymous to, and interchangeable with, entering a user-defined range of values as claimed.

However, as submitted by the opponent, the passage on page 36, second paragraph, of the earlier application as filed, and in particular the range referred to in this passage, is not related to the specific embodiment on which claim 1 as granted is based, i.e. the embodiment disclosed in the paragraph bridging pages 42 and 43 and, moreover, the mentioned disclosure involved other features. In addition, in the board's opinion the



term "enter" or "entering" is broad, and the feature "to enter into the controller a first range of values" of independent claim 71 of the earlier application as filed is not interchangeable with the feature "to enter into the controller [...] a first user-defined range of values" defined in claim 1 as granted (see point 2.2.1 above).

2.3 In view of the above considerations, the board concludes that the subject-matter of claim 1 as granted constitutes an intermediate generalisation that is not directly and unambiguously derivable from - and, consequently, goes beyond - the content of the earlier application as filed (Article 100(c) EPC). For these reasons, the main request is not allowable.

3. *Auxiliary requests 1 and 2 - Article 12(4) RPBA 2007*

3.1 The claims of auxiliary requests 1 and 2 are identical to the claims of the first and the second auxiliary requests filed during the first-instance oral proceedings, and in its decision the opposition division decided not to admit these two requests into the proceedings. In addition, during the appeal proceedings the patent proprietor submitted no argument contesting the non-admission of these two requests into the proceedings by the opposition division, and also no argument in support of their admission into the appeal proceedings.

In these circumstances, the board sees no reason to review the way the opposition division exercised its discretion in not admitting the two requests into the proceedings, and also no reason that would justify to exercise its own discretion under Article 12(4) RPBA

2007 (which applies in the present case, see Article 25(2) RPBA 2020) to admit auxiliary requests 1 and 2 into the appeal proceedings.

3.2 For these reasons, auxiliary requests 1 and 2 are not admitted into the proceedings (Article 12(4) RPBA 2007).

4. *Auxiliary request 3 - Article 12(4) RPBA 2007*

4.1 Auxiliary request 3 was filed with the patent proprietor's letter of reply to the statement of grounds of appeal of the opponent. The claims of this request correspond to the claims of auxiliary request 2, with claim 1 further amended to include the feature "wherein the controller is arranged to let the user elect a 'set the glucose ranges' option, wherein a set glucose ranges screen is displayed on the display" (*cf.* point IX above).

4.2 The board notes that during the first-instance proceedings the patent proprietor submitted the then third auxiliary request (and now auxiliary request 4) in reply to the decision of the opposition division not to admit the then second auxiliary request into the proceedings in view of issues raised under Articles 76(1), 84 and 123(2) EPC in respect of claim 1 of the request which comprised the amended feature "wherein the user may change a setting by pressing one of the keys until the correct setting appears on the display" (minutes of the first-instance oral proceedings, page 5, lines 5 to 11, and lines 18 to 20), this amended feature having been replaced in claim 1 of the then third auxiliary request by a series of features - see point IX above, paragraph indicating

the wording of claim 1 of auxiliary request 4, amendment "L2" - which represented a more detailed description of the same and which, according to the opposition division, overcame the mentioned issues under Articles 76(1), 84 and 123(2) EPC. In addition, claim 1 of the present auxiliary request 3 incorporates all the features of claim 1 of the then second auxiliary request and the further feature "wherein the controller is arranged to let the user [...] is displayed on the display" mentioned in point 4.1 above. When comparing claim 1 of the present auxiliary request 3 with the then third auxiliary request, the mentioned further feature is present in the series of features incorporated in claim 1 of the then third auxiliary request (i.e. in the series of features of amendment "L2", see point IX above, paragraph indicating the wording of claim 1 of auxiliary request 4) and replaces the whole series of features.

It follows that claim 1 of the present auxiliary request 3 constitutes an interpolation between claim 1 of the then second and third auxiliary requests and, therefore, a generalisation of claim 1 of the then third auxiliary request. In addition, it is apparent from the context of the discussion of the mentioned issues during the first-instance oral proceedings that claim 1 of the present auxiliary request 3 could - and should - already have been presented during the first-instance oral proceedings within the meaning of Article 12(4) RPBA 2007.

According to Article 12(4) RPBA 2007 it is within "the power of the Board to hold inadmissible [...] requests which could have been presented [...] in the first instance proceedings" and, in addition, according to Article 12(2) RPBA 2020 (which applies in the present

case, see Article 25(1) RPBA 2020) "[i]n view of the primary object of the appeal proceedings to review the decision under appeal in a judicial manner, a party's appeal case shall be directed to the requests [...] on which the decision under appeal was based".

In the circumstances of the present case exposed above, the board sees no reason that would justify exercising its discretion under Article 12(4) RPBA 2007 to admit the present auxiliary request 3 into the appeal proceedings. In particular, the submissions of the patent proprietor according to which the request was filed in response to the objections of the opponent and of the opposition division that a link between the features "user-defined range" and "change the setting" was allegedly missing do not support the admission of the request on appeal. On the contrary, the mentioned objections correspond to the objections already addressed during the first-instance oral proceedings preceding the filing of the then third auxiliary request (minutes, page 5, lines 5 to 20) and confirm that the present auxiliary request 3 could have been presented during the oral proceedings.

During the oral proceedings before the board the patent proprietor also referred in this respect to the procedural violation alleged by the opponent and involving the missing link between the features "user-defined range" and "change the setting" (see point 8.1 below). However, the procedural violation relates to the omission of reasoning in the decision under appeal as regards the objection of clarity raised by the opponent in respect of the mentioned missing link, and since this objection was already addressed during the first-instance oral proceedings, the board does not see in what respect the procedural violation

alleged by the opponent would justify the submission of auxiliary request 3 during the appeal proceedings.

4.3 In view of the above considerations, the board decided not to admit auxiliary request 3 into the proceedings (Article 12(4) RPBA 2007).

5. *Auxiliary request 4 - Article 84 EPC*

5.1 Auxiliary request 4 is directed to the dismissal of the appeal of the opponent, and therefore to the maintenance of the patent in amended form on the basis of the claims of the third auxiliary request underlying the decision under appeal and considered allowable by the opposition division.

5.2 Claim 1 of present auxiliary request 4 requires a controller arranged to permit the user to enter "a first user-defined range of values" and a display arranged to display "the first user-defined range", and also a series of features involving different operations (displaying, highlighting, changing, saving, etc.) with one or several "settings" in a "set the glucose ranges" option and in a "set glucose ranges screen". However, while according to the description of the patent (paragraph [0095]) the "settings" specifically correspond to the user-defined range of values - and in particular to the "Upper limit", the "Lower limit" and the "Hypo" (i.e. the hypoglycemic limit) of the range of values, see Fig. 65B and 65C and the corresponding description -, claim 1 is silent as to the correspondence between, on the one hand, the claimed "settings" and, on the other hand, the "user-defined range" and the "set glucose ranges" option and screen. As a consequence, there is - as

submitted by the opponent - no clear and unambiguous technical link and, if any, no clear correspondence in the claimed subject-matter between the claimed settings and the features relating to the ranges.

This lack of clarity is emphasised by the fact that the expression "the displayed settings" of claim 1 has - as submitted by the opponent - no antecedent in the text of the claim, with the consequence that it is also unclear in claim 1 what "displayed settings" are referred to and what is the relationship - if any - between "the displayed settings" and the previous feature specified in the claim and relating to the display of "a set glucose ranges screen".

- 5.3 The patent proprietor submitted that claim 1 specified how the user was permitted "to enter into the controller (110) a first-defined range of values", namely by letting the user electing a "'set the glucose ranges' option" such that "a set glucose ranges screen" is displayed and by letting the user entering, changing and saving settings by pressing keys. More particularly, the claimed feature "set glucose ranges screen" related to the settings which were shown on the set glucose ranges screen, and the person skilled in the art reading the claim and willing to understand would read this feature as establishing a clear and unambiguous link between the settings and the ranges.

However, in the opinion of the board the term "set" in the feature "set glucose ranges screen" does not imply in a clear and unambiguous way the presence of settings, nor determines a clear and unambiguous relationship between the claimed settings and the user-defined range of values. More particularly, and as submitted by the opponent, claim 1 does not specify the

content displayed on the screen or its relation with the settings as disclosed in the description, and in this respect claim 1 is not clear and not supported by the description.

5.4 In view of these considerations, the board concludes that claim 1 of auxiliary request 4 is not clear (Article 84 EPC). Therefore, auxiliary request 4 is not allowable.

6. *Auxiliary request 4A - Article 13(2) RPBA 2020*

6.1 The claims of auxiliary request 4A were filed after notification of the summons to oral proceedings. According to Article 13(2) RPBA 2020 (which applies in the present case, see Article 25(1) EPC 2020), "[a]ny amendment to a party's appeal case made after [...] notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned".

When compared with claim 1 of auxiliary request 4, claim 1 of auxiliary request 4A further contains a series of features (*cf.* point IX above) directed to overcome some of the objections under Articles 76(1), 123(2) and 84 EPC addressed by the board in the communication annexed to the summons to oral proceedings. The patent proprietor submitted that the board in its communication unexpectedly deviated from the opinion of the opposition division with respect to auxiliary request 4 (*i.e.* the third auxiliary request underlying the decision under appeal) and that, in addition, the claims of auxiliary request 4A were clearly allowable. In particular, the amendments of

claim 1 overcame the objections of lack of clarity relating to the lack of antecedent of the expression "the displayed settings" and to the link between the settings and the user-defined range of values.

However, as already noted in the corresponding passages of the board's communication, the mentioned objections addressed by the board correspond to the objections previously raised by the opponent during the appeal proceedings in respect of auxiliary request 4 and, in addition, they reflect objections already addressed during the first-instance proceedings. This is particularly the case for the objection of lack of clarity referred to by the patent proprietor and addressed in points 5.2 and 5.3 above. The fact that, as submitted by the patent proprietor, this objection only constituted one among numerous objections of lack of clarity raised by the opponent during the first-instance oral proceedings (minutes, page 6, first paragraph) has no effect on the issue under consideration in view of the fact that the mentioned objection was specifically and extensively addressed by the opponent in its statement of grounds of appeal both as such and in the context of the allegation of a procedural violation for lack of reasoning in the decision under appeal in respect of the objection. In addition, as long as the objections addressed by the board in its communication correspond to objections previously addressed in the proceedings, the mere fact that the preliminary opinion expressed by the board in its communication might have deviated from the opposition division's opinion does not *per se* constitute cogent reasons justifying exceptional circumstances for the admission of the amended request within the meaning of Article 13(2) RPBA 2020.



6.2 In view of these considerations, the board decided not to admit auxiliary request 4A into the proceedings (Article 13(2) RPBA 2020).

7. *Auxiliary requests 5 to 14 - Article 76(1) EPC*

7.1 The claims according to auxiliary requests 5 to 14 correspond to the claims of auxiliary requests 1, 2a, 3, 3a, 4, 4a, 5, 5a, 5b and 11 filed during the first-instance proceedings, respectively.

Claim 1 of each of auxiliary requests 5 to 14 differs from claim 1 as granted in one among a series of combinations of amendments M1 to M6 (*cf.* point IX above). Among these amendments, only amendment M2 ("wherein the first user-defined range is a first range entered by the user") may, at least in principle, have an effect on the objection under Article 100(c) EPC addressed in point 2 above in respect of claim 1 of the main request. The remaining amendments M1 and M3 to M6 (*cf.* point IX above) have no impact on this objection because

- amendment M1 only requires that the medically significant component is glucose,
- amendments M3 and M4 only relate to a second user-defined range of values and has no influence on the features of the first user-defined range of values,
- amendment M5 only relates to the determination of the concentration being constituted by a measurement of the concentration, and
- amendment M6 relates to features of the claimed instrument that have no effect on the features of the user-defined range of values.

7.1.1 Claim 1 of auxiliary requests 5, 7, 8, 11, 12 and 14 does not contain amendment M2, and the remaining amendments (i.e. amendments M1, M3, M5 and M6) to these claims have, as already noted in point 7.1 above, no impact on the objection under Article 100(c) EPC addressed in point 2 above.

Therefore, the subject-matter of claim 1 of auxiliary requests 5, 7, 8, 11, 12 and 14 goes beyond the content of the earlier application as filed (Article 76(1) EPC) for the same reasons given in point 2 above in respect of claim 1 of the main request.

This conclusion is independent of whether or not claim 1 of auxiliary request 11 contains amendment M1 (see point IX above, last paragraph).

7.1.2 Claim 1 of auxiliary requests 6, 9, 10 and 13 contains amendment M2. According to this amendment, "the first user-defined range" defined in claim 1 as granted "is a first range entered by the user". However, the corresponding unamended claim already required "to permit the user to enter into the controller (110) a first user-defined range of values", and the new feature introduced into the claim by way of amendment M2 appears to be superfluous because it has no effect on the claimed subject-matter. In any case, as already noted in point 2 above, enabling a user to enter into a controller "a first range of values" is more general than, and encompasses, enabling a user to enter into the controller "a first user-defined range of values", and the feature "a first user-defined range of values" is not affected by a mere amendment of the claim specifying that "the first user-defined range is a first range entered by the user" because the claimed subject-matter still requires the specific feature

relating to enabling a user to enter into the controller "a first user-defined range of values".

The remaining amendments to claim 1 of auxiliary request 6, 9, 10 and 13, i.e. amendments M1, M4 and M5, have no effect on the above considerations (see point 7.1 above).

Therefore, also the subject-matter of claim 1 of auxiliary requests 6, 9, 10 and 13 goes beyond the content of the earlier application as filed (Article 76(1) EPC) for the same reasons given in point 2 above in respect of claim 1 of the main request.

7.2 In view of these considerations, the board concludes that none of auxiliary requests 5 to 14 complies with the requirements of Article 76(1) EPC, and that these auxiliary requests are not allowable.

8. *Substantial procedural violation - Reimbursement of the appeal fee*

8.1 As submitted by the opponent in its statement of grounds of appeal, of the ten objections raised under Articles 83, 84, 76(1) and 123(2) EPC during the first-instance oral proceedings in respect of the then third auxiliary request (minutes of the oral proceedings, first paragraph of each of pages 6 and 7), only the objections raised under Articles 76(1) and 123(2) EPC and some of the objections raised under Articles 83 and 84 EPC were addressed by the opposition division in the decision under appeal (reasons, point 7). In particular, only some of the objections raised by the opponent under Articles 83 and 84 EPC

were addressed in the decision (see decision, reasons, point 7, together with point 3.4, second paragraph, second and third sentences), and other ones of the fundamental objections, and in particular the objection of lack of clarity relating to the lack of antecedent in claim 1 of the feature "the displayed settings" and to the unclear relationship between the "user-defined range" and the settings referred to in the claim and addressed in point 5 above in respect of the present auxiliary request 4, were not addressed in the decision under appeal.

- 8.2 This deficiency in the decision amounts, as submitted by the opponent, to a violation of the obligation to provide an adequate reasoning in the decision (Rule 111(2) EPC) and therefore of the right to be heard (Article 113(1) EPC), and thereby to a substantial procedural violation. Since the appeal of the opponent is allowable, this substantial procedural violation justifies in the circumstances of the case the reimbursement of the appeal fee under Rule 103(1)(a) EPC as requested by the opponent.

The board notes that the mentioned substantial procedural violation constitutes a fundamental deficiency within the meaning of Article 15 RPBA 2020 (which applies in the present case, see Article 25(1) RPBA 2020). However, the patent in suit had already lapsed in all the designated contracting states (Article 63(1) EPC), and for this reason the board has refrained from considering the possibility of remitting the case under Article 11 RPBA 2020 as a remittal would have further delayed a final decision and would have run counter to the principles of procedural efficiency and legal certainty.

**Order**

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

1. The decision under appeal is set aside.
2. The patent is revoked.
3. The appeal fee of the opponent is reimbursed.

The Registrar:

The Chairman:



L. Gabor

R. Bekkering

Decision electronically authenticated