

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 8 March 2017**

Case Number: T 1800/12 - 3.4.02

Application Number: 02790875.5

Publication Number: 1460414

IPC: G01N21/83, G01N33/53

Language of the proceedings: EN

Title of invention:
CONCENTRATION MEASURING METHOD

Applicant:
ARKRAY, Inc.

Relevant legal provisions:
RPBA Art. 13(1)
EPC Art. 52(1), 123(2)
EPC 1973 Art. 54(1), 56, 84

Keyword:
Admissibility of amended requests (fourth auxiliary request:
no)
Added subject-matter (main request: yes)
Clarity (first to third auxiliary requests: no)
Novelty and inventive step (fifth auxiliary request: yes)



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1800/12 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 8 March 2017

Appellant: ARKRAY, Inc.
(Applicant) 57, Nishiaketa-cho
Higashikujo
Minami-ku
Kyoto-shi
Kyoto 601-8045 (JP)

Representative: Jones, Elizabeth Louise
Dehns
St Bride's House
10 Salisbury Square
London
EC4Y 8JD (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted on 28 March 2012
refusing European patent application No.
02790875.5 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman R. Bekkering
Members: F. J. Narganes-Quijano
T. Karamanli

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal against the decision of the examining division refusing European patent application No. 02790875.5 (publication No. 1460414).
- II. In its decision the examining division held that claim 1 of all requests then on file failed to comply with the requirements of Article 84 EPC. In addition, further objections were raised under Article 123(2) EPC and/or Article 83 EPC with respect to claim 1 of some of those requests.

In an *obiter dictum* of the decision, the examining division also expressed its view that the subject-matter of independent claims 5 and 6 of the main request then on file was respectively anticipated (Articles 52(1) and 54 EPC) by the disclosure of documents

D1: WO-A-9825143 and
D2: US-B1-6284472.

- III. With the statement setting out the grounds of appeal the appellant submitted sets of amended claims according to a main request and first to fifth auxiliary requests.
- IV. In reply to a communication of the board annexed to the summons to oral proceedings, the appellant filed with its letter dated 8 February 2017 sets of amended claims according to a main request and first to third auxiliary requests replacing the claims of all previous requests on file.

V. Oral proceedings were held on 8 March 2017.

As final requests, the appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the claims of the main request filed with the letter dated 8 February 2017 or, in the alternative, on the basis of the claims of the first auxiliary request filed with the letter dated 8 February 2017, or of the claims of the second to fourth auxiliary requests filed at the oral proceedings of 8 March 2017. As fifth auxiliary request, the appellant requested that the decision under appeal be set aside and a patent be granted in the following version:

- claims: Nos. 1 and 2 according to the fifth auxiliary request "2.10 pm", filed at the oral proceedings of 8 March 2017;
- description: pages 1, 2, 2a, 3, 3A and 4 to 25, filed at the oral proceedings of 8 March 2017; and
- drawings: sheets 1/8 to 8/8 as originally filed.

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

VI. The claims of the present requests are as follows:

Main request:

Claim 1 of the main request reads as follows:

"1. A concentration measuring method for measuring a concentration of a measurement target substance and preventing deterioration of measurement accuracy in the measurement of a sample solution of a high concentration of the target substance due to the

influence of a prozone-like phenomenon, the method comprising:

selecting from a plurality of calibration curves a calibration curve optimum for computing concentration of a measurement target substance, said step of selecting being based on an output from a reaction system containing the target substance and a reactant capable of reacting with the target substance, said output being an optical response value obtained when said reaction system is irradiated with light; and

computing the concentration of the target substance based on the optimum calibration curve and the output;

wherein each of the calibration curves shows the relationship between the concentration of the target substance and the optical response value and each is prepared based on a plurality of optical response values generated upon lapse of a same reaction time from a plurality of standard reaction systems each containing the target substance of a known different concentration and the reactant, the plurality of standard reaction systems including a system containing a high concentration of the target substance, in which a prozone-like phenomenon is present, and a system containing a low concentration of the target substance, in which a prozone-like phenomenon is absent; and

wherein the plurality of calibration curves differ from each other in respect of said same reaction time based on which the calibration curves are prepared; and

wherein the plurality of calibration curves include a first calibration curve and a second calibration curve; and

wherein the first calibration curve is prepared based on the optical response values measured from the plurality of standard reaction systems in an initial

stage of the reaction, the initial stage being a reaction period in which the output varying with time in the standard reaction system containing the high concentration of the target substance becomes maximum; and

wherein the second calibration curve is prepared based on the optical response values measured after said optical response values measured at the initial stage of the reaction are measured, at a second stage in which the output varying with time in the standard reaction system containing the low concentration of the target substance reaches an equilibrium state, and

A: wherein the method comprises:

computing (S23) an estimated concentration (D) of the target substance by using the first calibration curve and a first output measured from the reaction system at the initial stage;

selecting (S27) the first calibration curve as the optimum calibration curve when the estimated concentration of the target substance is higher than a predetermined concentration threshold, wherein said predetermined concentration threshold is set to lie in a concentration range in which the first and second calibration curves are linear, or is set to a concentration corresponding to an intersection of the first calibration curve and the second calibration curve; and

selecting (S28) the second calibration curve as the optimum calibration curve when the estimated concentration (D) of the target substance is lower than the predetermined concentration threshold;

or:

B: wherein the method comprises:

computing (S4) an estimated concentration (D) of the target substance by using the first calibration curve and a first output measured from the reaction system at the initial stage;

computing (S6) an estimated concentration (d) of the target substance by using the second calibration curve and a second output measured from the reaction system at the second stage;

determining (S7) whether the estimated concentration (d) using the second calibration curve and the second output is higher or lower than a predetermined concentration threshold, wherein said predetermined concentration threshold is set to lie in a concentration range in which the first and second calibration curves are linear, or is set to a concentration corresponding to an intersection of the first calibration curve and the second calibration curve,

and if the estimated concentration (d) using the second calibration curve and the second output is lower than the concentration threshold, determining (S11) whether the prozone-like phenomenon is present;

and, if it is determined that the prozone-like phenomenon is absent, adopting (S9) the estimated concentration (d) using the second calibration curve and the second output as a conclusive computation value;

or, if it is determined that the prozone-like phenomenon is present, adopting (S10) the estimated concentration (D) using the first calibration curve and the first output as a conclusive computation value,

and if the estimated concentration (d) using the second calibration curve and the second output is higher than the predetermined concentration

threshold, comparing the estimated concentration (d) using the second calibration curve and the second output with the estimated concentration (D) using the first calibration curve and the first output, and adopting a higher one of the estimated concentration (D) using the first calibration curve and the first output and the estimated concentration (d) using the second calibration curve and the second output as a conclusive computation value."

First auxiliary request:

The wording of claim 1 of the first auxiliary request differs from that of claim 1 of the main request in that the text defining alternative "A" ("A: wherein the method comprises: [...] lower than the predetermined concentration threshold") is replaced by the following text:

"A: wherein the method comprises:

 computing (S23) an estimated concentration (D) of the target substance by using the first calibration curve and a first output measured from the reaction system at the initial stage;

 computing (S25) an estimated concentration (d) of the target substance by using the second calibration curve and a second output measured from the reaction system at the second stage;

 determining (S26) whether the estimated concentration (D) using the first calibration curve and the first output is higher than a predetermined concentration threshold, wherein said predetermined concentration threshold is set to lie in a concentration range in which the first and second calibration curves are linear, or is set to a

concentration corresponding to an intersection of the first calibration curve and the second calibration curve;

adopting (S27) the estimated concentration (D) using the first calibration curve and the first output as a conclusive computation value if the estimated concentration (D) using the first calibration curve and the first output is determined to be higher than said predetermined concentration threshold; and

adopting (S28) the estimated concentration (d) using the second calibration curve and the second output as a conclusive computation value if the estimated concentration (D) using the first calibration curve and the first output is determined to be not higher than said predetermined concentration threshold".

Second auxiliary request:

The wording of claim 1 of the second auxiliary request differs from that of claim 1 of the main request in the deletion of the text defining alternative "A" and consisting of the wording "A: wherein the method comprises [...] or: B:".

Third auxiliary request:

Independent claim 2 of the third auxiliary request reads as follows:

"2. A concentration measuring method for computing concentration of a measurement target substance based on an output from a reaction system containing the target substance and a reactant capable of reacting with the target substance, said output being an optical

response value obtained when said reaction system is irradiated with light, and a specific calibration curve showing a relationship between the concentration of the target substance and the optical response value;

wherein the specific calibration curve is prepared as a composite of a first calibration curve and a second calibration curve, each prepared using a plurality of standard reaction systems, the plurality of standard reaction systems including a system containing a high concentration of the target substance, in which a prozone-like phenomenon is present, and a system containing a low concentration of the target substance, in which a prozone-like phenomenon is absent, the first calibration curve being prepared based on optical response values measured from the plurality of standard reaction systems in an initial stage of the reaction, the initial stage being a reaction period in which the output varying with time in the standard reaction system containing the high concentration of the target substance becomes maximum, the second calibration curve being prepared based on the optical response values measured after said optical response values measured at the initial stage of the reaction are measured, at a second stage in which the output varying with time in the standard reaction system containing the low concentration of the target substance reaches an equilibrium state; and

wherein the specific calibration curve comprises a higher concentration portion for a concentration range higher than an intersection concentration which corresponds to an intersection of the first calibration curve and the second calibration curve, and a lower concentration portion for a concentration range lower than the intersection concentration, the higher concentration portion comprising a portion of the first calibration curve for a concentration range higher than

the intersection concentration, the lower concentration portion comprising a portion of the second calibration curve for a concentration range lower than the intersection concentration,

and wherein the method comprises computing the concentration of the measurement target substance based on the output from the reaction system and the specific calibration curve."

Fourth auxiliary request:

The wording of independent claim 2 of the fourth auxiliary request differs from that of independent claim 2 of the third auxiliary request in that the last paragraph of the claim ("and wherein the method comprises computing [...] and the specific calibration curve") is omitted, and in that the text of the first paragraph of the claim ("A concentration measuring method for [...] and the optical response value;") is replaced by the following text:

"A method of preparing a specific calibration curve for use in a concentration measuring method for computing concentration of a measurement target substance based on an output from a reaction system containing the target substance and a reactant capable of reacting with the target substance, said output being an optical response value obtained when said reaction system is irradiated with light;

wherein the specific calibration curve shows a relationship between the concentration of the target substance and the optical response value;".

Fifth auxiliary request:

Claim 1 of the fifth auxiliary request reads as follows:

"1. A concentration measuring method for computing a concentration of a measurement target substance and preventing deterioration of measurement accuracy in the measurement of a sample solution of a high concentration of the target substance due to the influence of a prozone like phenomenon, wherein said computing the concentration of the measurement target substance is based on an output from a reaction system containing the target substance and a reactant capable of reacting with the target substance, said output being an optical response value obtained when said reaction system is irradiated with light, and a calibration curve (α) showing a relationship between the concentration of the target substance and the optical response value;

the method comprising:

preparing the calibration curve (α);

measuring the output from the reaction system as a function of time;

determining the maximum value of the output; and

computing the concentration of the measurement target substance using the calibration curve (α) and the maximum output,

wherein the calibration curve (α) is prepared by measuring, as a function of time at predetermined time intervals, outputs from a plurality of standard reaction systems containing the target substance at known different concentrations and the reactant, and collecting a maximum output from the plurality of outputs for each of the standard reaction systems, and constructing the calibration curve (α) from the maximum outputs."

The set of claims of the fifth auxiliary request further includes a single dependent claim 2 referring back to the method of claim 1.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request*
 - 2.1 *Admissibility*

In its communication annexed to the summons to oral proceedings the board raised a series of objections under Article 84 EPC 1973 in respect of the claims of all requests then on file, and in particular in respect of each of the three independent claims of each of those requests, and more particularly in respect of alternative "A" defined in claim 1 of all those requests. In reaction to these objections, the appellant submitted with its letter dated 8 February 2017, among other sets of claims, a new set of amended claims constituting the present main request and addressing the objections under Article 84 EPC 1973 mentioned above.

The amendments made to the claims of the present main request are therefore directed to overcoming the objections raised by the board under Article 84 EPC 1973. In addition, some of these objections related to clarity issues that had not previously been addressed during the first-instance proceedings. Furthermore, although some of the amendments made to the claims gave

rise to new issues which were addressed for the first time during the oral proceedings (see point 2.2 below), the board found that none of these issues was particularly complex. Under these circumstances, the board, exercising its discretion under Article 13(1) RPBA (Rules of Procedure of the Boards of Appeal), decided to admit the main request into the appeal proceedings.

2.2 *Article 123(2) EPC and Article 84 EPC 1973*

2.2.1 Claim 1 is directed to a method of determination of the concentration of a target substance on the basis of optical measurements carried out in a reaction of the target substance with a reactant, the measurements exhibiting the so-called prozone-like phenomenon when the target substance is present at high concentrations. According to this phenomenon, the value of the optical measurement varies with time and increases from an initial stage of the reaction, and when the substance is present in relatively high concentrations the measurement value reaches a maximum and then decreases (see Fig. 3 and the corresponding description of the application as originally filed, together with page 1, line 6, to page 2, line 14, of the description of the application as originally filed).

According to the introductory paragraphs of claim 1, a first and a second calibration curve are first prepared, and then one of the two curves is selected as optimum for computing the concentration of the target substance according to the optical measurements carried out in the reaction of the target substance with the reactant.

In addition, according to alternative "A" of claim 1 the method further comprises the steps of first "computing (S23) an estimated concentration (D)" of the target substance by using the first calibration curve (see first paragraph of alternative "A" of claim 1), and then "selecting [...] as the optimum calibration curve" the first or the second of the calibration curves depending on whether the computed estimated concentration is higher or lower than a predetermined concentration threshold (see second and third paragraphs of alternative "A" of claim 1).

According to the submissions of the appellant, alternative "A" of claim 1 is based on the combination of claim 1 and dependent claims 2 and 5 of the application as originally filed, together with the flow chart represented in Fig. 6 and the corresponding description in the application as originally filed.

However, while in the claims as originally filed referred to by the appellant one of the first and the second calibration curves is first selected as the "optimum" curve depending on whether the concentration of the target substance is predicted to be higher or lower than a predetermined concentration threshold (see first paragraph of claim 1 together with dependent claim 2 as originally filed) and then the concentration of the target substance is computed on the basis of the selected calibration curve (see first paragraph of claim 1 as originally filed), in the flowchart shown in Fig. 6 two different concentration values (values "D" and "d" in steps S23 and S25 of Fig. 6) are first computed on the basis of the first and the second calibration curves, respectively, and then the first or the second of these values is adopted as the conclusive concentration value (steps S27 and S28 of the flow

chart) depending on whether the first of the values is higher or not than the predetermined concentration threshold (step S26 in the flowchart). In other words, in the method disclosed with reference to the flowchart of Fig. 6 no calibration curve is selected in the specific manner defined in alternative "A" of claim 1.

It follows that the sequence of steps defined in alternative "A" referred to above results from a combination of partial aspects of original claims 1, 2 and 5 and of partial aspects of the disclosure of the flowchart represented in Fig. 6. However, no clear and unambiguous basis can be found in the application as originally filed for this specific combination of partial aspects pertaining to two different, non-equivalent disclosures. Consequently, the subject-matter of alternative "A" of claim 1 of the main request extends beyond the content of the application as originally filed (Article 123(2) EPC).

2.2.2 In addition, alternative "A" of claim 1 is not clear in that the claim is directed to a method of measuring the concentration of the substance under consideration on the basis of the preparation of two calibration curves and the subsequent selection of one of the curves as "optimum for computing [the] concentration" of the substance (second paragraph of claim 1), but the claim fails to specify as an essential feature of alternative "A" how the concentration is actually computed once the optimum calibration curve has been selected. This is particularly the case when the second of the calibration curves is selected as the "optimum" curve (last paragraph of alternative "A"), the claim being silent as to the computation of any ("estimated" and/or final) value of the concentration of the substance on

the basis of the second of the calibration curves under consideration and the optical outputs measured in the reaction of the target substance.

Claim 1 of the main request is therefore not clear in respect of the alternative "A" defined in the claim (Article 84 EPC 1973).

3. *First auxiliary request*

3.1 *Admissibility*

The set of claims of the first auxiliary request was also submitted by the appellant with its letter dated 8 February 2017 in reaction to the objections raised under Article 84 EPC 1973 by the board in the annex to the summons to oral proceedings (see point 2.1 above, first paragraph).

As already noted in point 2.1 above, second paragraph, some of the objections raised under Article 84 EPC 1973 related to clarity issues that had not previously been addressed during the first-instance proceedings. Furthermore, as it was the case with the main request (point 2.1 above, second paragraph), some of the amendments made to the claims gave rise to new issues which were addressed for the first time during the oral proceedings (see point 3.2 below), but none of these issues was particularly complex. In addition, claim 1 of the first auxiliary request was not open to the objections of added subject-matter and of lack of clarity raised in point 2.2 in respect of claim 1 of the main request. Under these circumstances, the board, exercising its discretion under Article 13(1) RPBA, decided to admit the first auxiliary request into the appeal proceedings.

3.2 *Article 84 EPC 1973*

Alternative "A" of claim 1 involves, among other features, computing "an estimated concentration (d)" of the target substance by using the second of the calibration curves previously defined in the claim (see the fourth, fifth and eighth paragraphs of the section of claim 1 preceding the definition of alternative "A") and an output measured in the reaction of the substance at the second stage (second paragraph of alternative "A"). This second stage is defined in the claim as the stage at which the measurement output varying with time in reaction systems containing the target substance at low concentrations reaches an equilibrium state (eighth paragraph of the section of claim 1 preceding the definition of alternative "A"), and the second of the calibration curves consists of the measurement outputs in reaction systems each containing the target substance at a different concentration value running from a high concentration value in which the prozone-like phenomenon is present to a low concentration value in which the phenomenon is absent (fourth paragraph of the section of claim 1 preceding the definition of alternative "A"), these measurement outputs being also measured at the second stage under consideration (eighth paragraph of the section of claim 1 preceding the definition of alternative "A"). The technical nature of this second stage is such that the second calibration curve first increases, reaches a maximum, and then decreases (see "Calibration curve (2)" in Fig. 2). As a consequence, the computation of "an estimated concentration (d)" on the basis of the second calibration curve as required in alternative "A" of claim 1 is unclear in that the corresponding value is generally not uniquely determined. As an illustration

of the nonunivocal definition of the "estimated concentration (d)", it is noted that a value of the output within the relatively broad range of values between about 0.300 and about 0.550 in the example shown in Fig. 2 of the application generally leads in the second calibration curve ("Calibration curve (2)" of Fig. 2) to two different values of the "estimated concentration (d)".

During the written proceedings the appellant referred to different passages of the description of the application and submitted that the skilled person would, in view of these passages, reject the higher of the two possible values of the "estimated concentration (d)". However, Article 84 EPC 1973 requires that the claims are clear in themselves. Thus, irrespective of whether or not technical considerations based on the description of the application would suggest to the skilled reader to solve the ambiguity under consideration by selecting among the possible values of the "estimated concentration (d)" the smallest of the values, the appellant's arguments do not alter the board's view that claim 1 is unclear because it does not contain a clear definition of the "estimated concentration (d)". During the oral proceedings the appellant also submitted that claim 1 required the determination of the value of the "estimated concentration (D)" and that, in view of the technical significance of this value, the skilled reader would retain in the claimed method only the smallest of the two possible values of the "estimated concentration (d)". However, neither the value of the "estimated concentration (D)" nor the remaining claimed features, taken alone or in combination, would guide the skilled reader to only select the smallest value among the two possible values of the "estimated concentration (d)".

Having regard to the above considerations, the board concludes that claim 1 of the first auxiliary request is not clear in respect of alternative "A" defined in the claim (Article 84 EPC 1973).

4. *Second auxiliary request*

4.1 *Admissibility*

The set of claims of the second auxiliary request was submitted during the oral proceedings before the board in reaction to the objections of added subject-matter and of lack of clarity raised during these oral proceedings in respect of alternative "A" of claim 1 of the main and the first auxiliary requests (see points 2.2 and 3.2 above). Claim 1 of the second auxiliary request is directed to alternative "B" defined in claim 1 of the main request, alternative "A" having been deleted. In view of the fact that the main and the first auxiliary requests were admitted by the board into the appeal proceedings (see points 2.1 and 3.1 above) and that the amendment by way of deletion of alternative "A" in claim 1 overcame the objections raised in points 2.2 and 3.2 above in respect of the main and the first auxiliary requests, the board, exercising its discretion under Article 13(1) RPBA, decided to admit the second auxiliary request into the appeal proceedings.

4.2 *Article 84 EPC 1973*

Claim 1 is essentially directed to the same method of claim 1 of the main request (see first two paragraphs of point 2.2.1 above), after deletion of alternative "A". The claim is, however, not clear in several

respects. In particular, the claimed method also involves - as it was the case in alternative "A" of claim 1 of the first auxiliary request, see point 3.2 above - the step of computing "an estimated concentration (d)" of the target substance by using the second of the calibration curves previously defined in the claim (see claim 1 of the second auxiliary request, step "computing (S6) an estimated concentration (d) [...] from the reaction system at the second stage;"), and this step is not clear for the same reasons already given in point 3.2 above in respect of claim 1 of the first auxiliary request.

In addition, the claimed method also involves the step of "determining (S11) whether the prozone-like phenomenon is present" in the reaction of the target substance (see claim 1 of the second auxiliary request, step "and if the estimated concentration (d) [...] determining (S11) whether the prozone-like phenomenon is present;"). This step corresponds to step S11 of the flowchart shown in Fig. 5, and the corresponding disclosure was objected by the examining division under Article 83 EPC in respect of the invention defined in some of the claims then on file (cf. point II above). The incorporation of this feature in amended claim 1 according to the present second auxiliary request gives rise to an objection under Article 84 EPC 1973 for reasons similar to those given by the examining division in respect of the objection of Article 83 EPC raised in the decision under appeal (Reasons for the decision, point 6). In particular, as specified in the first paragraph of claim 1, the claimed method is directed to the determination of the concentration of a substance exhibiting the prozone-like phenomenon when it is present at high concentrations, and the claimed step of determining whether the prozone-like phenomenon

is present is unclear in the context of the claim because the method fails to specify how this step is carried out in the claimed method for a substance the concentration of which is to be determined according to the claimed method. The appellant has referred in this respect to different passages of the description, and submitted that the presence of the prozone-like phenomenon can be detected by a simple comparison of the two outputs measured in the reaction of the target substance at an initial and at a final stage, or by evaluating whether the measurement output at an initial stage is higher than a predetermined output threshold; however, no such comparison and no such evaluation, let alone any clear comparison criteria or any specific evaluation output threshold, are defined in the claim. In addition, the sequence of remaining steps of the claimed method addresses the problem of determining the concentration of the target substance while taking appropriately into account that the concentration of the substance might be sufficiently high to cause the prozone-like phenomenon in the measurement process; in this technical context, the fact of including in the claimed method the mentioned step of determining whether the prozone-like phenomenon is present appears to render technically redundant, if not superfluous, at least some of the remaining steps of the claimed method (in particular, the comparison of the "estimated concentration (d)" with both the predetermined concentration threshold and the "estimated concentration (D)", see claim 1, step "determining (S7) whether the estimated concentration (d) [...] and the second calibration curve,", and last paragraph of the claim, reflecting steps S7 and S8 of Fig. 5). As a result, claim 1 also lacks clarity as regards the distinction between the different claimed steps and the technical significance thereof.

Having regard to the above considerations, the board concludes that claim 1 of the second auxiliary request is not clear (Article 84 EPC 1973).

5. *Third auxiliary request*

5.1 *Admissibility*

The set of claims of the third auxiliary request submitted during the oral proceedings before the board differs from the set of claims of the main request in that claim 1 and dependent claim 2 of the main request have been deleted, thus overcoming all the objections under Article 84 EPC 1973 and Article 123(2) EPC considered in points 2.2, 3.2 and 4.2 above in respect of the main and the first and second auxiliary requests. In addition, independent claims 1 and 2 and dependent claim 3 of the third auxiliary request correspond to independent claims 3 and 4 and dependent claim 5 of the main request, respectively, the two independent claims 1 and 2 having been further amended by the introduction of additional features. These additional features overcome other objections raised by the board in its communication annexed to the summons to oral proceedings, and they did not raise any new complex issue. Under these circumstances, the board, exercising its discretion under Article 13(1) RPBA, decided to admit the third auxiliary request into the appeal proceedings.

5.2 *Article 84 EPC 1973*

Independent claim 2 is directed to a concentration measuring method for computing the concentration of a target substance on the basis of an optical output

measured in the reaction of the target substance with a reactant and a calibration curve showing a relationship between the concentration of the target substance and the optical output (first paragraph of independent claim 2). In addition, the claim specifies how the curve is prepared (second and third paragraphs of the claim). However, the claim is not clear in that it fails to specify one of the essential features of the claimed method, namely how the calibration curve is then used in the determination of the concentration of the substance as a function of the optical output measured in the reaction of the target substance. In particular, the method relates to substances exhibiting the prozone-like phenomenon when present at high concentrations (see second paragraph of the claim), and in this technical context the optical output under consideration does not consist of a unique measurement output, but - as it is also apparent in the preparation of the curves involving measurements at different stages, see second paragraph of the claim - of a measurement output varying with time. It is therefore not clear in the claim how a value of the concentration of the substance can be obtained from this time-varying measurement output and the calibration curve "showing a relationship between the concentration of the target substance and the optical response value" (claim 2, first paragraph).

As submitted by the appellant, the last paragraph of the claim specifies that the concentration of the target substance is computed "on the basis of the output from the reaction system and the specific calibration curve". However, this feature does not overcome the objection of lack of clarity under consideration because the feature merely rephrases the feature objected to under Article 84 EPC 1973 and fails

to specify how the concentration of the target substance can be computed with the calibration curve on the basis of the time-varying measurement output.

Therefore, independent claim 2 of the third auxiliary request is not clear (Article 84 EPC 1973).

6. *Fourth auxiliary request - Admissibility*

The set of claims of the fourth auxiliary request was filed during the oral proceedings. This set of claims differs from that of the third auxiliary request in that the first paragraph of independent claim 2 has been reformulated as being directed to "A method of preparing a specific calibration curve for use in a concentration measuring method", the concentration measuring method being as defined in the previous version of the claim, and in that the last paragraph of the claim has been omitted (see point VI above). According to the appellant, this amendment is directed to overcoming the objection of lack of clarity raised under Article 84 EPC 1973 by the board with regard to independent claim 2 of the third auxiliary request (see point 5.2 above).

Independent claim 2 of this request is therefore directed to "A method of preparing a specific calibration curve for use in a concentration measuring method for computing concentration of a measurement target substance [...]", and the claim further defines the method of preparation of the calibration curve (see two last paragraphs of the claim). However, as already held in point 5.2 above in respect of independent claim 2 of the third auxiliary request, the claim is not clear in that it is silent as to how the calibration curve is actually used in the computation of the

concentration of the target substance, and the redefinition of the claim as being directed to a method of preparation of the calibration curve has no impact on this finding. In particular, independent claim 2 is directed to a method of preparing a calibration curve without however specifying as an essential feature in what respect the curve constitutes a calibration curve, i.e. without specifying how the curve serves its calibration purpose of allowing for the computation of the concentration of the target substance as a function of the optical response value. In addition, contrary to the appellant's submissions, the disclosure in the description relating to the use of the calibration curve cannot overcome the lack of clarity under consideration because Article 84 EPC 1973 requires that the claims are clear in themselves.

In view of these considerations, the board found that the amendments made during the oral proceedings to independent claim 2 of the fourth auxiliary request did not fulfil their purpose, i.e. they did not overcome in substance the objection raised under Article 84 EPC 1973 with regard to independent claim 2 of the third auxiliary request. For this reason, the board, exercising its discretion under Article 13(1) RPBA, decided not to admit the fourth auxiliary request into the appeal proceedings.

7. *Fifth auxiliary request*

7.1 *Admissibility*

The set of claims of the fifth auxiliary request differs from the set of claims of the third auxiliary request in that independent claim 2 has been deleted and dependent claim 3 has been renumbered as dependent

claim 2. The deletion of independent claims 2 of the third auxiliary request overcomes the objection of lack of clarity raised in point 5.2 above and, in view of the reasons for which the board admitted the third auxiliary request into the appeal proceedings (see point 5.1 above), the board, exercising its discretion under Article 13(1) RPBA, decided to admit the fifth auxiliary request into the appeal proceedings.

7.2 *Amendments*

The board is satisfied that the amended application documents according to the fifth auxiliary request satisfy the requirements of Article 123(2) EPC. In particular, claim 1 is based on independent claim 11 and dependent claim 12 as originally filed and on the passage on page 2, line 23, to page 3, line 1, of the description of the application as originally filed, together with Fig. 9 and the corresponding description on page 24, lines 1 to 21, of the application as originally filed, this last passage referring to features previously disclosed in the description with reference to Figs. 2 and 3 and also applying to the embodiment of Fig. 9. Dependent claim 2 is based on page 7, lines 17 to 19, of the description of the application as originally filed.

As regards the description, its content has been brought into conformity with the invention as defined in the claims (Article 84, second sentence, EPC 1973 and Rule 27(1)(c) 1973), and the pertinent state of the art (documents D1 and D2) has been appropriately acknowledged in the introductory part of the description in accordance with Rule 27(1)(b) EPC 1973.

7.3 *Articles 83 and 84 EPC 1973*

In the decision under appeal the examining division held that claim 1 of the requests then on file contravened Article 84 EPC, and that the invention defined in claim 1 of some of those requests was not sufficiently disclosed within the meaning of Article 83 EPC (see point II above). The set of claims of the present fifth auxiliary request, however, no longer contains the alternative embodiment previously defined in claim 1 of the requests underlying the decision under appeal. Consequently, all the objections raised by the examining division under Articles 83 and 84 EPC in the decision under appeal no longer apply to the present fifth auxiliary request. In addition, the board is satisfied that the set of claims of the present fifth auxiliary request comply with the requirements of Article 84 EPC 1973, and that the invention defined in these claims is sufficiently disclosed within the meaning of Article 83 EPC 1973.

7.4 *Novelty and inventive step*

7.4.1 Claim 1 of the present fifth auxiliary request is directed to the same alternative embodiment of the invention previously defined in independent claim 5 of the main request underlying the decision under appeal, and in an *obiter dictum* of the decision the examining division expressed its view that the subject-matter of independent claim 5 of the main request then on file was anticipated by the disclosure of document D2 (see point II above).

7.4.2 Document D2 addresses essentially the same problem considered in the application (see point 2.2.1 above, first paragraph, and page 1, line 6, to page 2, line 14, of the description of the application), i.e. the

determination of the concentration of a substance on the basis of optical measurements carried out in a reaction of the substance with a reactant, the measurements exhibiting the prozone-like phenomenon or, in the terminology of document D2, the hook effect (document D2, abstract, together with column 1, lines 39 to 59).

Document D2 proposes, as it is the case in the claimed invention, the use of a calibration curve for the determination of the concentration of the target substance as a function of the values of measurements carried out in the reaction of the substance with the reactant (abstract, and column 3, line 42, to column 4, line 3). However, while in document D2 the calibration curve (Fig. 5) is generated by a combination of curves (Figs. 2 to 4), representing reaction rate measurements (column 5, lines 13 to 29, and column 5, line 43, to column 6, line 5) at different concentrations of the substance (abstract, and column 5, line 16, to column 6, line 60), according to claim 1 of the fifth auxiliary request the calibration curve is prepared by first carrying out the measurements as a function of time in a plurality of reaction systems containing the substance at different, known concentrations, and then collecting the maximum measurement output for each of the reaction systems. In addition, while in document D2 the determination of the concentration of the substance in a sample on the basis of the calibration curve is based on reaction rate measurements (column 7, lines 45 to 65), in the claimed invention the concentration of the substance in a sample is determined on the basis of the calibration curve and the maximum value of the measurements obtained with the sample.

Therefore, the method defined in claim 1 of the present fifth auxiliary request is new over the disclosure of document D2.

- 7.4.3 The remaining documents on file are less relevant than document D2. In particular, document D1 (referred to by the examining division in its decision in the assessment of patentability of an alternative embodiment not covered by the present claims and defined in independent claim 6 of the main request then on file, see point II above) also addresses the problem of the prozone-like phenomenon or hook effect under consideration (document D1, Figs. 4 and 5, and page 24, lines 14 to 20). However, in document D1 the concentration of the substance in the sample is determined by comparing the values measured in the reaction of the substance with the reactant with a first and a second calibration curve respectively representing, as a function of concentration of the substance, growth rates of the measurement values and final measurement values (page 8, lines 12 to 31, and page 20, line 28, to page 21, line 17, together with Figs. 4 to 6 and the corresponding description).
- 7.4.4 In addition, neither document D1 nor document D2 nor the remaining documents on file, taken alone or in combination with each other, suggest the claimed method, and in particular the determination of the concentration of the substance on the basis of the maximum output measured in the reaction of the substance with the reactant and a calibration curve representing maximum measurement outputs versus concentration values of the substance as defined in claim 1.

7.4.5 In view of the above, the board concludes that the subject-matter of claim 1 of the fifth auxiliary request is new and involves an inventive step over the documents of the prior art on file (Articles 54(1) and 56 EPC 1973). The same conclusion applies to dependent claim 2.

8. In view of the above conclusions and considerations, the fifth auxiliary request is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to grant a patent in the following version:
 - Claims: Nos. 1 and 2 according to the fifth auxiliary request "2.10 pm", filed at the oral proceedings of 8 March 2017;
 - Description: Pages 1, 2, 2a, 3, 3A and 4 to 25, filed at the oral proceedings of 8 March 2017; and
 - Drawings: Sheets 1/8 to 8/8 as originally filed.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

R. Bekkering

Decision electronically authenticated