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Datasheet for the decision of 16 March 2023

Case Number: T 0283/18 - 3.3.08

Application Number: 08734511.2

Publication Number: 2147307

IPC: G01N33/49

Language of the proceedings: EN

Title of invention:
A sensor assembly for body fluids

Patent Proprietor:
Radiometer Medical ApS

Opponent:
Siemens Healthcare Diagnostics Inc.

Headword:
A sensor assembly/RADIOMETER MEDICAL APS

Relevant legal provisions:
EPC Art. 100(a), 54(2), 56, 123(2)
RPBA Art. 12(4)
RPBA 2020 Art. 13(1), 13(2)

Keyword:
Grounds for opposition - lack of novelty (yes)
Amendment after summons - exceptional circumstances (no)
Amendments - extension beyond the content of the application as filed (yes)
Late-filed evidence - admitted (no)
Late-filed request - admitted (no)
Auxiliary request 3 - allowable (yes)

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Case Number: T 0283/18 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 16 March 2023

Appellant: (Opponent)	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591 (US)
Representative:	Potter Clarkson Chapel Quarter Chapel Bar Nottingham NG1 6HQ (GB)
Respondent: (Patent Proprietor)	Radiometer Medical ApS Åkandevej 21 2700 Brønshøj (DK)
Representative:	Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 November 2017 rejecting the opposition filed against European patent No. 2147307 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	R. Morawetz
	R. Romandini

Summary of Facts and Submissions

I. European patent No. 2 147 307 ("the patent") is based on European patent application No. 08 734 511.2, which was filed as an international patent application published as WO 2008/131767 ("the application as filed"). The patent is entitled "*A sensor assembly for body fluids*".

II. One opposition to the granted patent was filed. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) and (c) EPC. The opposition division rejected the opposition.

III. The following documents are referred to in the present decision:

E0 Appendix I to the notice of opposition, feature structure of claim 1 of the main request

E1 US2004/0043477

E3 US 5,520,787

E6 J. Wang *et al.*, Anal. Chem. 62, 1990, 1924-1927

E11a Clinical Methods, The History, Physical, and Laboratory Examinations, 3rd edition, 1990, H.K. Walker *et al*. editors, Chapter 49, 254-257

E11b Screenshot of a website providing a link to E11a

E12 Expert declaration by Prof. Minteer, dated 23 February 2023

IV. The opponent (appellant) filed notice of appeal against the opposition division's decision rejecting the opposition.

V. With the statement setting out the grounds of appeal the appellant submitted, *inter alia*, new document E6.

VI. In reply to the statement of grounds of appeal, the patent proprietor (respondent) requested that the appeal be dismissed, i.e. that the patent be maintained as granted (main request), and submitted sets of claims of new auxiliary requests 1 to 5.

VII. With a further submission, the respondent filed a set of claims of new auxiliary request 6.

VIII. With a letter dated 30 March 2021, the respondent submitted sets of claims of corrected auxiliary requests 2, 4, 5 and 6, a set of claims of auxiliary request 1B and documents E11a and E11b. It also stated that it maintained auxiliary requests 1 to 3 filed on 13 September 2017; with a later letter, dated 23 August 2022, these requests were re-submitted and renumbered as seventh to ninth auxiliary requests.

IX. The board scheduled oral proceedings, in accordance with the parties' requests, and subsequently issued a communication under Article 15(1) RPBA, in which it indicated its preliminary opinion with respect to, *inter alia*, the construction of claim 1 of the main request and novelty over document E1.

X. In response, the respondent filed further written submissions and document E12, with its letter dated 27 February 2023.

XI. The appellant filed observations on the respondent's submissions.

XII. The oral proceedings before the board took place as scheduled. The respondent withdrew the corrected auxiliary request 2 that had been filed with the letter dated 30 March 2021. At the end of the oral proceedings, the Chairwoman announced the board's decision.

XIII. The wording of claim 1 of each of the claim requests dealt with in this decision is set out below.

Claim 1 of the main request reads as follows:

"1. A sensor assembly (1) comprising:
- a first electronic wiring substrate (2) having a first and a second surface and at least two analyte sensors (6) formed on the first surface thereof, the at least two analyte sensors being connected with electrical contact points (5c),
- a second electronic wiring substrate (3) having a first and a second surface and at least two analyte sensors (6) formed on the first surface part thereof, the at least two analyte sensors being connected with one or more electrical contact points (5c), and
- a spacer (4) having a through-going recess (7) with a first and a second opening,
wherein the first substrate, the second substrate and the spacer are arranged in a layered structure, where the first surface of the first substrate closes the first opening of the spacer and the first surface of

the second substrate closes the second opening of the spacer, thereby forming a measuring cell (7a), characterised in that all the analyte sensors on the first surface part of the first substrate face the measuring cell through the first opening of the spacer and wherein all the analyte sensors on the first surface part of the second substrate face the measuring cell through the second opening of the spacer, the measuring cell having a shape allowing a fluid flowing through the measuring cell to perform an at least substantially linear movement."

Claim 1 of auxiliary request 1 is based on claim 1 of the main request, amended to specify "A sensor assembly (1) for blood gas measurements comprising: ..." (amendments compared to claim 1 of the main request are indicated by underlining, added by the board).

Claim 1 of auxiliary request 1B is based on claim 1 of the main request, with the following amendment: "to perform an at least substantially linear movement, and wherein the analyte sensors are adapted to measure at least one or more of the following parameters: pO2, pCO2, and pH." (amendments compared to claim 1 of the main request are indicated by underlining, added by the board).

Claim 1 of auxiliary request 3 is a combination of claims 1 and 2 of the main request and reads as follows:

"1. A sensor assembly (1) comprising:
- a first electronic wiring substrate (2) having a first and a second surface and at least two analyte sensors (6) formed on the first surface thereof, the at

least two analyte sensors being connected with electrical contact points (5c),
- a second electronic wiring substrate (3) having a first and a second surface and at least two analyte sensors (6) formed on the first surface part thereof, the at least two analyte sensors being connected with one or more electrical contact points (5c), and
- a spacer (4) having a through-going recess (7) with a first and a second opening,
wherein the first substrate, the second substrate and the spacer are arranged in a layered structure, where the first surface of the first substrate closes the first opening of the spacer and the first surface of the second substrate closes the second opening of the spacer, thereby forming a measuring cell (7a), characterized in that all the analyte sensors on the first surface part of the first substrate face the measuring cell through the first opening of the spacer and wherein all the analyte sensors on the first surface part of the second substrate face the measuring cell through the second opening of the spacer, the measuring cell having a shape allowing a fluid flowing through the measuring cell to perform an at least substantially linear movement, and wherein the electrical contact points (5c) of the first substrate (2) are arranged on the second surface of the first substrate and wherein the electrical contact points (5c) of the second substrate (3) are arranged on the first surface of the second substrate." (amendments compared to claim 1 of the main request are indicated by underlining, added by the board).

XIV. The appellant's arguments, insofar as they are relevant to the decision, are summarised below.

Admittance of the respondent's new facts, arguments and evidence submitted with the letter dated 27 February 2023 (Article 13(2) RPBA)

There was no justification for the respondent to be permitted to present new facts, arguments and evidence at this late stage of the proceedings merely because it was surprised by the board's preliminary opinion. To the extent that the submission was saying what had been said in the reply, the respondent could rely on previous submissions instead.

Main request - claim 1

Claim construction

"analyte sensor"

The term "*analyte sensor*" was to be construed in accordance with the description of the patent (paragraph [0040]), as encompassing "a sensor that comprises a single electrode" that was used (possibly in combination with other, separate means, such as another electrode) to sense a physical parameter of the analyte. Nothing in claim 1 limited the "*analyte sensors*" to sensors that were capable of measuring independently of any other analyte sensor, or that were fully functional on their own.

"*through-going recess*"

The "through-going recess" was through-going in a direction perpendicular to the plane of the spacer, and

there was no limitation in claim 1 that prohibited the through-going recess having a third or more openings or that restricted the recess to mean a "secluded inner area".

Novelty (Article 100(a) and Article 54 EPC)

Document E1 disclosed features F1, F1c, F2, F2c, F3b, F3c, F5, F6 and F9 of claim 1 (see E0 for the feature structure of claim 1).

The subject-matter of claim 1 was not novel over document E1.

Auxiliary request 1
Amendments (Article 123(2) EPC)

The passages at page 1, lines 9 to 11 and 21 to 22 of the application as filed related to the background to the invention and not to an embodiment of the invention, and even in that context described blood gas measurements that were inextricably linked with other measurements which did not appear in the claim.

The claimed wording "*for blood gas measurement*" had a different meaning from "*blood parameter*", which included measurements of non-blood-gas parameters, as was explicit from the passage on page 4 of the application as filed that was quoted by the respondent. Selection was required to arrive at the combination of pCO2, pO2 and pH. That the assembly was suitable for blood gas measurement was therefore not directly and unambiguously derivable at that level of generalisation from the application as filed. The amendment therefore contravened Article 123(2) EPC.

Auxiliary request 1B
Admittance and consideration (Article 13(1) RPBA)

Auxiliary request 1B contravened Article 123(2) EPC for the same reasons as given for auxiliary request 1, and it introduced new issues because it was unclear how the sensors were adapted.

Auxiliary request 3
Admittance and consideration (Article 12(4) RPBA 2007)

Auxiliary request 3 could and should have been filed during the opposition proceedings, because it was an attempt to overcome an objection (novelty over E1) which had already been raised with the notice of opposition. Moreover, auxiliary request 3 did not apply a convergent approach in relation to auxiliary request 1.

Novelty (Article 54(2) EPC) - claim 1

In document E1, contacts 14 were located on the upper surface of upper part 2 for the following reasons: (i) they were shown on the side facing away from the intermediate layer 5 in Figure 1, (ii) paragraph [0041] stated that the electrodes on the upper part 2 were "*identical*" to those on the lower part and (iii) the upper part 2 was indented so that the contacts 14 on the lower part 3 were accessible from above the upper part. The upper part 2 would not need to be indented if connections 14 were not made from above the upper part 2, in the orientation shown in Figure 1 of E1.

The subject-matter of claim 1 was not novel over document E1.

Inventive step (Article 56 EPC) - claim 1

Document E1 as closest prior art

Claim 1 lacked an inventive step over document E1, because it related to a routine modification that would be obvious to the skilled person when addressing the problem of how to improve access to the electrical contacts.

Admittance and consideration of document E6

Document E6 was prior art, as defined by Article 54(2) EPC. The appellant had not been aware of document E6 when the opposition was filed. Document E6 had come to light during post-grant proceedings in the United States, and was *prima facie* relevant. In addition, its teaching overcame the alleged deficiency in document E3 that had been noted at point 17.3 of the decision under appeal.

XV. The respondent's arguments, insofar as they are relevant to the decision, are summarised below.

Admittance of the respondent's new facts, arguments and evidence submitted with the letter dated 27 February 2023 (Article 13(2) RPBA)

The facts, arguments and expert declaration E12 were filed in direct response to the very surprising preliminary opinion of the board, which adopted the appellant's interpretation of the "*analyte sensor*" and "*through-going recess*" of claim 1 of the main request. It was very surprising to the respondent that, although the opposition division had correctly identified a plurality of distinguishing features over document E1,

the board could not in its preliminary opinion identify any difference at all in claim 1 over document E1. The submission used different words to say what had been said before; only the evidence of E12 was new. Regarding the admittance of auxiliary requests 1 to 5, the considerations were in addition to what had been presented before.

Main request - claim 1

Claim construction

"analyte sensor"

The skilled person would understand that an analyte sensor of claim 1 was a fully functional and independent sensor in its own right and did not need to operate with another sensor, and that a reference electrode was not essential but could be utilised in addition in cases where an analyte sensor was an electrochemical sensor comprising only one electrode (paragraphs [0008], [0010] and [0011] of the patent).

"through-going recess"

From the detailed sensor construction defined in claim 1, it was clear to the skilled person that the purpose of a through-going recess was to have a continuous wall around the sensors to create the measuring chamber as defined in claim 1. The skilled person would thus appreciate that the "*through-going recess*" was a secluded or inner area that was delimited and entirely surrounded by non-recessed material.

Novelty

Document E1

In document El a sensor was constituted by a pair of electrodes, with a first one of the pair on one part of the biosensor and a second one of the pair on a second part of the biosensor. One sensor was therefore not formed on a single surface as specified by claim 1, but was distributed over the first and second surfaces. Therefore, document El did not disclose features F1, F1c, F2, and F2c of claim 1.

Moreover, document E1 did not disclose a recess as specified by claim 1. In document E1 the capillary channel 20 was connected to the supply inlet 16, which extended all the way to the edge of the intermediate layer 5, and therefore was not a recess (paragraph 40 and Figure 1 of document E1). Rather, the single use sensor of document El provided a notch, as correctly concluded by the opposition division. The capillary channel in E1 had a single opening, the slit, which could not be closed by the substrates and remained open. Therefore, document El did not disclose features F3, F3a, F3b and F3c of claim 1.

Furthermore, document El did not disclose features F5 and F6, because in document El there was no spacer having a through-going recess with a first opening, where that first opening was closed by a first substrate, on the one hand because there was no recess as claimed and on the other because the capillary channel 20 of document El was necessarily kept open, and not closed, at the supply inlet 16. The same was true of the second, down-facing opening of the capillary channel, which was not closed by the lower

part 3 according to document E1.

Furthermore, document E1 did not disclose feature F9 of claim 1: flow through the measurement cell was impossible in document E1, since the capillary channel 20 was closed at the end.

The subject-matter of claim 1 was novel over document E1.

Auxiliary request 1
Amendments (Article 123(2) EPC)

A basis for the amendment "*for blood gas measurements*", could be found on page 1, lines 5 to 7, 9 to 10 and 21 to 22 and on page 4, lines 27 to 29 of the application as filed.

On page 1, the application as filed disclosed which parameters were typically measured. On page 4, lines 27 to 29, the application as filed disclosed that the analyte sensors of the claimed sensor assembly could be adapted to measure pCO_2, pO_2, and pH. In the embodiment on page 15, lines 24 to 28 of the application as filed blood gas was mentioned first, followed by electrolytes.

For a person skilled in blood analysis, the term "*blood gas measurement*" was a synonym for measuring pCO_2, pO_2 and pH. The skilled reader therefore saw no technical difference between the disclosure that the blood parameters pCO_2, pO_2 and pH were measured and the statement that the device was for "*blood gas measurements*". The skilled person understood that the sensor assembly of the invention was suitable for blood gas measurements.

Auxiliary request 1B
Admittance and consideration (Article 13(1) RPBA)

Auxiliary request 1B had been filed in direct response to the appellant's objections to auxiliary request 1. Auxiliary request 1B resolved the Article 123(2) EPC issue, raised no new issues and should be admitted. The basis for the amendment and the arguments were the same as for claim 1 of auxiliary request 1. The application as filed disclosed that different parameters of the blood sample could be measured with one sensor assembly (page 2, lines 26 to 29 of the application as filed).

Auxiliary request 3
Admittance and consideration (Article 12(4) RPBA 2007)

The appellant had raised new lines of argument in its statement of grounds of appeal, and the respondent had responded to these by filing auxiliary request 3.

Novelty (Article 54(2) EPC) - claim 1

Document E1 did not disclose that the electrical contact points of the first substrate were arranged on the second surface of the first substrate and the electrical contact points of the second substrate were arranged on the first surface of the second substrate.

In paragraph [0039] of document E1 it was made clear that the electrodes 10 and 11 shown on the top surface of a part 2 of Figure 1 faced downwards. In document E1, the lower part 3 contacts 14 are clearly shown facing upwards (Figure 1). In paragraph [0041] of document E1 it was stated that electrodes 8, 9 were connected to contacts 14 on the lower part 3, and the electrodes 10 and 11 were connected to identical

contacts 14 on the upper part 2. In order to be identical, not only had the electrodes 10 and 11 shown in Figure 1 to face downwards, but the contacts 14 on the upper part 2 also had to face downwards.

Inventive step (Article 56 EPC) - claim 1

Document E1 as closest prior art

The technical effect of having electrical contact points facing in the same direction was disclosed in paragraph [0023] of the patent. The objective technical problem to be solved was the provision of a sensor assembly that was convenient and reliable.

The appellant had not provided any evidence or reasoned argument that claim 1 related to a routine modification that would have been obvious to the skilled person when addressing the technical problem of how to improve access to the electrical contact points. There was no teaching in document El to overturn the arrangement of document El and arrive at the claimed structure, and the skilled person would not do so.

Admittance of document E6

The reason given by the appellant for filing document E6 only at the appeal stage did not justify the admission of document E6 into the proceedings at such a late stage.

XVI. The final requests of the parties, insofar as they are relevant to the present decision, were the following:

The appellant requested that the decision under appeal be set aside and that the patent be revoked; that none

of the auxiliary requests of the respondent be admitted into the appeal proceedings; that document E6 filed with the statement of grounds of appeal be admitted into the appeal proceedings; that documents E11a and E11b not be admitted into the appeal proceedings; that the respondent's new facts, arguments and evidence (E12) submitted with the letter dated 27 February 2023 not be admitted into the appeal proceedings.

The respondent requested that the appeal be dismissed (implying rejection of the opposition and maintenance of the patent as granted, main request); or, in the alternative, that the patent be maintained in amended form on the basis of one of the following sets of claims: the set of claims of auxiliary request 1 filed with the reply to the appeal on 16 August 2018, auxiliary request 1B filed with the letter dated 30 March 2021, or auxiliary request 3, filed with the reply to the appeal on 16 August 2018; that document E6 not be admitted into the appeal proceedings; that documents E11a and E11b be admitted into the appeal proceedings; that the expert declaration of Prof. Minteer (document E12) be admitted into the appeal proceedings.

Reasons for the Decision

Admittance of the respondent's submissions made with the letter dated 27 February 2023

1. The submissions were filed shortly before the oral proceedings. The respondent submitted that only document E12 was new; the rest of the submissions did not constitute an amendment of its case, but merely said in different words what had been said in the reply

to the appeal.

2. According to the the appellant, by contrast, the submissions comprised new facts, arguments and evidence which amounted to a reworking of the respondent's case. For this reason, it requested that the entire submission not be admitted into the appeal proceedings.

3. Much of the respondent's submissions focused on how the terms "*through-going recess*" and "*analyte sensor*" should be construed, while the remainder concerns admittance of auxiliary requests 1, 1B, 2, 3, 4 and 5 into the appeal proceedings. For the reasons set out below, the board was not persuaded by the respondent's argument that the submissions did not constitute an amendment of its case.

4. First, the part of the submissions concerning claim construction comprises new facts, evidence and arguments not previously relied on by the respondent. This includes, *inter alia*, references to an online dictionary (see respondent's letter dated 27 February 2023, paragraphs 29 and 44), an explanatory figure (*ibid.*, page 6), illustrations 1 and 2 (*ibid.*, pages 13 and 14), arguments that the through-going recess "must be surrounded on all sides of the recess by material and has a continuous outer perimeter of spacer material" or is a "bore" (*ibid.*, paragraphs 8 to 37) and the expert declaration E12. Secondly, the part of the submissions concerning the admittance of the auxiliary requests was said to be "in addition" to considerations presented previously (*ibid.*, paragraph 90).

5. Pursuant to Article 13(2) RPBA, which applies in the case at hand (Article 25(1) and (3) RPBA), any

amendment to a party's appeal case after notification of a summons to oral proceedings is, as a rule, not to be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned. Article 13(2) RPBA implements the third level of the convergent approach applicable in appeal proceedings and imposes the most stringent limitations on a party wishing to amend its appeal case at an advanced stage of the proceedings (see document CA/3/19, section VI, Explanatory remarks on Article 13(2) RPBA, in Supplementary publication 2 to OJ EPO 2020). Exceptional circumstances are new or unforeseen developments in the appeal proceedings which lie outside the sphere of influence of the party affected by them, such as new objections raised by the board or by another party (see Case Law of the Boards of Appeal, 10th edition 2022 ("CLBA"), V.A.4.5.1).

6. As its justification for filing the submission shortly before the oral proceedings, the respondent submitted that it had been very surprised by the board's preliminary opinion, which adopted the appellant's interpretation of the "analyte sensor" and "through-going recess" of claim 1 of the main request. It was furthermore also very surprising that the board, in its preliminary opinion, could not identify any difference of claim 1 over document E1, although the opposition division had identified several distinguishing features over E1.

7. For the following reasons, the board was not persuaded that the respondent's reasons were indicative of exceptional circumstances justified with cogent reasons within the meaning of Article 13(2) RPBA.

8. In its statement of grounds of appeal, the appellant disputed the way the features "analyte sensor" and "through-going recess" had been construed in the decision under appeal, and maintained that claim 1 of the main request lacked novelty over document E1. In its reply, the respondent argued for a different way of construing the terms in claim 1 of the main request, and maintained that its subject-matter was novel over document E1. The respondent had to expect that the board would accept either the argument of the appellant or that of the respondent here. As it turned out, in its preliminary opinion the board agreed with the appellant (see section IX. above) - one of the possible outcomes - which is therefore not a new or unforeseeable development (see Case Law, V.A.4.5.4a) and V.A.4.5.6c)).

9. Accordingly, the board considers that the respondent's surprise cannot be objectively justified as resulting from an unforeseeable development, and is merely subjective. It is not therefore a suitable way to explain why the new facts and evidence were not filed and the new arguments made at an earlier stage, i.e. in reply to the statement of grounds of appeal, when the respondent should have made its appeal case (Article 12(3) RPBA).

10. The board concludes that the submissions are an amendment of the respondent's case, and that there is no justification for submitting it only in response to the preliminary opinion of the board. The board furthermore agrees with the appellant that, to the extent that the submissions do not go beyond what has been said before with respect to claim construction, they are not needed: the respondent can rely on its previous submissions. Analogous considerations apply to

that part of the submissions focusing on the admittance of auxiliary requests 1 to 5.

11. The board therefore decided not to admit into the appeal proceedings the respondent's submissions made with the letter dated 27 February 2023.

Main request (patent as granted) - claim 1

The claimed invention - claim construction

12. Claim 1 concerns a sensor assembly comprising a first substrate, a spacer and a second substrate, each of the substrates having at least two "*analyte sensors*" formed on one of their two surfaces, the spacer having a *"through-going recess"* with a first and a second opening (see section XIII. above for the complete wording of the claim).

13. Novelty of the subject-matter of claim 1 turns, among other things, on how the terms "*analyte sensor*" and "*through-going recess"* are construed.

14. The board construes these terms according to the normal rules of claim construction, in which the terms used in the claims are given their broadest technically sensible meaning in the context in which they appear and having regard to the common general knowledge and the teaching in the patent (see also CLBA, II.A.6.1).

"analyte sensor"

15. The board considers that the broadest technically sensible meaning of the term *"analyte sensor"* as used in the context of claim 1 is that it relates to any device that is used to sense a physical parameter of an

analyte.

16. The board has not been presented with any evidence which would point to a different, generally accepted understanding of the term in the art. This understanding of the term is furthermore in line with the definition provided in the patent, according to which "[i]*n this description the term analyte sensor denotes any sensor capable of measuring a physical parameter, such as the concentration of a chemical substance. An analyte sensor may comprise one of more electrodes and one or more membranes*" (see paragraph [0040]).

17. The respondent's argument that the skilled person would, based on paragraphs [0008], [0010] and [0011] of the patent, understand that an "*analyte sensor*" of claim 1 is a fully functional independent sensor in its own right and does not need to operate with another sensor is not found persuasive.

18. First, none of paragraphs [0008], [0010] and [0011] of the patent provides a definition of the term "*analyte sensor*". This definition is provided in paragraph [0040] of the patent (see point 16. above). Moreover, paragraph [0008] of the patent refers to "*fully functional sensor elements*", not to a fully functional analyte sensor. Paragraphs [0010] and [0011] again merely state that two or more parameters can be measured without any significant interference between opposing analyte sensors. This does not imply that an "analyte sensor" of claim 1 is a fully functional sensor in its own right.

19. Secondly, and more importantly, none of the features in claim 1 (see section XIII. above) restrict the term

"*analyte sensor*" or imply that it works independently and is a "*fully functional*" analyte sensor in its own right. According to the established case law of the boards of appeal, even limiting features explicitly mentioned in the description but not in the claims are not to be read into the claims (see CLBA, II.A.6.3.2 and II.A.6.3.4).

20. The board agrees with the appellant that the term "*analyte sensor*" as used in claim 1 also encompasses a sensor that comprises a single electrode that is used (possibly in combination with other, separate means, such as another electrode) to sense a physical parameter of the analyte.

"*through-going recess*"

21. The "*through-going recess*" is defined in claim 1 as having *"a first and a second opening, wherein the first substrate, the second substrate and the spacer are arranged in a layered structure, where the first surface of the first substrate closes the first opening of the spacer and the first surface of the second substrate closes the second opening of the spacer, thereby forming a measuring cell"* (see section XIII. above).

22. In view of the described layered structure, the through-going recess is understood to be "through-going" in a direction perpendicular to the plane of the spacer and having a closed first and second opening. None of the other features in claim 1 prohibit the through-going recess having a third or more openings, in addition to the recited first and second openings (see section XIII. above).

23. The respondent's argument that the skilled person would recognise that the purpose of a through-going recess is to have a continuous wall around the sensors to create a measuring chamber and that therefore the "through-going recess" is a secluded or inner area that is delimited and entirely surrounded by non-recessed material is not found persuasive.

24. According to claim 1, the measuring cell is formed by the specific arrangement of the first substrate, the spacer and the second substrate, "*thereby forming a measuring cell*" (point 21. above). The idea that the through-going recess is a secluded area, entirely surrounded by non-recessed material, is neither implied by the described arrangement of the first substrate, second substrate and spacer nor by any of the other technical features in claim 1 or the wording of the claim (see section XIII. above).

25. The board therefore agrees with the appellant that the through-going recess of claim 1 need not be "*a secluded inner area*" but may have further openings, e.g. to the side.

Novelty (Article 100(a) and Article 54(2) EPC)

26. The feature structure of claim 1 of the main request is set out in document E0. This structure was followed in the decision under appeal and is also followed in this decision.

27. Document E1 discloses a biosensor (see Figure 1 and paragraphs [0039] and [0040]) consisting of an upper part 2, a lower part 3 and an intermediate layer 5 arranged between the upper part 2 and the lower part 3 and connecting the two parts with each other. On its

surface lying adjacent the intermediate layer 5, the upper part 2 has two electrodes 10 and 11. The lower part 2 is provided with similar electrodes 8, 9. The upper part 2 has an air vent 7, and the intermediate layer 5 has a slit 6 formed therein which extends via the pairs of electrodes 9, 11 and 8, 10 up to the air vent 7. Said slit 6 starts at an edge of the biosensor and, together with the upper part 2 and the lower part 3, forms a capillary channel 20 which serves to transport body liquid for analysis. The electrodes are located in pairs opposite each other and are arranged such that each pair of electrodes forms a measuring region located in the capillary channel (see paragraph [0005] of E1).

28. The opposition division held that claim 1 of the main request was novel over the disclosure in document E1 because this document disclosed electrodes, not sensors formed on the first or second substrate (features F1, F1c and F2, F2c of claim 1), and a capillary channel forming a notch, not a recess with a through-hole (features F3, F3a of claim 1). For the following reasons, the board disagrees with the decision under appeal on this point.

29. As set out in point 19. above, claim 1 of the main request does not specify that each analyte sensor is fully functional in its own right. In view of the claim construction adopted by the board (see point 20. above), the biosensor of document E1 having individual electrodes 8, 9 and 10, 11 which are formed on the surfaces of the upper and lower parts and which perform their function as part of a pair of electrodes falls within the definition of features F1, F1c, F2 and F2c of claim 1.

30. Contrary to what was held in the decision under appeal, claim 1 specifies that there is a through-going recess, not a through-hole (see section XIII. above). Furthermore, as set out in point 25. above, this through-going recess may have further openings, e.g. to the side.

31. The capillary channel 20 in document E1, which reaches into the intermediate layer 5 from the supply inlet 16 formed at the edge of the biosensor up to an air vent 7 and extends through the thickness of the intermediate layer 5 (see Figure 1 of E1), is not a notch, as held by the opposition division, but a through-going recess which falls within the definition of features F3 and F3a of claim 1.

32. The respondent's argument that document E1 did not disclose features F1, F1c, F2, F2c, F3 and F3a of claim 1 rests on the premise that an analyte sensor of claim 1 is a fully functional sensor in its own right and a through-going recess is entirely surrounded by non-recessed material and not a notch (see section XV. above). This line of argument likewise fails in the light of the claim construction adopted by the board (see points 20. and 25. above), and for the reasons set out in points 29. to 31. above.

33. The respondent's further argument that document E1 did not disclose features F3b and F3c of claim 1 because the capillary channel in E1 had a single opening, the slit, which could not be closed by the substrates and remained open is not found persuasive either.

34. It is immediately apparent from the description of the layered structure in claim 1 (see point 21. above) that the first and the second opening of claim 1 are

adjacent to the first surface of the first and the second substrate respectively. The openings of the capillary channel 20 on the upper and lower surface of intermediate layer 5 are adjacent to the first surface of the upper part 2 and the lower part 3 respectively, and correspond to a first and a second opening as defined in features F3b and F3c of claim 1. Slit 6 in document E1 is a further opening, located at the edge of the biosensor (see legend of Figure 1 in paragraph [0040] and Figure 1).

35. The respondent's additional argument that document E1 did not disclose features F5, F6 and F9 of claim 1 is not found persuasive either.

36. It is immediately apparent from Figure 1 of document E1 that the surface of upper part 2 lying adjacent the intermediate layer 5 closes the first opening, and the surface of lower part 3 lying adjacent the intermediate layer 5 closes the second opening, thereby forming a measuring region in the capillary channel 20 and hence disclosing features F5 and F6 of claim 1.

37. Furthermore, the capillary channel 20 of document E1 (see Figure 1) has a linear shape, allowing a fluid flowing through the measuring cell (see paragraph [0005] of E1) to perform an at least substantially linear movement, thus also disclosing feature F9 of claim 1.

38. The board therefore agrees with the appellant that document E1 discloses features F1, F1c, F2, F2c, F3, F3a, F3b, F3c, F5, F6 and F9 of claim 1 of the main request. The fact that the biosensor disclosed in document E1 also fulfils the other technical features of the sensor assembly defined in claim 1 is

uncontested.

39. The subject-matter of claim 1 of the main request is therefore not novel over document E1.
Article 100(a) EPC in combination with Article 54 EPC prejudices the maintenance of the patent as granted.

Auxiliary request 1

40. Auxiliary request 1 was filed with the respondent's reply to the appeal. The respondent submitted that the amendment to claim 1 served to further distinguish the claimed subject-matter from the disclosure in document E1. The appellant requested that auxiliary request 1 not be admitted into the proceedings, because the respondent should already have submitted its fall-back positions during the opposition proceedings.

41. The board decided to admit auxiliary request 1 into the proceedings pursuant to Article 12(4) RPBA 2007. However, in view of the conclusions reached under Article 123(2) EPC (see below), there is no need to provide reasons for this part of the decision.

Amendments (Article 123(2) EPC) - claim 1

42. Claim 1 of auxiliary request 1 has been amended to include the feature "*for blood gas measurements*" (see section XIII. above). The respondent submitted that page 1, lines 5 to 7, 9 to 10 and 21 to 22, page 4, lines 27 to 29 and page 15, lines 24 to 28 of the application as filed disclosed that the sensor assembly of the invention could be adapted to measure pCO2, pO2, and pH and hence blood gas.

43. The relevant passages relied on by the respondent on page 1 of the application as filed are reproduced below in full for ease of reference:

"*The sensor assembly of the present invention is particularly suitable for simultaneously measuring a plurality of different parameters, e.g. blood parameters*" (see page 1, lines 5 to 7);

"*In a variety of instances it is desirable to measure e.g. the partial pressure of blood gasses* [sic] *in a whole blood sample, concentrations of electrolytes and metabolites in the blood sample, as well as the hematocrit value of the blood sample*" (see page 1, lines 9 to 11);

"*For example, patients in intensive care require a sampling frequency of 15-20 per day for blood gas and clinical chemistry measurements, leading to a potentially large loss of blood during patient assessment*" (see page 1, lines 21 to 23).

44. The board considers that the skilled person would understand from page 1 of the application as filed that the sensor assembly of the invention was suitable for simultaneously measuring a plurality of different parameters, which can be blood parameters. Which blood parameters these would be is not disclosed on page 1. The skilled person would moreover understand that blood gas is among the plurality of different parameters which are typically measured in a blood sample, other parameters being for example electrolytes, metabolites and hematocrit. As noted by the appellant, on page 1 of the application as filed, blood gas measurements are linked with other measurements which do not appear in

claim 1.

45. Page 4, lines 27 to 29 of the application as filed then discloses that "*In a preferred embodiment the analyte sensors are blood parameter sensors. The analyte sensors may preferably be adapted to measure one or more of the following parameters: pCO_2, pO_2, pH, Na^+, K^+, Ca^{2+}, Cl^-, glucose, lactate, urea, and creatinine*".

46. Contrary to the respondent's submission, page 4, lines 27 to 29 of the application as filed does not disclose that the analyte sensors of the claimed sensor assembly could be adapted to measure pCO2, pO2, and pH specifically. It is disclosed that the analyte sensors may be adapted to measure one or more of a number of parameters, including "*pCO_2, pO_2, pH*" amongst others. Moreover, pCO2, pO2 and pH are not disclosed as being preferred or otherwise singled out on page 4 of the application as filed. Rather, they are disclosed together with other parameters and, according to page 1 of the application as filed, these other parameters are non-blood-gas parameters which are typically measured together with blood gas in blood samples (see points 43. and 45. above).

47. Accordingly, even accepting that the term "*blood gas measurement*" is, for a person skilled in blood analysis, a synonym for measuring pCO2, pO2 and pH and hence that the first three parameters mentioned on page 4, lines 27 to 29 of the application as filed relate to the measurement of blood gas, this passage of the application as filed does not disclose an analyte sensor specifically for "*blood gas measurements*".

48. Contrary to the respondent's submissions, the embodiment disclosed on page 15, lines 24 to 28 of the

application as filed does not disclose the measurement of "*blood gas*" either. It discloses "*analyte sensors for measuring pCO_2, pO_2, pH, Na^+, K^+, Ca^{2+}, Cl^-, Mg^{++}, Ca^{++}*", i.e. analyte sensors for measuring pCO2, pO2, pH in combination with electrolytes.

49. The board concludes from the above observations that, from the disclosure on page 4, lines 27 to 29 of the application as filed, when read in the context of the disclosure on page 1 and page 15 of the application as filed, the skilled person would not derive directly and unambiguously, using common general knowledge, that the application as filed discloses an analyte sensor specifically for "*blood gas measurements*" only. The subject-matter of claim 1 of auxiliary request 1 therefore extends beyond the content of the application as filed, and auxiliary request 1 contravenes Article 123(2) EPC.

Auxiliary request 1B

Admittance and consideration (Article 13(1) RPBA)

50. Auxiliary request 1B was submitted by the respondent after it had filed its reply to the statement of grounds of appeal (see section VIII. above). In claim 1, the feature "*for blood gas measurements*", present in auxiliary request 1, was removed and the following feature added at the end of the claim: "*wherein the analyte sensors are adapted to measure at least one or more of the following parameters: pO2, pCO2, and pH.*"

51. According to the respondent, this claim request had been submitted in direct response to the appellant's objections under Article 123(2) EPC to auxiliary

request 1, and it resolved the Article 123(2) EPC issue of auxiliary request 1 and raised no further issues. The appellant requested that auxiliary request 1B not be admitted into the proceedings, because it did not overcome the Article 123(2) EPC issue of auxiliary request 1 and because it raised new issues, since it was not clear what was meant by "*the analyte sensors are adapted to measure*".

52. Pursuant to Article 13(1) RPBA, which applies in the case at hand (Article 25(1) RPBA and CLBA, V.A.4.4.2), the admittance of auxiliary request 1B is at the board's discretion. The criteria considered by the board when exercising its discretion in the case of an amendment to a patent include whether the respondent has demonstrated that any such amendment *prima facie* overcomes the issues raised and does not give rise to new objections.

53. The board observes that auxiliary request 1B represents a further attempt by the respondent to distinguish the claimed subject-matter from the disclosure in document E1. However, the respondent is not entitled to repeatedly modify its claim requests until a set of claims is found which meets at least the requirements of Article 123(2) EPC. The fact that the appellant had raised an objection under Article 123(2) EPC to an earlier such attempt, i.e. auxiliary request 1 filed with the respondent's reply to the appeal, cannot justify the admittance of further amendments aimed at addressing the issue. This could and should have been done earlier.

54. Furthermore, as regards the basis for the amendment in claim 1, the respondent relied on the same basis and line of argument as submitted for auxiliary request 1.

This line of argument had failed to persuade the board that the application as filed provided a basis for singling out the measurement of the three parameters "*pO2, pCO2, and pH*" from the measurement of the other parameters recited on page 4, lines 27 to 29 of the application as filed (see points 44. to 49. above). The amendment made in auxiliary request 1B did not in the board's view address the finding that the application as filed provided no basis for specifically measuring the parameters pO2, pCO2, and pH.

55. Finally, since the amendment came from the description and not from a granted claim, the question of whether the expression "*the analyte sensors are adapted to measure*" had a clear meaning to the skilled person (Article 84 EPC) needed to be discussed.

56. The board was therefore not persuaded that the amendment made in auxiliary request 1B *prima facie* overcame the Article 123(2) EPC issue of auxiliary request 1 and did not give rise to new objections.

57. The board therefore decided not to admit auxiliary request 1B into the appeal proceedings.

Auxiliary request 3

Admittance and consideration (Article 12(4) RPBA 2007)

58. Auxiliary request 3 was submitted with the respondent's reply to the appeal, and its admittance is governed by Article 12(4) RPBA 2007. The appellant requested that auxiliary request 3 not be admitted into the appeal proceedings because it had been filed late and was not convergent with auxiliary request 1.

59. Pursuant to Article 12(4) RPBA 2007, which applies in the case at hand (Article 25(1) and (2) RPBA), whether or not to admit requests which could have been presented by the patent proprietor during the opposition proceedings but were not is at the board's discretion. The question of whether a request could have been presented during the opposition proceedings is dependent on whether the patent proprietor could have been expected to present its request during the opposition proceedings in the circumstances of the specific case (CLBA, V.A.5.11.3e).

60. In the case at hand, the ground of lack of novelty over document E1 was raised by the appellant in the opposition proceedings. However, in response to the decision under appeal, the appellant refined its arguments with respect to the construction of claim 1 and novelty over document E1 in the statement setting out its grounds of appeal.

61. Under these circumstances, the filing of alternative lines of defence against the novelty attack based on document E1 represented an appropriate and legitimate response to the appeal. The non-convergence of auxiliary request 3 with auxiliary request 1 is therefore considered acceptable. The board decided to admit auxiliary request 3 into the appeal proceedings.

62. Regarding the merits of auxiliary request 3, the only objections raised by the appellant were lack of novelty of claim 1 over document E1 and lack of inventive step of claim 1 when taking either document E1 or document E6 as closest prior art (see section XIV.).

63. The respondent requested that the appellant's objections regarding novelty and inventive step not be

admitted into the appeal proceedings.

64. In view of the board's conclusions as regards the issues of novelty and inventive step starting from document E1, no reasons need to be given as to why the board admitted and considered these objections in substance. Admittance of document E6 is dealt with in points 76. to 83. below.

Novelty - claim 1

65. Claim 1 of auxiliary request 3 specifies that the electrical contact points (5c) and the analyte sensors (6) are on opposite surfaces of the first substrate (2) and are on the same surface of the second substrate (3)(see section XIII. above for the complete wording of the claim).

66. The appellant argued that in document E1 contacts 14 had to be located on the upper surface of upper part 2 and that document E1 therefore disclosed electrodes and contacts on the same surface of one substrate (lower part 3) and on opposite surfaces of the other substrate (upper part 2).

67. For the following reasons, the board is not persuaded by the appellant's argument. In the exploded view of the biosensor in Figure 1 of document E1, contacts 14 and electrodes 10 and 11 are shown on the upper surface of upper part 2. Document E1 explains in paragraph [0039] that the electrodes 10 and 11 shown on the top surface of upper part 2 in Figure 1 are shown in that way only "*for better illustration*", and actually face downwards towards electrodes 8 and 9 on lower part 3. Contrary to the appellant's submissions, paragraph [0041] in document E1 does not state that the

electrodes on the upper part (2) are identical to those on the lower part but that "[t]*he electrodes 8, 9 are connected to contacts 14 on the lower part 3, while the electrodes 10 and 11 are connected to identical contacts 14 on the upper part 2*". The board agrees with the respondent that, in order to be identical, the contacts 14 shown together with electrodes 10 and 11 on the top surface of upper part 2 of the biosensor must also face downwards, i.e. must be located on the lower surface of upper part 2. In view of the clear technical teaching in paragraph [0041] of document E1, the appellant's argument that indentation of the upper part 2 in Figure 1 would lead the skilled person to understand that contacts 14 of the upper and lower part may be accessed from the top is not found persuasive.

68. The board concludes from the above observations that document E1 discloses a biosensor in which the electrical contacts and the sensors on the upper part 2 are on the same surface, not on opposite surfaces.

69. The subject-matter of claim 1 of auxiliary request 3 is therefore novel over document E1.

Inventive step - claim 1

70. The subject-matter of claim 1 differs from the disclosure in document E1 in the arrangement of the electrical contact points and analyte sensors.

71. The appellant considered that the technical effect of the difference was improved access to the electrical contacts. The objective technical problem to be solved was therefore the provision of a sensor assembly with improved access to the electrical contacts.

72. The question to be answered is whether or not the skilled person, in the expectation of solving the technical problem, would have modified the teaching in document E1 in the light of other teachings in the prior art so as to arrive at the claimed invention. To answer this question it is necessary to identify conclusive reasons on the basis of tangible evidence.

73. For the following reasons, the appellant's submission that the claimed arrangement related to a routine modification that would be obvious to the skilled person when addressing the objective technical problem formulated above is not found persuasive.

74. In document E1 the electrical contact points face in opposite directions (see Figure 1, paragraphs [0039] and [0041] and points 67. and 68. above). Document E1 itself does not disclose or suggest a different arrangement of the electrical contact points. The board has not been presented with any evidence supporting the appellant's assertion that the claimed arrangement of electrical contacts was conventionally employed in biosensors at the relevant date, let alone that it was known that such an arrangement would allow for improved access to the electrical contacts in the context of a biosensor as disclosed in document E1. Starting from document E1, the skilled person therefore had no reason to change the arrangement of the electrical contact points so as to arrive at electrical contact points facing in the same direction. The proposed solution would not therefore have been obvious to the person skilled in the art who started from document E1 and sought to provide a sensor assembly with improved access to the electrical contacts.

75. The subject-matter of claim 1 of auxiliary request 3 is therefore not obvious when document E1 is taken to represent the closest prior art.

Admittance and consideration of document E6 (Article 12(4) RPBA 2007)

76. In addition, the appellant raised an objection of a lack of inventive step of claim 1 of auxiliary request 3, based on document E6.

77. Document E6 was filed with the appellant's statement of grounds of appeal, and the respondent requested that the document not be admitted into the appeal proceedings.

78. Under Article 12(4) RPBA 2007, which applies in the case at hand (Article 25(1) and (2) RPBA), whether or not to hold inadmissible documents which could have been presented during the proceedings before the opposition division or were not admitted into the opposition proceedings is at the board's discretion. The board can make admittance of a document dependent on whether or not it is *prima facie* relevant, but is not obliged to do so (CLBA, section V.A.5.11.3.a)).

79. The appellant submitted that document E6, published in the year 1990, had come to light during post-grant proceedings in the United States, that the appellant had not been aware of this document when the opposition was filed, and that the document was *prima facie* relevant.

80. The primary object of the appeal proceedings is to review the decision under appeal in a judicial manner on the basis of the issues in dispute before the

opposition division. The decision under appeal, where the inventive step of a claim corresponding to claim 1 of auxiliary request 3 (claim 2 as granted) was concerned, was taken without considering document E6. Admitting document E6 into the appeal proceedings would compel the board either to give a first ruling on inventive step with respect to document E6 or to remit the case to the opposition division.

81. The fact that the appellant was not aware of document E6 when it filed its notice of opposition is immaterial. Document E6 belonged to the state of the art when the appellant filed its notice of opposition. Hence, it could and should have been filed with the notice of opposition if the appellant wanted to base an objection as regards lack of inventive step on this document.

82. The board is furthermore of the opinion that the opposition division's findings in point 17.3 of the decision under appeal were not surprising or unexpected in view of point 6.2.3 of the opposition division's communication annexed to the summons to oral proceedings, in which it had explained why document E3, alone or in combination with the other documents on file then, did not render the subject-matter of claim 1 as granted obvious. Thus, admittance of document E6 cannot be justified by reference to point 17.3 of the decision under appeal either.

83. The board therefore decided not to admit document E6 into the proceedings.

84. As a consequence, and in view of the board's finding in point 75. above, the subject-matter of claim 1 of auxiliary request 3 meets the requirements of

Article 56 EPC. As there are no outstanding objections (see point 62. above), auxiliary request 3 is also allowable.

Conclusion

85. The patent can be maintained in amended form on the basis of auxiliary request 3. Admittance of documents E11a and E11b did not need to be addressed. For the purpose of the assessment of added subject-matter in auxiliary request 1, the board accepted that the term "blood gas measurement" is, for a person skilled in blood analysis, a synonym for measuring pCO2, pO2 and pH.

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 in amended form on the basis of the following documents:
- Claims 1 to 9 of auxiliary request 3 filed with the reply to the appeal on 16 August 2018 and a description possibly to be adapted thereto
- Drawings: figures 1 to 9 of the patent as granted.

The Registrar: The Chairwoman:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated