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Datasheet for the decision of 22 June 2020

Case Number: T 0249/18 - 3.4.02

Application Number: 12183629.0

Publication Number: 2535703

IPC: G01N27/327

Language of the proceedings: EN

Title of invention:
Multi-electrode biosensor system

Applicant:
Ascensia Diabetes Care Holdings AG

Headword:

Relevant legal provisions:
EPC Art. 123(2), 76(1)
RPBA 2020 Art. 11, 12(2)

Keyword:
Amendments of application - allowable (yes)
Remittal to the department of first instance - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0249/18 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 22 June 2020

Appellant: (Applicant)	Ascensia Diabetes Care Holdings AG Peter-Merian Strasse 90 4052 Basel (CH)
Representative:	Cohausz & Florack Patent- & Rechtsanwälte Partnerschaftsgesellschaft mbB Postfach 10 18 30 40009 Düsseldorf (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 August 2017 refusing European patent application No. 12183629.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	R. Bekkering
Members:	C. Kallinger
	G. Decker

Summary of Facts and Submissions

I. The appellant lodged an appeal against the decision of the examining division refusing European patent application No. 12183629.0 on the basis of Articles 76(1) and 123(2) EPC.

II. In the statement setting out the grounds of appeal the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request or, in the alternative, according to the auxiliary request, both claim sets filed with the statement of grounds of appeal dated 22 November 2017. As a precaution, the appellant requested oral proceedings.

III. The appellant was summoned to oral proceedings before the board to be held on 17 June 2020. In a communication pursuant to Article 15(1) RPBA 2020 the board set out its preliminary opinion on the merits of the case.

IV. In its reply to the board's preliminary opinion, the appellant requested to set aside the decision of the examining division and to grant a patent based on the claims according to the main request, the first auxiliary request or the second auxiliary request, all sets of claims filed with the letter of reply dated 6 May 2020.

V. The board informed the appellant in a further communication that the claims according to the second auxiliary request met the requirements of Articles 123(2) and 76(1) EPC.

VI. With a letter dated 3 June 2020 the appellant withdrew its request for oral proceedings and changed the order of its requests.

The appellant's final request is that the decision of the examining division be set aside and a patent be granted on the basis of the sets of claims according to the:

- main request: claims 1 to 13 filed as second auxiliary request with the letter dated 6 May 2020;
- first auxiliary request: claims 1 to 13 filed as main request with the letter dated 6 May 2020; or
- second auxiliary request: claims 1 to 13 filed as first auxiliary request with the letter dated 6 May 2020.

Subsequently the oral proceedings were cancelled.

VII. Claim 1 of the main request reads:

"1. An analyte biosensor system (1200), characterized by:
a test sensor (1204) including a sample interface (1214) disposed on a first substrate, where the sample interface (1214) is in electrical communication with a reservoir (1208) formed by the first substrate and a second substrate, where the reservoir has a sample port (1212) connected to a first, a second, a third, and a fourth secondary analysis region, wherein the secondary analysis regions are substantially chemically isolated, and
where the test sensor has:

- *a first working electrode (W), where the first working electrode has a third conductor (1290),*
- *a first counter electrode (Cl) having a first conductor (1290) and at least one first redox*

species disposed in the first secondary analysis region,

- *a second counter electrode (C2) having a second conductor (1290) and at least one second redox species disposed in the second secondary analysis region,*
- *a third counter electrode (C3) having a fourth conductor (1290) and at least one third redox species disposed in the third secondary analysis region, and*
- *a fourth counter electrode (C4) having a fifth conductor (1290) and at least one fourth redox species disposed in the fourth secondary analysis region,*

where the working electrode, the first counter electrode, the second counter electrode, the third counter electrode, and the fourth counter electrode are independently addressable;

the sample interface being in electrical communication with the first conductor, the second conductor, the third conductor, the fourth conductor, and the fifth conductor;

a measurement device (1202) including a computer readable storage medium (1228), a processor (1222), and a signal generator (1224), where the signal generator is in electrical communication with the sensor interface, and where the sensor interface is in electrical communication with the sample interface;

where the processor is operable to apply:

- *a first input signal at a first potential from the signal generator to the first working electrode and the first counter electrode,*
- *a second input signal at a second potential from the signal generator to the first working electrode and the second counter electrode;*

- *a third input signal at a third potential from the signal generator to the first working electrode and the third counter electrode, and*
- *a fourth input signal at a fourth potential from the signal generator to the first working electrode and the fourth counter electrode;*

where the processor is operable to measure:

- *a first output signal from the first working electrode and the first counter electrode, where the first output signal is responsive to the first input signal,*
- *a second output signal from the first working electrode and the second counter electrode, where the second output signal is responsive to the second input signal,*
- *a third output signal from the first working electrode and the third counter electrode, where the first output signal is responsive to the first input signal, and*
- *a fourth output signal from the first working electrode and the fourth counter electrode, where the fourth output signal is responsive to the fourth input signal;*

where the processor is operable to analyze the first, the second, the third, and the fourth output signals;

where the processor is operable to determine:

- *a first concentration of at least one first measurable species in a biological sample disposed in the reservoir at the potential of the first input signal,*
- *a second concentration of at least one second measurable species in the biological sample disposed in the reservoir at the potential of the second input signal,*
- *a third concentration of at least one third measurable species in a biological sample disposed*

in the reservoir at the potential of the third input signal, and

- *a fourth concentration of at least one fourth measurable species in the biological sample disposed in the reservoir at the potential of the fourth input signal; and*

where the processor is operable to convert at least one of the first, the second, the third, and the fourth concentrations into a concentration of an analyte in the biological sample disposed in the reservoir."

Reasons for the Decision

1. Main request - Articles 123(2) and 76(1) EPC

Claim 1 of the main request is based on originally filed claims 1 to 3 and differs from this combination in that the electrode arrangement comprises in addition a fourth counter electrode and that, as a consequence, the processor is operable to

- apply four input signals at four potentials to the respective pairs of working and counter electrodes;
- measure four output signals responsive to the respective input signals;
- analyze the four output signals;
- determine first to fourth concentrations of measurable species in a biological sample disposed in the reservoir at the respective applied potentials; and
- convert at least one of the first to fourth concentrations into a concentration of an analyte in the biological sample disposed in the reservoir.

1.1 Different potential

Originally filed claim 1 defined that (emphasis added by the board)

"... the processor is operable to apply at least one input signal from the signal generator to the working and counter electrodes, where the at least one input signal includes input signals having at least one different potential ...".

Originally filed claim 2 further defined that

"... the processor is operable to apply
a first input signal at a first potential from the signal generator to the at least one working electrode and the at least one first counter electrode,
a second input signal at a second potential from the signal generator to the at least one working electrode and the at least one second counter electrode ... ".

Present claim 1 does not comprise the expression *"different potential"* and defines that

"... the processor is operable to apply:
- *a first input signal at a first potential from the signal generator to the first working electrode and the first counter electrode,*
- *a second input signal at a second potential from the signal generator to the first working electrode and the second counter electrode;*

- *a third input signal at a third potential from the signal generator to the first working electrode and the third counter electrode, and*
- *a fourth input signal at a fourth potential from the signal generator to the first working electrode and the fourth counter electrode;".*

The term *"different potential"* in originally filed claim 1 is unclear because a single potential as such cannot be different. For the purpose of Article 123(2) EPC this term is interpreted as a potential in the sense of a potential difference. This is in line with originally filed claims 2 and 3 as well as the description (see paragraph [003] and figure 10) where the term potential is used in the sense of an applied voltage.

In conclusion, the term *"different potential"* in originally filed claim 1 was unclear but claims 2 and 3 and the description disclose that potentials (in the sense of voltages) are applied between working and counter electrodes. Therefore, the use of the term *"potential"* alone, i.e. without *"different"*, meets the requirements of Article 123(2) EPC.

1.2 Chemically isolated secondary analysis regions

1.2.1 The examining division argued that claim 1 on which the appealed decision was based had been amended by removing the feature that the secondary analysis regions were substantially chemically isolated (see communication dated 8 February 2016) and that, contrary to the appellant's assertion, an analyte biosensor without this feature could not be derived from figures 12A or 12D.

1.2.2 In comparison to claim 1 on which the appealed decision was based, amended claim 1 according to the present main request comprises the feature that the secondary analysis regions are substantially chemically isolated.

1.2.3 As this feature was present in originally filed claim 1 and is disclosed in the summary of the invention (see paragraph [0013]) and in conjunction with the disclosure of individually addressable electrodes (see paragraph [0055]), the feature of individually addressable electrodes disposed in chemically isolated secondary regions is originally disclosed.

1.3 Disclosure of figures 12A and 12D

1.3.1 The examining division argued that the claimed subject-matter could neither be derived from the embodiment shown in figure 12A alone nor from figure 12A in combination with the embodiment in figure 12D.

1.3.2 The appellant argued that the subject-matter of claim 1 was sufficiently supported by a combination of figures 12A and 12D: Figure 12A disclosed four secondary regions with four counter electrodes C1-C4 which were electrically connected as shown in figure 12D. The corresponding part of the description (see paragraph [0137]) disclosed that the electrodes extended or projected into the reservoir, i.e. the four secondary analysis regions were located in the reservoir. In addition, also other parts of the description (see paragraphs [0002] and [0010]) disclosed that the claimed analyte biosensor had four counter electrodes disposed in separate analysis regions.

1.3.3 The board is of the opinion that figure 12A alone does not disclose the claimed subject-matter, as it does not show a working electrode. In conjunction with figure 12D, the skilled person learns that four counter electrodes (C1, C2, C3, C4) can be used together with a single working electrode (W). However, figure 12D shows an electrical wiring diagram and therefore does not disclose the claimed location of the working electrode in the reservoir.

1.4 Disclosure of figure 7B

1.4.1 The examining division further argued that figure 7B could not serve as a basis for the disclosure of the claimed subject-matter. This figure showed four secondary analysis regions, each with a counter electrode (731-734). It did however not show a *"first working electrode (W) disposed in the reservoir"* as claimed, but four secondary analysis regions, each with a working electrode (741-744).

1.4.2 The appellant argued with respect to figure 7B that this figure also illustrated secondary analysis regions similar to those shown in figure 12A.

1.4.3 The board is of the opinion that figure 7B does not disclose the claimed subject-matter of a biosensor system with a single working electrode because figure 7B discloses four working electrodes (741-744).

1.5 Disclosure of figure 1A in combination with figure 12A

1.5.1 The examining division argued that the only basis for the claimed electrode arrangement (four independently addressable counter electrodes and a single working electrode) could be found in figure 1A and paragraph [0064]. However, this disclosure related to a different embodiment than the one shown in figure 12A. Therefore, the claimed subject-matter was based on a combination of features extracted from separate embodiments shown in separate figures (figures 1A and 12A) which clearly did not show different views of the same product but indeed different products. As the application did not contain a hint to combine these different embodiments, the claimed subject-matter could not be directly and unambiguously derived from the content of the application as filed.

1.5.2 With respect to figures 1A and 12A the appellant argued that the examining division agreed that these figures disclosed all features of the claimed subject-matter. Furthermore, it was clear from the description (see in particular paragraphs [0055] and [0085]) that the invention was directed at a biosensor with a test sensor, and the description (see paragraphs [0018], [0134] and [0164]) also disclosed that other configurations, implementations and embodiments were apparent to those of ordinary skill in the art and intended to be within the scope of the invention.

Therefore, the specification as a whole presented the skilled person sufficient hints that the test sensor 100 of figure 1A could be used with the biosensor system 1200 of figure 12A.

1.5.3 The board is of the opinion that paragraphs [0018], [0134] and [0164] referred to by the appellant do not provide the skilled person with a specific hint to combine the teachings of figures 1A and 12A because the statements made therein are of a very general nature.

However, figure 1A and paragraph [0064] provide a basis for the claimed electrode arrangement, i.e. an arrangement with a single working electrode and four counter electrodes, all independently addressable (see paragraph [0064], first and second sentence) and disposed in four secondary analysis regions (see figure 1A and paragraph [0055]).

Furthermore, the description (see paragraph [0055]) discloses that the test sensor (as shown e.g. in figure 1A) is part of a biosensor system. Such a biosensor system is shown in general in figure 12A and described in paragraph [0133] as comprising, in addition to the test sensor (1204), a sample interface for connecting the test sensor to a measurement device, which in turn comprises a computer readable storage medium, a processor (1222) and a signal generator (1224) in electrical communication with the sample interface. Figure 12B through Figure 12F represent multiple potentiostat variations that may be used with the signal generator of Figure 12A (see paragraph [0049]). In particular, figure 12D and paragraph [0140] disclose the electrical set-up of the arrangement of a single working electrode and four counter electrodes.

1.6 The board therefore comes to the conclusion that the application discloses the biosensor system of claim 1 and that claim 1 of the main request meets the requirements of Article 123(2) EPC.

1.7 As the relevant parts of the description and figures of the current divisional application and its earlier application (EP08832808.3) are identical, claim 1 also meets the requirements of Article 76(1) EPC.

2. Remittal

2.1 The applicable version of the Rules of Procedure of the Boards of Appeal is the revised version that entered into force on 1 January 2020 (Articles 24 and 25(1) RPBA 2020). Under Article 11 RPBA 2020, a case is not to be remitted to the department whose decision was appealed unless special reasons present themselves for doing so. The board notes that this provision has to be read in conjunction with Article 12(2) RPBA 2020, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner.

2.2 After receipt of the extended European Search Report, in which the search division raised objections with respect to Articles 76(1), 84 and 54 EPC, the applicant amended the claims at seven instances during first-instance proceedings. The examining division examined in none of its subsequent respective communications anything else but the requirements of Articles 123(2) and 76(1) EPC with respect to claim 1. Therefore, clarity, novelty and inventive step of the present claims have not been assessed yet.

2.3 Not remitting the case to the examining division would require the board to perform these tasks in both first- and last-instance proceedings and to effectively replace the examining division rather than review the contested decision in a judicial manner. It follows that special reasons within the meaning of Article 11 RPBA 2020 present themselves.

2.4 Hence the board remits the case to the examining division for further prosecution on the basis of the main request.

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 for further prosecution.

The Registrar: The Chairman:

S. Sánchez Chiquero R. Bekkering

Decision electronically authenticated