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**Datasheet for the decision
of 14 May 2013**

Case Number: T 1200/09 - 3.2.02

Application Number: 99951731.1

Publication Number: 1121048

IPC: A61B 5/145

Language of the proceedings: EN

Title of invention:

Multi-channel non-invasive tissue oximeter

Applicant:

Somanetics Corporation

Headword:

-

Relevant legal provisions:

EPC Art. 56, 123(2)

Keyword:

"Inventive step (no)"

Decisions cited:

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Catchword:

-



Case Number: T 1200/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 14 May 2013

Appellant: Somanetics Corporation
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 4 December 2008
refusing European patent application
No. 99951731.1 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: C. Körber
D. Ceccarelli

Summary of Facts and Submissions

- I. On 4 December 2008 the Examining Division posted its decision to refuse European patent application No. 99951731.1 under Article 123(2) EPC, which contained an obiter dictum dealing with lack of inventive step.
- II. An appeal was lodged against this decision by the applicant by notice received on 3 February 2009, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 9 April 2009.
- III. By communication of 15 February 2013, the Board summoned the appellant to oral proceedings and forwarded its provisional opinion.
- IV. Oral proceedings were held on 14 May 2013. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, of one of the auxiliary requests I and II, all filed during the oral proceedings. Auxiliary request III was withdrawn during the oral proceedings.
- V. The following documents are of importance for the present decision:
- D3: US-A-5 088 493
D5: WO-A-92/21283.
- VI. The independent claims of the main request read:

"1. A method for spectrophotometric in vivo monitoring of blood oxygen saturation within each of a plurality of different internal regions (38', 38") on an ongoing and substantially instantaneous basis, comprising the steps of:

applying each of a plurality of spectrophotometric sensors (16, 116) to a corresponding testing site of a test subject (10);

coupling each such sensor (16, 116) to a control and processing station (20);

operating each of said sensors (16, 116) to spectrophotometrically irradiate a different one of said internal regions (38', 38") within said test subject (10);

detecting and receiving the light energy resulting from said spectrophotometric irradiation at each said sensor (16, 116),

wherein each sensor (16, 116) includes both a near detector (26) and a far detector (28); and

wherein each sensor (16, 116) includes an emitter, conveying signals to said control and processing station (20) which correspond to the light energy so received;

analyzing said conveyed signals to determine regional blood oxygen saturation levels representative for at least two such internal regions (38', 38");

wherein information from a near detector (26, 28) is differentiated from information obtained from a far detector (26, 28); and

visually displaying said levels for each of said at least two internal regions for direct mutual comparison."

"24. Apparatus for spectrophotometric in vivo monitoring of blood oxygen saturation within each of a plurality of different internal regions (38', 38") on a substantially concurrent basis, comprising:
a plurality of spectrophotometric sensors (16, 116), each attachable to a test subject (10) at different test locations and each adapted to spectrophotometrically irradiate a different one of said internal regions (38', 38") within the test subject (10) associated with such test location;
wherein each sensor (16, 116) includes both a near detector (26) and a far detector (28); and wherein each sensor (16, 116) includes an emitter;
a controller and processor (20), and circuitry coupling each such sensor (16, 116) to said controller and processor (20) for individually operating certain of said sensors (16, 116) to spectrophotometrically irradiate a given internal region (38', 38") within the test subject (10) associated with each such test location;
said sensors (16, 116) each further adapted to receive light energy resulting from the spectrophotometric irradiation produced by that sensor (16, 116) and to produce corresponding signals; and said circuitry acting to convey said signals to said controller and processor (20) for analytic processing;
said controller and processor (20) adapted to analytically process said conveyed signals and thereby determine regional blood oxygen saturation levels therefrom for each sensor (16, 116);
by differentiating information from a near detector (26, 28) from information obtained from a far detector (26, 28);

and a visual display (40) coupled to said controller and processor (20) adapted to display the regional blood oxygen saturation levels so determined for each of a plurality of internal regions (38', 38") in a mutually-comparative manner."

Claims 2 to 23 and 25 to 43 are dependent claims.

Claim 1 of auxiliary request I corresponds to claim 1 of the main request with the additional phrase "wherein said internal regions comprise regions of organs or test sites other than the brain;" inserted at the end of penultimate step of "analysing ...", i.e. before the step of "visually displaying".

Claim 24 of auxiliary request I corresponds to claim 24 of the main request with the additional phrase "wherein said internal regions comprise regions of organs or test sites other than the brain;" inserted before the third last line, i.e. before "and a visual display ...".

Claim 1 of auxiliary request II corresponds to claim 1 of the main request with the phrase "to a corresponding testing site of a test subject (10)" in its first step of "applying ..." being replaced by "to a different organ or testing site of a test subject (10)".

Claim 24 of auxiliary request II corresponds to claim 24 of the main request with the phrase "each attachable to a test subject (10) at different test locations" in its second paragraph being replaced by "each attachable to a test subject (10) at different organs or test locations".

Auxiliary requests I and II no longer comprise dependent claims 42 and 43 of the main request.

VII. The appellant's arguments are summarised as follows:

It was nowhere disclosed in document D5 that instantaneous measurements at a plurality of different locations with a single apparatus comprising a plurality of sensors was performed, so that the regional oxygen saturation rSO_2 in these multiple regions could be compared directly. Taking document D5 into consideration, the person skilled in the art would thus detach the single sensor, select a new location, and re-attach the sensor in order to perform a second measurement. However, by this time, the patient's condition could change, thereby drastically changing and influencing the rSO_2 readings in either or both of the two regions. Even more, a situation with more than two regions for comparison would obviously be more complicated. Thus, document D5 neither disclosed nor suggested instantaneous or substantially concurrent monitoring of two or more different regions with two or more sensors. The last line of page 4 stated that the regions examined in D5 were "cranial or otherwise", i.e. not "different" as in the present application, where it was mentioned at the top of page 3 that organs and body locations other than the brain could be monitored. Also, the three separate compartments (arterial, venous and microcirculatory) referred to in the paragraph bridging pages 20 and 21 of D5 did not represent "different internal regions". The problem solved by the invention was to allow a direct mutual comparison between different internal regions (2nd

paragraph of page 7 of the application) with the best possible signal quality, avoiding a mutual interference of the different light paths within the tissue with one another due to scattering (page 2, lines 10 et seq. of the application). These partial problems were interrelated and the claimed solution thus provided a synergistic effect.

Document D3 was focused on the determination of cerebral oxygen at a single point, it being mentioned that multiple measurements could be taken to enable imaging of the brain by "mapping of the metabolism and vascular state of cerebral cortex" (column 5). Further, document D3 did not disclose the particular mechanism for cancelling out the interference created by overlying tissue as recited in claim 1. Document D3 did not teach that one should – for two or more different internal regions – compare detected light that had travelled different distances through the internal region in order to account for the overlying tissue, whereby it was ensured that a true rSO₂ reading was obtained for the internal region. The embodiment shown in Figure 8 of D3 did not disclose a plurality of sensors, each having one emitter and two detectors – there was only a single light source FL, corresponding to the claimed emitter, illuminating all four regions at the same time.

Therefore, the subject-matter of claim 1 according to the main request was based on an inventive step over the prior art. Even more, the same applied mutatis mutandis to the subject-matter of auxiliary requests I and II, which more clearly defined that organs other than the brain were examined. The teaching of D3 was

limited to the brain, as became clear from line 45 of column 6.

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 Amendments

The amendments introduced by the appellant in independent claims 1 and 24 are based on the paragraph bridging pages 5 and 6 of the original application as published (WO-A-00/21435). The Board is satisfied that the requirements of Article 123(2) EPC are met.

2.2 Main request - inventive step

2.2.1 Document D5 (a patent family member of which is cited in line 20 of page 1 and in the paragraph bridging pages 1 and 2 of the present application) undisputedly represents the closest prior art. It discloses, in the wording of claim 1, a method for spectrophotometric in vivo monitoring of blood oxygen saturation within each of a plurality of different internal regions (last sentence of page 4), comprising the steps of: applying a spectrophotometric sensor (12"; Figure 4) to a corresponding testing site of a test subject (10); coupling such sensor (12") to a control and processing station (20; Figure 2); operating said sensor to spectrophotometrically irradiate a different one of said internal regions

within said test subject (page 8, lines 1 to 6 and last sentence of page 4);
detecting and receiving the light energy resulting from said spectrophotometric irradiation at said sensor (page 8, lines 1 to 6),
wherein said sensor (12") includes both a near detector (140) and a far detector (142); and wherein said sensor (16, 116) includes an emitter (138),
conveying signals to said control and processing station (20) which correspond to the light energy so received (page 8, lines 1 to 11);
analyzing said conveyed signals to determine regional blood oxygen saturation levels representative for at least two such internal regions (page 4, first sentence of bottom paragraph);
wherein information from a near detector is differentiated from information obtained from a far detector (page 16, first sentence of penultimate paragraph); and
visually displaying said levels for each of said at least two internal regions (22) for mutual comparison (last full sentence of page 5).

The Board does not accept the appellant's argument that D5 does not disclose the monitoring of blood oxygen saturation within each of a plurality of **different** internal regions and the sensor does not spectrophotometrically irradiate a **different** one of said internal regions since this is clearly the case, as mentioned in the last sentence of page 4 of D5. The fact that the last line of page 4 states that the regions examined in D5 are "cranial or otherwise" cannot be seen as a distinction since claim 1 does not further specify the "internal regions".

2.2.2 Accordingly, the subject-matter of claim 1 differs from the method disclosed in D5 in that

(i) the monitoring is performed with a **plurality** of spectrophotometric sensors on an **ongoing and substantially instantaneous** basis,

(ii) that the subsequent steps are performed with **each** of these sensors and

(iii) that the levels for the at least two internal regions are displayed for **direct** mutual comparison.

2.2.3 As correctly explained in the statement of grounds of appeal, D5 does not explicitly describe instantaneous measurements at a plurality of locations and concurrent monitoring thereof - instead, the single sensor has to be moved from one location to another for a comparative consideration of different regions (bottom of page 4 of D5), with storage of the measurement obtained at the previous location for later comparison (bottom paragraph of page 5), which has the drawback that the patient's condition might have changed in the meantime. Accordingly, the objective technical problem to be solved by the distinguishing features is to avoid this drawback and to permit a more accurate monitoring of different internal regions. The Board does not accept that avoiding a mutual interference of the different light paths within the tissue with one another due to scattering, resulting in a reduced signal quality, constitutes an additional partial problem to be solved by the claimed method, since it is not seen how the

distinguishing features of claim 1 over D5 could solve this problem.

2.2.4 D5 itself already gives strong hints pointing to the distinguishing features (i) to (iii). In lines 4 to 7 of page 21 of D5 it is mentioned that an ideal reference methodology would simultaneously measure blood oxygen saturation of three different compartments (defined in the final paragraph of page 20), preferably on a **regional** basis. Moreover, D5 discloses in Figure 10 a concurrent display of deeper and superficial brain tissues for **direct** mutual comparison (yet from the far and near light detectors, and not obtained from different sensors comprising such detectors).

2.2.5 In any case, the skilled person looking for a solution of the above-mentioned objective problem would take into consideration the teaching of document D3, which also deals with spectrophotometric monitoring of internal body regions. In the first paragraph of column 2 it is explicitly mentioned as a specific advantage of the disclosed system that it allows simultaneous assessment, with temporal variations being taken into account. Figure 8 discloses an embodiment with a plurality of sensors for simultaneously monitoring different internal regions (column 7, lines 28 to 31), corresponding to distinguishing feature (i). Each sensor comprises a light emitter in the form of the distal end of an optical fibre (FO), the other end of which is coupled to a light source (FL), and a detector, also constituted by an optical fibre (FO) and a solid state silicon detector (A) coupled thereto. The Board does not accept the appellant's argument that, due to the fact that the optical fibres of D3 are

connected to a single light source (FL), D3 does not anticipate a plurality of sensors, each including an emitter. The term "emitter" in claim 1 does not require that each emitter must comprise its own light source and leaves it open where the light source is located. It merely defines a structure which emits light. The claim is silent on any further features of the "emitter" included in the sensor.

Furthermore, each of the thus defined sensors of D3 is applied to a testing site of the test subject (Figure 8), coupled to a controller and processor (column 7, lines 45 to 47) and operated to spectrophotometrically irradiate a different one of the internal regions within said test subject, corresponding to distinguishing feature (ii). The fact that the four regions shown in Figure 8 of D3 are all illuminated at the same time does not constitute a difference vis-à-vis the subject-matter of claim 1, as argued by the appellant. The wording of the claim does not exclude such simultaneous illumination. On the contrary, at the beginning of the claim it is stated that the monitoring of blood oxygen saturation within each of a plurality of different internal regions is to be performed on an ongoing and substantially instantaneous basis. The fact that line 50 of column 7 of D3 explicitly refers to the cerebral cortex and that D3 fails to disclose cancelling out the interferences created by overlying tissue is of no relevance since claim 1 does not define the internal body region to be monitored and since cancelling out the interferences created by overlying tissue is already known from D5, as explained above.

Finally, D3 explicitly mentions mapping of the results in column 7, lines 48 to 51, which is a form of visual display for direct mutual comparison (distinguishing feature (iii)).

2.2.6 Accordingly, D3 discloses all the above-mentioned distinguishing features, and the skilled person starting from D5 and aiming to solve the above-mentioned problem would thus obviously arrive at the subject-matter of claim 1, which is therefore not based on an inventive step within the meaning of Article 56 EPC. The same applies to claim 24, which corresponds to claim 1 in terms of apparatus features.

3. Auxiliary requests I and II

Compared to the main request, claim 24 of auxiliary request I defines in its penultimate paragraph that the internal regions **comprise regions of organs or test sites other than the brain**, and claim 24 of auxiliary request II defines that the sensors are attachable to a test subject at different **organs or testing locations**.

The only additional argument brought forward regarding these auxiliary requests was that the teaching of document D3 was limited to the analysis of the brain. This is not accepted by the Board since D3 generally refers to a "body organ" in its claim 1 (also in column 7, lines 31 and 54). Accordingly, the additional specification of the internal regions or areas of sensor application according to these requests does not change the reasoning presented above with regard to the main request.

It follows that the subject-matter of claim 24 of these requests is likewise not based on an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Schalow

E. Dufrasne