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Datasheet for the decision of 11 July 2012

Case Number: T 2024/08 - 3.2.02

Application Number: 98914727.7

Publication Number: 971625

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:
Method of assessing tissue viability using near-infrared spectroscopy

Applicant:
NATIONAL RESEARCH COUNCIL OF CANADA

Headword:
-

Relevant legal provisions:
EPC Art. 53(c), 54, 56, 83, 84, 123(2)
RPBA Art. 13(1)

Keyword:
"Admissibility of late-filed requests: no (main and 1st to 3rd auxiliary requests filed during oral proceedings)"
"Extended subject-matter: yes (main request filed 11 June 2012 and 1st auxiliary request filed 18 June 2012)"
"Clarity and sufficiency of disclosure: yes (2nd auxiliary request (A) filed during oral proceedings)"
"Exception from patentability: no (2nd auxiliary request (A) filed during oral proceedings)"
"Novelty and inventive step: yes (2nd auxiliary request (A) filed during oral proceedings)"

Decisions cited:
T 0041/04

Catchword:
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Case Number: T 2024/08 **-** 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 11 July 2012

Appellant: (Applicant)
NATIONAL RESEARCH COUNCIL OF CANADA
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Representative:
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 2 May 2008 refusing European patent application No. 98914727.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: C. Körber
P. L. P. Weber

Summary of Facts and Submissions

I. On 2 May 2008 the Examining Division posted its decision to refuse European patent application No. 98914727.7 for lack of clarity (Article 84 EPC), inconsistency of terminology (Rule 49(11) EPC) and added subject-matter (Article 123(2) EPC), following a remittal after decision T 41/04.

II. An appeal was lodged against this decision by notice received on 1 July 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 1 September 2008.

III. By communication of 2 April 2012, the Board summoned the appellant to oral proceedings and forwarded its provisional opinion.

IV. Oral proceedings were held on 11 July 2012.

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 1st to 3rd auxiliary requests, all filed during the oral proceedings, or of the main request filed with letter dated 11 June 2012, or of the 1st auxiliary request filed with letter dated 18 June 2012, or of the 2nd auxiliary request (A) filed during the oral proceedings, or of the 3rd auxiliary request filed with letter dated 18 June 2012.

V. The following documents are of importance for the present decision:

D1: M.S. Irwin et al.: "Near infra-red spectroscopy: a non-invasive monitor of perfusion and oxygenation within the microcirculation of limbs and flaps", British Journal of Plastic Surgery, Vol. 48, 1995, pages 14-22;

D2: WO-A-96/08201.

VI. Claim 1 of the **main request** (filed during the oral proceedings) reads (last amendments shown in strikethrough):

"1. A non-invasive method of measuring total haemoglobin, oxygen saturation and hydration of a compromised tissue portion of a patient, the method comprising:
placing a visible and near-infrared ~~emitting~~ probe at a portion of tissue of the patient wherein the communication of fluids between the portion and a main body of the patient is compromised;
~~emitting visible and near-infrared light into the tissue portion;~~
collecting with the probe, in a single reading, absorbency of the tissue portion at two or more wavelengths on either side of the isobestic point for hemoglobin (800 nm);
determining total hemoglobin and oxygen saturation of said tissue portion by analysing said absorbencies at said two or more wavelengths on either side of the isobestic point for hemoglobin; and
assessing tissue viability of the compromised tissue portion based on said total hemoglobin and oxygen saturation measurements;
characterized in that total hemoglobin and oxygen saturation are determined based on said single reading."

Claims 2 to 9 are dependent claims.

Claim 1 of the **1st auxiliary request** (filed during the oral proceedings) reads (last amendments shown in strikethrough):

"1. A method of determining total hemoglobin and oxygen saturation, for assessing tissue viability of a patient, the method comprising:
accessing a portion of tissue of the patient wherein the communication of fluids between the portion and a main body of the patient is compromised such that the viability of the tissue portion is in question;
locating a visible and near-infrared light ~~emitting~~ probe at the tissue portion;
~~emitting visible and near-infrared light into the tissue portion;~~
collecting from the probe a single spectrum of visible and near infrared light from the tissue portion;
analyzing the spectrum to measure absorbency of the light at two or more wavelengths centered about the isobestic point; and
determining total hemoglobin and oxygen saturation of the portion of tissue by analysing said absorbencies."

Claims 2 to 11 are dependent claims.

Claim 1 of the **2nd auxiliary request** (filed during the oral proceedings) reads (last amendments shown in strikethrough):

"1. A method of generating data, for assessing tissue viability of a patient, the method comprising:

accessing a portion of tissue of the patient wherein the communication of fluids between the portion and a main body of the patient is compromised such that the viability of the tissue portion is in question;
locating a visible and near-infrared light ~~emitting~~ probe at the tissue portion;
~~emitting visible and near-infrared light into the tissue portion;~~
collecting from the probe a single spectrum of visible and near infrared light from the tissue portion;
analyzing the spectrum to measuring absorbency of the light at a wavelength between 790 nm and 810 nm and at a wavelength between 740 nm and 780 nm;
generating data relating to the levels of deoxyhemoglobin and oxyhemoglobin and to oxygenation of the portion of tissue by measuring the ratio of absorbance at a wavelength between 790 nm and 810 nm to absorbance at a wavelength between 740 nm and 780nm."

Claims 2 to 9 are dependent claims.

Claim 1 of the **3rd auxiliary request** (filed during the oral proceedings) reads (last amendments shown in strikethrough):

"1. A method of assessing tissue viability of a patient comprising:
accessing a portion of tissue of the patient wherein the communication of fluids between the portion and a main body of the patient is compromised such that the viability of the tissue portion is in question;
locating a visible and near-infrared light ~~emitting~~ probe at the tissue portion;

~~emitting visible and near-infrared light into the tissue portion;~~
collecting from the probe a single spectrum of visible and near infrared light from the tissue portion;
analyzing, using a computer, the spectrum to measure absorbency of the light at two or more wavelengths centered about the isobestic point;
determining total hemoglobin and an oxygen saturation index of the portion of tissue by analysing said absorbencies; and
determining the viability of the tissue portion,
wherein, if said oxygen saturation index is greater than 1, determining that the tissue remains viable, and if the oxygen saturation index is below 1, determining that the tissue is not viable."

Claims 2 to 11 are dependent claims.

The set of claims of the **main request filed with letter dated 11 June 2012** corresponds to that of the main request filed during oral proceedings as indicated above, with the terms of claim 1 shown in strikethrough being reintroduced.

The set of claims of the **1st auxiliary request filed with letter dated 18 June 2012** corresponds to that of the 1st auxiliary request filed during oral proceedings as indicated above with the terms of claim 1 shown in strikethrough being reintroduced.

Claim 1 of the **2nd auxiliary request (A)** filed during the oral proceedings reads as follows:

"1. A method of generating data, for assessing tissue viability of a patient, the method comprising:
accessing a portion of tissue of the patient wherein the communication of fluids between the portion and a main body of the patient is compromised such that the viability of the tissue portion is in question;
locating a visible and near-infrared light emitting probe at the tissue portion;
emitting visible and near-infrared light into the tissue portion;
collecting from the probe a single spectrum of visible and near infrared light from the tissue portion;
analyzing the spectrum by measuring absorbence of the light at a wavelength between 790 nm and 810 nm and at a wavelength between 740 nm and 780 nm;
generating data relating to the levels of deoxyhemoglobin and oxyhemoglobin and to oxygenation of the portion of tissue by comparing levels of deoxahemoglobin and oxyhemoglobin by determining the ratio of absorbance at a wavelength between 790 nm and 810 nm to absorbance at a wavelength between 740 nm and 780nm."

Claims 2 to 9 are dependent claims.

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

The late filing of the main and 1st to 3rd auxiliary requests at the beginning of the oral proceedings and the deletion of the features from claim 1 of these requests shown above (point VI) in strikethrough was due to instructions received by the representative from the appellant.

Support for the features introduced into claim 1 of the main request filed with letter dated 11 June 2012 could be found throughout the description, in particular on page 10, lines 20 to page 13, line 6.

The term "assessing tissue viability" in claim 1 of the 1st auxiliary request filed with letter dated 18 June 2012 could be deleted without infringing Article 123(2) EPC since this feature was non-technical and merely limited the scope of protection. Support for measuring the absorbance of the light at two or more wavelengths centred about the isobestic point and determining total hemoglobin and oxygen saturation of the portion of tissue by analysing said absorbances could be found throughout the description, in particular at page 12, lines 19 to 21.

Starting from D1, the distinguishing feature of claim 1 of the 2nd auxiliary request (A) filed during the oral proceedings, namely determining the claimed ratio of absorbances, offered the advantage of reducing interferences due to changes in tissue scatter and blood volume and thus allowed an improved and simple assessment of viability. Neither D2, which related entirely to fluorescence spectroscopy, nor any of the other cited prior art documents gave a hint towards the solution according to claim 1 of this request, which was therefore inventive.

Reasons for the Decision

1. The appeal is admissible.

2. Main and 1st to 3rd auxiliary requests filed during the oral proceedings - admissibility

Pursuant to Article 13(1) RPBA, amendments to a party's case after it has filed its grounds of appeal may only be admitted at the Board's discretion. This discretion is to be exercised in view of inter alia the state of the proceedings and the need for procedural economy.

The present requests were filed at the beginning of the oral proceedings, i.e. at a very late stage of the procedure. Claim 1 of all these requests has been amended by omitting the step of emitting visible and near-infrared light into the tissue of the patient. This feature had been introduced with the statement of grounds of the first appeal (T 41/04) filed on 21 November 2003 and was maintained in the independent claims of all requests filed during the proceedings since then. Apart from the statement that the appellant's representative had only recently received instructions from his client to remove this feature, no justification was given for the late filing and no explanation was given as to why the amendment was made. Under these circumstances the Board cannot see any valid reason to exercise its discretion in the appellant's favour.

Accordingly, the Board declines to admit these requests into the proceedings under Article 13(1) RPBA.

3.1 Main request filed with letter dated 11 June 2012 - amendments

Claim 1 comprises the step of "determining total hemoglobin and oxygen saturation of said tissue portion by analysing said absorbencies at said two or more wavelengths on either side of the isobestic point for hemoglobin". Concerning the determination of total hemoglobin in this manner, the Board sees no basis in the application as originally filed for this feature, in particular not in the passage on page 10, line 20 to page 13, line 6 of the original application as published (WO-A-98/44839), indicated by the appellant in this regard. Total hemoglobin is mentioned at the end of the paragraph bridging pages 11 and 12, but it is not disclosed therein that this quantity is determined by analysing absorbances at two or more wavelengths on either side of the isobestic point for hemoglobin. At the bottom of page 12 it is stated that two or more wavelengths centred about the isobestic point were used for the evaluation of oxygen saturation (which is more specific than "two or more wavelengths on either side of the isobestic point"), but there is no mention of total hemoglobin in this passage. Moreover, this passage relates back to the preceding paragraph (lines 6 to 18) wherein it is described that relative changes in hemoglobin and oxyhemoglobin concentrations were determined by fitting the absorption coefficients of the hemoglobins to the observed changes in the reflectance attenuation (ΔOD) at several wavelengths. Accordingly, determining (total) hemoglobin has only been disclosed by analysing absorbance in combination with reflectance attenuation, but not by analysing absorbances alone, as defined in claim 1.

For the above reasons, the subject-matter of claim 1 of the main request filed with letter dated 11 June 2012 extends beyond the content of the application as originally filed, in breach of Article 123(2) EPC.

3.2 1st auxiliary request filed with letter dated 18 June 2012 - amendments

Claim 1 of this request comprises the step of "determining total hemoglobin and oxygen saturation of the portion of tissue by analysing said absorbencies", i.e. the absorbencies at two or more wavelengths centred about the isobestic point (thus avoiding the generalisation "at two or more wavelengths on either side of the isobestic point" in claim 1 of the above-mentioned request). However, the above-mentioned objections regarding the determination of total hemoglobin still apply.

Accordingly, the subject-matter of claim 1 of the 1st auxiliary request filed with letter dated 18 June 2012 is also in breach of Article 123(2) EPC.

4. 2nd auxiliary request (A) filed during oral proceedings

4.1 Claim 1 of this request is based on original claims 1 and 6 to 8. A basis for generating data, as defined at the beginning of the claim, and the step of emitting visible and near-infrared light into the tissue portion, can be found throughout the description. The incorporation of the features of dependent claims 6 to 8 clarifies the unclear definition of the number of

spectral points and data in the last two lines of original claim 1.

Accordingly, the Board is satisfied that this request is free from objections under Articles 123(2) and 84 EPC, as well as from further objections under Articles 53(c) and 83 EPC, raised with regard to requests previously filed in the proceedings.

4.2 None of the prior art documents on file discloses in combination the features of claim 1 of the 2nd auxiliary request (A) filed during oral proceedings.

Accordingly, its subject-matter is novel within the meaning of Article 54 EPC.

4.3 Document D1, acknowledged at page 3 of the description, is regarded as closest prior art. D2 is more remote since it mainly deals with fluorescence and infrared reflectance spectroscopy.

The subject-matter of claim 1 is distinguished from the disclosure of D1 by the features of measuring absorbance of the light at a wavelength between 790 nm and 810 nm and at a wavelength between 740 nm and 780 nm, and generating data relating to the levels of deoxyhemoglobin and oxyhemoglobin and to oxygenation of the portion of tissue by comparing levels of deoxyhemoglobin and oxyhemoglobin by determining the ratio of absorbance at a wavelength between 790 nm and 810 nm to absorbance at a wavelength between 740 nm and 780nm.

The technical effect of measuring absorbance at these ranges of wavelengths and taking the above-mentioned ratio is that the data relating to oxygenation determined therefrom are largely independent of changes in tissue scattering and blood volume and that it is possible to predict tissue viability from a single reading on that basis, without the need to analyse trends (page 4, lines 21 to 22; page 11, lines 8 to 15; page 17, lines 4 to 8, of the description of the present application as published).

The objective technical problem to be solved by the distinguishing features over D1 is to provide a quicker yet accurate determination of oxygenation of the tissue.

Neither D2 nor any of the other prior art documents cited in the search report give a hint towards determining the ratio of absorbances at the above-mentioned ranges of wavelengths in order to solve this problem.

Accordingly, the Board is satisfied that the subject-matter of claim 1 of the 2nd auxiliary request (A) filed during oral proceedings is based on an inventive step within the meaning of Article 56 EPC, and that the amended set of claims and application documents meet the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of:

   - Claims 1 to 9 of the 2nd auxiliary request (A);
   - Pages 1 to 4, 6 to 37 and 42 to 54 of the description; and
   - Figures 1 to 20,

   all filed during the oral proceedings.

The Registrar: The Chairman:

D. Hampe E. Dufrasne