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D E C I S I O N
of 30 October 2001

Case Number: T 0931/99 - 3.2.2

Application Number: 92905626.5

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Language of the proceedings: EN

Title of invention:
Non-invasive device and method for determining concentrations of various components of blood or tissue

Applicant:
CADELL, Theodore E.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 56

Keyword:
"Inventive step (yes, after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0931/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 30 October 2001

Appellant: CADELL.Theodore E.
200 Shakespeare Drive
Apartment 902
Waterloo
Ontario N2L 6CI (CA)

Representative: Warren, Anthony Robert
BARON & WARREN
18 South End
Kensington
London W8 5BU (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 14 April 1999 refusing European patent application No. 92 905 626 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
C. Holtz

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 14 April 1999 to refuse European patent application No. 92 905 626.5.

The ground of refusal was that, having regard to document D2 (US-A-4 975 581), the subject-matter of independent claims 1 and 30 lacked inventive step.

The examining division argued that, starting from the closest prior art document D2, the solitary distinguishing feature of the device of claim 1 was the use of the wavelength range of 650 to 1250 nm, whose selection involved no more than routine experimentation by the person skilled in the art when optimising known apparatus. One obvious reason for the limitation of the wavelength was that detectors at the selected range of wavelengths were cheaper than those for longer wavelengths.

II. On 15 June 1999 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on 21 June 1999. On 19 August 1999 a statement of grounds of appeal was filed.

III. Following a communication dated 25 May 2001 and telephone consultations between the appellant's representative and the rapporteur on 14 August 2001 and 9 October 2001, the appellant filed new claims, description pages, and drawing sheets.

IV. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

- Claims 1 to 41 filed on 15 October 2001 with the letter dated 11 October 2001.

- Description pages 1, 2, 2a, 3 to 12, and 15 to 17 filed on 15 October 2001 with the letter dated 11 October 2001.

- Drawing sheets 1/2 and 2/2 filed on 15 October 2001 with the letter dated 11 October 2001.

V. Independent claims 1 and 29 of this request read as follows:

1. "A non-invasive device for measuring concentration levels of constituents of blood and tissue in a finger (7) of a living human subject, said device having a polychromatic light source (1), powered by a stabilised power source, that emits a broad spectrum of light in the near infrared range, means (9) for collecting simultaneously substantially all of the wavelengths of said light after said light has been directed onto said finger (7), means (12) for dispersing said collected light into component wavelengths of said collected light, a receptor (6) shaped so that said finger can be placed in contact with said receptor, said receptor having means for eliminating extraneous light, said receptor (6) being located relative to said light source (1) so that when said finger (7) is properly placed in contact with said receptor, said light source can be activated and light from said light source is directed onto said finger, means (15, 16, 17) for taking absorbence measurements from transmitted light from said collected and dispersed light at several wavelengths, means (16, 17)

for transforming said absorbence measurements to enhance detection of at least one constituent from other constituents by using a calibration equation for said at least one constituent, and means (16, 17) for determining the concentration level of said at least one constituent of said blood and then producing a result for each concentration level determined, wherein said receptor (6) has an entrance (5) and an exit (8) for light from said light source (1), located generally opposite one another, with a constant distance therebetween, in the optical path between said light source (1) and collecting means (9) so that said finger, when properly placed in the receptor (6) between the entrance and exit, will contact the receptor adjacent both the entrance and exit with the length of the optical path through said finger corresponding to the distance between said entrance and exit, a filter (2) is provided through which said light from said light source (1) passes to limit the light directed onto said finger through said entrance to a range of wavelengths from approximately 650 nm to approximately 1250 nm, said dispersing means (12) is operable to disperse said collected light into a dispersed spectrum comprising the component wavelengths of the collected light, and said means (15, 16, 17) for taking absorbence measurements being operable to take absorbence measurements at several different wavelengths simultaneously over said dispersed spectrum."

29. "A non-invasive method for measuring concentration levels of blood and tissue constituents within a finger (7) of a living human subject, using a polychromatic light source (1) that emits a broad spectrum of light in the near infrared range, which

comprises locating the finger (7) in contact with a receptor (6), directing said light onto said finger, collecting simultaneously substantially all of the wavelengths of said light after said light has been directed onto said finger (7), collimating the collected light, dispersing the collimated light into component wavelengths of said collected light onto a linear array detector (15), taking absorbence measurements with said linear array detector of transmitted light from said dispersed light at several different wavelengths, scanning said linear array detector and passing measurements from transmitted light from said dispersed light at several different wavelengths simultaneously to a microprocessor (16), taking a reference set of measurements, transforming said measurements to enhance the detection of at least one constituent from other constituents by using a calibration equation for said at least one constituent, and determining the concentration level of said at least one constituent of said blood and tissue and producing a result for each concentration level determined, the method including locating said finger (7) in contact with the receptor (6) adjacent an entrance (5) and an exit (8) for light in said receptor (6), said entrance and exit being located generally opposite each other with a constant distance therebetween in the optical path between said light source (1) and linear array detector (15) so that the length of the optical path through said finger corresponds to the distance between said entrance and exit, directing said light from said fight source (1), through a filter (2) which limits the light directed onto said finger to a range of wavelengths from approximately 650 nm to approximately 1250 nm, onto said finger through said entrance (5), dispersing said

collimated light from said exit into a dispersed spectrum comprising the component wavelengths of the collected light onto said linear array detector (15), and taking absorbence measurements from transmitted light from said dispersed light at several different wavelengths simultaneously over said dispersed spectrum."

Claims 2 to 28 and 30 to 41 are dependent on claims 1 and 29, respectively.

VI. With respect to claim 1 the appellant argues as follows:

The receptor defined in claim 1 provided technical advantages by virtue of the arrangement of the entrance and exit for light from the light source, which prevented extraneous light from reaching the detector in a manner not possible in the arrangements of document D1. The examining division also did not appreciate the technical merits of the specific wavelength range defined in claim 1, which was also by itself novel and inventive.

The examining division misunderstood the embodiments of Figures 4 and 5 of document D2. The embodiment of Figure 4 did not have two optical fibres opposite one another, it disclosed only a single continuous fibre. The embodiment of Figure 5 did not have an entrance or an exit, and consequently other features of claim 1, such as the constant optical path length, were also not disclosed.

Reasons for the Decision

1. *The appeal is admissible*.

2. *Amendments*

2.1 Claim 1 includes the following amendments compared to claim 1 of the application as originally filed [emphasis in bold added]:

(a) The new claim defines means for taking **absorbence** measurements, instead of transmittance and reflectance measurements in the original claim.

(b) The feature that the entrance and the exit for the light from the light source are located generally **opposite one another**, with a constant distance therebetween, **in the optical path between the light source and the collecting means,** has been added.

(c) The feature that the finger, when properly placed in the receptor between the entrance and exit, **will contact the receptor adjacent both the entrance and exit**, has been added.

(d) The feature that the length of the optical path through said finger corresponds to the distance between said entrance and exit, has been added.

2.2 The new features of claim 1 are allowable under Article 123(2) EPC since they are supported by the application as originally filed as follows:

(a) Devices of the type to which the application pertains measure the transmission or reflection of light, but it is ultimately the absorption spectrum that is studied. The

description also makes frequent reference to absorption and uses this term interchangeably with transmission, the one being the inverse of the other. This feature is therefore allowable.

(b) The feature that the entrance and the exit for the light from the light source are located generally opposite one another, with a constant distance therebetween may be deduced from the drawing. That the entrance and the exit are located in the optical path between the light source and the collecting means is clearly a necessary feature if the device is to work as intended, and it is an explicit statement of what was already implicit.

(c) This feature may be deduced from the drawing, which shows a finger in the receptor between the entrance and exit, and contacting the receptor adjacent both the entrance and exit. In practice, a wide range of finger thicknesses will fulfil this condition because the fleshy parts thereof are deformable. The purpose of this feature, as may be deduced upon reading the description and as explained in more detail in point 5.2. below, is that the finger should obstruct the light path between the entrance and exit, and this feature is now fairly defined in the claim.

(d) Since the finger is cradled in the receptor as shown in the drawing it will fill the space between said entrance and exit, the length of the optical path through the finger will correspond to the distance between the entrance and exit. This feature is therefore fairly based on the original drawing.

2.3 The same considerations apply to method claim 29. The dependent claims and are equally supported by the

application as originally filed, their subject-matter being derivable from and corresponding to the original dependent claims. The description has been amended for consistency with the new claims and includes a review of the relevant prior art. The description and drawing include reference numerals, which were not originally included.

Therefore, there is no objection to the claims and description under Article 123(2) EPC.

3. *Novelty*

This has not been an issue during the examination procedure and the Board sees no reason to re-visit it.

4. *Inventive step*

4.1 The prior art

There are different optical methods of non-invasively monitoring the concentrations of different constituents of a biological sample known in the prior art, of which the measurement of absorption of infra red light through the sample is well known. By measuring the amount of light absorbed by the sample at certain specific wavelengths, a quantitative measurement of the constituents is possible.

These methods may be broadly divided into two categories. The first one uses measurement at a single or two different and discrete wavelengths, wherein the relative absorption at the single frequency or differential absorption at the two different wavelengths gives quantitative information on the constituent. Oximeters, for example, use this method. The document D2 refers to these methods as a univariate analysis and gives its disadvantages.

The second one, called a multivariate analysis, relies on taking measurements at several points over a broad spectrum in the near infra red range, and using statistical methods to match the spectrum with a calibration model stored in a computer. This gives a more reliable method of discriminating a given constituent from several others in a sample. For example, the amount of glucose in blood may be so determined even though blood contains numerous constituents such as oxygen, urea, alcohol, etc.

4.2 The closest prior art

The presently claimed invention belongs to the second category and relates to a non-invasive device and method for continuously monitoring and measuring concentration levels of blood constituents in humans or animals, using a broad band near infrared portion of the light spectrum. Measurements are made at several wavelengths over the broad band spectrum, and the measurements are used to detect one or more constituents by means of a calibration equation. An indication of the meaning of "several" is given by the fact that 256 detector elements, each for a specific wavelength, are deployed over the entire broad band spectrum.

Document D2 is the only document on file which describes methods of the second category, and is, therefore, the closest prior art document.

4.3 The apparatus of document D2 employs a broad band infra red source that covers the spectra of various blood constituents, so that the entire spectrum over the broad band may be sampled in one measurement. The broad band range may be in the mid infra red range or in the near infra red range of 700 to 2500 nm (see, for example, column 12, lines 29 to 31).

4.4 In contrast thereto, the presently claimed apparatus employs a more limited wavelength range of about 650 to about 1250 nm. The reason for this limitation is given on page 7 of the application as originally filed, which is to eliminate the light rays that heat the finger, thereby allowing a higher intensity bulb to be used. With a higher intensity bulb, a measurement can be taken more quickly, thereby minimizing the opportunity for movement of the body part. Thus, errors induced by movement of the finger may be avoided. This problem is of greater importance when children are the subjects.

The Board has no reason for doubting the efficacy of the claimed solution.

4.5 The problem of movement of a body part owing to a long measurement time falsifying a measurement is not addressed in any of the cited prior art documents. Nor is the presently adopted solution of limiting the wavelength range suggested in the prior art for this purpose. The claimed wavelength range of about 650 to about 1250 nm is a clear limitation of the range of 700 to 2500 nm used in document D2 and it results in a well defined technical effect.

4.6 For this reason the device of claim 1 involves an inventive step, and the same arguments apply to the independent method claim.

4.7 The impugned decision states that the wavelength range of about 650 to about 1250 nm was the solitary distinguishing feature of claim 1 over the disclosure of document D2, and then dismisses the selection of this range as lacking an inventive step, on the grounds that the selection merely involves optimisation of the apparatus by routine experimentation, and that the range was obvious in view of

the fact that detectors that work up to about 1200 nm were relatively cheap in comparison with detectors working at 2µ and higher.

None of these reasons is tenable, however. Firstly, as shown in point 5. below, the wavelength range is not the solitary distinguishing feature of claim 1. Secondly, the examining division has made assertions regarding the selection of the wavelength range without providing any support therefor by way of documentary or other evidence, and has ignored the stated technical effect of this selection.

4.8 The selection of the wavelength range involves more than mere optimisation of the apparatus by routine experimentation, as the examining division argues. This argument might be valid if a single given constituent is to be detected, for example, since this constituent has a known absorption spectrum so that a source with a matching wavelength would be selected and the wavelength range optimised to overlap the absorption spectrum in question.

In the present case, rather than a relatively small wavelength range for overlapping the absorption spectrum of the single given constituent, a broad band spectrum is required so as to cover the spectra of different constituents, from which at least one may then be examined. No question of optimisation arises here, the entirety of the broad spectrum is necessary for simultaneously making the measurements of the different constituents.

It is with respect to this broad spectrum that the present application defines and seeks to solve a specific technical problem, that the finger is heated during measurement, which could corrupt the result. In order to overcome this

problem the wavelength range is limited. The solution of this problem also brings with it the further technical effect that measurements may be made more rapidly and therefore without movement artifacts spoiling the result.

The fact that detectors may be cheaper when working below the limit of about 1200 nm is subordinate to the fact that a technical problem has been recognised and solved. In any case this allegation was not supported by any evidence.

5. Since a single inventive feature renders the claimed subject-matter allowable under Article 52(1) EPC, the inventive merits of the receptor that forms part of the claimed device need not be discussed. Nevertheless, since the question of inventive step turned on the form of the receptor during the examination procedure, rather than on the wavelength range, it is worth going into this point briefly here.

5.1 Amended Claim 1 includes the following features: (i) the receptor has means for eliminating extraneous light, (ii) the receptor has an entrance and an exit located opposite each other, and (iii) so that the body part covers both the entrance and the exit.

5.2 None of these features is disclosed in Document D2.

Regarding (i): There are two sources of extraneous light that might lead to errors of measurement. The first is ambient light from the outside of the device, and the second is stray light from the infra red light source that does not traverse the body part being investigated but reaches the detector by reflection in the device. This is clear from the context upon reading the description. The present application seeks to eliminate both of these

sources of error. The feature (i), which may be a flexible seal, see the end of page 11 of the application as originally filed, is provided to eliminate the first source of error. The arrangement of the light entrance and exit, ie features (ii) and (iii) are provided to eliminate the second source of error. The means for eliminating extraneous light in the preamble of claim 1 refers to the first of these features.

In Figure 5 of document D2, it is the finger itself that is meant to block ambient light from entering the apparatus, there is no separate constructional means, such as a seal, provided. Clearly, the effectiveness of the seal in the arrangement of document D2 depends on the size of the finger that is inserted, and the seal might be ineffective in the case of a child's finger, for example, that is not thick enough to fill the opening or not long enough to reach the lower opening, for example.

Regarding (ii): The entrance and exit defined in claim 1 are features for eliminating extraneous light from the infra red source, and are therefore so located with respect to the source and the detector as to eliminate light reflected from the apparatus that might reach the detector. Clearly there is little scope for extraneous light from the infra red source bypassing a finger properly placed in the receptor.

The receptor in Figure 5 of document D2 is the housing 111, within which are located the light source 116, the finger, as well as the light disperser and detector arrangement 118 and 119, and the finger extends through the housing intermediate top and bottom apertures 114. There is no entrance and exit arrangement in the sense of the application, which eliminates stray light from the source.

Here, the light from the source 116 is free to bounce around inside the housing 111 before entering the detector and without passing through the finger.

Regarding (iii): Since there is no entrance or exit the finger cannot cover them. According to the decision the entrance and exit are implicit otherwise the apparatus would not work. This is an argument made with hindsight since document D2 neither mentions nor implies these features in the description of the apparatus of Figure 5, nor is it clear why the apparatus would not work. On the contrary it would seem that the apparatus would work, although the signal to noise ratio would be low on account of the internally reflected light.

5.3 The embodiment of Figure 4 of document D2 employs optical fibres to bring light to and remove light from an ear. In this embodiment there is only a single and continuous coated fibre loop that pierces through the ear, that part of the fibre within the ear having its coating removed so that light may enter the ear and be reflected back into the fibre (see column 13, lines 50 to 66). Thus, there is no receptor and there are no fibre ends opposite to each other.

5.4 In addition to the above differences, there is another significant difference between the presently claimed device and that of Figure 5 of document D2. The path length of light through the finger in the prior art device is determined by factors such as the thickness of the finger and the extent of its insertion through the apertures 114, and is therefore variable from person to person or even for a given person. The examining division argues in this respect in its decision that a conical cylinder is provided in this prior art device, but this is not correct, there is

no such cylinder present.

By contrast, the path length of light through the finger in the claimed device is determined primarily by the spacing of the entrance and an exit, and this is a constant. The advantage of this is that calibration for finger thickness can be dispensed with.

5.5 The above are reasons why the arguments of the examining division regarding the disclosure of document D2 are no longer valid for the amended claims, as is the deduction of lack of inventive step of the claimed subject-matter on the basis of this document.

6. The same arguments apply to independent method claim 29.

7. For the above reasons the claims meet the requirements of Art 52(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance to grant a patent on the basis of the main request according to paragraph IV. of the "Summary of Facts and Submissions".

The Registrar: The Chairman:

V. Commare W. D. Weiß