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Datasheet for the decision of 24 November 2023

Case Number: T 1609/20 - 3.2.02

Application Number: 10759220.6

Publication Number: 2413784

IPC: A61B5/00

Language of the proceedings: EN

Title of invention:
OPTICAL SPECTROSCOPY DEVICE FOR NON-INVASIVE BLOOD GLUCOSE DETECTION AND ASSOCIATED METHOD OF USE

Applicant:
St. Louis Medical Devices, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - main request (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Office européen des brevets

Beschwerdekammern

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Case Number: T 1609/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 November 2023

Appellant: (Applicant)	St. Louis Medical Devices, Inc. 1754 Technology Drive, Ste. 126 San Jose, CA 95110 (US)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 13 February 2020 refusing European patent application No. 10759220.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	C. Schmidt

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division to refuse European patent application No. 10759220.6. The examining division concluded that the independent claims of all the requests then on file lacked an inventive step.

II. 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, on the basis of one of the first to fourth auxiliary requests, all filed on 19 December 2019.

III. Claims 1 and 7 of the main request read as follows:

"1. An apparatus for optical detection of a biological sample, the apparatus comprising:
a) a light illumination funnel (412) having:
(i) a first outer wall (502) having an anterior end, a posterior end, an inner surface (506) and an outer surface, the inner surface defining an interior portion, the interior portion having an anterior end and a posterior end; and
(ii) a light source (402) disposed within the interior portion;
wherein the first outer wall has an opening (416) in the posterior end, the opening having an opening diameter;
wherein the interior portion has a substantially frusto-conical shape;
wherein the interior portion has a first cross-sectional diameter at the opening (416) equal to the opening diameter and a second cross-sectional

diameter (414) near the anterior end that is less than the opening diameter (416); and
wherein the inner surface is photo-reflective;
wherein a biological sample can be positioned below the opening in the first outer wall such that it receives light from the light source;
wherein the light illumination funnel has a half angle of the frusto-conical shape that is less than 45 degrees, wherein the half angle of the frusto-conical shape is an angle between the longitudinal axis of the frusto-conical shape and a line which extends from the second cross-sectional diameter to the first cross-sectional diameter;

b) a light collector configured to be positioned below the biological sample and receive light from the biological sample, when the biological sample is present;

c) a plurality of light filters (426) located below the light collector; and,

d) a plurality of photo detectors (428) located below the plurality of light filters (426),

wherein each light filter of the plurality of light filters (426) is positioned to receive light from the biological sample and emit filtered light onto a corresponding photo detector of the plurality of photo detectors (428) and each photo detector of the plurality of photo detectors (428) is tuned to detect light in the spectrum emitted by the corresponding light filter of the plurality of light filters."

"7. A method for optical detection of a biological sample using an apparatus comprising:

a) a light illumination funnel (412) having:

(i) a first outer wall (502) having an anterior end, a posterior end, an inner surface (506) and an outer surface, the inner surface defining an

interior portion, the interior portion having an anterior end and a posterior end; and
(ii) a light source (402) disposed within the interior portion;
wherein the first outer wall has an opening (416) in the posterior end, the opening having an opening diameter;
wherein the interior portion has a substantially frusto-conical shape;
wherein the interior portion has a first cross-sectional diameter at the opening (416) equal to the opening diameter and a second cross-sectional diameter (414) near the anterior end that is less than the opening diameter (416); and
wherein the inner surface is photo-reflective;
wherein a biological sample can be positioned below the opening in the first outer wall such that it receives light from the light source;
wherein the light illumination funnel has a half angle of the frusto-conical shape that is less than 45 degrees, wherein the half angle of the frusto-conical shape is an angle between the longitudinal axis of the frusto-conical shape and a line which extends from the second cross-sectional diameter to the first cross-sectional diameter;

b) a light collector configured to be positioned below the biological sample and receive light from the biological sample, when the biological sample is present;

c) a plurality of light filters (426) located below the light collector; and,

d) a plurality of photo detectors (428) located below the plurality of light filters (426),

wherein each light filter of the plurality of light filters (426) is positioned to receive light from the biological sample and emit filtered light onto a

corresponding photo detector of the plurality of photo detectors (428) and each photo detector of the plurality of photo detectors (428) is tuned to detect light in the spectrum emitted by the corresponding light filter of the plurality of light filters, the method comprising:
utilizing the light source (402);
positioning a biological sample below the opening in the first outer wall and above the light collector such that the biological sample receives light from the light source (402) and the light collector receives light from the biological sample;
utilizing the light collector below the biological sample to collect the light from the biological sample;
utilizing the plurality of light filters (426) located below the condenser lens; and
utilizing a plurality of photo detectors (428) located below the plurality of light filters (426), wherein each light filter of the plurality of light filters (426) is positioned to receive light from the biological sample and emit filtered light onto a corresponding photo detector of the plurality of photo detectors (428) and each photo detector of the plurality of photo detectors (428) is tuned to detect light in the spectrum emitted by the corresponding light filter of the plurality of light filters."

IV. The following documents are relevant to the present decision:

D1 EP 1 300 712 A2
D2 WO 2009/035669 A1
D5 EP 0 781 527 A1

V. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

Main request - inventive step over D2 and D5

The subject-matter of claims 1 and 7 was inventive over the combination of D2 and D5. In Figure 7 of D5 the light sources 38 were not disposed within the illuminating frusto-conical funnel but close above it - in contrast with what was required by the claims.

Main request - inventive step over D2 and D1

The subject-matter of claims 1 and 7 was not rendered obvious by the combination of D2 and D1 because the teaching of D1 would not have been considered by the person skilled in the art starting from D2.

Reasons for the Decision

1. The application

An important element of diabetes management is the self-monitoring of blood glucose concentration. Current monitoring techniques discourage patients from regular self-monitoring due to the inconvenient and distressing nature of drawing blood through the skin. A non-invasive technique for measuring glucose concentration is thus desirable.

Claim 1 deals with an apparatus for optical detection of a biological sample. The apparatus comprises a light illumination funnel, a light collector, a plurality of light filters and a plurality of photo detectors. The light illumination funnel has a first outer wall having, among other things, a photo-reflective inner

surface defining an interior portion which has a substantially frusto-conical shape. A light source is disposed within the interior portion. Claim 7 deals with a method of using a corresponding apparatus for optical detection of a biological sample. Reproduced below is Figure 4A of the application, which shows an embodiment of the claimed invention.

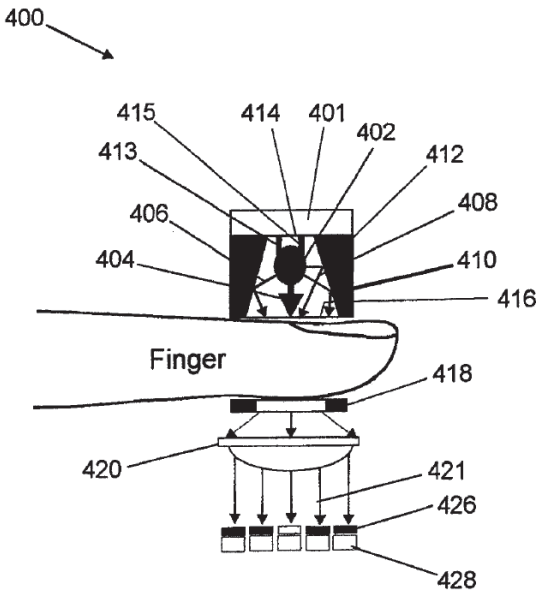

Figure 4A of the patent application

2. Admissibility of the appeal

The appellant did not explicitly address the examining division's finding of lack of inventive step starting from the prior art in Figure 3 of the application. However, since the appealed decision (point 1.7.2.4) referred in this respect to the reasoning presented for the objections starting from D2, the Board understands that the appellant likewise intended that their arguments in respect of the objections starting from D2 also apply to the objections starting from Figure 3. Hence, the statement of grounds of appeal is deemed to deal with all those reasons on which the decision under

appeal was based and complies with the requirements set out in Rule 99(2) EPC.

3. Main request

3.1 The appealed decision concluded that the subject-matter of each of claims 1 and 7 was rendered obvious by the combinations of D2 and D5, D2 and D1, and the combination of the prior art described in Figure 3 of the patent application with either D5 or D1. These combinations will be separately addressed below.

3.2 Inventive step over D2 and D5

3.2.1 D2 discloses an apparatus for optical detection of a biological sample. The starting point for the objection of lack of inventive step is the embodiment of Figure 4, reproduced below:

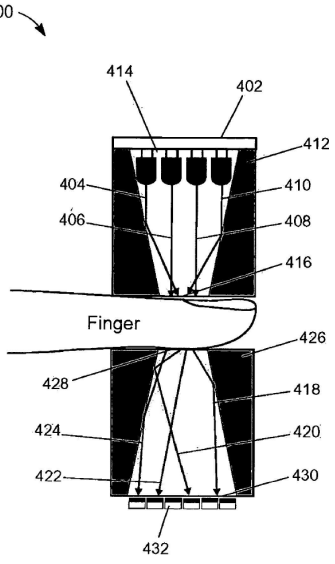

Figure 4 of D2

3.2.2 The apparatus of Figure 4 comprises, among other things, a light illumination funnel 412 with an entrance opening 414, an exit opening 416 and a light source 402 generating a plurality of light beams (404,

406, 408, 410). The inner wall of the funnel 412 is highly reflective (see lines 28 and 29 of page 11).

3.2.3 The appealed decision found - and the appellant does not dispute - that two features distinguish the subject-matter of claim 1 from the embodiment of Figure 4 of D2:

(1) the second cross-sectional diameter near the anterior end is less than the opening diameter; and

(2) the light illumination funnel has a half angle of the frusto-conical shape that is less than 45 degrees, wherein the half angle of the frusto-conical shape is an angle between the longitudinal axis of the frusto-conical shape and a line which extends from the second cross-sectional diameter to the first cross-sectional diameter.

3.2.4 As stated in point 1.3 of the appealed decision, the problem solved by these two features can be regarded as that of how to increase the amount of light power that enters into and is transmitted through the biological sample (see last two sentences of paragraph [0044] of the application as filed).

3.2.5 D2 emphasises that the diameter of the exit opening (416 in Figure 4 above) of the illumination funnel should be smaller than or equal to that of the entrance opening (414 in Figure 4 above) in order to increase the light power received by the target area and to provide adequate space to accommodate a sufficient number of light sources (see claim 1 as well as paragraphs [0043]-[0044] and [0051]-[0052] of D2).

3.2.6 Hence, D2 discourages the use of an exit opening larger than the entrance opening, i.e. it teaches away from a solution which includes the feature of claim 1 "the second cross-sectional diameter near the anterior end is less than the opening diameter". Furthermore, D2 teaches that the light power delivered to the sample can be increased by using a larger amount of light sources, arranged in a three-dimensional array matrix of infrared light sources ([0055]-[0056]), thus addressing the problem above with a different solution.

3.2.7 If the person skilled in the art starting from D2 and facing the above problem had consulted the embodiment of Figure 7 of D5, they would have refrained from inverting the shape of the illumination funnel due to the central teaching of D2 against this modification.

3.2.8 Even if the person skilled in the art had modified the apparatus of Figure 4 of D2 using the illumination funnel of Figure 7 of D5 (reproduced below), they would not have arrived at an apparatus falling within the scope of claim 1, for the reasons explained below.

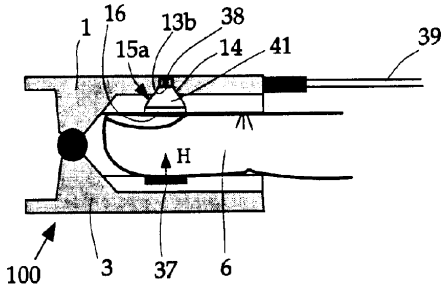

Figure 7 of D5

3.2.9 Claim 1 specifies that "the inner surface defin[es] an anterior portion" and that the interior portion has "an anterior end and a posterior end" and "a substantially frusto-conical shape". In Figure 7 of D5, the reflective surface 14 corresponds to the inner surface

within the meaning of claim 1, the cavity 41 corresponds to the interior portion within the meaning of claim 1, and the bottom surface of the inner end wall 13b corresponds to the anterior end of the interior portion within the meaning of claim 1.

3.2.10 Figure 7 of D5 shows the light sources 38 provided within the inner end wall 13b and thus above the bottom surface of that wall. Using the terminology of claim 1, the light sources 38 are above the anterior end and thus not within the interior portion.

3.2.11 The passage of D5 cited in the appealed decision (namely column 13, lines 11 to 14) refers to "inner end wall 13b, along with radiation sources 38 included therein". This passage confirms that the light sources 38 are within the inner end wall 13b, but does not disclose that the light sources are "within the interior portion" within the meaning of claim 1.

3.2.12 Consequently, even if the person skilled in the art had modified the apparatus of D2 using the illumination funnel of Figure 7 of D5, they would not have arrived at an apparatus having "a light source disposed within the interior portion", as required by claim 1.

3.2.13 For the reasons set out above, the subject-matter of claim 1 is not rendered obvious by the combination of D2 and D5.

3.2.14 The method of claim 7 uses an apparatus as defined in claim 1. Hence, the subject-matter of claim 7 is not rendered obvious by the combination of D2 and D5 either.

3.3 Inventive step over D2 and D1

3.3.1 Points 3.2.1 to 3.2.6 above relate to the disclosure of D2 and apply equally to the combination of D2 with D1.

3.3.2 As stated in point 3.2.4 above, the problem to be solved starting from D2 is how to increase the amount of light power that enters into and is transmitted through the biological sample. As further stated in points 3.2.5 and 3.2.6 above, D2 teaches away from inverting the shape of the illumination funnel.

3.3.3 D1 relates to optical systems including reflectors. D1 remains very vague as to the advantages of the systems disclosed therein and, in particular, it does not teach any advantageous effect as far as the amount of light power output by the system is concerned. Instead, the primary focus of D1 is on the solid angle of the emitted light that can be achieved by the disclosed optical systems (see paragraphs [0007] to [0013]). There is thus no reason for the person skilled in the art starting from D2 and faced with the above problem to consult D1. Hence, the subject-matter of claims 1 and 6 is not rendered obvious by this combination.

3.3.4 For the sake of argument, even if the person skilled in the art had consulted D1, the subject-matter of claim 1 would not have been rendered obvious by the combination of D2 and D1. The optical system of Figures 1 and 2 of D1 uses a single light source (LED 1) that occupies most of the "small throat 4", which defines the anterior end of the frusto-conical reflector 3 as shown in Figure 1 (see also paragraph [0007] of D1). If the apparatus of D2 had been modified using the reflector illustrated in Figures 1 and 2 of D1, the area available at the small throat would have allowed the

use of only one emitting diode instead of four, as used in Figure 4 of D2 (see paragraph [0044] of D2, discussing the restrictions - resulting from having a small area available - on the number of diodes and, consequently, on the light power output). In other words, the modification of the illumination funnel of D2 based on the teaching of D1 would have resulted in a reduction in the light power output. The person skilled in the art, faced with the problem of increasing the amount of light power output, would therefore have rejected this modification.

3.4 Inventive step over Figure 3 and either of D5 or D1

3.4.1 The patent application describes Figure 3 as depicting a "conventional, prior art apparatus for measuring the amount of light absorbed by a sample" (see paragraph [0041]). Following that information, the apparatus depicted in Figure 3 of the patent application defines a valid starting point for the claimed invention.

3.4.2 According to point 1.7.2.2 of the appealed decision, several features distinguish the subject-matter of claim 1 from the apparatus of Figure 3. The problem to be solved is said to be the same as if starting from D2, i.e. how to increase the amount of light power that enters into and is transmitted through the biological sample. The appealed decision then states that the reasoning set out in relation to the objections of lack of inventive step starting from D2 applies. Without any further reasoning being provided, the claimed invention is said not to involve an inventive step.

3.4.3 The Board interprets this reasoning as meaning that the examining division considered the claimed invention to be obvious when starting from Figure 3 in view of

either D5 or D1 for the same reasons as those given in relation to the objections starting from D2.

3.4.4 As set out above, the Board is not convinced by the reasoning given in the appealed decision in relation to the objections starting from D2. In the absence of any additional reasoning in relation to the objections starting from Figure 3 of the application, the Board is likewise not convinced by these objections. In particular, the Board holds that the combination with D5 would not lead to an apparatus falling within the scope of claim 1 (see points 3.2.8 to 3.2.12 above) and that D1 would not have been consulted when faced with the problem above (see point 3.3.3 above).

4. Conclusions

4.1 The only ground indicated in the appealed decision for refusing the application was lack of inventive step. For the reasons set out above, the Board is satisfied that the subject-matter of claims 1 and 7 involves an inventive step within the meaning of Article 56 EPC.

4.2 The minutes of the telephone conversation dated 16 January 2020 indicate that the examining division considered objections of lack of clarity and added subject-matter raised against previous claim requests to have been overcome by the main request filed on 19 December 2019. The same minutes indicate that lack of inventive step was the only reason why the main request was not considered to be allowable. The Board is therefore satisfied that there are no outstanding objections to 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 examining division with the order to grant a patent on the basis of claims No. 1 to 10 of the main request filed on 19 December 2019 and a description to be adapted thereto.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated