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**Datasheet for the decision
of 2 September 2009**

Case Number: T 1211/07 - 3.2.02

Application Number: 00108970.5

Publication Number: 1048265

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:

Apparatus and method for detecting a substance

Applicant:

V.Lilienfeld-Toal, Hermann, Prof. Dr. med.

Opponent:

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Headword:

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Relevant legal provisions:

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Relevant legal provisions (EPC 1973):

EPC Art. 52(1), 56

Keyword:

"Inventive step (no) - alleged effect not derivable from the application as filed"

Decisions cited:

T 0386/89

Catchword:

-

Case Number: T 1211/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 2 September 2009

Appellant: V.Lilienfeld-Toal, Hermann, Prof. Dr. med.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 2 January 2007
refusing European application No. 00108970.5
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: M. Noël
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 2 January 2007 to refuse European patent application No. 00 108 970.5.

The grounds of refusal were that claim 1 of each of the main and auxiliary requests did not involve an inventive step having regard to the following documents:

D1: WO 91/18548 A

D4: WO 99/07277 A

D5: Paldus B et al.: Photoacoustic Spectroscopy Using Quantum-Cascade Lasers, Optics Letters, US Optical Society of America, Vol.24, no.3, 1 February 1999, pages 178-180.

Also of interest in the appeal procedure is:

D2: EP-A-0 282 234 (mentioned in the application as originally filed).

II. On 12 March 2007 the appellant lodged an appeal against the decision and paid the prescribed fee on the same day. On 14 May 2007 a statement of grounds of appeal was filed.

Oral proceedings were held on 2 September 2009.

The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 6 filed on 14 May 2007 (main request) or on the basis of claims 1 to 5 filed on 31 July 2009 (auxiliary request).

III. Independent claims 1 and 6 of the main request read as follows:

"1. An apparatus for non-invasive detection of glucose in a person's body (1, 2), comprising: a device (4,5) for irradiating the body with a light beam (10) which penetrates into the body, an acoustic detector (3,6) for detecting acoustic signals (11) originating within the body from absorption of the light beam, and an indication unit (7) coupled to the acoustic detector for indicating the presence of glucose from the detected acoustic signals, characterised in that said device (4,5) includes a quantum cascade laser (5) for generating infrared light of at least two discrete wavelengths in the mid-infrared region, each discrete wavelength being at a different peak or valley in the mid-infrared absorption spectrum of glucose in the body and having a bandwidth not exceeding $2/3$ the width of the respective peak or valley, and that the indication unit (7) indicates the presence of glucose based on acoustic signals detected for each of said discrete wavelengths.

6. A method for non-invasive detection of glucose in a person's body (1,2), comprising the following steps: irradiating the body with a light beam (10) which penetrates into the body, detecting acoustic signals (11) originating within the body from absorption of the light beam, and indicating the presence of glucose from the detected acoustic signals, characterised in that said light beam is generated at at least two discrete wavelengths in the mid-infrared region by a quantum cascade laser (5), each discrete

wavelength being at a different peak or valley in the mid-infrared absorption spectrum of glucose in the body and having a bandwidth not exceeding $2/3$ the width of the respective peak or valley, and that the presence of glucose is indicated based on the acoustic signal detected for each of said discrete wavelengths."

Claims 2 to 5 are dependent claims.

Claims 1 and 5 of the auxiliary request incorporate the subject-matter of claim 4 of the main request, according to which the laser device emits said at least two discrete wavelengths as individual laser beam pulses at different times to the same location of the body.

IV. The appellant argued as follows:

Starting from document D2 claim 1 had the following three new features which interacted together to give the invention:

- i) The present apparatus exploited the mid-infrared (MIR) absorption spectrum of glucose whereas D2 was concerned with the near-infrared range,
- ii) The present apparatus used a quantum cascade laser, and
- iii) The present apparatus used a laser having a bandwidth not exceeding $2/3$ the width of the respective peak or valley of the absorption spectrum.

The teaching of D2 did not lead to a practically usable device for noninvasive detection of glucose. At infrared intensities which were practically usable without unduly heating or even burning a person's skin, none of the known techniques was sensitive and reliable

enough, or was too bulky for daily use. The present problem was to provide technology which the patient could use easily and by himself.

While spectroscopy with mid- infrared light had the capability of detecting more absorption lines of glucose, it has also had the disadvantage of high parasitic absorption by water in the tissue. The invention solved this problem by using a quantum cascade laser to confine the irradiated light to only discrete wavelengths at peaks or valleys in the mid- infrared absorption spectrum of glucose where the most significant response in relation to the irradiated light intensity could be obtained. Thus, the invention avoided measurement of the entire absorption spectrum as a continuum which would greatly increase measurement time and body heating and would only achieve a further slight improvement of the detection error.

Since the invention used the photoacoustic effect to detect absorption of the light in the body, there was no need for higher light intensities as would be necessary for optical detection of light transmission or reflection where a significant fraction of the incident light would be required to emerge again from the body. The claimed combination of a quantum cascade laser as a light source for the discrete wavelengths and the photoacoustic measurement was most sensitive for detection of glucose in the lower layer of the human skin which had almost the same glucose concentration as the blood.

A quantum cascade laser was ideal for MIR and could be operated with very narrow bandwidths. The inventor

unexpectedly found that this led to deeper penetration into the body tissue. It was believed that the human skin was much thicker than it actually was so that high light power was necessary to reach tissue below the skin. In fact, the stratum corneum was only 10 to 20 microns thick and the claimed combination of features provided the right light intensity to reach the glucose-containing layers under the skin and cause the photoacoustic response. This effect was discussed on pages 8 and 9 of the application.

The prior art used measurement and reference beams at different locations. The advantage of having the same location of the two beams was that measurement accuracy was increased. This additional feature of the auxiliary request combined with the other three new features to provide the effect of increased accuracy of measurement.

Reasons for the Decision

1. The appeal is admissible.
2. *Inventive step - main request*
 - 2.1 D2 is the closest prior art document since it describes a device and method for non-invasively detecting and measuring the concentration of glucose in a person's body by optoacoustic spectroscopy in which laser (6) light of selected discrete frequencies is directed into the body and the acoustic response thereof is detected. The device comprises an acoustic detector (7) for detecting acoustic signals originating within the body from absorption of the light beam, and an indication

unit (12) coupled to the acoustic detector for indicating the presence of glucose from the detected acoustic signals (see the abstract).

The laser (6) generates infrared light of at least two discrete wavelengths in the near-infrared region (column 8, lines 4 to 6), each discrete wavelength being at a different peak or valley in the near-infrared absorption spectrum of glucose in the body (column 8, lines 10 to 16 and 27 to 31), and the indication unit (12) indicates the presence of glucose based on acoustic signals detected for each of said discrete wavelengths.

- 2.2 The apparatus of claim 1 differs from that of D2 in that it employs a quantum cascade emitting frequencies in the MIR and having a bandwidth not exceeding 2/3 the width of the respective peak or valley of the glucose absorption spectrum.
- 2.3 D2 teaches to use a tunable laser so that absorption measurements may be made at different frequencies (column 10, lines 14 to 18). This is a convenient way of providing light at different frequencies since only a single laser source is necessary.
- 2.4 Since the disclosure of D2 in 1988, quantum cascade lasers became available. These lasers have decided advantages in that wavelength can be tuned over a wide spectral range from the mid-infrared to the submillimeter range. Quantum cascade lasers, accordingly, found use in various spectroscopic applications, including photoacoustic spectroscopy, as evidenced by D5. The advantages of being widely tunable

over the mid-infrared range, high power output, and narrow linewidths made such lasers attractive light sources (D5, page 178, lines 19 to 24 of the main text). Also according to D4, which concerns the spectroscopic determination of an analyte in vivo, for measurements in the mid-infrared quantum cascade lasers are preferred (D4: page 19, lines 6 to 9).

To be sure, D5 relates to the photoacoustic spectroscopy of air for pollution monitoring, but the person skilled in the art would realise that the advantages of quantum cascade lasers as light sources per se and consider employing them also for the photoacoustic spectroscopy of blood.

The use of a quantum cascade laser in the present context does not involve an inventive step, accordingly.

- 2.5 The other distinguishing features of claim 1, that the quantum cascade emits frequencies in the MIR and having a bandwidth not exceeding $2/3$ the width of the respective peak or valley of the glucose absorption spectrum, also do not involve an inventive step.

The use of radiation for photoacoustic spectroscopy in the MIR range for the non-invasive detection of glucose is described with reference to the second embodiment of D1 (Figure 8), and its use in the present non-invasive detection of glucose does not involve any new considerations.

The mechanism of laser spectral line absorption is that if the line lies within an absorption spectral line of interest, then the laser light will be effectively

absorbed, the optimum condition being that the laser line coincide with the peak of the absorption spectral line. The laser line width does not matter much, the important consideration being that it lies wholly within the absorption spectral line. It is notable that the application does not state any advantage of this feature.

2.6 For the above reasons the apparatus of claim 1 does not involve an inventive step. The same considerations apply to the method of claim 6.

2.7 The same conclusion results if the analysis were to be based on D1 as the closest prior art document. This prior art employs light in the mid-infrared range, so that this is not a distinguishing feature of claim 1.

2.8 The appellant's chief argument in support of inventive step is that the three new features (point 2.2 above) combine to provide an unexpected effect. In particular, a quantum cascade laser operating in the MIR with narrow bandwidths leads to deeper light penetration into the body tissue.

However, this effect is not disclosed in the application as originally filed. According to the case law of the EPO (see the Case Law, 5th Edition, 2006, I.D.4.2) alleged advantages to which the applicant refers, without offering sufficient evidence to support the comparison with the closest prior art, cannot be taken into consideration in determining the problem underlying the invention, and therefore in assessing inventive step.

According to the catchwords of T 386/89 "the alleged effect of a described feature cannot be taken into account when determining the problem underlying the invention for the purpose of assessing inventive step, if it cannot be deduced by the skilled person from the application as filed considered in relation to the nearest prior art".

This effect is not disclosed in the application, nor can it be derived by the skilled person. The appellant argues that pages 8 and 9 of the application do indeed discuss this effect, but this argument is not correct. These pages merely describe the well known principle that absorption spectroscopy is most effective when the wavelength of the investigating light coincides with a peak of the analyte's spectrum. There is no discussion here that a quantum cascade laser operating in the MIR with narrow bandwidths leads to deeper light penetration into the body tissue. The fact that D1 uses a broad spectrum of light does not negate this principle, because at the time D1 was filed (1990) no suitable narrow band (i.e. laser) light sources were available at the MIR range.

3. *Inventive step - auxiliary request*

- 3.1 Claims 1 and 5 include the additional feature that the laser device emits said at least two discrete wavelength as individual laser beam pulses at different times to the same location of the sample.

This feature is already implicit in the use of a tunable laser, because the laser is tuned by sweeping over its spectral range, which means that it emits its

discrete wavelengths as individual laser beam pulses at different times to the same location of the sample. This feature does not involve an inventive step, accordingly.

For these reasons claims 1 and 5 of the auxiliary request also do not involve an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

D. Sauter

M. Noël