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**Datasheet for the decision  
of 23 September 2008**

**Case Number:** T 1255/06 - 3.2.02

**Application Number:** 96203169.6

**Publication Number:** 0763349

**IPC:** A61B 19/02

**Language of the proceedings:** EN

**Title of invention:**

Radiation detector for tympanic temperature measurement

**Patentee:**

EXERGEN CORPORATION

**Opponent:**

S.A.A.T. Ltd.

**Headword:**

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**Relevant legal provisions (EPC 2000):**

EPC Art. 52(1), 53(c), 123(2)

**Relevant legal provisions (EPC 1973):**

EPC Art. 54(1), 56, 100(c)

**Keyword:**

"Added subject-matter (no)"

"Diagnostic method (no)"

"Novelty (yes)"

"Inventive step (yes)"

**Decisions cited:**

G 0001/04

**Catchword:**

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Case Number: T 1255/06 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 23 September 2008

**Appellant:** S.A.A.T. Ltd.  
(Opponent) 17 Nachshon St. Segula  
IL-49277 Petach Tikva (IL)

**Representative:** Vossius & Partner  
Siebertstrasse 4  
D-81675 München (DE)

**Respondent:** EXERGEN CORPORATION  
(Patent Proprietor) One Bridge Street  
Newton  
Massachusetts 02158 (US)

**Representative:** Jenkins, Peter David  
Page White & Farrer  
Bedford House  
John Street  
London WC1N 2BF (GB)

**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 29 May 2006  
rejecting the opposition filed against European  
patent No. 0763349 pursuant to Article 102(2)  
EPC 1973.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** S. Chowdhury  
M. J. Vogel  
M. Noel  
A. Pignatelli

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division relating to European patent No. 0 763 349, rejecting its opposition to the grant thereof. The decision was dispatched on 29 May 2006.

The appeal was received on 8 August 2006 and the fee for the appeal was paid on the same date. The statement setting out the grounds of appeal was received on 6 October 2006.

II. The opposition was filed against the entire patent and based on Article 100 (a) EPC 1973 (lack of inventive step, patentability of excluded diagnostic method), and Article 100 (c) EPC 1973. As part of its case the opponent alleged public prior use of the claimed device.

The opposition division decided that public prior use had not been proved and that the patent met the requirements of the EPC, and rejected the opposition, accordingly.

III. Oral proceedings were held before the Board on 23 September 2008, at which the following requests were submitted:

The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 763 349 be revoked.

The respondent (patentee) requested that the appeal be dismissed.

IV. The following documents were of particular interest in the appeal procedure:

D1: US-A-4 602 642

D2: US-A-3 282 106

D3: Brochure "PET<sup>TM</sup> Physician's Electronic Thermometer"

D4: US-A-4 634 294

D5: WO-A-86/06163.

V. Independent claims 1 and 16 of the patent as granted read as follows: -

"1. An ear temperature detector, comprising: a housing (14); a probe (18) adapted to be inserted into an ear and for passing radiation from the ear to a radiation sensor (28); a temperature display (16) on the housing (14) for displaying ear temperature; and electronics in the housing (14) for converting radiation sensed by the sensor (28) to temperature displayed by the display (16); characterised in that the electronics include a radiation peak detector such that a peak temperature is displayed with rotation of the probe (18) in an ear; the housing (14) is adapted to be held by hand; and the probe (18) is an extension (18) from the housing (14).

16. A method of determining ear temperature, comprising the steps of: providing a radiation detector comprising an extension (18) for passing infrared radiation from an external target to a sensor (28) and electronics for converting the radiation sensed by the sensor (28) to temperature; inserting the extension (18) into an ear; and detecting the radiation; characterised in that the method further comprises the step of pivoting or

rotating the extension (18) to scan an ear canal, the sensor (28) sensing radiation during scanning, and determining the peak radiation sensed by the sensor (28) and converting the peak radiation sensed to a peak ear temperature."

Claims 2 to 15 are dependent claims.

VI. The parties argued as follows:

Appellant

Claim 1 of the patent in suit specified that the probe was an extension from the housing. This could not be derived from the application as originally filed, which referred only to a probe extension, not to a probe, extending from the housing. The figures only showed an angular assembly of extensions which did not form the probe whose function was to pass radiation to the sensor. The sensor was disclosed as being supported by the probe and this feature had been taken out of its context and generalised, especially since the location of the sensor was extensively disclosed as being essential to the invention. The scope of claim 1 was such that it covered embodiments not disclosed.

Claim 16 was directed to a method which was applied with the patient present, an extension of a detector was inserted into the ear and rotated, and the temperature in the ear canal measured to diagnose whether a person suffered from fever. Thus, according to G 1/04 it defined a diagnostic method.

Both Mr. O'Hara and Mr. Benincasa, who had no interest in the outcome of the present procedure, had submitted, in affidavits and declarations, a sound and credible story regarding the development and demonstration of the PET prototype and the distribution of the brochure D3 at a conference in California. All facts and statements provided were consistent with each other and added up to a convincing narrative proving public prior use of the device.

Claim 1 of the patent in suit defined a housing, not a single housing, and the claim wording did not exclude a plurality of housings as used in D1. The patent in suit even disclosed an embodiment (Figure 7) which showed other components in a separate housing.

The term "radiation peak detector" was meaningless. D1 disclosed the measurement of a patient's core temperature by comparing stored calibration data with the maximum output of a thermopile during a succession of ear canal samplings. To the person skilled in the art it was clear that the maximum output of a thermopile was directly proportional to the maximum or peak radiation. Thus, D1 disclosed a radiation peak detector and, since it also disclosed all the other features of claim 1, its subject-matter lacked novelty.

The device of D2 could also be used as a radiation peak detector because it could be rotated and the maximum temperature value stored and displayed. As shown in Figure 8 thereof, D5 also disclosed a radiation peak detector. Since these documents also disclosed all the other features of claim 1, they anticipated the claimed device.

Starting from D1 the objective technical problem was to minimise the calculation required and the imprecision of the temperature reading. The person skilled in the art would be aware, upon seeing the flow chart of Figure 17 of D1, that a different algorithm could be employed, namely that a plurality of radiation scans could be stored and the maximum temperature displayed at the end. This was trivial, so that claims 1 and 16 did not involve an inventive step.

Respondent

The reference numerals and terminology used in the patent were misleading, but it was nevertheless clear that the probe comprised both the parts termed "extension" and "probe". The combined assembly was stated to curve like an otoscope and rotated with the head. Claim 1 did not contain new subject-matter, accordingly.

Method claim 16 did not include a single diagnostic step and, according to G 1/04, was not excluded from patentability.

The appellant was arguing that, since the alleged public prior use occurred so long ago, the burden of proof should be relaxed in the appellant's favour. The opposite was the case, i.e. the burden should be all the more greater, and the "beyond reasonable doubt" criterion should be applied strictly in order to prove public prior use. The allegations of O'Hara and Benincasa were not supported by a single contemporaneous document, and it was not clear which

version of D3 had been distributed at the trade show in Anaheim, if at all, or whether a prototype or a mock-up was made available to the public, if at all.

The patent used a radiation peak detector which measured the peak radiation impinging on the sensor, whereas all the prior art documents disclosed measuring the peak output signal of a thermopile or pyroelectric sensor, which was not the same as measuring the radiation peak. The claimed subject-matter was both novel and inventive by virtue of this feature since its use was not known and it provided the technical advantage of reducing the data processing involved.

### **Reasons for the decision**

1. The appeal is admissible.
2. *Article 100 (c) EPC 1973*

To the person skilled in the art it is clear that, in the context, the probe comprises both the parts referenced 18 and 20. For example, the sentence in column 7, lines 17 to 21 of EP-A-0 763 349 states that the head of the detector, including the extension 18 and 20, has the appearance of a conventional otoscope, and column 8, lines 6 and 7 states that the probe is curved like an otoscope. While the use of the word "curved" is wrong ("bent" is what is meant) these passages show that the probe, which resembles an otoscope, comprises both the parts 18 and 20.



The use of terminology in the patent is not consistent, but the feature in claims 1 and 16, that "the probe (18) is an extension (18) from the housing (14)", is nevertheless clearly derivable from the application as originally filed.

The invention is concerned with the technical problem of reducing the data processing involved in an ear thermometer, and the solution comprises a radiation peak detector (see point 7. below). The location of the sensor is irrelevant to this problem and its solution, and is consequently not an essential feature of the invention. The location of the sensor is, moreover, not specified in original claim 1 so that by not including this feature in the independent claim no new technical information is added.

The claimed subject-matter does not extend beyond the content of the application as filed accordingly.

3. *Article 53(c) EPC*

3.1 The appellant argued that the method of claim 16 represents a diagnostic method and is therefore excluded from patentability.

3.2 Article 53(c) EPC is applicable to European patents already granted at the time of entry into force of the EPC 2000 according to Article 7 of the Act revising the European patent convention of 29 November 2000 and Article 1 of the Decision of the Administrative Council of 28 June 2001. Since in the present case the European patent had been granted at the time of entry into force of Article 53(c) EPC, this Article is to be applied.

3.3 In its opinion G 1/04, the Enlarged Board of Appeal gave an interpretation of the term "diagnostic method" when Article 52(4) EPC 1973 was in force. Although this Article is not applicable in the present case, the interpretation of this article, as elaborated in G 1/04, is still valid because the wording of article 52(4) EPC 1973 re-appears unchanged in new Article 53(c) EPC, so the amendment to the EPC has not changed the application of this provision.

According to this interpretation, in order that the subject-matter of a claim relating to a diagnostic method practiced on the human or animal body falls under the prohibition of Article 53(c) EPC, the claim is to include the features relating to the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise i.e. the attribution of the detected deviation of values to a particular clinical picture. If this step is missing, the method is only one of data acquisition or data processing that can be used in a diagnostic method. Such a data acquisition method does not constitute a sufficient basis for denying patentability under Article 53(c) EPC unless this method allows *per se* the attribution of the detected deviation to a particular clinical picture (see point 6.2 of the reasons).

Claim 16 only defines the data acquisition steps (the temperature of the body) which can be used in a diagnostic method. Although the acquisition of the temperature data leads to the detection of a deviation from the normal values, it does not allow *per se* the

attribution of the detected deviation to a particular clinical picture. Therefore the claim does not define the features relating to the diagnosis for curative purposes *stricto sensu*.

For these reasons claim 16 does not relate to a diagnostic method excluded from patentability by Article 53(c) EPC.

4. *Public prior use*

The appellant alleges that a PET thermometer, as described in D3, was made available to the public before the priority date of the patent in suit, by means of a presentation at a conference and of the distribution of a brochure on the same occasion.

To prove its allegations, the appellant offered, during the opposition proceedings, the hearing of Mr. O'Hara as a witness, a statutory declaration of Mr. Benincasa, and a copy of the brochure itself (D3).

As recorded in the minutes of the hearing of the witness Mr. O'Hara by the opposition division, he did not remember, *inter alia*, the following details of the alleged public prior use:

- the year in which the conference took place (page 4 of the minutes)
- whether or not the brochure accurately reflects what was displayed, and which version of the brochure was distributed (page 5)

- whether there was a re-print of the brochure D3 or if there were differences between the device described in it and the prototype shown (page 5)
- whether there was any feedback from customers (page 6)
- whether any sales were made (page 11)
- whether or not an actual functional prototype was shown (page 14)
- whether he talked to anyone about the prototype despite being proud of it (page 15), etc.

As far as the declaration of Mr. Benincasa is concerned, the Board notes that he does not remember in which year the conference at which a prototype of the invention is alleged to have been made available to the public took place. Mr. Benincasa does not give any further details about the features of the thermometer shown to visitors. He declares, somewhat vaguely, that he was at the conference and demonstrated the functions of a thermometer to visitors.

The declarations of Mr. O'Hara and Mr. Benincasa, regarding the public prior use of the claimed invention are, therefore, not sufficiently definite regarding details about when the public prior use occurred, what exactly was shown, and the circumstances of the disclosure.

As regards the brochure D3 itself, the copy filed at the EPO is not dated. An original is said to exist but has not been presented to the EPO. The appellant submitted that the year of distribution must have been 1981 because in 1982 the telephone number of the relevant district was changed and the old number was printed on the brochure, and because the company was

sold in October 1982 and the old name was no longer used. However, no evidence of these facts has been submitted by the appellant.

No other contemporaneous document or any other corroborating evidence has been filed to support the allegations that a prototype of the PET device was indeed exhibited at the conference, that Mr. O'Hara actually attended the conference, that D3 was actually distributed to the public, what the exact construction of the prototype displayed was, etc. No laboratory notebook, manual, invoices, etc. have been found to definitively demonstrate what was displayed. Of all the material which could be presented as evidence only D3 appears to have survived.

The appellant submitted that it was not possible to find any other document because the public prior use took place over 20 years ago. However, the established practice of the EPO is to require an allegation of public prior use to be proved "up to the hilt". The fact, that in the present case the alleged public prior use occurred over 20 years ago, is no reason to relax the burden of proof, and this requirement must be met also in the present case.

Therefore, the evidence provided does not establish beyond reasonable doubt that the public prior use as alleged actually did take place. For these reasons neither the public prior use of the claimed invention nor the date of publication of D3 have been proven, so these are not to be regarded as prior art.

5. *Radiation peak detector*

The appellant contends that the expression "radiation peak detector" in claims 1 and 16 is meaningless. For the following reasons the Board disagrees:

As explained in the patent in column 7, lines 29 to 36, the probe is rotated in use and the ear canal is thereby scanned and, at some orientation of the probe during that scan, one can be assured that the maximum temperature is viewed, and the peak detected during the scan is taken as the tympanic temperature. Thus, the temperature detector is used in an environment in which the radiation field changes with rotation of the detector, and the peak of the changing radiation is detected and converted into a temperature reading. The function of the radiation peak detector is, therefore, clear.

The radiation peak detector of the patent also has a particular construction which enables this function to be performed, which may be understood by first looking at prior art sensors. The output signal of a conventional thermopile, for example as used in D1, comprises three components, the radiation itself, the cold junction drift, and the hot junction drift. By designing the device so that the last two components contribute a negligible signal the thermopile output corresponds to the incident radiation only. The sensor of the patent is so designed, and it responds substantially only to radiation viewed through the window 57 (see the patent column 9, lines 14 to 16).

The features which ensure stability and that the hot and cold junction drifts are negligible are described in paragraphs [0045], [0049], and [0050] and include, inter alia, the following: the waveguide is maintained at the same temperature as the cold junction, any temperature changes are distributed rapidly to the cold junction to avoid any thermal gradients, temperature changes are minimised, and the waveguide is well insulated.

Therefore, by "radiation peak detector", as objectively derivable from the patent, is meant a detector sensitive substantially to radiation only and which registers the maximum value of the radiation during a scan. This detector, as defined in claims 1 and 16 implicitly includes those features necessary to ensure stability and sensitivity predominantly to radiation only. The question whether or not the claims define all the essential features of the invention is a matter to be considered under Article 84 EPC and not, therefore, to be examined in opposition proceedings.

6. *Novelty*

The temperature probes of the documents D1 and D2 are used by inserting them into the ear and measuring the detector signal while the probe is held stationary, which means that a single, unchanging radiation field is incident on the detector during a temperature reading. The signal from the detector varies, nevertheless, owing to the hot and cold junction drifts and other instabilities, caused for example, because the waveguide is heated.

In particular, D1 and D2 do not disclose the use of a radiation peak detector. The reference in D1 to the maximum output of the thermopile (see the end of the abstract, column 12, lines 44 to 47, and column 13, lines 4 to 10) is not a reference to detecting a radiation peak, it is a description of measuring the maximum thermopile signal (owing to instabilities) in a constant radiation environment.

D5 describes the use of a pyroelectric sensor, also to be used in a constant radiation environment, and also discloses no radiation peak detector. The pyroelectric signal is shown in Figure 8 to vary and have a maximum, but this is not due to the radiation changing, it is due to the hysteresis in the signal between the opening and closing of a radiation shutter.

For the reason alone that none of D1, D2, or D5 discloses a radiation peak detector the temperature detector of claim 1 and the method of claim 16 are novel. Other features, such as the use of a single or multiple housings, need not be considered.

7. *Inventive step*

As shown above, the sensor of the patent in suit is primarily a radiation sensor which can scan a changing radiation field such as in an ear canal and register the maximum radiation sensed during a scan. The corresponding temperature can then be determined, which enables a reliable determination of the tympanic temperature (see the patent, column 7, lines 29 to 36).



The algorithm used involves a pre-selection of data, in that only the radiation peak value is identified and only this value is converted into a temperature value, which corresponds to the maximum temperature. This clearly involves less processing power than the case where each radiation value is converted into a temperature value and then the maximum temperature value identified and stored.

D1 describes the latter algorithm, that is, a plurality of thermopile output signals (each being the maximum of a thermopile output) is converted to a corresponding temperature value, and then the maximum temperature is identified (see column 12, lines 48 to 56 and Figure 17) and stored.

Neither D1 nor any of the other cited prior art documents suggests using a radiation peak detector for scanning the body and determining a temperature from the maximum radiation identified. For these reasons the subject-matter of claims 1 and 16 involves an inventive step.

**Order**

**For these reasons, it is decided that:**

The appeal is dismissed.

The Registrar

The Chairman

V. Commare

T. Kriner