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D E C I S I O N
of 18 June 2003

Case Number: T 0368/00 - 3.2.2

Application Number: 89910765.0

Publication Number: 0388463

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:
Infrared Clinical Thermometer

Patentee:
Becton, Dickinson and Company

Opponent:
TERUMO CORPORATION
Braun Aktiengesellschaft

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 83, 84

Keyword:
"Clarity (yes)"
"Sufficiency (yes)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
T 0190/99

Catchword:
-



Case Number: T 0368/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal
of 18 June 2003

Appellant I:

TERUMO CORPORATION
Shonan Center, 1500 Inokuchi, Nakai-machi
Ashigarakami-gun, Kanagawa Pref.259-01 (JP)

Representative:

Calderbank, Thomas Roger
MEWBURN ELLIS
York House
23 Kingsway
London WC2B 6HP (GB)

Appellant II:

Braun Aktiengesellschaft
Frankfurter Strasse 145
D-61476 Kronberg (DE)

Representative:

-

Respondent: Becton, Dickinson and Company
(Proprietor of the patent) 1 Becton Drive
Franklin Lakes
New Jersey 07417 (US)

Representative: Lawrence, Peter Robin Broughton
GILL JENNINGS & EVERY
Broadgate House
7 Elton Street
London EC2M 7HL (GB)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
16 February 2000 concerning maintenance of
European patent No. 0388463 in amended form.

Composition of the Board:

Chairman: S. S. Chowdhury
Members: M. G. Noël
U. J. Tronser

Summary of Facts and Submissions

I. The appellants (opponents, Terumo Corporation and Braun Aktiengesellschaft (hereinafter appellants I and II respectively), lodged an appeal against the decision of the opposition division to maintain the patent No. 0 388 463 in amended form. The decision was dispatched on 16 February 2000.

The appeals and the fees for the appeals were received on 5 April and 7 April 2000, respectively. The statements setting out the grounds of appeal were received on 23 June and 15 June 2000, respectively.

The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step), Article 100(b) EPC (the patent did not disclose the invention sufficiently clearly and completely for it to be carried out by the person skilled in the art), and Article 100(c) EPC (the patent as amended contains subject-matter that extends beyond the content of the patent as filed).

The opposition division decided that the amended claims submitted during the opposition procedure met all the requirements of the EPC, in particular those of Article 52(1) EPC and Articles 100(b) and (c) EPC.

The following prior art documents were of importance during the appeal proceedings:

D1: US-A-4 602 642

D2: US-A-4 636 091

D6: WO-A-86 06163

D7: JP-A-63-91526 (English translation).

II. Oral proceedings took place on 18 June 2003, at the end of which the following requests forming the basis of the decision were put forward:

The appellants requested that the decision under appeal be set aside and that European patent No. 0 388 463 be revoked.

The respondent (patent proprietor, Becton, Dickinson and Company) requested that the appeals be dismissed and that the patent be maintained on the basis of the main request filed at the oral proceedings or on the basis of the auxiliary requests 1 or 2 filed with the letter dated 9 May 2003.

III. The independent claims 1 and 9 read as follows:

"1. An apparatus for determining the body temperature of a patient by measuring infrared radiation from the patient comprising: a housing (5) having at least one infrared radiation receiving port; an infrared radiation sensor means (10) enclosed in said housing (5) comprising a wave guide means (11) having one end accessible to infrared radiation from the patient, a thermopile type infrared radiation detector means (18) positioned to receive infrared radiation from said patient as directed by said wave guide means (11), and further to generate a signal corresponding to a quantity of infrared radiation detected, a detector

temperature sensor means (13) positioned to measure a temperature of said infrared radiation detector means (18) and further to generate a signal corresponding to said temperature of the infrared radiation detector means (18), said wave guide means (11) and an isothermic block means (12) which is a heat conducting material positioned proximate to said wave guide means and which is of sufficient mass that the cold reference junction(s) of said infrared radiation detector means (18), said wave guide means (11) and said detector temperature sensor means (13) are held at substantially the same temperature, at or about an ambient temperature even when the ambient temperature changes, by said isothermic block means (12); and a signal processing means (35) for receiving said infrared radiation detector means signal and said detector temperature sensor means signal, and generating an output signal corresponding to the temperature of said patient."

"9. a method using the apparatus of any of claims 1 to 8 for measuring internal body temperature of a patient comprising the steps of:

(a) positioning an infrared radiation sensor (10) adjacent to an ear (100) of the patient in a manner so that radiation emitted by a tympanic membrane of the ear (100) is directed into said infrared radiation sensor (10), and further said radiation is directed by an open ended wave guide means (11) in said sensor (10) onto a thermopile type infrared radiation detector means (18);

(b) converting said radiation impinging onto said infrared radiation detector means (18) into a signal that is dependent on a quantity of infrared radiation received per unit time;

(c) measuring a temperature of said infrared radiation detector means (18) and wave guide means (11);

(d) adjusting said radiation detector signal in response to said temperature of the radiation detector means (18) and wave guide means (11);

(e) displaying the tympanic membrane temperature as derived from said adjusted radiation signal, wherein the cold reference junction(s) of the infrared said radiation detector means (18) and the wave guide means (11) are held by the isothermic block means (12) at substantially the same temperature, at or about an ambient temperature, even when the ambient temperature changes, and further, steps b-d above are essentially concurrently performed."

Claims 2 to 8 and 10 to 11 are dependent on claims 1 and 9, respectively.

IV. The appellants argued as follows:

Appellant I

The expression "ambient temperature" was unclear since it normally meant "of or related to the immediate surroundings", so claim 1 meant that the various components should correspond to the immediate surroundings. Column 8, lines 18 to 27, on the other

hand, suggested that the temperature should be maintained independent of the "external environment".

No information was given as to how to achieve a device which maintained the components at or about ambient temperature. If "ambient temperature" was taken to be the temperature of the components themselves, then the subject-matter of claim 1 was not novel (see below). Further confusion arose from the fact that the isothermic block should resist rapid temperature changes and also hold the components at ambient temperature, which two requirements were contradictory.

The patent in suit referred to a "same temperature" feature and a "stable temperature" feature. The isothermic block carried out the "same temperature" feature only, and the only disclosure of the "stable temperature" feature was in connection with the air space 3. The term "sufficient mass", moreover, was too imprecise to enable the person skilled in the art to determine the mass needed.

The housing 94 of D1 enclosing the detector and the temperature sensor necessarily had some mass, and since it was of metal and thermally contacted these components as well as the waveguide, this arrangement provided both the same temperature and the stable temperature features. Therefore, the apparatus of claim 1 lacked novelty.

Alternatively, starting from D1 the technical problem was to prolong the time period over which a temperature measurement could be taken. The person skilled in the art knew that a thermal mass would cool more slowly and

maintain a constant temperature for a longer time, so the addition of this feature to the apparatus of D1 was obvious.

Moreover, D2 disclosed the use of a potting material of "high conductivity" and "sufficient thermal mass", so if the above difference between D1 and claim 1 was real then it wasn't inventive.

Appellant II

The expression "isothermic block" was self contradictory since it required contradictory properties of the block, and, moreover, the desired properties were no more than wishful thinking since they did not exist.

Figure 2 of document D7 showed an inner metal cylinder which was a waveguide and at the same time an isothermic block. Only the inner surface of this cylinder acted as a waveguide, whereas its body acted as the block, whose isothermal function was described in this document. If the block of the disputed patent was considered to have "sufficient mass" then the cylinder of D7 must equally be considered have sufficient mass.

There was a trivial difference between making the waveguide and the block as two separate pieces and making them as a one-piece device. This was the only difference between the claimed apparatus and the D1 apparatus, and was not inventive.

V. The respondent argued as follows:

The expression "isothermal block means" described the isothermal function of the block. At the same time the use of words like "maintaining", "holding", and "retain" emphasised the time factor, ie the stable temperature property of the block. The notice of opposition of appellant I made it clear that it realised that the described function of the isothermic block was the stable temperature function. An appreciable thermal capacity was required of the block to fulfil this function, and the figures of the patent in suit showed such a bulky block.

The words "good conductor" and "sufficient" were described clearly by their effect. The housing 94 of D1 could not be considered to have "sufficient mass" since it had to adjust to rapid temperature changes, which pointed to a small mass. Claim 1 required the block and the waveguide to be separate features, which was not the case in D7.

The technical problem should be defined starting from the patent in suit and not with hindsight. D1 described an active control system and the patent in suit provided a passive system that worked well, but if the system of D1 were to be modified as suggested by the appellants, then the result would still be an active system.

In D2 the potting compound was mentioned only in the context of measuring high temperatures, and in this context the compound was for rapid heat transfer, not for stabilising the temperature. Similarly, the

teaching of D7 was that heat should be dispersed rapidly, which was the opposite effect to that sought after in the patent in suit.

Reasons for the Decision

1. The appeals are admissible.

Main request

2. *Clarity*

- 2.1 The action of the "isothermic block means" and the meaning of the expression "an ambient temperature" are of fundamental importance and these terms will be discussed first.

The Board takes the view that the "ambient temperature" is normally that prevailing about the apparatus at any given time, and clearly changes depending on the ambience, ie on whether the apparatus is in a standby condition prior to use, for example in a holder, or in the measuring condition in the proximity of the ear of a patient. In claim 1, however, this expression refers to the standby condition in which the apparatus has time to attain an isothermal state, and it is required of the isothermic block to hold the apparatus at this ambient temperature while a temperature reading is taken, even if thermal transients may tend to change this temperature. This interpretation of the wording of claim 1 is the only one consistent with the disclosure of the patent in suit as a whole, as discussed below.

The following passages of the original PCT application WO 90/02521 support the above conclusion: Claim 12 of the application states that the radiation detector means and the wave guide are held at or about an isothermic condition by said heat conducting block means at or about a temperature corresponding to the air temperature immediately adjacent to said heat conducting block means, and claim 14, which is dependent on claim 12, says that the block further is of sufficient mass to substantially maintain said isothermic condition of said wave guide and radiations sensor. Similar wording is found in claim 5 of the PCT application.

These claims define the two different functions of the block. Further, page 10, lines 20 to 24 says that the isothermic conditions among the various components in the sensor assembly are maintained even when the ambient temperature changes. This means that the block brings about thermal equilibrium amongst the different components, which condition is maintained even if the ambient temperature changes.

The appellant acknowledged, in its notice of opposition dated 21 May 1997, page 2, paragraph A.2, that the description meant that the isothermic block has sufficiently great thermal mass that it resists rapid temperature changes, ie is responsible for the stable temperature feature. This appellant now argues that the description only supports the view that the block is responsible for the same temperature feature. The Board prefers the former interpretation since this is not only consistent with the terminology used, but also means that the claims can be read in a manner

consistent with the description, whereas the latter interpretation renders the claims at odds with the description, and should not be adopted, according to well established practice of the EPO, as stated in decision T 190/99 (see Catchwords).

- 2.2 The temperature measuring apparatus of the patent in suit comprises an infra red sensor within a housing and a waveguide that guides infra red radiation from the body of a patient (for example the tympanic membrane) to a thermopile type radiation detector which is provided with a thermistor for correcting temperature readings should the temperature of the detector drift. Precautions are taken to minimise errors in temperature measurement by configuring the detector part of the apparatus such that the detector, the cold junctions, and the thermistor are held at the same temperature by a heat conducting material. This is a normal precaution in the art, as exemplified by D1 (column 7, lines 29 to 31, 63 and 64), and D2 (column 5, lines 10 to 14).

The patent in suit describes a heat conductive block for this purpose, termed an "isothermic block means" in claim 1. The word "isothermic" suggests that the block maintains temperature equilibrium between these components at the ambient temperature, so that the arrangement corresponds to the prior art arrangement in that the detector, the cold junctions, and the thermistor are maintained at the same temperature by a material of good heat conductivity.

The claim also says that the block should have sufficient mass so that the infrared radiation detector means, the wave guide means and the detector

temperature sensor means are held at substantially the same temperature, at or about an ambient temperature, even when the ambient temperature changes. The use of the terms "mass" and "block" carries the connotation that the block is relatively massive, and indeed is shown in the cross-sectional view of Figure 4 as being relatively massive compared to the waveguide and the detector assembly. The technical implication of this is that the block has a substantial thermal capacity.

Therefore, the block as defined in claim 1 has two different functions: (i) to cause temperature equilibrium amongst the elements in the block, and (ii) to resist temperature change of the block should the ambient temperature change. It is these that appellant I refers to as the "same temperature" and "stable temperature" features, respectively.

2.3 Appellant I sees a contradiction in the two requirements, that the block should be a good conductor so as to rapidly equalise temperature, and it should also have sufficient mass to prevent temperature changes. This apparent contradiction vanishes if the time scales involved are considered.

Before a temperature measurement of a patient is made the apparatus would be held or supported in a holder in the standby condition, somewhat in the manner of the apparatus of D1, in which state the detector, the cold junctions, and the thermistor would have a time of at least the order of minutes to come into temperature equilibrium with each other because of the good thermal conductivity of the block and despite the mass of the block. This equilibrium temperature is the ambient

temperature in the standby condition, and is referred to in the claims. When a temperature reading is taken the apparatus is removed from its support and moved towards the ear of the patient, and the proximity of the waveguide with the ear, for example, could cause a thermal transient to be applied at the end of the waveguide. However, the time scale involved in taking a reading is about a second or two (patent in suit column 8, lines 52 to 55, D1, column 6, lines 55 to 59 or less, D2, column 1, lines 24 to 26), and in this short time block would have sufficient thermal capacity for the transient not to materially alter the temperature prevailing at the detector. Claim 1 states that the apparatus strives to maintain the ambient temperature at the detector, even if this changes, which is consistent with the above understanding of the description.

- 2.4 According to appellant I the above considerations are not based on the wording of the patent in suit. However, that the mass of the block is responsible for resisting rapid temperature changes is admitted by the appellant itself, in the notice of opposition, as is the fact of the time scale involved, since the above applies in the case of rapid temperature changes.

With the above interpretation of the expressions used in claim 1, and taking into consideration the effects involved, a self-consistent reading of the application, including the claims, is possible. The appellants' current interpretation of the term "ambient temperature" and the role of the isothermic block not only contradicts its initial interpretation in its

notice of opposition, but also excludes a sensible reading of the claims, which is not permissible.

The Board is also satisfied that it is implicit from the context of claim 1 that the isothermic block means must be made of a good heat conducting material, even though this is not specified in the claim.

3. *Article 100(c) EPC*

The isothermic block means of the claimed apparatus is required to be a good conductor of heat so as to rapidly equalise temperature amongst the components, and also have sufficient mass to act as a heat sink of sufficient thermal capacity to absorb thermal transients during the relatively short period during which a temperature measurement is taken.

The person skilled in the art would be able, by simple calculation or trial and error, to determine what mass is "sufficient" for the purpose. This would depend on the configuration of the mass since its thermal conductance would depend on its shape, its thermal conductivity, the temperatures involved, the time scales involved, and the allowable error of the temperature reading. The last three factors would be known by the medical staff using the apparatus.

Assuming a substantially cylindrical configuration as shown in the particular embodiment, for example, and assuming a time scale of minutes in the standby condition and of seconds during a measurement, the person skilled in the art could estimate the mass of the block for a given material, also taking into

consideration what measurement errors of body temperature are permissible, for example 0.1°C. Alternatively, simple tests would determine whether the mass was sufficient to maintain the temperature of the assembly stable enough to achieve a medically acceptable accuracy of the temperature reading.

The person skilled in the art would also know how to position the block relative to the components to be stabilised in order to achieve the desired effect. In practice this would mean that the block should substantially enclose and be in intimate contact with the components.

The Board, therefore, considers that the patent meets the requirement of Article 100(b) EPC.

4. *Article 123 EPC*

4.1 Article 123(2) EPC

Claim 1 of the main request combines the subject-matter of original claims 1, 4, 5, and 6, and additionally refers to a patient rather than an emissive target, and includes the phrase "even when the ambient temperature changes". These additions are supported by the application as originally filed and are allowable. Similar considerations apply to claim 9.

4.2 Article 123(3) EPC

The "cold reference junction" feature of claim 1 was removed at the opposition stage, but has now been reinstated, so an objection in this respect has been met.

5. Novelty

5.1 The isothermic block means of the claimed apparatus and method is a heat conducting material positioned proximate to the wave guide means and is of sufficient mass that not only the infrared radiation detector means and detector temperature sensor means, but also the wave guide means are held at substantially the same temperature, at or about an ambient temperature even when the ambient temperature changes. As discussed above this means that the mass must act as a heat sink of sufficient thermal capacity to absorb thermal transients during the short period during which a temperature measurement is taken. It is implicit that it must also have a certain physical relationship with the components to be able to act effectively in the required manner.

This implies an appreciable mass, considerably greater than the combined masses of the radiation detector, the wave guide, and the temperature sensor, and also that the mass substantially encloses these components, so that the temperature drift thereof owing to change of ambience between the standby condition and the measurement position is kept sufficiently low so that the error in the temperature reading is also kept acceptably low, for example 0.1°C.

5.2 Bearing in mind that a prior art document must unambiguously disclose all the features of a claim for it to anticipate the claimed apparatus or method, none of the documents D1, D2, D6, or D7 discloses such an isothermic block means.

In document D1 the thermopile detector is embedded in a metal housing and good thermal conductivity is provided between them (column 7, lines 17 to 20 and 29 to 31). The thermal relationship between these components is also schematically illustrated in Figure 8a, where the block 20 includes the housing 94 holding these components in intimate thermal contact with each other. Moreover, the housing is heated by resistors to a precise temperature controlled by a circuit shown in Figure 9. This points to a housing having a low thermal capacity since the heat from the resistors must be dispersed quickly throughout the housing in order to follow changes set by the variable resistor R15 in a precise manner (column 7, lines 52 to 55). Moreover, the metal waveguide 96 has an end that is merely secured to the housing 94 (column 7, lines 19 and 20), so the housing is not clearly capable of resisting the effects of thermal transients, acting on the other end of the waveguide, during a measurement. Nor is there a statement in D1 that this would be useful.

The radiation detector of document D2 does not include a waveguide or a thermopile type detector, and for these reasons alone it does not anticipate the apparatus of claim 1 of the patent in suit.

The radiation detector of document D6 also does not include a thermopile type detector. The waveguide (barrel 14) of this apparatus is said to be interconnected to the pyroelectric sensor 18 so as to be in thermal equilibrium therewith, but it is not clear how this is achieved with an intervening shutter as shown in Figures 1 and 2. There is also no

disclosure of an isothermic block means for resisting temperature changes in the waveguide. The appellant I equates the housing 164 in Figure 17 with the isothermic block means, but even this is no more than the arrangement of D1, since the housing is not so positioned proximate the waveguide that it is clearly capable of resisting the effects of thermal transients on the waveguide during a measurement. For these reasons D6 does not anticipate the apparatus of claim 1 of the patent in suit.

In D7 it is doubtful that the inner cylinder 3 may be regarded as a waveguide since a lens focuses the radiation onto a detector. Moreover, there is no disclosure of the cylinder being in contact with a block. Rather than resisting temperature changes, this arrangement is meant to have the opposite effect, that is any temperature variations are passed rapidly on to the case 9 of the detector and the temperature compensating element. The inner cylinder 3 is formed of a high conductivity metal and the intention is that the temperature of the case 9 should adapt promptly to the temperature of the cylinder 3 (page 5, lines 1 to 6). This points to the cylinder having a low thermal capacity. The important point, however, is that there is no mass that tends to resist temperature changes of the cylinder.

The appellants' arguments, that the housing 94 of D1 and the tube 3 of D7 would inevitably have a stable temperature function in addition to their same temperature function, is not accepted by the Board since the mass of the block and its physical relationship with the waveguide must be significant

such as to cause the desired effect, as set out in point 2.1 above. The stable temperature function of the heat conducting parts of the cited prior art apparatus cannot be inferred in the absence of some explicit teaching to this effect, and the arguments of the appellants in this respect are based on an ex post facto analysis of the prior art.

For these reasons the claimed apparatus is novel, as is its use as defined in method claim 9.

6. *Inventive step*

6.1 Closest prior art: document D1 discloses a probe with a thermopile type infrared sensor for insertion into the ear canal and taking temperature measurements of the tympanic membrane (column 6, lines 55 to 59), and has all the features of claim 1 of the patent in suit, save that there is no mass of high heat capacity for resisting temperature changes, during a temperature reading, of the waveguide means.

6.2 The radiation detector of D2 is a fundamentally different type of detector in that a conical cup is used to gather radiation instead of a waveguide in order to negate the effects of emissivity of a surface, which is not a consideration in the case of the apparatus of the patent in suit. Since the apparatus of document D2 does not use a waveguide, there is obviously no teaching that temperature changes in a waveguide must be resisted. The potting material of this document is mentioned only in the context of measuring temperatures of about 500°F, and the Board understands the statement in column 5, lines 14 to 19,

and in particular the reference to "sufficient mass", only to mean that the potting material should transfer heat rapidly away from the sensor, not that temperature changes owing to thermal transients should be resisted, since there is no disclosure that significant transients would occur in this apparatus.

In D6 a shutter control mechanism 68 places a shutter 66 between the waveguide (barrel 14) and the radiation sensor 18, so it is not clear how thermal coupling between the two is achieved. However, assuming this coupling is achieved somehow, then this is equivalent to the arrangement of D1, where there is a block for maintaining the radiation detector and the detector temperature sensor at ambient temperature, but the block does not act on the waveguide.

In D7 the inner cylinder is not for resisting thermal transients, it is for rapidly equalising the temperature.

Thus, none of the prior art documents, taken singly or in combination, discloses the importance either of maintaining a waveguide in thermal equilibrium with the detector at ambient temperature, or the use of a conducting block for this purpose, as well as for the purpose of maintaining the radiation detector and the detector temperature sensor at the ambient temperature despite thermal transients. In particular there is no teaching in these documents that the means for achieving isothermal conditions between the radiation detector and the temperature sensor should additionally be configured with the intention of providing the stable temperature feature, especially for the

waveguide. These features provide certain technical effects that are not envisaged in the prior art, and enable a passive temperature control system to be used instead of the active one of document D1. For these reasons the subject-matter of claim 1 involves an inventive step. Method claim 9 similarly involves an inventive step.

7. Therefore, the main request meets 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 first instance with the order to maintain the patent in amended form on the basis of claims 1 to 11 according to the main request filed at the oral proceedings, description and drawings as maintained by the opposition division.

The Registrar

The Chairman:

A. Counillon

S. S. Chowdhury