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**D E C I S I O N**  
of 20 August 2002

**Case Number:** W 0001/02 - 3.2.2

**Application Number:** PTC/US00/24191

**Publication Number:** W001/17425 A2

**IPC:** A61B 5/00

**Language of the proceedings:** EN

**Title of invention:**

Smart physiologic parameter sensor and method

**Applicant:**

TENSYs Medical Inc.

**Opponent:**

-

**Headword:**

Non-unity "*a posteriori*" (no)

**Relevant legal provisions:**

PCT R. 68.2, 68.3, 13.1, 13.2

**Keyword:**

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**Decisions cited:**

W 0004/96, W 0006/97

**Catchword:**

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Boards of Appeal

Chambres de recours

**Case Number:** W 0001/02 - 3.2.2  
**International Application No.** PCT/US00/24191

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 20 August 2002**

**Applicant:** Tensys Medical, Inc.

**Representative:** Gazdzinski & Associates

**Subject of the Decision:** Protest according to Rule 68.3(c) of the Patent Cooperation Treaty made by the applicants against the invitation of the European Patent Office (International Preliminary Examining Authority) to restrict the claims or pay additional fees dated 27 July 2001.

**Composition of the Board:**

**Chairman:** W. D. Weiß  
**Members:** R. Ries  
B. Schachenmann

## Summary of Facts and Submissions

- I. International patent application No. PCT/US00/24191 (international publication number WO 01/17425) was examined by the European Patent Office, acting in its capacity as an International Preliminary Examination Authority (IPEA).
- II. On 27 July 2001 the IPEA found that the international application covered five (5) inventions and invited the applicant pursuant to Rule 68.2 PCT to restrict the claims or to pay four (4) additional fees. The groups of claims were held to relate to the following inventions:
- (1) Claims 1 to 8, (invention A):  
a medical transducer assembly with an ultrasonic transducer and a data storage device
  - (2) Claims 9 to 11, 17, 18, 23 to 26 (invention B):  
methods for enabling or disabling a medical sensor
  - (3) Claims 12 to 16 (invention C):  
a method for data storage subject to an acceptance criterion
  - (4) Claims 19 to 22 (invention D):  
a method for calibrating a pressure sensor
  - (5) Claims 27 to 31 (invention E):  
a blood pressure measuring apparatus including an ultrasonic transducer and a pressure transducer

The IPEA held that the subject matter of claim 1 of the first group (group A) was known from document D1 US-A-5 072 733 and that the inventions of groups A to E shared no novel and inventive feature as required by Rule 13.2 PCT.

III. On 24 August 2001 the applicant paid three (3) additional examination fees for inventions A, B, D and E, and indicated that "a portion of the fees" were paid under protest. In the applicant's view, the inventions of group A and E had a novel common feature i.e. a sensor assembly having at least one transducer element with an associated data storage device adapted to store data relating to that transducer element, the sensor assembly being adapted for data communication with a host system adapted to measure a physiological parameter (the blood pressure). This relationship was shown in Figure 5 of the specification by element 200 which is coupled to the host system 500 via interface 437. The applicant therefore requested withdrawal of the non-unity objection with respect to inventions A and E and reimbursement of one of the additional examination fees.

IV. The protest was reviewed in accordance with Rule 68.3 e) PCT by a review panel of the European Patent Office. It was found that document D1 disclosed an "ultrasound transducer" and a display for displaying the sector scan (63 in Figure 3B). For generating the sector image or for operating the transducer, "a storage device adapted to store data related to the transducer" were held to be implicitly provided in the ultrasound sector scanning assembly. Moreover, the display (60 in Figure 3B of D1) constituted a "host system adapted to measure a physiological parameter. Consequently, no novel features were shared between claims 1 and 27.

Hence, the IPEA held on 17 October 2001 that the invitation to pay one additional examination fee for invention E was justified and invited the applicant to pay a protest fee for the examination of the protest by a "three-member board" or another "special instance" of the IPEA or any competent higher authority in accordance with Rule 68.3 c) PCT.

V. The applicant duly paid the protest fee on 24 November 2001 without submitting further arguments.

VI. Independent claims 1 (invention A) and 27 (invention E) read as follows:

"1. A medical sensor assembly, comprising  
at least one transducer element adapted to generate an electrical signal; and  
a storage device, operatively connected to said at least one transducer element, adapted to store a plurality of data related to said at least one transducer element and said electrical signal therein, said data being retrievable from said storage device subsequent to being stored;  
wherein said sensor assembly is adapted for data communication with a host device for measuring said at least one physiologic parameter of a living organism based at least in part on said electrical signal."

"27. An apparatus for measuring the blood pressure of a plurality of living subjects, comprising:

a first transducer element adapted for transmitting and receiving acoustic waves, said first transducer further being adapted to generate a first electrical signal in response to said acoustic waves received thereby;

a second transducer element adapted to sense pressure and generate a second electrical signal related thereto;

a first storage device adapted to store an algorithm in the form of a plurality of program instructions;

a processor in data communication with said first transducer and said second transducer and said first storage device, said processor being adapted to estimate the blood pressure of said living subjects based at least in part on data derived from said first and second electrical signals and said algorithm; and

at least one second storage device in data communication with said second transducer and adapted to store data relating to said second transducer element;

wherein at least said second transducer and said at least one second storage device are adapted to be removable from said apparatus after use on a first of said living subjects and replaced prior to use on a second of said living subjects."

### **Reason for the Decision**

1. The protest is admissible.
2. Rule 68.3 c) PCT states that an applicant may pay an additional search fee under protest, that is, accompanied by a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional examination fee is excessive.
3. In the present case, the applicant paid examination fees for the inventions A, B, D and E identified in the invitation of the IPEA to restrict or to pay additional fees. However, as follows from the statement accompanying the protest, only one of these fees was paid under protest as the applicant only discusses the

novel technical feature common to inventions A and E but gives no arguments as to inventions B and D. The Board therefore needs only to consider the question of whether the IPEA's reasoning with respect to inventions A and E is sufficient to substantiate a finding of lack of unity.

4. In its invitation referred to above the IPEA argued that document D1 (US-A-5072733) completely anticipated the sensor assembly set out in claim 1 ("invention A"). It is thus apparent that the IPEA's objection is an "*a posteriori*" objection made after taking prior art document D1 into consideration. Thus, it has to be examined first whether the first group of inventions ("invention A") was anticipated by this prior art.
  
- 5.1 Document D1 is concerned with a shock wave lithotripter designed to fragment urinary tract stones, gall stones, renal and ureteral stones. For calibrating and focussing the lithotripter, ultrasound imaging is employed to locate the stone to be fragmented. To this end, a conventional ultrasound probe (for example a sector scan probe) having a transducer for producing ultrasound beams defining a plane of radiation during calibration of the lithotripter is used (cf. D1, column 2, lines 38 to 52; column 3, lines 7 to 12). The ultrasound probe is associated with a display apparatus comprising a screen on which the echoes produced at the interfaces between different tissue in the plane illuminated by the ultrasonic beams in the patient can be identified as differences in brightness (cf. D1, column 5, lines 6 to 15; Figure 3B).
  
- 5.2 Compared with the medical sensor assembly stipulated in claim 1 of the application, document D1 does not explicitly mention a "storage device operatively connected to the transducer to store data which are retrievable from the storage device subsequent to being

stored". It may be argued - as has been done by the IPEA - that for generating a sector image or for operating the transducer, a storage device adapted to store data related to the transducer is always necessary and, therefore, implicitly provided in the ultrasound sector scanning assembly disclosed in D1 so that the medical sensor according to claim 1 lacks novelty vis-à-vis the conventional ultrasound probe given in D1. In the Board's view it nevertheless remains doubtful whether the storage device according to claim 1 of the application and the device implicitly disclosed in document D1 are in fact in all technical details the same.

6.1 It follows from Rule 13.2 PCT, setting out the circumstances in which the requirement of unity of invention shall be fulfilled, that a group of inventions (in the present case inventions A and E defined by claims of the same category) claimed in the same international application is only linked so as to form a single general inventive concept within the terms of Rule 13.1 PCT when there is a technical relationship among those inventions involving one or more of the same or corresponding **special technical features**. Given that these **special technical features** shall define the contribution which each of the claimed inventions, considered as a whole, makes **over** the prior art, either a common structural feature or a common functional technical feature must be present which does not yet belong to or is not rendered obvious by the state of the art (see W 0004/96, point 7).

6.2 As to "invention A", the claimed medical sensor assembly is, however, not restricted to the technical features given in independent claim 1 but comprises further embodiments given in five dependent claims. After the possible demise of independent claim 1 on account of the subject-matter's lack of novelty, the



question, therefore, arises whether the subject matter of the remaining claims 2 to 6 and any new independent claim formed by combining claim 1 with a dependent claim are still so linked as to form a single general inventive concept. As can be noted, any of dependent claims 2 to 6 is directed to a medical sensor assembly comprising a transducer element which allows to determine the blood pressure. Hence, in the Board's view, the dependent claims 2 to 6 are so linked as to form a single general concept which is not disclosed in document D1 and therefore novel. In the absence of any evidence to the contrary, the Board has no reason to conclude that this concept would not be "inventive", either.

- 6.3 Likewise, the apparatus according to claims 27 to 31 of "invention E" is designed for measuring the blood pressure. It includes first and second transducer elements, first and second storage devices whereby at least the second transducer element and the second storage device are removable, and a processor. Moreover, the second transducer element in "invention E" is selected to be a "pressure transducer" which corresponds to the embodiment claimed in claims 2 to 6 of "invention A". Although the apparatus claimed in "invention E" has to be regarded as being more sophisticated than the sensor assembly claimed in "invention A", both inventions nevertheless include the same "special technical features" which aim at solving the same technical problem. This problem is, however, neither addressed in D1 and also appears to be different from that underlying the conventional ultrasound probe disclosed in document D1 which is directed to ultrasound imaging.

7. If, as in the present case, the search revealed prior art more relevant than that already acknowledged in the description of the international patent application (in the present case: document D1), it is indispensable for determining unity of invention to define, on the basis of the disclosure of this prior art (here document D1), the technical problem(s) to be solved by the different invention(s). Thus, unity of invention can be assessed only after having determined the technical problem in such a manner (see W 0006/97, points 6.2 to 6.4).
  
8. In the present case, however, neither the annex to the IPEA's invitation to restrict or to pay additional fees of 27 July 2001 nor the finding of the review panel of 17 October 2001 comprised a detailed analysis of the technical problem(s) underlying the identified inventions A and E in view of both, the disclosure of the international application and document D1 as relevant state of the art. Rather, it was objected that the features common to independent claims 1 and 27 were not novel vis-à-vis the teaching of document D1 was objected. This approach is, however, not sufficient to substantiate the objection of lack of unity between inventions A and E.
  
9. Given this situation, the IPEA's statement cannot be accepted as a valid argument in support of the finding of lack of unity of invention. In this situation, the Board is unable to concur with the reasoning in the IPEA's invitation to pay an additional fee for "invention E" based exclusively on its finding that claim 1 of "invention A" was anticipated by document D1. Rather it follows from the above considerations that the special technical features common to both inventions A and E are neither known nor derivable in an obvious way from the teaching given in document D1.

**Order**

**For these reasons it is decided:**

Reimbursement of one additional examination fee and of the protest fee is ordered.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß