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Title of invention:
HEMODYNAMIC PARAMETER (HDP) MONITORING SYSTEM FOR DIAGNOSIS OF A HEALTH CONDITION OF A PATIENT

Applicant:
TheraBionic Inc.

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - (no)

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Case Number: T 1159/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 March 2024

Appellant: (Applicant)	TheraBionic Inc. 4108 Ryan Way Winston-Salem, NC 27106-3567 (US)
Representative:	Schneiders & Behrendt München Schneiders & Behrendt PartmbB Patentanwälte München Mühlthaler Straße 91c 81475 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 13 December 2021 refusing European patent application No. 16786952.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. This appeal was filed by the applicant (the appellant) against the examining division's decision to refuse the patent application at issue.

One of the grounds for the refusal was that the invention as claimed in the main request and in the first to third auxiliary requests was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, contrary to the requirement of Article 83 EPC.

II. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of one of the requests on which the decision was based.

III. Oral proceedings were held before the Board on 21 March 2024, at the end of which the present decision was announced.

IV. Claim 1 of the **main request** reads as follows:

"*A hemodynamic parameter (Hdp) monitoring system for diagnosing a health condition of a patient, for establishing Hdp marker values or Hdp surrogate marker values for purposes of comparison with Hdp values of a patient is provided,*

an Hdp monitor senses, measures, and records Hdp values exhibited by the patient during a basal or non-exposure period and furthermore Hdp values exhibited by the patient during or after an exposure period during which the patient is exposed to low-energy electromagnetic output signals, an electrically-powered generator is

adapted to be actuated to generate said low-energy electromagnetic carrier output signals for exposing or applying to the patient such output signals during said exposure period,

the Hdp monitoring system provides means for establishing and identifying marker values for use in diagnosis of health conditions of a patient, the marker values are termed surrogate markers in that the marker values are determined by the monitoring system following on treatments and Hdp value measurements performed on patients pre-diagnosed either healthy or suffering from a known form of poor health condition, wherein

for purposes of defining representative Hdp marker values, such multiple Hdp values are analyzed by statistical procedure means for purposes of obtaining representative Hdp values for each of the Hdp parameters, wherein

statistical procedure means including principle [sic] *component analysis (PCA), a statistical procedure that uses an orthogonal transformation to convert a set of observations of possibly correlated variables into a set of values of linearly uncorrelated variables called principal components (PCs), wherein*

the representative values of principle [sic] *component analysis are divided into three groups, pressure, flow and beat.*"

V. Compared to claim 1 of the main request, claim 1 of **auxiliary request 1** includes the following additional wording appended to the end of the claim:

"*representative of a number of sensed and recorded hemodynamic parameter values for each of the nine values:*

RR interval (RRI),
heart rate (HR),
systolic blood pressure (sBP),
diastolic blood pressure (dBP),
median blood pressure (mBP),
pulse pressure (PP),
stroke volume (SV),
cardiac output (CO), and
total peripheral resistance (TPR)."

VI. Compared to claim 1 of auxiliary request 1, claim 1 of **auxiliary request 2** includes the following additional feature appended to the end of the claim:

"*the monitoring system further comprises analytical geometry means for discrimination by use of canonical coordinates and vectors obtained from PC values.*"

VII. Compared to claim 1 of auxiliary request 2, claim 1 of **auxiliary request 3** is amended in that the following feature has been deleted:

"~~*wherein the representative values of principle component analysis are divided into three groups, pressure, flow and beat,*~~"

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

The invention as claimed in the main request and the first to third auxiliary requests was sufficiently disclosed in the application.

Principal Component Analysis (PCA) was a well-known statistical data analysis technique and the person skilled in the art would have had no difficulty or undue burden in implementing it in a monitoring system as claimed in order to derive representative Hdp ("hemodynamic parameter") marker values as the principal components (PCs) of multiple Hdp values recorded from the patient.

In Examples 1 to 3, the application provided an example of how such representative marker values could be obtained using PCA on measured values of the nine Hdp parameters listed on page 4, lines 6-15, and then used for diagnostic purposes; as shown in Example 2, the pressure PC values P1 and P2 could be used to distinguish between healthy patients and cancer patients. This example was sufficiently detailed for the invention to be considered sufficiently disclosed.

The examining division's objection that the disclosure of the invention was insufficient was based on incorrect assertions about the characteristics of PCA. In particular, since the Hdp values processed using PCA were values of hemodynamic parameters, i.e. parameters related to the flow of blood through the blood vessels, they were naturally divided into three groups: pressure, flow and beat, respectively. As expressly acknowledged in claim 1 of the various requests, the effect of the PCA was simply to decorrelate the set of possibly correlated Hdp values. Contrary to the examining division's assertion in the decision, applying PCA to the Hdp values did not change their physiological nature, and the resulting principal components (PCs) were therefore also inherently divided into the same three groups. This was the case, *inter alia*, for the nine PC values shown in Table 2.

Reasons for the Decision

1. The subject-matter of the application

The application at issue relates to a "hemodynamic parameter (Hdp) monitoring system for diagnosing a health condition of a patient" on the basis of "representative Hdp values", also referred to as "Hdp marker values" or "Hdp surrogate marker values", that the claimed system derives from multiple "Hdp values" recorded from the patient (page 3 of the description as filed, section entitled "Summary of the invention"). Claim 1 of each of the appellant's requests is directed to this monitoring system.

The "Hdp values" are values measured under certain conditions and over a certain period of time for each of several "Hdp parameters" of the patient, including heart rate, blood pressure and, more generally, the nine parameters listed on page 4, lines 6-15. An example data set of such measurements is shown in Table 1 of Example 1 on page 8.

Using a specific statistical technique, namely Principal Component Analysis (PCA; referred to as "Principle [sic] Component Analysis" in the patent application), the claimed system processes the measured Hdp values in order to derive "representative Hdp [marker] values for each of the Hdp parameters", where the representative Hdp marker values are defined as the "principal components (PCs)" of the measured Hdp values (page 5, lines 12-26; claim 1 of each of the requests). These marker values also have other names in the patent application, namely "the representative values of principle [sic] component analysis" (claim 1 of the

main request); "Principal Component (PC) values, representative of a multiple number of sensed and recorded hemodynamic parameter values" (page 8, lines 19-20); "representative pressure, flow and beat PC values of Hdp's exhibited by patients" (page 9, lines 2-3); "the PC representative values" (page 9, line 15). Examples of such representative marker values obtained as PC values of measured Hdp values from several healthy patients or cancer patients are shown in Table 2 of Example 2 on page 9, where they are divided into three groups: "Pressure", "Flow" and "Beat" (page 8, lines 21-22).

The description and claim 1 of each of the various requests specify that the PC values obtained can be used as markers for diagnosing a patient's health condition. In particular, according to Example 2, the comparison of the values of the two "Pressure principal components" P1 and P2 indicate whether the patient suffers from cancer (page 9, lines 8-10: "all patients with a diagnosis of cancer [...] reflect P1 PC values which are significantly greater than the P2 PC values"). Table 3 of Example 3 presents the results of a so-called "discrimination by analytical geometry using canonical coordinates and vectors obtained from PC values", in which the PCs for three groups of patients are also described as being divided into the three groups mentioned above (page 9, last paragraph).

2. Insufficiency of the description

2.1 The Board shares the view of the examining division expressed in the decision under appeal that the application does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, in breach of Article 83 EPC. This objection applies to all of the appellant's requests.

It is acknowledged that PCA is a generally known statistical technique for the analysis of large data sets. However, as explained below, given the paucity of information provided in the application, the person skilled in the art would not be able to implement PCA without undue burden, even when using their common general knowledge, in order to obtain representative Hdp marker values for use in diagnosing the patient's health conditions as defined in claim 1 of the various requests.

2.2 The application does not provide any technical details on the required practical implementation of PCA.

In the passage on page 5, lines 20-24, where PCA is first referred to, PCA is merely described as "a statistical procedure that uses an orthogonal transformation to convert a set of observations of possibly correlated variables into a set of values of linearly uncorrelated variables called principal components". This wording, used literally in claim 1 of the different requests, essentially amounts to no more than a general definition of PCA; it is of little help to the person skilled in the art seeking to implement PCA in practice in the context of the application.

The only other passages in the application dealing with PCA are Examples 2 and 3 of the description. While it is disclosed that the PC values shown in Tables 2 and 3 were obtained by "PC Analyses" (in other words, by PCA) of data recorded from each of the patients for each of the nine Hdp parameters listed on page 4, lines 6-15, these examples do not disclose how PCA was used in practice to arrive at the PC values shown in the tables.

2.3 The Board takes the view that contrary to the appellant's argument, in the absence of guidance in the application the implementation of PCA in the present context would not be straightforward for the person skilled in the art, even when using their common general knowledge.

This lack of disclosure is all the more problematic as the PC values, which are entirely dependent on the technical implementation of PCA and, in particular, on the scaling of the Hdp values from which they are constructed, are intended to have a diagnostic relevance, e.g. to allow a diagnosis of cancer to be made on the basis of a comparison between two different PC values (page 9, lines 8-10). Regardless of whether the Hdp values are unspecified and therefore arbitrary (as in the system of claim 1 of the main request) or whether the Hdp values are the nine specific Hdp values listed on page 4, lines 6-15 (as in Examples 2 and 3 and in the system of claim 1 of the first and second auxiliary requests), the Hdp values have different units and therefore different scales.

For this reason alone, the main request and the first to third auxiliary requests all fail to meet the requirement of Article 83 EPC.

2.4 Furthermore, Examples 2 and 3 consistently disclose that the PC values obtained from the Hdp values are "divided into three groups: Pressure, Flow and Beat" (page 8, lines 21-22; page 9, line 15). This feature is also defined in claim 1 of the main request and of the first and second auxiliary requests.

As criticised by the examining division (point 1 of the reasons for the decision under appeal), the patent application does not disclose how this division is achieved.

The Board is not convinced by the appellant's argument that this division of the PC values results inherently from the fact that PCA is applied to Hdp values which are themselves divided into the same three groups - even assuming, as asserted by the appellant, that this is indeed the case for "hemodynamic" values. As the appellant acknowledged (page 8 of the statement of grounds of appeal, last paragraph), PCA is applied to the entire input data set formed by the Hdp values recorded from the patient for the various Hdp parameters, and not separately to several subsets each corresponding to a selection of certain Hdp parameters. The resulting PC values obtained by applying PCA are constructed as a (linear) combination of the Hdp values of the input data set, which the appellant did not dispute. Therefore, even if the input data set comprises Hdp values belonging to the three groups, pressure, flow and beat, the lack of any information in the application concerning a particular implementation of PCA renders the division of the PC values into the three groups completely obscure.

The Board also notes that the patent application does not explain how the PC values corresponding to a given group, such as the PC values P1, P2 and P3 associated with pressure in Table 2, are respectively obtained and assigned within that group. Yet this is a crucial issue in view of the diagnostic relevance of the PC values. For example, in Example 2, it is disclosed that the comparison of P1 and P2, and not P3, allow a diagnosis of cancer.

The Board therefore agrees with the examining division that the person skilled in the art is left in the dark as to how to derive representative PC values that are divided into the three groups mentioned above. The invention as claimed in the main request and the first and second auxiliary requests, where this division is explicitly defined in claim 1, is therefore insufficiently disclosed.

This conclusion applies irrespective of the particular characteristics of PCA discussed in point 1 of the decision under appeal, in particular even if the dimensionality of the data is preserved during the application of PCA. Moreover, the fact that, as further defined in claim 1 of the second auxiliary request, "discrimination" of cancer patients from healthy patients can be carried out by "analytical geometry using canonical coordinates and vectors obtained from PC values" (Example 3 on page 9, last paragraph) is - in so far as this passage can be understood - of no help in this respect.

2.5 The feature that "the representative values of principle [sic] component analysis are divided into three groups, pressure, flow and beat" is absent from claim 1 of the third auxiliary request. However, as mentioned in point 2.2 above, the disclosure in the description of a monitoring system using PCA to derive the representative Hdp marker values is limited to Examples 2 and 3, which expressly provide that the PC values derived by the system are divided into these three groups, and to the general passage on page 5, lines 20-24, which, as noted above, is limited to defining PCA and thus does not itself enable the person skilled in the art to put the invention into practice. It follows that the invention as claimed in the third auxiliary request is also insufficiently disclosed.

2.6 The Board therefore concludes that none of the appellant's requests meets the requirement of Article 83 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated