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**Datasheet for the decision
of 18 September 2025**

Case Number: T 1884 / 23 - 3.2.02

Application Number: 13701877.6

Publication Number: 2839277

IPC: G01N33/497, A61B5/00

Language of the proceedings: EN

Title of invention:

DETECTION OF RATE CHANGES IN SYSTEMATIC OSCILLATIONS OF
METABOLIC PATHWAYS BY MONITORING ISOTOPE RATIOS

Applicant:

Wisconsin Alumni Research Foundation

Headword:

Relevant legal provisions:

RPBA 2020 Art. 12(4), 11

EPC Art. 53(c)

Keyword:

Amendment to case - amendment overcomes objection (yes) -
amendment admitted (yes)

Exceptions to patentability - diagnostic method (no)

Remittal - (yes)

Decisions cited:

G 0001/04, T 1016/10

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1884/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 September 2025

Appellant: Wisconsin Alumni Research Foundation
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 29 June 2023 refusing European patent application No. 13701877.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: M. Alvazzi Delfrate
Members: A. Martinez Möller
C. Schmidt

Summary of Facts and Submissions

I. The appeal was filed by the applicant against the examining division's decision refusing European patent application No. 13701877.6.

In that decision, all requests were found to comprise added subject-matter and to be unclear. Additionally, the then main request as well as auxiliary requests 1 and 2 were found to be diagnostic methods excluded from patentability under Article 53(c) EPC.

II. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request (filed as auxiliary request 5 with the statement of grounds of appeal) or, in the alternative, on the basis of one of auxiliary requests 1 to 4 (filed as auxiliary requests 6 to 9 with the statement of grounds of appeal).

III. Claim 1 of the main request reads as follows.

"A method of determining if an individual is transitioning from:

(i) a healthy state to an unhealthy state, the method comprising:

(a) monitoring breath taken from the individual and measuring a relative amount of a first isotope to a second isotope therein over a total time interval (t_{total}), wherein the individual is healthy during the time interval t_0 -healthy, wherein t_0 is a time point at the start of time interval t_{total} , and

t_{healthy} is [sic] time point during t_{total} in which the individual is healthy,

(b) identifying a healthy functional oscillation pattern in the relative amount of the first isotope to the second isotope therein during time interval $t_{0-\text{healthy}}$,

(c) identifying a test functional oscillation pattern in the relative amount of the first isotope to the second isotope therein [sic] a test time interval t_{test} within t_{total} , wherein t_{test} does not overlap $t_{0-\text{healthy}}$, and

(d) determining that the individual is transitioning from a healthy state to an unhealthy state when the healthy functional oscillation pattern and the test functional oscillation pattern are distinct in period of oscillation, oscillations per unit time, and/or variability in oscillation period,

(ii) an unhealthy state to a healthy state, the method comprising:

(a) monitoring breath taken from the individual and measuring a relative amount of a first isotope to a second isotope therein over a total time interval (t_{total}), wherein the individual is unhealthy during the time interval $t_{0-\text{unhealthy}}$, wherein t_0 is a time point at the start of time interval t_{total} , and $t_{\text{unhealthy}}$ is [sic] time point during t_{total} in which the individual is unhealthy,

(b) identifying an unhealthy functional oscillation pattern in the relative amount of the first isotope to the second isotope therein during time interval $t_{0-\text{unhealthy}}$,

(c) identifying a test functional oscillation pattern in the relative amount of the first isotope to the second isotope therein [sic] a test time

interval t_{test} within t_{total} , wherein t_{test} does not overlap $t_{0-unhealthy}$, and

(d) determining that the individual is transitioning from an unhealthy state to a healthy state when the unhealthy functional oscillation pattern and the test functional oscillation pattern are distinct in period of oscillation, oscillations per unit time, and/or variability in oscillation period,

wherein the first and second isotopes are a pair of ^{13}C and ^{12}C ."

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

Admittance of the main request

The main request, filed as auxiliary request 5 with the statement of grounds of appeal, omitted claims 13 to 15 of the main request on which the contested decision was based. This amendment was straightforward, addressed the objections in points 7 and 8 of the contested decision and did not raise any new issues. It should therefore be admitted.

Article 53(c) EPC

Detecting a change from a healthy state to an unhealthy state, or vice versa, amounted to determining whether or not there was a deviation from the healthy state, i.e. whether a symptom had developed. The method of claim 1 did not include a step of attributing the finding of a deviation to a clinical picture, let alone a particular clinical picture. The term "unhealthy" was broad and did not fall under a particular clinical

picture. While the description mentioned disease states and conditions, these were not included in the claim.

Reasons for the Decision

1. Application
- 1.1 Catabolism produces energy by breaking down molecules. The catabolic state refers to the condition wherein the body uses stores of carbohydrates, amino acids or fats as a source of energy. Their isotopic ratios differ from the isotopic ratios of metabolised food. Therefore, a catabolic state changes the isotope ratios in exhaled breath.
- 1.2 The catabolic state can be induced in various ways, including being caused by infection, disease and malnutrition. Its onset can thus be an indicator of disease. In particular, during infection or in an acute disease state, breath is enriched with ^{12}C and there is less ^{13}C in the exhaled CO_2 content. The oscillation pattern in the isotope ratios also changes, and different diseases and infections will modify isotope oscillation patterns in different ways (see paragraphs [0025] to [0032]).
- 1.3 The application deals with the determination of whether an individual is transitioning from a healthy state to an unhealthy state, or vice versa, by monitoring breath taken from the individual and measuring an amount of a first isotope (^{13}C) relative to a second isotope (^{12}C) therein. This determination relies on differences between an oscillation pattern in the relative amount during a time interval wherein the individual is healthy/unhealthy (healthy/unhealthy functional

oscillation pattern) and an oscillation pattern in the relative amount during a test time interval (test functional oscillation pattern).

2. Main request - admittance

2.1 The main request was filed for the first time with the statement of grounds of appeal and was labelled "Auxiliary Request 5". Therefore, it represents an amendment within the meaning of Article 12(4) RPBA.

2.2 The current main request corresponds to the main request underlying the decision under appeal except for claims 13 to 15 being deleted. This is the sole amendment. The amendment is not complex and it overcomes the objections of added subject-matter, which - together with the exception under Article 53(c) EPC - led to the contested decision. In view of these circumstances, the board admits the main request into the appeal proceedings.

3. Main request - objections under Articles 84 and 123(2) EPC

3.1 The clarity and added-matter objections set out in points 7 and 8 of the Reasons in the contested decision relate to claims 13 to 15, which have been deleted in the current main request. Therefore, these objections have been overcome.

4. Main request - Article 53(c) EPC

4.1 The examining division considered that claim 1 defines a diagnostic method practised on the human or animal body.

4.2 According to G 1/04 (see point 5 of the Reasons thereof), a claim relating to a diagnostic method includes:

- (i) the examination phase involving the collection of data,
- (ii) the comparison of these data with standard values,
- (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and
- (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.

4.3 The examining division found that step (iv) was derivable from the wording of claim 1 "determining if an individual is transitioning from a healthy state to an unhealthy state" (and vice versa). The appellant contests this finding.

4.4 The examining division based its finding on two aspects. Firstly, according to the Guidelines, identification of the underlying disease was not required (see Guidelines for Examination in the EPO, April 2025, G-II.4.2.1.3). Secondly, the application focused on diagnosis of catabolic or infected states and mentioned several medical conditions. The application also explained that oscillation patterns could be used to distinguish between bacterial infections and viral infections.

4.5 Regarding the first aspect, step (iv) requires attribution to a particular clinical picture. It is true that this should not be construed as requiring the specific disease to be identified (see T 1016/10, point 2.6 of the Reasons). However, the term "unhealthy" does not provide any information whatsoever as to the nature

of the underlying medical condition; hence, it cannot represent a "particular clinical picture".

Consequently, determining that an individual is unhealthy does not represent attribution to a particular clinical picture.

4.6 Step (ii) (d) of claim 1 includes determining that the individual is transitioning from an unhealthy state to a healthy state. The board is aware of the fact that, according to decision G 1/04, diagnosis also includes a negative finding, namely in the sense that a particular condition can be ruled out (see point 5.1 of that decision). However, as set out above, an "unhealthy state" is not a particular clinical picture. Accordingly, in the context of claim 1, a "healthy state" does not refer to any particular clinical condition either, nor does it rule out any particular condition. In other words, the attribution to a healthy state does not constitute a negative finding in the sense that a particular condition can be ruled out.

4.7 Regarding the second aspect, the description refers in the field of the disclosure and in the background (paragraphs [0002] and [0003]) to the catabolic state, which can arise due to various causes. The description also mentions several medical conditions that could potentially be distinguished from one another using the oscillation patterns (e.g. bacterial infections and viral infections in paragraphs [0027] to [0029]). However, these passages of the description do not mean that further limitations should be read into the claim. Claim 1 does not refer, either explicitly or implicitly, to a catabolic state, a bacterial infection or a viral infection. Nor is it claimed that a deviation is attributed to any of those states or conditions. At most, the term "unhealthy" may encompass

these states and conditions as well as virtually any other conceivable condition. However, it still does not represent a particular clinical condition.

4.8 It follows from the above that claim 1 does not include attribution to a particular clinical picture.

Consequently, claim 1 does not define a diagnostic method practised on the human or animal body within the meaning of Article 53(c) EPC.

4.9 The dependent claims likewise neither specify the unhealthy state nor include attribution to a particular clinical picture either. Consequently, the claims of the main request do not define any diagnostic method excluded from patentability under Article 53(c) EPC.

5. Remittal

5.1 The decision under appeal does not contain any other objection which would apply to the current main request. However, the board cannot rule out the possibility that the examining division had concerns regarding other requirements, such as novelty and/or inventive step (see points 4 to 12 of the communication dated 4 January 2023 accompanying the summons to oral proceedings, although this communication relates to a different claim request). There are thus special reasons within the meaning of Article 11 RPBA for remitting the case to the examining division.

5.2 According to its submission of 12 August 2025, the appellant's request for oral proceedings was limited to the scenario of the board taking a decision other than that of remitting the case to the examining division on the basis of the main request (previous auxiliary request 5). Since the present decision is to remit the

case on the basis of the main request, the decision has been taken without holding oral proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated