Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 17 January 2019

Case Number: T 1000/14 - 3.3.01

Application Number: 05817337.8

Publication Number: 1810038

IPC: G01N33/92

Language of the proceedings: EN

Title of invention:
QUANTITATIVE ANALYSIS OF A BIOLOGICAL SAMPLE OF UNKNOWN QUANTITY

Applicant:
Home Access Health Corporation

Relevant legal provisions:
EPC Art. 84, 111

Keyword:
Remittal to the department of first instance (no)
Claims - clarity (no)

Decisions cited:
G 0010/93

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1000/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 17 January 2019

Appellant: (Applicant)	Home Access Health Corporation 2401 West Hassell Road, Suite 1510 Hoffman Estates, IL 60195 (US)
Representative:	WP Thompson 8th Floor 1 Mann Island Liverpool L3 1BP (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 14 October 2013 refusing European patent application No. 05817337.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. The decision under appeal is the decision of the examining division, announced on 26 September 2013 and posted on 14 October 2013, refusing European patent application No. 05 817 337.8.

II. The decision under appeal is based on a sole amended claim request, filed with the applicant's letter dated 28 August 2013 and consisting of five claims. Claim 1 of that request reads as follows:

"1. A method for determining the level of an analyte in blood from a solution formed from a dried blood fluid specimen, said blood fluid specimen being a plasma or serum specimen, comprising:

in either order, measuring the analyte level in said solution and measuring the level of at least one normalizing analyte; and

determining the analyte level in the blood from which said blood fluid specimen was collected based on said analyte level in said solution and on the level of said normalizing analyte in said solution, wherein, in determining the analyte level in the blood from which said blood fluid specimen was collected, a recovery delta is added to the analyte level [sic] *in said solution to provide a recovery delta corrected solution analyte level, and the analyte level in the blood from which said blood fluid specimen was collected is determined as a function of said recovery delta corrected solution analyte level and on* [sic] *the level of said normalizing analyte,*

wherein said recovery delta is determined as a function of the time elapsed since said blood fluid specimen was collected

wherein said recovery delta is determined in accordance with the function:

A+B(time)

wherein A is 0, a positive value, or a negative value, and B is a positive or negative non-zero value, and

wherein B is determined based on climactic [sic] *conditions."*

III. It will be assumed hereinafter that "climactic" should read "climatic" (as confirmed by the appellant).

IV. In the decision under appeal, the examining division found that, starting from the technical teaching of document D1 (J. Nutr. 132(2), 318-321 (2002)) and in view of the disclosure of document D2 (WO 03/091 736), the subject-matter of claims 1 to 4 did not involve an inventive step (Articles 52(1) and 56 EPC). Claim 5 contained subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

V. The applicant (appellant) lodged an appeal against that decision.

In the statement setting out the grounds of appeal, the appellant maintained the claim request of 28 August 2013. With the same letter, the appellant filed a further set of claims entitled "auxiliary request".

The claims of the auxiliary request are identical to those of the request of 28 August 2013, except that claim 5 was deleted.

VI. In a communication dated 5 November 2018, issued in preparation for oral proceedings and advising the appellant of its preliminary opinion, the board mentioned *inter alia* the following points:

(a) Claim 1 lacked clarity with regard to the undefined term "recovery delta", the undefined parameters "A" and "B" and the determination of "B" (Article 84 EPC).

(b) A proper assessment of novelty and inventive step was only possible once the claimed subject-matter had been clearly defined and its mandatory technical features could be identified and compared with the prior art. Apart from the elements which were unclear, the subject-matter of claim 1 was identical to that of claim 1 in document D2.

VII. The appellant did not reply in writing to the board's communication.

VIII. Oral proceedings took place on 17 January 2019.

IX. The appellant requested that the decision under appeal be set aside and

- that the case be remitted to the examining division for further prosecution on the basis of claims 1 to 5 of the request filed with the letter dated 28 August 2013 (main request); or, in the alternative,

- that a patent be granted on the basis of claims 1 to 5 of the request filed with the letter dated 28 August 2013, or of the set of claims 1 to 4 of the auxiliary request filed with the statement setting out the grounds of appeal.

X. The appellant's arguments may be summarised as follows:

Remittal (Article 111 EPC)

The board had raised new objections in the appeal proceedings which had not been discussed in the decision under appeal, in particular the objection concerning lack of clarity. The board's further remarks implied that it regarded document D2 rather than D1 as the closest prior art. It was not fair for the appellant to have only one chance to respond to these new issues.

Clarity (Article 84 EPC)

The term "recovery delta" would readily be understood by a person skilled in the art to refer to a corrective factor. Specific values of recovery deltas ("RD") had been calculated and were disclosed in examples 9 to 11 of the application.

The function A+B(time) provided in claim 1 should be regarded as a result to be achieved, which in the present case was the only appropriate way of defining the invention. The formula defined clearly how the corrective factor should be calculated.

The principle of the invention was that the corrective factor should vary with time, depended on climatic conditions and should be calculated according to the formula A+B(time). As soon as the person skilled in the art recognised the inventive principle, they would have no difficulty in determining parameters A and B and a corrective factor (or recovery delta) for any number of different analytes by straightforward routine work.

The wording of claim 1 was commensurate with the inventive contribution to the art, since it was the

purpose of the invention to be applicable to a large variety of analytes, and it would not be fair to require the appellant to introduce specific parameter values or other limitations into claim 1.

Reasons for the Decision

1. Remittal (Article 111 (1) and (2) EPC)

1.1 Under Article 111(1) EPC, a board of appeal has the discretionary power either to exercise any power within the competence of the department of first instance or to remit the case to that department for further prosecution.

1.2 Thus the appropriateness of remittal is a matter for decision by the boards, which assess each case on its merits.

1.3 In its Decision G 10/93 (OJ EPO 4/1995, 172), the Enlarged Board of Appeal held that in an appeal from a decision of an examining division in which a European patent application was refused, the board of appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC, including requirements which the examining division did not take into consideration or which it regarded as having been met. If there is reason to believe that such a requirement has not been met, the board shall include this ground in the proceedings.

1.4 In the present instance, the board observes that both the claims under examination and the issues to be discussed have remained the same. The appellant could not have been taken by surprise by the aspects of the

case pointed out by the board, for the following reasons:

1.4.1 The issue of clarity and the disclosure content of document D2 (which is an earlier patent application by the appellant) are addressed in the board's preliminary written communication, issued more than two months before the scheduled oral proceedings. The appellant chose not to reply in writing (see points VI and VII above).

1.4.2 On a general note (and as previously pointed out in the board's preliminary opinion), the meaning of the terms used in a claim must be established for proper claim assessment; thus the appellant could expect that it would be required to explain the definition and meaning of the technical features of claim 1, in particular since those features were essential for delimiting the claimed subject-matter from the prior art, e.g. D2.

1.4.3 The board furthermore observes that a crucial objection in the examining division's reasoning on inventive step was the lack of technical information regarding parameters A and B, leading to the examining division's conclusion that those parameters were not defined in sufficient detail to be clearly distinctive and establish an inventive step of the claimed subject-matter over the prior art (see the decision under appeal, reasons 3.6). Thus it was to be expected that the definition of the parameters A and B and the meaning of the term A+B(t) would be discussed in the appeal proceedings. The board merely finds it more appropriate to deal with this issue under Article 84 rather than Article 56 EPC.

1.4.4 The disclosure of document D2 is discussed both in the decision under appeal (reasons 3.4), where it is

acknowledged that this earlier application discloses the general principle of the method of present claim 1, and in the statement setting out the grounds of appeal (various passages relating to D2 or the European patent issued from D2).

1.5 Since the substantive basis of the discussion has not changed, the board finds it appropriate not to remit the case to the department of first instance.

2. Clarity (Article 84 EPC)

2.1 In the appellant's favour, and in line with the teaching of paragraphs [0035] to [0038] of the description, the board accepts that the unusual term "recovery delta" means "corrective factor".

2.2 Thus, according to the instructions in claim 1, after the concentration of an analyte has been measured to yield a "solution analyte level", a corrective factor ("recovery delta") is added to that measured concentration. The analyte can be any substance that may be present in a dried blood specimen.

2.3 According to lines 15 to 21 of claim 1, the corrective factor must meet several further mandatory criteria:

(a) it is determined as a function of the time elapsed since the blood fluid specimen was collected,

(b) it is determined "in accordance with" the function A+B(time),

(b.1) A is 0, a positive value or a negative value,

(b.2) B is a positive or negative non-zero value, and

(b.3) B is determined based on climatic conditions.

2.4 Thus, the definition of claim 1 does not cover all methods by which a corrective factor is added to the solution analyte level, but only addresses a certain sub-group of corrective factors that meet all of the above-mentioned further criteria. The scope of claim 1 can therefore only be determined if it is clear what is meant by each of those criteria.

2.5 The board's assessment in that regard is as follows:

2.5.1 While it may be inferred from criterion (a) that the corrective factor is not a constant but varies with time, the definition of criterion (b) is not clear, in that it neither explains the meaning of the term *"A+B(time)"* nor indicates how to determine the corrective factor "*in accordance with*" that term. The wording is rather vague and does not necessarily require, for instance, that the corrective factor be equal to the term "A+B(time)".

2.5.2 As far as criteria (b.1) and (b.2) are concerned, the parameters "A" and "B" are not defined at all, other than as a numeric value of any possible kind (with B being different from zero). It is not mentioned whether these parameters should be concentration values or something else, nor how they could be measured or otherwise determined.

2.5.3 The statement that parameter "B" is determined based on climatic conditions (criterion (b.3)) does not remedy that deficiency, since no further instruction is provided.

2.6 As a consequence, a person skilled in the art would not be able to determine with any certainty whether a given method involving a corrective factor falls within the scope claimed, since the technical detail provided in claim 1 is insufficient to identify parameters A and B.

2.7 The meaning of a claim must be clear from the claim alone, without any reference to the content of the description. This requirement is not met in the present instance.

2.8 The board also considers that the description does not contain a definition of parameters "A" and "B" which could be introduced into claim 1 for further clarification.

Paragraph [0038] of the description relates to a corrective factor ("recovery delta") needed to take into consideration the decay of an analyte which is generally based on time, and further mentions a formula "A+B(time)" and parameters "A" and "B", stating that values A and/or B may be determined or estimated based on climatic conditions. This does not add anything to the information provided in claim 1.

The next sentence of paragraph [0038] refers to further alternatives and thus to different embodiments. The appellant did not dispute that further paragraphs of the description mentioning parameters designated "A" or "B" (such as paragraphs [0039] or [0044] to [0050]) do not relate to the same parameters "A" and "B" as claim 1.

Examples 9 to 11 invoked by the appellant do not disclose a corrective factor which is determined as a function of time elapsed:

- According to example 9 (see paragraph [93]) "Cholesterol RD was equal to 0.10 mg/dL";

- According to example 10 (see paragraph [97]), "HDL RD was calculated as 0.0342 x Measured Cholesterol"; and

- According to example 11 (see paragraph [99]), "Triglycerides RD was equal to -4.51 mg/dL".

2.9 For the reasons explained in points 2.2 to 2.7 above, the board has arrived at the conclusion that the subject-matter of claim 1 of the main request and of the auxiliary request lacks clarity within the meaning of Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated