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**Datasheet for the decision
of 9 January 2019**

Case Number: T 0612/12 - 3.3.01

Application Number: 05708362.8

Publication Number: 1733227

IPC: G01N33/487

Language of the proceedings: EN

Title of invention:

DEVICES AND METHODS FOR MEASURING CLINICALLY RELEVANT ANALYTES
IN FLUIDS

Applicant:

PA Knowledge Limited

Headword:

Measuring analytes in fluids/PA KNOWLEDGE

Relevant legal provisions:

EPC Art. 84, 123(2)
EPC R. 103(1) (a)

Keyword:

Claims - clarity (yes)
Amendments - allowable (yes)
Reimbursement of appeal fee - (no)

Decisions cited:

G 0010/93

Catchword:



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Case Number: T 0612/12 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 9 January 2019

Appellant: PA Knowledge Limited
(Applicant) 10 Bressenden Place
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Representative: Mewburn Ellis LLP
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 10 October 2011 refusing European patent application No. 05708362.8 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman A. Lindner
Members: T. Sommerfeld
L. Bühler

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division, in which European patent application 05708362.8, based on an international application published as WO 2005/080970, was refused under Article 97(2) EPC.
- II. The decision of the examining division is based on the set of claims filed by letter of 11 November 2010, of which independent claim 21 reads as follows:
- "21. A method for testing, in a portable device (10), levels of clinically relevant analytes in a fluid including the steps of:
- mixing, in the portable device, a sample of the fluid with a known amount of said analyte (20) to form a calibration sample;
 - measuring the analyte level in an unadulterated sample of the fluid;
 - measuring the analyte level in said calibration sample; and
 - adjusting the analyte level measured in said unadulterated sample using the analyte level measured in said calibration sample."
- III. The examining division decided that claim 21 did not meet the requirements of Article 123(2) EPC and 84 EPC.
- IV. The applicant (hereinafter, the appellant) lodged an appeal against the decision of the examining division. In its statement of the grounds of appeal, the appellant requested that the decision be set aside and that a patent be granted on the basis of the documents on which the appealed decision was based. The appellant also requested a refund of the appeal fee pursuant to

Rule 103(1) (a) EPC on the basis that its right to be heard under Article 113(1) EPC had been violated.

- V. On 12 September 2017, the board issued a communication pursuant to Rule 100(2) EPC and Article 17(1) RPBA expressing its preliminary opinion regarding Articles 123(2) and 84 EPC and the request for reimbursement of the appeal fee.
- VI. By letter dated 19 January 2018, the appellant submitted a new main request and requested that the case be remitted to the department of first instance for further prosecution.
- VII. The appellant's arguments, in so far as relevant to the present decision, may be summarised as follows:

Reimbursement of the appeal fee under Rule 103(1) (a) EPC was justified on the basis that the change in reasoning for the grounds of rejection between the final written communication of the examining division and the decision violated the applicant's right to be heard under Article 113(1) EPC.

As to Article 123(2) EPC, the objected feature was based on originally filed claim 25 and the original statement of the invention on page 7 of the application as originally filed.

Contrary to the conclusions of the examining division on Article 84 EPC, the knowledge of the volume of fluid being mixed with the analyte and the calculation of the concentration were optional or preferred features of the invention but not essential. The skilled person would be aware of the existence of alternative methods of calibration.

VIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution on the basis of the main request filed by letter of 19 January 2018. Furthermore, the appellant requested reimbursement of the appeal fee and oral proceedings in the event that the board did not allow the appeal in respect of the main request.

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 Articles 123(2) and 84 EPC

2.1.1 In the appealed decision, the examining division considered that the claims of the then sole request were not allowable because claim 21 did not meet the requirements of Articles 123(2) and 84 EPC. Claim 21 read as follows (with amendments shown in relation to originally filed claim 25, from which it derived):

"2521. A method for testing, in a portable device (10), levels of clinically relevant analytes in a fluid including the steps of:

mixing, in the portable device, a sample of the fluid with a known amount of said analyte (20) to form a calibration sample;

 measuring the analyte level in an unadulterated sample of the fluid;

 measuring the analyte level in said calibration sample; and

adjusting the analyte level measured in said unadulterated sample using the analyte level measured in said calibration sample."

2.1.2 In the appealed decision (page 2, section II.1), the examining division considered that the feature "in the portable device" in the context of the first step of the method ("mixing, in the portable device, a sample ...") constituted an unallowable extension of subject-matter, contrary to Article 123(2) EPC, arguing that "at no point do the original application documents disclose the step of mixing the known amount of analyte with the fluid at an arbitrary location within the portable device. On the contrary, it is clear from the description and the drawings that the mixing can only take place within the flow path". The examining division then concluded that "Consequently, said broader feature of 'mixing, in the portable device, a sample of the fluid with a known amount of said analyte' cannot be permitted under Article 123(2) EPC".

2.1.3 Claim 20 of the present main and sole request (labeled "MAIN REQUEST (20.01.18)") corresponds to claim 21 of the set of claims pursuant to the appealed decision, with the difference that the disputed feature "in the portable device" has been deleted. It hence differs from originally filed claim 25 solely in that reference signs have been inserted, as shown below:

"2520. A method for testing, in a portable device (10), levels of clinically relevant analytes in a fluid including the steps of:

 mixing a sample of the fluid with a known amount of said analyte (20) to form a calibration sample;

 measuring the analyte level in an unadulterated sample of the fluid;

measuring the analyte level in said calibration sample; and

adjusting the analyte level measured in said unadulterated sample using the analyte level measured in said calibration sample."

2.1.4 The objection raised by the examining division has thus been overcome by the new claims. The examining division has raised no objections as regards the insertion of the reference signs, and the board has no objections either. Since these are the only differences between present claim 20 and originally filed claim 25, it is immediately apparent that claim 20 fulfils the requirements of Article 123(2) EPC. For the sake of completeness, it is noted that the board disagrees with the conclusions of the examining division that there was added subject-matter by addition of the disputed feature above. Said amendment was based on original claim 25 itself, which, being directed to "A method for testing, in a portable device, levels of clinically relevant analytes in a fluid including the steps of:...", rendered it implicit that each of the method steps were to be performed in the device (unless otherwise stated). The fact that some passages of the description may further specify in which parts of the device the mixing step takes place does not impose any further limitation to the disclosure of original claim 25, which refers generally to the device only. The board, however, found that the amendment in suit was in fact redundant, thereby rendering the claim unclear (for lack of conciseness).

2.1.5 In its preliminary opinion, the board had raised further objections under Article 123(2) EPC concerning other claims (claims 2 and 22 of the previous claim

set). Said claims have now been deleted and thus these objections no longer apply.

2.1.6 As to present claim 1, this claim has been amended by deletion of features which had been added during examination and which the board found, in its preliminary opinion, to render the claim unclear. It is almost identical to originally filed claim 1, the only difference from it being the inserted reference signs.

2.1.7 Thus, the present claims comply with the requirements of Article 123(2) EPC.

2.1.8 As to Article 84 EPC, the board disagrees with the conclusions of the examining division, according to which claim 21 (now claim 20) lacked essential features. For a method claim to fulfil the requirements of Article 84 EPC, it is not necessary to introduce all method steps or features when these are implicit to the skilled person. It follows that it would be implicit that the volume of the sample should be known, when relying on concentration measurements for assessing the analyte level. Moreover, while one method of generating a calibration sample requires knowing the volume of the fluid which is mixed with the known amount of analyte, alternative methods do exist, as illustrated in the application on pages 14 to 16 and further discussed in the expert declaration by the inventor (declaration by Dr Michael Noble, submitted with the statement of grounds of appeal). Hence this feature is not considered essential. It is only optional and not required for the purposes of Article 84 EPC. Whether it may be necessary in the context of Articles 54 and 56 EPC is another issue, to be examined vis-à-vis the prior art in the context of these legal provisions.

2.1.9 In its preliminary opinion, the board had raised further objections under Article 84 EPC with regard to claim 1. Claim 1 has been amended by deletion of the disputed features and hence these objections have been overcome as well.

2.1.10 The present claims thus fulfil the requirements of Article 84 EPC.

3. Remittal to the department of first instance

3.1 According to G 10/93 (OJ EPO 1995, 172), setting out the principles governing ex parte proceedings, "proceedings before the boards of appeal in ex parte cases are primarily concerned with examining the contested decision", and the power accorded to the boards "does not however mean that boards carry out a full examination of the application as to the patentability requirements" (point 4. of the Reasons). In other words, appeal proceedings are intended to review the correctness of the decision of the department of first instance rather than to continue the examination by other means.

3.2 In the present case, the appealed decision has been based solely on Articles 123(2) and 84 EPC. No other EPC requirement has been decided upon. Hence, the board considers it appropriate to remit the case to the department of first instance for further examination.

4. Request for reimbursement of the appeal fee

4.1 According to Rule 103(1)(a) EPC the reimbursement of appeal fees shall be ordered where the board of appeal deems an appeal allowable, if such reimbursement is

equitable by reason of a substantial procedural violation.

- 4.2 The appellant's arguments concerning violation of the right to be heard under Article 113(1) EPC only concern the objection under Article 84 EPC. Hence, even without this alleged procedural deficiency, the appellant would have had to file an appeal to have the decision with respect to Article 123(2) EPC reviewed. It follows that, independently of whether a substantial procedural violation took place, it is not equitable to reimburse the appeal fee.

Order

For these reasons it is decided that:

1. The appealed decision is set aside.
2. The case is remitted to the examining division for further prosecution.
3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:



N. Maslin

A. Lindner

Decision electronically authenticated