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# Datasheet for the decision of 5 June 2012

T 0933/09 - 3.2.02 Case Number:

Application Number: 01991976.0

Publication Number: 1349583

IPC: A61M 1/00

Language of the proceedings: EN

### Title of invention:

System and method for closed loop controlled inspired oxygen concentration

## Applicant:

University of Miami

#### Opponent:

### Headword:

# Relevant legal provisions:

EPC Art. 108, 109, 110 EPC R. 99(2), 101(1) RPBA Art. 12(2)

# Relevant legal provisions (EPC 1973):

# Keyword:

"Admissibility of appeal: no"

#### Decisions cited:

T 0934/02

# Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 0933/09 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 5 June 2012

Appellant: University of Miami (Applicant) P.O. Box 016960

Miami

FL 33101 (US)

Representative: Gervasi, Gemma

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted 29 October 2008

refusing European patent application

No. 01991976.0 pursuant to Article 97(2) EPC.

Composition of the Board:

C. Körber

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# Summary of Facts and Submissions

- I. The applicant lodged an appeal against the decision of the Examining Division, dispatched on 29 October 2008, refusing European application No. 01 991 976.0.
- II. The application had been refused by the Examining Division on the grounds that claim 1 did not fulfil the requirements of Article 123(2) EPC. The Examining Division had objected, inter alia, that no basis for the "initial algorithm" and "subsequent algorithm" defined in the characterising portion of feature e)iii) of claim 1 of the main request could be established, particularly since the features of these algorithms seemed to be cherry-picked from the description, leading to an intermediate generalisation which went beyond the content of the original application (points 4.1 and 4.2 of the Reasons of the impugned decision).
- III. The notice of appeal was received on 18 December 2008 and the appeal fee was paid on the same day. With the statement setting out the grounds of appeal, received on 19 February 2009, an amended set of claims comprising a reworded claim 1 was filed. This claim no longer includes the features of section e)iii) objected to in the impugned decision, but, according to the appellant's statement, "includes all the steps necessary to carry out the algorithm described in the flow diagram 106 (figure 6) and consequently further comprises all the steps needed to perform the processing of blocks 204 and 206; support of this features can be easily found in the description from page 8 line 6 to page 34 line 13."

- IV. Claim 1 reads as follows (underlinings and strikethrough text added by the Board to indicate, respectively, features added to and deleted from claim 1 of the main request on which the impugned decision was based):
  - "A computer readable medium having an executable component for adjusting fractionally inspired oxygen delivery (FiO2) for a patient in response to receiving an arterial hemoglobin oxygen saturation (SpO2) signal, wherein the executable component contains computer executable instruction for:
  - computer-executable instruction for increasing a hypoxemia, hyperoxemia, or normoxemia adjust interval counter and computer-executable instruction for:
  - a) specifying a plurality of hemoglobin oxygen saturation levels and being a normoxemic, a hyperoxemic and a hypoxemic target range;
  - b) reading the arterial hemoglobin oxygen saturation signal;
  - c) determining if the arterial hemoglobin oxygen saturation signal is a valid signal;
  - d) if the hemoglobin oxygen saturation signal is a [sic] not a valid signal, determining a value for the fractionally inspired oxygen delivery to the patient based on backup value;
  - e) if the hemoglobin oxygen saturation signal is a valid signal,
  - i) determining the hemoglobin oxygen saturation level based on the arterial hemoglobin oxygen saturation signal as being in one of the normoxemic, the hyperoxemic and the hypoxemic ranges;

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- ii) determining a trend by calculating a slope using a plurality of recent hemoglobin oxygen saturation signals;
- iii) if a closed loop mode is enabled, determining the fractionally inspired oxygen to deliver to the patient based on the hemoglobin oxygen saturation level and the trend indicated by the slope;
- 1) Reading the SpO2 signal and storing it as SpO2READ
- 2) Checking if SpO2READ is within the acceptable SpO2 range
- 3) If SpO2 is not within the acceptable SpO2 range then
- Alerting the user
- performing the SpO2 signal OUT processing by setting FiO2 Set is the FiO2 backup level,
- 4) If SpO2 is within the acceptable SpO2 range then performing the SpO2 signal OK processing and:
- classifying and confirming the actual SpO2 level using counters of time continuously updated
- performing appropriate timing processing based on SpO2READ and
- o <u>if SpO2 READ is in the target range for normoxemia</u> then performing normoxemia timing
- o <u>if Sp02 READ</u> is greater than the target range then performing hyperoxemia timing
- o <u>if SpO2 READ</u> is less than the target range then performing hypoxemia timing
- performing Sp02 slope calculation
- determining the FiO2 max and min timing
- checking if closed loop control is enabled and if so performing FiO2Set determination if not setting FiO2Set to FiO2Backup
- <u>determining if FiO2 Base Calc is enabled and performing FiO2Base Determination</u>

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- performing FiO2Set checking
- performing FiO2Base/backup checking
- passing the updated FiO2Set value to the output routine that control the air-oxygen mixer
- 5) monitoring if user settings have been changed and if so updating the variables according and starting again from iii;
- iv) if the closed loop mode is not enabled, determining the fractionally inspired oxygen to deliver to the patient based on the backup value; and
- f) delivering the fractionally inspired oxygen to the patient,

characterized in that in step iii)

- o an initial algorithm calculates a respectively initial increase/decrease of the fractionally inspired oxygen as a function of the calculated negative/positive trend of the hemoglobin oxygen saturation level, and
- o a subsequent algorithm determines adjusting of the fractionally inspired oxygen proportional to the slope of the hemoglobin oxygen saturation level."
- V. In an annex to the summons to oral proceedings under Article 15(1) RPBA dated 12 March 2012, the Board informed the appellant of its provisional view that the appeal did not seem to comply with Rule 99(2) EPC and was therefore likely to be rejected as inadmissible pursuant to Rule 101(1) EPC.
- VI. Oral proceedings took place on 5 June 2012.

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. - 5 - T 0933/09

VII. The arguments of the appellant are summarised as follows:

With its statement of grounds of appeal, the appellant had removed from claim 1 the wording objected to by the Examining Division. Thus, in the light of decision T 934/02, the present appeal should be considered sufficiently substantiated within the meaning of Article 108, third sentence, EPC, since amended claims had been filed which deprived the contested decision of its basis, even though it did not state any specific reasons why the contested decision was wrong. Claim 1 attached to the statement of grounds of appeal no longer contained the wording objected to in the decision. Instead, the appellant had introduced all the technical features of the embodiment of Figure 6, supplemented by those features of Figures 7 and 8 explicitly referred to in Figure 6. The arguments provided in the statement of grounds of appeal relating to the fulfilment of the requirements of Article 123(2) EPC were indeed quite concise, and the reference to the description was indeed quite broadly worded. The additional arguments presented in response to the communication from the Board should be considered as a clarification of the quite concise arguments in the statement of grounds of appeal.

The appellant also explained that when the statement of grounds of appeal was filed it had been fully convinced that, based on the amended set of claims, the Examining Division would have rectified its decision under Article 109 EPC and full examination would have continued based on the amended set of claims.

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#### Reasons for the Decision

- 1. Article 108 EPC in conjunction with Rule 99(2) EPC requires that a statement setting out the grounds of appeal be filed which indicates the reasons for setting aside the decision impugned, or the extent to which it is to be amended, and the facts and evidence on which the appeal is based.
- 2. This requirement is reflected in Article 12(2) RPBA which states: "The statement of grounds of appeal and the reply shall contain a party's complete case. They shall set out **clearly** and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify **expressly** all the facts, arguments and evidence relied on" [emphasis added].
- 3. In the present case the appellant filed with the statement of grounds of appeal an extensively reworded claim 1. In particular, this claim contains a full page of newly formulated features in section e)iii), mainly replacing those features in claim 1 of the main request which had been objected to in the impugned decision. Beyond the general information given by the appellant in its statement of grounds of appeal that these newly formulated features included all the steps necessary to carry out the algorithm of the flow diagram of Figure 6, the only indication of any reasons why these new features might fulfil the requirements of Article 123(2) EPC is the appellant's statement:

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"support of this [sic] features can be easily found in the description from page 8, line 6 to page 34 line 13" (that is, amongst 26 pages).

- 4. This statement merely conveys the information that the contents of 26 pages of the originally filed description (comprising a total of 34 pages) had been condensed into the newly formulated features in section e)iii). It does not enable the Board to immediately understand, without first having to make investigations of its own, if and if so, where there is a direct and unambiguous basis for each of the amendments made (in terms of both additions of features as well as omissions of other features belonging to the same context). Thus, the statement of grounds of appeal is not sufficient to allow to recognise the relevance of the amendments for remedying the raised objections of added subject-matter.
- 5. The lack of self-evidence for such basis for more than a dozen added method steps becomes particularly apparent from inspection of the large list of citations of numerous passages scattered throughout the mentioned 26 description pages which the appellant filed before the oral proceedings in an attempt to provide a purported basis for the added features. However, contrary to the appellant's view, additional arguments filed after the time limit fixed in Article 108 EPC cannot be taken into consideration for assessing the admissibility of the appeal.
- 6. Consequently, the aforementioned statement cannot be considered to set out **clearly** the reasons for reversing the impugned decision and to specify **expressly** all the

arguments relied on for establishing the appellant's complete case as prescribed by Article 12(2) RPBA.

7. It is not denied that in some cases an appeal may be found to be substantiated as a result of filing amended claims which self-evidently deprive the contested decision of its basis. In the case underlying decision T 934/02 cited by the appellant, the statement of grounds of appeal did in fact give detailed reasons why the subject-matter of the amended claims satisfied the requirements of novelty and inventive step vis-à-vis the documents cited in the impugned decision (point 2 of the Reasons), whereas in the present case the appellant has remained effectively silent as to why the amendments introduced into claim 1 now meet the requirements of Article 123(2) EPC.

Thus, in the present case, contrary to the appellant's view, the Board considers that the mere filing of amended claims does not exonerate the appellant from the task of expressly specifying in the statement of grounds of appeal the relevance of the amendments for overcoming the objections on which the decision under appeal was based.

8. In view of the circumstances explained above, the Board also considers that the appellant's acknowledged expectation of obtaining a continuation of the examination procedure before the Examining Division by means of interlocutory revision under Article 109 EPC is irrelevant, since the Examining Division did not rectify its decision and remitted the appeal to the Board.

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9. For the aforementioned reasons, the Board finds that the appeal does not comply with the requirements of Rule 99(2) EPC and is therefore to be rejected as inadmissible under Rule 101(1) EPC.

In consequence, the allowability of the appellant's request that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution is not examined (Article 110 EPC).

### Order

# For these reasons it is decided that:

The appeal is rejected as inadmissible.

The Registrar: The Chairman:

D. Hampe E. Dufrasne