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Datasheet for the decision of 8 January 2013

Case Number: T 0466/09 - 3.2.02

Application Number: 97904470.8

Publication Number: 883371

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:
A method for monitoring the health of a patient by measuring and predicting the glucose level of the patient's blood sample

Patent Proprietor:
Nokia Corporation

Opponents:
Novo Nordisk A/S
Roche Diagnostics GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56, 83

Keyword:
"Sufficiency of disclosure (yes, after amendment)"
"Inventive step (yes, after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0466/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 8 January 2013

Appellant: (Patent Proprietor)	Nokia Corporation Keilalahdentie 4 FI-02150 Espoo (FI)
Representative:	Ruuskanen, Juha-Pekka Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Respondent I: (Opponent 1)	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd (DK)
Representative:	Zacco Denmark A/S Hans Bekkevolds Allé 7 DK-2900 Hellerup (DK)
Respondent II: (Opponent 2)	Roche Diagnostics GmbH Sandhoferstr. 116 D-68305 Mannheim (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 17 December 2008 revoking European patent No. 883371 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: E. Dufrasne
Members: C. Körber
M. Stern

Summary of Facts and Submissions

I. On 17 December 2008 the Opposition Division posted its decision to revoke European patent No. 0 883 371.

II. An appeal was lodged against this decision by the patent proprietor by notice received on 11 February 2009, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 20 April 2009.

III. By communication of 18 September 2012, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.

IV. With letter dated 21 November 2012 the respondent-opponent 1 informed the Board that it would not attend the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party. The respondent-opponent 1 requested that the appeal be dismissed.

V. Oral proceedings were held on 8 January 2013.

The final requests of the attending parties were as follows:

The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of its main request submitted during the oral proceedings.

The respondent-opponent 2 requested that the appeal be dismissed.

VI. The following documents are of importance for the present decision:

D1: V. Tresp et al.: "Neural network modeling of physiological processes", in "Computational learning theory and natural learning systems", (Eds. S.J. Hanson et al.), Chapter 21 (pages 363 to 378), MIT Press (1994);

D5: E.D. Lehmann and T. Deutsch: "Application of computers in diabetes care - a review", parts 1 and II, Medical Information, Vol. 20, No. 4, pages 281 to 329 (1995);

D6: R. Bellazzi et al.: "The T-IDDM project: telematic management of insulin diabetes mellitus", in "Proceedings of health telematics" (Eds. M. Bracale and F. Denoth) Ischia, pages 271 to 276 (1995);

D7: R. Bellazzi et al.: "Adaptive controllers for intelligent monitoring", Artificial Intelligence in Medicine, Vol. 7, pages 515-540 (1995);

D17: D.R.L. Worthington: "The use of models in the self-management of insulin-dependent diabetes mellitus", Computer Methods and Programs in Biomedicine, Vol. 32, pages 233-239 (1990);

D19: B. Widrow and S.D. Stearns: "Adaptive signal processing", Prentice-Hall, pages 1 to 15 and 99 to 111 (1985);

D20: CA-C-2190283.

VII. Independent claims 1 and 2 of the main request read:

"1. A method of predicting the glucose level $g(t_i)$ in a patient's blood, comprising:

formulating an adaptive mathematical model (H) about the behaviour of the patient's blood glucose level, the model taking into account at least the patient's diet, medication and physical strain and comprising comparing predictive values $\hat{g}(t_i)$, provided by the model, to measured glucose levels $g(t_i)$ and correcting the mathematical model (H) on the basis of the result of said comparison, and

providing the patient with means for utilizing said mathematical model (H), so that the patient can himself monitor and predict the effect of the treatment he is to follow on the behaviour of his blood glucose level, the means comprising a mobile phone of a cellular radio system or to a two-way pager connected to a measuring unit, the measuring unit and the mobile phone or to a two-way pager constituting a combined element, wherein a battery of the mobile phone or two-way pager and the measuring unit are integrated into one component (14') that fits into the battery space of the mobile phone or two-way pager, the method further comprising:

measuring the glucose level of a patient's blood sample by the measuring unit and storing the data indicating the moment of measurement of the first measurement result in first memory means (10'),

transmitting the data stored in the first memory means (10') via a data transmission link to a data processing system that is available to a person treating the patient,

calculating a predictive value $\hat{g}(t_i)$ on the basis of the data stored in the first memory means (10, 10'),

the predictive value indicating the patient's predicted blood glucose level at a predetermined moment,

calculating the difference between the calculated predictive value $\hat{g}(t_i)$ and the patient's actual blood glucose level $g(t_i)$ calculated at said predetermined moment, and correcting the mathematical model to calculate a predictive value in order to take into account said difference in subsequent calculations of predictive values."

"2. Monitoring equipment for predicting the glucose level in a patient's blood, comprising:

means (15, 15) for receiving a measurement result indicating the glucose level in the patient's blood sample and for storing it in a first memory means (10, 10') together with data indicating the moment of the measurement, wherein the monitoring equipment comprises means (15, 15') for receiving data concerning at least the patient's diet, medication and physical strain and for storing the data in the first memory means (10, 10'),

data processing means (11, 12, 11', 12') for calculating a predictive value $\hat{g}(t_i)$ on the basis of the data stored in the first memory means (10, 10'), the predictive value indicating the patient's predicted blood glucose level at a predetermined moment, and

corrector means (13, 13') for calculating the difference between the calculated predictive value $\hat{g}(t_i)$ and the patient's actual blood glucose level $g(t_i)$ calculated at said predetermined moment, and for correcting the mathematical model utilized by the data processing means (11, 12, 11', 12') to calculate a predictive value in order to take into account said difference in the subsequent calculations of predictive values,

a measuring unit for measuring the glucose level of a patient's blood sample, and for storing the data indicating the moment of measurement of the first measurement result in the first memory means (10'),

a communications device (MS) connected to the measuring unit, the communications device (MS) comprising a mobile phone of a cellular radio system or to a two-way pager, and means for transmitting the data stored in the first memory means (10') via data transmission link to a data processing system that is available to a person treating the patient, the measuring unit and the communications device constituting a combined element, wherein a battery of the mobile phone or two-way pager and the measuring unit are integrated into one component (14') that fits into the battery space of the mobile phone or two-way pager."

Claims 3 and 4 are dependent claims.

VIII. The appellant's arguments are summarised as follows:

The adaptive mathematical model referred to in the claims had to be distinguished from the complex mathematical models attempting to describe the glucose metabolism in the human body. Widrow's adaptive LMS algorithm was mentioned in the specification as a well-known example of an adaptive mathematical model. With regard to sufficiency of disclosure, the fact that the model took into account the patient's diet, medication and physical strain was of relevance. How exactly these parameters were incorporated into the model was not so important. Even if this were done in a rudimentary manner, the adaptive algorithm would still work, it might just require more time.

D17 was to be regarded as closest prior art. It was not obvious to replace the hand-held computer of D17 by a mobile phone or two-way pager, with the battery and the measuring unit being integrated into one component that fitted into the battery space. In fact, none of the cited prior art documents disclosed these features and the advantages achievable thereby as mentioned in the specification.

IX. Even though respondent-opponent 1, absent from the oral proceedings, has not raised any objections against the set of claims of the main request at issue, the insufficiency objection raised in its counter-statement with respect to the previous requests, all withdrawn by the appellant, is to be regarded as also applicable to the present main request. The corresponding arguments of respondent-opponent 1 are summarised as follows:

The description mentioned only a single mathematical model, namely Widrow's adaptive algorithm. No indication was provided as to how to actually construct a mathematical model that would provide the claimed effect, nor as to how to determine whether a given model was suitable therefor. Furthermore, the description did not provide any guidance as to how the inputs (such as physical exercise) to the model should be quantified, scaled, pre-processed and represented. These issues were not part of the common general knowledge either. On the contrary, D5 stated that there were no well-established models for describing the effects of exercise and stress on glucose metabolism. Similarly, Dl noted that a quantitative model which was sufficiently sophisticated for therapeutic use had not yet been developed. Moreover,

the specification did not disclose any details of how the adaptive mathematical model H was to be constructed in the example of Figure 4. The specification referred to correction coefficients and provided a formula for updating these correction coefficients. However it was not disclosed how the correction coefficients were used in the model. Furthermore the formula presented in column 8, line 35 for updating the correction coefficients involved the weighting coefficients h_{ik}, a calculated difference e and initial value x_i and a constant. Neither the term initial value was explained, nor what x_i was an initial value of and what the term "initial" referred to.

X. The arguments of respondent-opponent 2 are summarised as follows:

The invention was not sufficiently disclosed for it to be carried out by the skilled person for the same reasons as given by respondent-opponent 1.

Starting from D17 as closest prior art it was obvious to replace the hand-held computer by a mobile phone in view of D5 or D6 which both disclosed in Figures 2 and 1, respectively, telecommunication via a mobile phone between a patient unit and a remote unit available to the medical doctor. Furthermore Figure 1 of D6 disclosed a measuring unit in form of a glucometer which was connected to the patient unit, corresponding to the mobile phone as claimed. When trying to make such a unit more compact, the battery space of the mobile phone would be the most obvious possibility to accommodate a combined element constituted of the battery and the measuring unit. Figure 1 of D20 also showed a sensor

device connected to a cellular phone, being additionally provided with a memory wherein the moment of measurement of a first measurement result could be stored. Moreover, the difference between the calculated predictive value and the patient's actual blood glucose level could only be calculated by storing the moment of measurement of a first measurement result. The claimed first memory means was thus implicitly disclosed. Consequently, the subject-matter of claim 1 did not involve an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments

Independent claims 1 and 2 are based on claims 1 and 2 of the granted patent, respectively, both combined with claims 5 to 7 of the granted patent. The set of claims of the granted patent corresponds to the original set of claims. The respondents have not raised any objections under Article 123(2) and (3) EPC against this set of claims, nor does the Board see any reason to raise an objection in this respect.

3. Clarity

In view of the above-mentioned circumstances, in which any potential clarity deficiency was already present in the claims of the granted patent, a respective clarity objection under Article 84 EPC cannot be considered in the present opposition appeal proceedings.

4. Sufficiency

The Board considers that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. At the end of paragraph [0027] of the specification, Widrow's adaptive LMS algorithm is mentioned as an example of the mathematical model to be utilized. This algorithm is further described in detail in the pertinent technical literature forming part of the common general knowledge of the skilled person in this technical field, for instance in document D19. Accordingly, at least one way is clearly indicated enabling the person skilled in the art to carry out the invention with regard to the mathematical model to be used. The skilled person further knows how to quantify the input parameters or "basic data $\underline{X}$" of the mathematical model, namely the patient's diet, medication and physical strain. It is merely required that these parameters are "taken into account" by the model. Respective information is provided in paragraphs [0028] and [0029], with paragraph [0029] indicating specific formulae for this purpose. Contrary to the assertion of respondent-opponent 2, the "initial value x_i" mentioned with respect to the formula in lines 35 to 38 of column 8 is previously explained, for instance in lines 11 and 18 to 19. Accordingly, the formula for updating the correction coefficients and its use in the mathematical model is sufficiently disclosed.

To establish insufficiency, the burden of proof generally lies upon an opponent. The statement in D5 (bottom of page 293) that there are no well-established

models for describing the effects of exercise and stress on glucose metabolism, and the statement in Dl (page 363, penultimate paragraph) that a quantitative model which is sufficiently sophisticated for therapeutic use had not yet been developed, referred to by respondent-opponent 2, do not represent sufficient proof in this respect. The mathematical model taking into account the patient's diet, medication and physical strain does not have to be "well-established" or "sufficiently sophisticated". A rudimentary incorporation of these parameters into the mathematical model in view of the wording of the claim is already sufficient. Respective examples may, for instance, be found in section 21.4.1 of D1.

In the absence of any further evidence presented by the respondents, the Board considers that the requirements of Articles 83 and 100(b) EPC are met.

5. Novelty

Novelty has not been contested by the respondents, nor does the Board see any reason to raise an objection in this respect against the amended set of claims.

6. Inventive step

Document D17 undisputedly represents the closest state of the art. It discloses providing the patient with a hand-held computer for utilizing a mathematical model as defined in the first paragraph of claim 1, so that the patient can himself monitor and predict the effect on his blood glucose level of the treatment he is to follow (section 6 at pages 237 and 238). This section of D17,

which makes explicit reference to D19 by its citation [19], further discloses measuring the glucose level of a patient's blood sample by a measuring unit (disclosed implicitly) and calculating a predictive value indicating the patient's predicted blood glucose level at a predetermined moment, and calculating the difference between the calculated predictive value and the patient's actual blood glucose level, and correcting the mathematical model to calculate a predictive value in order to take into account said difference in subsequent calculations of predictive values.

Claim 1 is distinguished over D17 in that the means for utilizing the mathematical model comprise a mobile phone of a cellular radio system or a two-way pager connected to the measuring unit, the measuring unit and the mobile phone or two-way pager constituting a combined element, wherein a battery of the mobile phone or two-way pager and the measuring unit are integrated into one component that fits into the battery space of the mobile phone or two-way pager, and in that data indicating the moment of measurement of a first measurement result are stored in first memory means and transmitted via a data transmission link to a data processing system that is available to a person treating the patient, and that the predictive value is calculated on the basis of the data stored in the first memory means.

The technical effects achieved by the above-mentioned distinguishing features are that the measurement results and time are tracked automatically instead of having to be entered manually, that the doctor treating the patient has access to his data without need for an appointment, and that the patient does not have to carry

with him several separate conspicuous instruments, as explained in paragraphs [0011], [0012], [0016] and [0026] of the specification.

The objective technical problem underlying the invention is to make the treatment and its surveillance more effective and reliable and more comfortable for the patient (paragraph [0006]).

Document D17 itself gives no hint of deviating from the disclosed concept involving a hand-held computer.

Document D6 anticipates a portion of the distinguishing features by disclosing a portable patient unit PU connected to a glucometer, with the PU automatically collecting the patient's data and being in telecommunication, for instance via GSM (Global System Mobile), with a medical workstation MW giving a physician access to the patient's data (Figure 2 and section 3 "System Architecture" beginning at page 273). However, D6 fails to disclose or suggest the battery and the measuring unit being integrated into one component that fits into the battery space of the mobile phone and gives no hint towards the above-mentioned advantages achievable thereby. In contrast to the view expressed by respondent-opponent 2 and in the absence of any further evidence, including these features cannot be regarded as a routine measure that the skilled person would obviously consider in order to achieve a more compact patient unit.

With respect to the distinguishing features, the teachings of documents D5 and D20 do not go beyond that of D6.

Documents D1 and D7, which have also been cited as starting points for challenging inventive step, are not closer to the invention than D17. The other prior art documents cited by the respondents are more remote.

Under these circumstances the Board is of the opinion that the subject-matter of claims 1 and 2, the latter corresponding to claim 1 in terms of apparatus features, is based on an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:

   – claims 1 to 4 of the main request filed during the oral proceedings before the Board;

   – description columns 1 to 8 filed during the oral proceedings before the Board;

   – figures 1 to 4 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne