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**Datasheet for the decision  
of 22 January 2016**

**Case Number:** T 1367/12 - 3.5.05

**Application Number:** 02017012.2

**Publication Number:** 1281351

**IPC:** G06F19/00, A61B5/00, A61M5/00

**Language of the proceedings:** EN

**Title of invention:**  
Diabetes management system

**Patent Proprietors:**  
Roche Diagnostics GmbH  
F. Hoffmann-La Roche AG

**Opponent:**  
Medtronic MiniMed, Inc.

**Headword:**  
Diabetes management system/ROCHE

**Relevant legal provisions:**  
EPC Art. 83, 100(b), 111(1)

**Keyword:**  
Grounds for opposition - insufficiency of disclosure (no)  
Remittal to the department of first instance - (yes)

**Decisions cited:**  
T 0042/90

**Catchword:**



**Beschwerdekammern  
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Chambres de recours**

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Case Number: T 1367/12 - 3.5.05

**D E C I S I O N  
of Technical Board of Appeal 3.5.05  
of 22 January 2016**

**Appellant:** Roche Diagnostics GmbH  
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**Representative:** Roche Diagnostics GmbH  
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**Appellant:** F. Hoffmann-La Roche AG  
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**Respondent:** Medtronic MiniMed, Inc.  
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**Representative:** Madgwick, Paul Roland  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 27 April 2012  
revoking European patent No. 1281351 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chair** A. Ritzka  
**Members:** M. Höhn  
G. Weiss

## **Summary of Facts and Submissions**

- I. This appeal is against the decision of the Opposition Division of the European Patent Office posted on 27 April 2012 revoking European patent No. 1281351 pursuant to Article 101(3)(b) EPC.
- II. The opponent had withdrawn its opposition and the opposition division decided to continue the proceedings of its own motion without the opponent being party to these proceedings.
- III. The notice of appeal was received on 18 June 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 30 July 2012.
- IV. The appellant requested that the appealed decision be set aside and that the patent be maintained as granted or on the basis of the first to sixth auxiliary requests, filed with letter dated 26 January 2012, or that the case be remitted to the opposition division for further prosecution. Oral proceedings were requested on an auxiliary basis.
- V. Independent claim 1 as granted reads as follows:

"1. A system for providing glycemc control to a subject, the system comprising:  
an insulin delivery unit (12),  
a glucose sensor (16), and  
a control unit (14) including a processor unit that receives glucose value readings from the glucose sensor, executes a feedback algorithm that predicts a glucose value at a pre-determined time in the future, compares that predicted glucose value to a pre-

determined glucose value range, and determines a corrective amount of insulin to be administered when the predictive glucose value lies outside of the pre-determined glucose value range and a communication unit that transmits the corrective amount to the delivery unit whereby the feedback algorithm anticipates the future effects of insulin that has been previously delivered to the patient, characterized in that the feedback algorithm excludes insulin equivalents for meals and exercise from the prediction of the glucose value at a pre-determined time in the future."

### **Reasons for the Decision**

1. Admissibility

The appeal complies with Articles 106 to 108 EPC (see Facts and Submissions, point III above). It is therefore admissible.

2. The decision under appeal refusing the patent in suit is based only on an objection under Article 100(b) in conjunction with Article 83 EPC that the opposed patent did not disclose the invention sufficiently clearly and completely for it to be carried out by a person skilled in the art. This was found to apply to all requests.

In particular, equation (1) was regarded as essential for the invention as described in the patent but was considered to be unclear, since it contained ambiguities and contradictions which could not be resolved. Thus, the person skilled in the art was not able to carry out the invention, taking into account

the information provided in the opposed patent and the general knowledge of the person skilled in the art.

- 2.1 The claimed system uses a feedback algorithm in a predictive model to predict the future glucose level of a subject at a pre-determined time. The feedback algorithm is disclosed by equations (1-3). Equation (1) is used to predict a current glucose value for an expected delay in glucose measurement with the following parameters:

$G(i)$  = glucose concentration  $i$  cycles in the past ( $i$ =cycle),

$InsuTrace(i)$  = series of pulses of insulin that were administered in the past (excluding meal-related insulin doses and exercise-related insulin reductions) normalized,

$InsuGluDrop(i)$  = amount that the glucose is expected to drop on the next cycle due to insulin delivered at times in the past,

$\Delta T$  = time interval between cycles (in minutes),

$Basal\ Requirement(i)$  = amount of insulin required in the  $i$ 'th cycle to maintain current glucose in the absence of disturbances and

$Sensitivity$  = expected magnitude of glucose drop for 1 unit of insulin.

- 2.2 The subject-matter of claim 1 refers to a feedback algorithm, but does not specify it in exact terms of equation (1). Only dependent claim 11 as granted is directed to the concrete equation (1). Independent claim 1 is therefore broader in scope and not limited to equation (1).

- 2.3 In the decision under appeal it was argued that equation (1) lacked clarity (see point 12) and had to be regarded as essential for the invention.

The board agrees with the appellant that lack of clarity is not a ground for opposition. However, claim 1 does not comprise this equation and it was rejected, because the person skilled in the art was not able to carry out the invention, taking into account the information provided in the opposed patent and the general knowledge of the person skilled in the art (Articles 100(b) and 83 EPC).

- 2.4 The invention of the patent in suit has to deal with complex calculations, glucose measurements and insulin injections, whereby feedback-based insulin dose adjustment is used in a feedback algorithm considering time-dependent variations of physiological conditions. The claimed system compensates for delays on the measurement side such as physical or technology-related lags and physiological lags between subcutaneous space and blood, as well as on the delivery side such as delayed insulin action due to peripheral delivery (see [0013] of the published application).

- 2.5 According to claim 1 the feedback algorithm predicts a glucose value at a pre-determined time in the future. According to [0031] of the published application, equation (1) is used to predict a current glucose value for an expected delay in glucose measurement. The board therefore does not agree with the appellant's argument (see page 2, third paragraph of the statement setting out the grounds of appeal) that equation (1) concerns merely an exception to which only dependent claim 11 is directed.

No other disclosure is found in the original application for how to predict a glucose value, in particular not on a more general level than equation (1). By specifying that an amount of insulin is to be administered due to a deviation from a target glucose value a determination has to be carried out using equation (3) (see [0033] of the published application). This equation (3) takes into account a current glucose level  $G(0)$ . Since the prediction of glucose values is made using equation (1), also for this reason claim 1 has to be interpreted to refer to the disclosure of equation (1) in order to specify a technical teaching that is workable by a person skilled in the art. In so far the board concurs with the decision under appeal that equation (1) is to be regarded as essential for the subject-matter of independent claim 1.

- 2.6 The board agrees with the appellant (see page 3, first paragraph of the statement setting out the grounds of appeal) and with the reasoning in the decision under appeal that equation (1) has to be understood in that  $G(i)$  is a glucose value  $i$  cycles in the past, and that  $G(i+1)$  should be the current glucose value, thereby causing  $i$  to be negative values. In this context the parameter " $i$ " in  $G(i)$  describes previous glucose values  $G$ .
- 2.7 In the decision under appeal it was argued that an index " $i$ " of the sigma-operator in the equation was running from " $i=i$ " to a certain defined value above the sigma. The terms behind the sigma in the equation all referred to the index " $i$ ". Since this index " $i$ " was used in two ways, namely in a fixed way to define the glucose values  $G(i)$  and  $G(i+1)$  and as a running index for the sigma-operator, it was not clear to which kind

of "i" the index "i" in the three terms behind the sigma-operator referred to.

The appellant argued that the use of the index "i=i" was unfortunate, but did not cause a clarity problem. The board agrees with the appellant that, in spite of different indices "i" being present in equation (1), the skilled person would know how to deal with it. In equation (1) the description indicates that BasalRequirement(i) refers to the amount of insulin required in the i-th cycle (see page 6, lines 20 and 21 of the published application), i.e. it is referred to the running index i. As far as the parameters InsuTrace(i) and InsuGluDrop(i), both following the sigma operator, are concerned they both refer to values in the past (see page 6, lines 15 to 18) and, hence, are considered to also refer to the running index i. Hence, the skilled person finds enough information in the application documents indicating that it is the running index that it is referred to regarding the algebraic terms following the sigma operator.

- 2.8 In the decision under appeal the disclosure of equation (1) was further objected to, because it was not clear whether in the term above the sigma operator there was a minus after the "i" or simply the fraction line. In the board's view, even if the quality of the reproduction of equation (1) on page 10 of the original description is not optimal, it is possible to see that there is a minus after the "i". This is also in accordance with the above mentioned argument that "i" is supposed to have negative values which are worked out by subtracting the fraction (InsulinDuration/Delta T). This fraction represents the time (normalised in intervals Delta T; see original claim 24 and page 6, line 20 of the A2 publication) in the past during which



insulin that was administered influenced the glucose concentration G.

The original application provides a concrete basis for the parameter "InsulinDuration" in this regard which is specified as the total time action of insulin (see original claim 24 and claim 11 as granted).

- 2.9 In the decision under appeal (see point 13.3) it was argued that in case that no insulin was administered at all, the term  $\text{InsuTrace}(i)$  should be zero at all cycles  $i$ . In this case the BasalRequirement was thus summed over the number of cycles pharmacologically active insulin could be present and multiplied by the sensitivity. This resulted in a glucose increase over this number of cycles.

The body requires a flow of insulin to enable the body to utilize glucose in the blood stream, so the energy in glucose can be used to carry out bodily functions. In healthy individuals, basal rate is monitored by the pancreas, which provides a regular amount of insulin at all times. Together with a bolus of insulin, the basal insulin completes the total insulin needs of an insulin-dependent person. Basal rate requirements can differ for individuals depending on the activities and food consumption.

While the board agrees that in the above mentioned scenario the "BasalRequirement" was summed over the number of cycles pharmacologically active insulin could be present and multiplied by the sensitivity, the conclusion that this results in a glucose increase is not necessarily correct. Depending on the actual basal rate the amount of natural insulin available in the individual could also result in a decrease of the

glucose concentration  $G$ . The appellant is correct when arguing that a possible glucose decrease could result, since the sensitivity is defined as the expected magnitude of a glucose drop for one unit of insulin (see [0031] of the A2-publication).

The scenario raised by the opposition division therefore does not necessarily lead to a contradiction according to point 13.3 of the decision under appeal.

- 2.10 In the section titled "Further Observations" of the decision under appeal, doubts were raised that the claimed algorithm could provide a glyceemic control to a subject unless an additional compensation for meals and exercises was provided, e.g. in form of a feedforward algorithm described in the patent. Hence, it appeared that the invention could not be performed over the whole breadth of claim 1 of the main request.

However, the appellant is correct in arguing that the subject-matter according to claim 1 of the main request was not directed to total glyceemic control of a subject, but it was sufficient to regulate the basal rate of a subject according to claim 1.

- 2.11 In conclusion, even if considering equation (1) to be essential for interpreting the subject-matter of claim 1, it is not unclear and the skilled person, when using their common general knowledge, finds enough information in the original application documents which enables him/her to carry out the claimed invention according to the main request.

For this reason, the board does not uphold the objections under Articles 83 and 100(b) EPC on which the decision under appeal is based.

3. However, the board is not in a position to follow the appellant's request to maintain the patent as granted, since further grounds for opposition raised in the notice of opposition have not been dealt with during the first-instance proceedings.

The board therefore uses its discretion under Article 111(1) EPC to remit the case to the opposition division for further prosecution on the basis of the main request, thereby following the appellant's corresponding auxiliary request.

As stated in decision T 42/90, the decision to remit the case to the first instance is not to be considered as being adverse to the party, so that no oral proceedings before the board need to be appointed.

Hence, the board was in a position to issue a decision in the written proceedings without the need for 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 department of first instance for further prosecution on the basis of the main request.

The Registrar:

The Chair:



K. Götz-Wein

A. Ritzka

Decision electronically authenticated