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Datasheet for the decision of 20 February 2019

Case Number: T 0684/14 - 3.2.02

Application Number: 03777594.7

Publication Number: 1575656

IPC: A61M31/00, A61K9/22

Language of the proceedings: EN

Title of invention:
Insulin delivery system with sensor

Patent Proprietor:
Becton Dickinson and Company

Opponent:
Medtronic MiniMed, Inc.

Headword:

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - main request and auxiliary requests 1 to 7 (no)

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It can be changed at any time and without notice.

Decisions cited:

Catchword:

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Case Number: T 0684/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 February 2019

Appellant: (Patent Proprietor)	Becton Dickinson and Company One Becton Drive Franklin Lakes, NJ 07417 (US)
Representative:	Whiting, Gary Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Respondent: (Opponent)	Medtronic MiniMed, Inc. 18000 Devonshire Street Northridge, CA 91325-1219 (US)
Representative:	Madgwick, Paul Roland Ruschke Madgwick Seide & Kollegen Postfach 86 06 29 81633 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 January 2014 revoking European patent No. 1575656 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	E. Dufrasne
Members:	S. Böttcher
	P. L. P. Weber

Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision of the Opposition Division, dispatched on 14 January 2014, that European patent No. 1 575 656 be revoked.

II. Opposition was filed against the patent as a whole and based on the grounds for opposition pursuant to Articles 100(a), 100(b) and 100(c) EPC.

III. Notice of appeal was filed by the appellant/proprietor on 24 March 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 26 May 2014.

IV. The parties were summoned to oral proceedings by letter dated 10 December 2018.

V. Oral proceedings took place on 20 February 2019.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request and the auxiliary requests 1 to 7, all filed by letter dated 23 May 2014.

The respondent/opponent requested that the appeal be dismissed.

VI. The following documents are referred to in this decision:

D15: Sorensen, "A physiologic model of glucose metabolism in man and its use to design and assess improved insulin therapies for diabetes", PhD thesis M.I.T. (April 1985)

D17a: Expert Opinion by Marc Breton on European Patent EP 1 575 656, 21 May 2014

VII. Claim 1 of the main request reads as follows:

"A system for controlling the concentration of glucose in a patient, the system comprising:
a delivery device (204) comprising a needle (212) adapted to deliver insulin to the patient intradermally to result in at least one of rapid uptake of said material and rapid clearance of said material; and
a controller (202), adapted to determine the concentration of said glucose in the patient that occurs in response to said insulin delivered to the patient, and to provide an output that is adaptable for use to control the delivery device to control an amount of said insulin delivered to the patient based on the concentration of said glucose,
characterised in that
said controller (202) employs an algorithm to compare a pre-delivery concentration of said glucose present prior to said delivery of said insulin to a target or predicted glucose concentration, to compare a post-delivery concentration of said glucose present after said delivery of said insulin to a target or predicted glucose concentration, and to determine an appropriate insulin dose based on these comparisons."

VIII. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the algorithm is a Model Based Control (MBC) algorithm.

IX. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the algorithm is a Model Predictive Control (MPC) algorithm.

X. Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the following feature has been added at the end of the claim:

"wherein said controller employs a control model that includes a physiologically based model or a data based (empirical) model, and said controller adjusts said model based on the comparison of said post-delivery glucose concentration and said target or predicted glucose concentration."

XI. Auxiliary requests 4 to 7 are based on the main request and auxiliary requests 1 to 3, respectively. Claim 1 of each of these requests further comprises the feature:

"an insulin storage device comprising fast-acting insulin for delivery to said patient;"

XII. The appellant's arguments relevant for the present decision can be summarized as follows:

Main request - Article 83 EPC

The patent disclosed how to build an algorithm as defined in claim 1. Figure 7 showed a curve describing the pharmacokinetics of intradermal insulin delivery which could be combined with the known pharmacodynamics (PD) of insulin in the blood stream to predict future glucose levels resulting from an insulin dose. The PD model known from D15 could be employed in the algorithm.

Paragraph [0048] of the patent described the model predictive controller shown in Figure 6, and how the output of this model predictive controller could be incorporated in the calculation of the control command.

Paragraphs [0049] and [0052] explained how the model predictive controller worked. Paragraph [0052] referred to a physiological model for generating the arterial insulin response curves described in D15. Sample response curves were shown in Figure 7.

Hence, the model predictive controller could be constructed using the physiological model described in D15 and the upper curve of Figure 7.

This was also confirmed by renowned expert in the field Dr Marc Breton in his declaration (D17a). He concluded that the combination of models found in the literature and the response function in Figure 7 would have been sufficient for the person skilled in the art to have made glycemic predictions, and that the mathematical description which he derived from Figure 7 could have been used for instance with the model of D15 in a model based control methodology. Dr Breton was of the opinion that the patent contained sufficient information to elaborate the intradermal pharmacokinetics of insulin and that the person skilled in the art could have carried out the claimed invention based on this information and the common general knowledge in the field.

As to the four combinations of the two comparisons defined in claim 1:

To compare pre- and post-delivery glucose concentrations with a respective target was described in paragraphs [0040] to [0044] of the patent. Likewise, to compare both the pre- and post-delivery concentrations with a predicted value was also disclosed in the patent (paragraphs [0049] and [0052]).

Furthermore, the patent described models for establishing predicted glucose concentrations. The skilled person would have known that sometimes a combination of one comparison with a target and one with a predicted value based on a model would make more sense.

Auxiliary requests 1 and 2 - Article 83 EPC

In claim 1 of these requests the algorithm was specified as a model based or model predictive control algorithm. From the general knowledge and the description of the patent, the skilled person would have known that such controllers were suitable for the sort of multi-variable system defined in the invention and how to implement this kind of algorithm.

XIII. The respondent's arguments are essentially those on which the present decision is based.

Reasons for the Decision

1. The appeal is admissible.

2. The invention relates to a system for controlling the concentration of glucose in a patient. The system comprises a delivery device with a needle adapted to deliver insulin to the patient intradermally and a controller adapted to control the delivery device to control the amount of insulin delivered to the patient. The controller employs an algorithm to compare pre- and post-delivery concentrations of glucose to respective target or predicted glucose concentrations and to determine an appropriate insulin dose based on these

comparisons.

3. Main request - Article 83 EPC

3.1 According to the characterising portion of claim 1, the controller employs an algorithm for determining an insulin dose based on one of four possible embodiments that differ according to the comparisons they use, namely:

Embodiment 1: Both the pre- and post-delivery glucose concentrations are compared to a target.

Embodiments 2 and 3: A pre-delivery glucose concentration is compared with a target and a post-delivery glucose concentration is compared with a predicted value, or vice versa.

Embodiment 4: Both the pre- and post-delivery glucose concentrations are compared to a predicted value.

3.2 At first sight, embodiment 1 appears to be in accordance with the disclosure of paragraphs [0040] to [0044] and Figures 1 and 2 of the patent, as brought forward by the appellant.

Paragraph [0040] states that a reference signal, which indicates the target level, is input into the controller (column 7, lines 32 to 34). Furthermore, a comparison between the sensor signal of a glucose sensor and the reference signal is mentioned in paragraph [0044]. It can also be derived from this paragraph that this (pre-delivery) comparison is used to adjust the amount of insulin to be delivered to the patient (column 8, lines 47 to 56).

However, the claim requires determining an insulin dose based on both the comparison of the pre-delivery glucose concentration with a target and the comparison of a post-delivery glucose concentration with a target.

The cited paragraphs do not include an enabling disclosure of how to implement this. For instance, at what time the post-delivery glucose concentration is measured after the insulin delivery can be assumed to be important for the algorithm since the glucose concentration is expected to change due to the insulin administration. However, the patent does not include any information on the time between insulin delivery and glucose measurements. In addition, it may be expected that the amount of insulin delivered, before and after which the glucose level is measured, plays a role in the algorithm. However, this insulin dose is not mentioned in the patent. It is furthermore not taught whether the pre-delivery target is the same as the post-delivery target and, if not, how they differ.

Thus, the patent does not include sufficient information to carry out embodiment 1 of claim 1.

3.3 The same reasoning applies to embodiments 2 and 3. These embodiments involve a comparison with a target and a comparison with a predicted value to determine an insulin dose. Such embodiments are not described in the patent. Nor would it have been possible for the skilled person to imagine how they could have been carried out.

The appellant referred to paragraph [0070] of the patent which mentions a model predictive control algorithm "to compute an insulin dose which will bring the patient to a target glucose level" (column 15, lines 48 to 54). However, this algorithm relies on

current and past glucose levels (instead of pre- and post-delivery glucose levels) and on insulin doses delivered recently, while taking into account a predicted glucose level (based on a model of the patient's pharmacodynamic response to insulin) and a target.

Hence, this passage does not teach how to determine an insulin dose based on either the pre- or post-delivery glucose level compared with a predicted value and the other compared with a target.

Moreover, the skilled person would not have found any information that would have enabled deciding in which cases to use which pair of comparisons.

3.4 Embodiment 4, in which both the pre- and post-delivery glucose concentrations are compared to a predicted value, is also not sufficiently disclosed.

The appellant referred to paragraph [0049] of the patent. This paragraph describes a model predictive controller for determining an insulin dose based on the current state of the patient (i.e. the pre-delivery glucose concentration) and the model response of the patient (i.e. a predicted post-delivery glucose concentration). Paragraph [0049] further discloses that for each subsequent control step the patient response (i.e. the post-delivery glucose concentration), is compared to the predicted value.

However, this paragraph does not contain any information of how to use the comparison of a pre-delivery glucose concentration and the comparison of a post-delivery glucose concentration to a predicted value in one control step to determine an insulin dose.

The appellant further referred to paragraph [0052] and Figure 7, which supposedly describe how a model can be used to generate the predicted glucose concentration.

In fact, paragraph [0052] relates to the application of a mathematical model for generating insulin response curves. However, it cannot be derived from this passage how the model is used to obtain the predicted glucose values required by the different embodiments of the claim. Figure 7 shows sample response curves indicating the correlation between measured swine data and a model for two different insulin delivery methods, namely, intradermal and subcutaneous insulin delivery. Even when taking into account the text in the boxes of Figure 7, it is not derivable from this figure and its associated text how the model is generated and how the predicted values can be deduced from the model.

3.5 The appellant further referred to the statement of Marc Breton (D17a), who considered the claimed invention to be sufficiently disclosed.

D17a includes a description of a possible way to obtain a prediction function. However, it appears that rather complex considerations and calculations would have been necessary, and that these calculations would have required the skilled person to have made certain assumptions and have selected certain models from the literature. Hence, an undue burden would have been involved in determining the prediction function, in particular since the patent contains only very little information. Moreover, the statement of Mr Breton does not even mention the four embodiments specified in the claim and the respective algorithm. In other words, the declaration does not relate to the question of whether

any of the four embodiments is sufficiently disclosed in the patent.

3.6 Consequently, the patent does not disclose the invention in a manner sufficiently clear and complete for it to have been carried out by the person skilled in the art over each of the four embodiments covered by claim 1 of the main request.

4. Auxiliary requests 1 to 7

Claim 1 of all auxiliary requests also includes the feature that the controller employs an algorithm to compare a pre-delivery concentration of the glucose to a target or predicted glucose concentration, to compare a post-delivery concentration of the glucose to a target or predicted glucose concentration, and to determine an appropriate insulin dose based on these comparisons.

Consequently, for the same reasons applicable to the main request, the objection as to insufficiency of disclosure applies equally to all auxiliary requests.

Even the fact that in claim 1 of auxiliary requests 1, 2, 5 and 6 the algorithm is specified as a model based or model predictive control algorithm, does not help to overcome this objection since the skilled person would still have been faced with an undue burden to select an appropriate model and implement it.

The appellant did not provide any comments on auxiliary requests 3 to 7.

5. Therefore, none of the requests meet the requirements of Article 83 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated