Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 3 November 2022

Case Number: T 1295/18 - 3.2.02

Application Number: 10702137.0

Publication Number: 2393415

IPC: A61B5/00, A61M5/142, G06F19/00

Language of the proceedings: EN

Title of invention:
MEDICAL SYSTEM AND METHOD FOR PROVIDING INFORMATION FOR GLYCEMIC CONTROL

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponent:
Roche Diabetes Care GmbH

Headword:

Relevant legal provisions:
EPC Art. 83
RPBA 2020 Art. 11

Keyword:
Sufficiency of disclosure - enabling disclosure (yes)
Remittal - (yes)

Decisions cited:
T 0684/14, T 0723/10

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1295/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 3 November 2022

Appellant: (Patent Proprietor)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50 65929 Frankfurt am Main (DE)
Representative:	Derry, Paul Stefan Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Respondent: (Opponent)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 March 2018 revoking European patent No. 2393415 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	Y. Podbielski

Summary of Facts and Submissions

I. The patent proprietor filed an appeal against the opposition division's decision to revoke the patent because the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

II. The opposition division held that the invention was not sufficiently disclosed since

- there was no indication in the patent how the five parameters mentioned in claim 1 (specific initial dose value, specific time interval for increasing the dose, specific dose increase step, specific low blood glucose threshold value and specific target blood glucose value) might contribute to the claimed profile, and since

- the influence of the personalisation step on the profile was not disclosed.

III. Oral proceedings before the Board took place on 3 November 2022.

IV. The appellant (patent proprietor) requested that the decision be set aside and that the patent be remitted to the opposition division for further prosecution. In the event that the Board did not decide to remit the case to the opposition division, it was requested that the patent be maintained as granted or that the patent be maintained on the basis of one of auxiliary requests 1.0 to 2.6 filed with letter dated 8 February 2017.

The respondent (opponent) requested that the appeal be

dismissed. In the event that the Board decided that the opposed patent was sufficiently disclosed, the respondent requested that the case be remitted to the opposition division for further prosecution.

V. Claim 1 of the patent as granted reads as follows.

"A method for configuring 4 process for determining a dose of insulin to be administered for glycemic control, wherein the dose is stepwise adapted, the method being characterised by the steps of:

defining different dose adjustment profiles for stepwise adapting the dose, wherein each of the different dose adjustment profiles is based at least on a specific initial dose value,
a specific time interval for increasing the dose, a specific dose increase step and a specific low blood glucose threshold value;
storing the different dose adjustment profiles;
selecting one of the stored different dose adjustment profiles based on specific requirements for stepwise adapting the dose; and
personalising the selected dose adjustment profile by defining at least a specific target blood glucose value for a specific user."

Claim 9 of the patent as granted reads as follows.

"A system for configuring a process for determining a dose of insulin to be administered for glycemic control, wherein the dose is stepwise adapted, the system being characterised by:

defining means (2610) arranged to define different dose adjustment profiles for stepwise adapting the dose,

wherein each of the different dose adjustment profiles is based at least on a specific initial dose value, a specific time interval for increasing the dose, a specific dose increase step and a specific low blood glucose threshold value;
a storing unit (130, 2650) arranged to store the different dose adjustment profiles;
selection means (2620) arranged to select one of the stored different dose adjustment profiles based on specific requirements for stepwise adapting the dose;
personalising means (2630) arranged to personalise the selected dose adjustment profile by defining at least a specific target blood glucose value for a specific user; and
adapting means arranged to stepwise adapt the dose according to the selected dose adjustment profile."

Claim 17 of the patent as granted reads as follows.

"A computer program for configuring a process for determining a dose of insulin to be administered for glycemic control, wherein the dose is stepwise adapted, the computer program being characterised by:

code for defining different dose adjustment profiles for stepwise adapting the dose,
wherein each of the different dose adjustment profiles is based at least on a specific initial dose value, a specific time interval for increasing the dose, a specific dose increase step and a specific low blood glucose threshold value;
code for storing the different dose adjustment profiles;
code for selecting one of the stored different dose adjustment profiles based on specific requirements for stepwise adapting the dose; and

code for personalizing the selected dose adjustment profile by defining at least a specific target blood glucose value for a specific user."

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

D7 Nat Pernick et al., "Personal Computer Programs to Assist with Self-Monitoring of Blood Glucose and Self-Adjustment of Insulin Dosage", Diabetes Care, Vol. 9, No. 1, Jan-Febr. 1986, pp. 61-69

D11 David Rodbard et al., "A data management program to assist with home monitoring of blood glucose and self adjustment of insulin dosage for patients with diabetes mellitus and their physicians", Proc. Annu. Symp. Cumput. Appl. Med. Care, Nov. 1984, pp. 321-324;

D13 Jay Skyler et al., "Algorithms for Adjustment of Insulin Dosage by Patients Who Monitor Blood Glucose", Diabetes Care, Vol., 4, No. 2, March/ April 1981, pp. 311-318

D14 D. M. Nathan et al., "Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy" Diabetes Care, Volume 32 (Number 1), 2009, pp. 193-203

D15 M. Davies et al., (2008). Initiation of insulin glargine therapy in type 2 diabetes subjects suboptimally controlled on oral antidiabetic agents: results from the AT.LANTUS trial. Diabetes, Obesity and Metabolism, Volume 10, pp. 387-399

D16 M. Davies et al., "Improvement of Glycemic Control in Subjects with Poorly Controlled Type 2 Diabetes" Diabetes Care, Volume 28 (Number 6), 2005, pp. 1282-1288

VII. The arguments of the appellant may be summarized as follows.

Dose adjustment profiles for stepwise adapting a dose of insulin to be administered for glycemic control and their definition according to claim 1 were known to the person skilled in the art (D7, D11 and D13). It was self-explanatory that such a dose adjustment profile was based on a "specific initial dose value", a "specific time interval for increasing the dose", a "specific dose increase step" and a "specific low blood glucose threshold value" by specifying these parameters.

It was also self-evident from claim 1 itself how the selected dose adjustment profile was to be personalised, namely, "by defining at least a specific target blood glucose value for a specific user". Hence, if the selected profile did not have a defined target value yet, this value had to be set to any value. In case the profile already included a target blood glucose value, this value had to be adjusted in the personalising step.

Moreover, the patent in its entirety disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Paragraphs [0209] to [0217] of the patent set out examples of how a dose adjustment algorithm (which was equivalent to a profile) was defined and how it was based on the various parameters. It was mentioned that the algorithms were based on templates comprising parameters and parameter sets (paragraph [0210]) defining e.g. a specific initial dose value, a specific first dose increase step, a specific first time interval for increasing the dose, a specific first

target blood glucose value, a specific second dose increase step, a specific second time interval for increasing the dose, a specific second target blood glucose value, a specific low blood glucose threshold value, etc. (paragraph [0212]). Furthermore, the steps for defining a new algorithm were illustrated in Figure 28 and described in paragraphs [0215] to [0217].

Paragraphs [0223] to [0236] of the patent, in combination with Figures 29, 30a and 30b, also disclosed how the parameters were used in an algorithm. Paragraph [0094] further explained that a low blood glucose threshold value was used in an algorithm in the definition of specific actions which were to be taken if the blood glucose value was below this threshold.

As to the step of personalising a profile or algorithm, paragraphs [0089], [0110] and [0112] explained that specific parameters (e.g. the target values) of the selected algorithm could be further specified and/or selected in relation to the needs and requirements of the user of the medical device. Hence, the person skilled in the art was taught that "defining...a target blood glucose value" meant that the target value had to be set or adjusted.

Moreover, it was within the common general knowledge of the person skilled in the art how to define a dose adjustment algorithm in terms of parameters such as those recited in claim 1. Such algorithms were disclosed in documents D14, D15, D16 and D11.

It was not a requirement for the patent to provide an explicit example of an algorithm. Rather, the invention was concerned with allowing a user to set up an algorithm. This was evidenced at least by the preamble

of claim 1 of the patent, which recited "A method for configuring [a] process for determining a dose of insulin to be administered for glycemic control". Specific examples of algorithms were therefore not required.

For these reasons, the invention was sufficiently disclosed to be carried out by the person skilled in the art.

VIII. The arguments of the respondent may be summarized as follows.

Contrary to the requirements of Article 83 EPC, the invention as claimed in claims 1, 9 and 17 was not sufficiently disclosed to be carried out by the person skilled in the art.

First, claim 1 related to a method for configuring a process for determining a dose of insulin to be administered. Hence, the result of the claimed method had to be a dose rather than a profile. However, the patent did not disclose an embodiment determining a dose.

Second, according to claim 1 a specific target blood glucose value had to be defined, not a target range as depicted in Figure 31a. However, the patent did not include any teaching on how the specific target blood glucose value could be accurately achieved by applying the adjustment profile.

Third, the patent did not teach how a selected profile should be personalized by defining a specific blood glucose value, i.e. how an administration profile needed to be changed in order to achieve perfect

glycemic control.

The "personalization procedure" referred to in Figure 9 and in paragraphs [0110] to [0113] only mentioned a target value that had to be entered (paragraph [0112], second sentence). However, there was no teaching how a selected profile had to be changed by defining a target blood glucose value.

Paragraphs [0210], [0212], [0213] and [0217] referred to by the appellant did not even mention a personalization step or a target blood glucose value. Paragraphs [0211] and [0214] to [0216] only mentioned in relation to "personalization" that values could be input by a user. With respect to the target blood glucose value, paragraphs [0223] to [0236] did not provide a teaching how to personalize an administration profile either. Paragraphs [0094] and [0130] did not relate to the target blood glucose value, but to a low blood sugar level.

The patent disclosed in paragraph [0089] that either a predefined algorithm was chosen, or a new algorithm was defined by using a template. Paragraph [0216] also mentioned that a new algorithm was defined by composing one or more templates to a new algorithm. However, claim 1 did not refer to any templates but required the algorithm to be defined based on specific parameters. Hence, the teaching in paragraphs [0209] to [0217] could not be regarded as an enabling disclosure of the invention.

In decisions T 684/14 and T 723/10, also relating to defining algorithms in medical applications, the same board held that the invention was insufficiently disclosed although the algorithms were described with

even more detail than in the present patent.

Moreover, it was not sufficiently disclosed how the step of selecting one of the dose adjustment profiles should be performed. It was not taught which specific requirements mentioned in claim 1 should be taken into account.

The claim wording was not about somehow considering a target blood glucose value. This value should rather be used to personalize a selected profile. However, there was no information on how a target blood glucose value should be used to change a selected algorithm.

Therefore, the opposed patent did not provide a sufficient teaching which could be carried out by the skilled person, contrary to Article 83 EPC.

Reasons for the Decision

1. Summary of the invention

People with diabetes are either deficient in insulin or are unable to make sufficient insulin to overcome underlying insulin resistance or to normalize the glucose metabolism. In order to achieve a better glycemic control or even to regain almost full glycemic control, basal insulin or insulin glargine treatment is used.

In order to get as close as possible to "perfect glycemic control", blood glucose values are monitored once or several times during the day. If the blood glucose value is too high, e.g. over 130 mg/ dl,

insulin or insulin analogues can be administered.

For insulin therapy, long-acting basal insulin or insulin glargine, which are long-acting basal insulin analogues, are used. These insulin or insulin analogues are usually given once daily to help control the blood sugar level of patients with diabetes. The advantage of long-acting basal insulin or insulin glargine is that they have a duration of action of more than 24 hours. Thus, it more closely resembles the basal insulin secretion of the normal pancreatic β-cells.

For good or perfect glycemic control the dose of basal insulin or insulin glargine has to be adjusted for each individual in accordance with a blood glucose level to be achieved. The process of adjusting the dose until a desired result is achieved is known as titration. Usually, the dose of insulin or insulin glargine is increased from an initial dose to a final dose over a certain time period until the specific blood glucose value (typically the fasting blood glucose (FBG) value) has reached the target range.

The present invention relates to a method for configuring a process for determining a dose of insulin to be administered for glycemic control (see claim 1 preamble). This method involves defining different dose adjustment profiles for stepwise adapting the dose, storing the dose adjustment profiles, selecting one of the dose adjustment profiles, and personalising the selected dose adjustment profiles by defining at least a specific target blood glucose value for a specific user.

2. Sufficiency of disclosure

Claim 1 relates to a method for configuring a process for determining a dose of insulin to be administered for glycemic control. Hence, contrary to the respondent's view, the result of the claimed method is not a specific dose of insulin to be administered. The claimed method rather accounts for instructions of how to stepwise adapt a dose of insulin. These instructions are represented by a dose adjustment profile in which a specific initial dose value, a time interval for increasing the dose, a dose increase step, and a specific low blood glucose threshold value are defined.

It is undisputed that the person skilled in the art knows how to realise such profiles (see respondent's letter of 27 November 2018, page 2, second paragraph). Examples of such profiles and of the algorithms used to produce them are given in D14 and D15. As can be seen from Figure 1 of D14, the algorithm starts with an initial dose of insulin, which can be 10 units. As an example, the dose is then increased by 2 units (specific dose increase step) every 3 days (specific time interval for increasing the dose) until fasting blood glucose levels are consistently in a target range (i.e. below a specific target blood glucose value). However, if the measured fasting level falls below 3.9 mmol/l (specific low blood glucose value) then the bedtime dose is reduced. Hence, this algorithm is based on the parameters mentioned in claim 1.

Table 1 on page 389 of D15 shows two different treatment titration algorithms for insulin glargine. The table shows an initial dose value ("Starting dose") of 10 U/day for algorithm 1 and 12 U/day for algorithm 2, a dose increase step ("Increase in daily basal insulin glargine dose (U)"), a time interval for increasing the dose ("titration every 3 days") for

algorithm 2, a target blood glucose value ("Target FBG 100 mg/dl"), and a low blood glucose threshold value ("titration occurred only in the absence of blood glucose levels <72 mg/dl").

Furthermore, a procedure for defining a new algorithm including the parameters required by claim 1 is described in paragraphs [0209] to [0217] of the patent in suit. This procedure includes the selection of templates to which the specific parameters or parameter sets have to be assigned (paragraph [0216], Figures 27 and 28). The Board agrees with the appellant that the patent does not have to provide an explicit example of an algorithm. It is rather sufficient that at least one way of establishing an algorithm is described.

The respondent alleged that claim 1 did not cover the definition of a profile which was composed of templates. The Board does not concur with this view. Claim 1 also covers profiles in which the specific parameters are assigned to templates as described in paragraphs [0209] and [0216]; the use of templates does not render the teaching insufficient.

Paragraphs [0219] to [0221] describe how the defined algorithms correspond to specific types of users and other boundary conditions. Hence, the person skilled in the art is taught which specific requirements are to be considered by the authorised person when selecting one of the stored dose adjustment profiles.

As described in paragraphs [0110] to [0112], a selected profile can be personalised by adjusting the target blood glucose value, i.e. the value that should be aimed at when administering the insulin dose. Hence, in case that the selected profile already includes a

defined target value (as in the profiles of D14 and D15), the personalising step of claim 1 merely requires that this target value is amended according to the needs of a specific patient. In case the target value is not yet defined in the selected profile, the personalising step consists of setting this target value to any value by the authorised person.

Hence, it can be derived from the patent that the selected dose adjustment profile is personalised by setting or amending the target blood glucose value. No further amendment of the selected profile is required by claim 1. The person skilled in the art would have no problem to define a target value and adjust the profile accordingly and thus to carry out the invention as claimed.

Contrary to the respondent's view the invention is sufficiently disclosed although it requires the definition of an exact target value and not a target range as shown in Figure 31a. It is within the technical knowledge of the person skilled in the art to define a target range in a control routine based on a target value.

The decisions T 684/14 and T 723/10 referred to by the respondent are not pertinent to the present case since they relate to algorithms which are insufficiently disclosed because they are based on unknown parameters. On the contrary, in the present invention, the algorithm is defined by selecting values for specific parameters.

3. Hence, the ground of opposition under Article 100(b) EPC does not prejudice the maintenance of the patent according to the main request.

The Board notes that also the other grounds for opposition under Articles 100(a) and 100(c) EPC were raised in opposition and that none of them was decided upon by the Opposition Division. Thus, according to the requests of both parties, the Board remits the case to the Opposition Division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division for further prosecution.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated