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Datasheet for the decision of 20 April 2026

Case Number: T 0811/24 - 3.2.02

Application Number: 10702133.9

Publication Number: 2393412

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

Language of the proceedings: EN

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

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponent:
Roche Diabetes Care GmbH

Relevant legal provisions:
EPC Art. 54, 56, 83

Keyword:
Sufficiency of disclosure - main request (yes)
Novelty - main request (yes)
Inventive step - main request (yes)

Decisions cited:
T 0862/20

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Case Number: T 0811/24 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 April 2026

Appellant: (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)
Respondent: (Patent Proprietor)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50 65929 Frankfurt am Main (DE)
Representative:	Colonna, Matthew Oliver Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 12 April 2024 concerning maintenance of the European Patent No. 2393412 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. This appeal was filed by the opponent against the opposition division's interlocutory decision posted/ electronically transmitted on 12 April 2024 finding that the contested patent as amended on the basis of the patent proprietor's main request filed on 12 January 2024 complied with the requirements of the EPC ("the decision under appeal").

II. In the decision under appeal, the opposition division held that the invention as claimed in the main request was sufficiently disclosed, and that the subject-matter of claim 1 of that request was novel over D3 and involved an inventive step starting from either D3 or D2, even when considering D11 and D12.

D2, D3, D11 and D12 are the following documents:

D2 WO 2009/001349 A1

D3 WO 2007/000427 A1

D11 D. Nathan *et al.*, "Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes", Diabetes Care 32(1), 2009, 193-203

D12 M. Davies *et al.*, "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 10, 2008, 387-399

The decision under appeal was taken after the Board had set aside an earlier decision of the opposition division revoking the patent, and remitted the case to the opposition division for further prosecution, following an earlier appeal by the patent proprietor, dealt with as T 862/20.

III. The parties' requests on appeal were as follows.

The **appellant (opponent)** requested that the decision under appeal be set aside and that the patent be revoked.

The **respondent (patent proprietor)** requested that the appeal be dismissed and that the patent be maintained as amended on the basis of the main request, or, if the decision under appeal were to be set aside, that the patent be maintained on the basis of one of auxiliary requests 1 to 17 filed with its reply to the appellant's statement of grounds of appeal.

IV. Oral proceedings before the Board were held on 20 April 2026, at the end of which the present decision was announced.

V. The independent claims of the **main request**, claims 1, 8, 13 and 14, read as follows:

Claim 1:

"*Medical device for providing information for glycemic control, namely a dose of insulin to be set, the device (100) comprising:*

storage means (130) arranged to store data comprising profile parameters for different dose adjustment

profiles each comprising 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;

receiving means (120) arranged to receive blood glucose value data and security data;

data processing means (140, 1710) arranged

to execute a first processing function for adjusting profile parameters for a selected dose adjustment profile, and

to execute a second processing function for stepwise adapting the dose of insulin based at least on the selected dose adjustment profile and thereby determining the value for the dose of insulin to be set based on the received blood glucose value data;

validating means (140, 1720) arranged to validate the received security data and to provide validation data corresponding to the validation of the received security data; and

safety means (140, 1730) arranged to unlock at least a predetermined function out of the first and second processing functions for execution based on the validation data."

Claim 8:

"*Computer-implemented method for providing information for glycemic control, namely a dose of insulin to be set, the method comprising the steps of:*

receiving security data;

validating the received security data;

providing validation data corresponding to the validation of the received security data;

and unlocking at least a predetermined function out of at least one first and at least one second processing function for execution based on the validation data,

wherein the at least one first processing function is for adjusting profile parameters for a selected dose adjustment profile, and

the at least one the second processing function is for stepwise adapting the dose of insulin based at least on the selected dose adjustment profile and thereby determining the value for the dose of insulin to be set based on received blood glucose value data,

wherein the profile parameters for each different dose adjustment profile comprise a specific initial dose value, a specific time interval for increasing the dose, a specific dose increase step and a low blood glucose threshold value."

Claim 13:

"*A computer program for providing information for glycemic control, namely a dose of insulin to be set, the computer program comprising:*

code for receiving security data;

code for validating the received security data;

code for providing validation data corresponding to the validation of the received security data; and

code for controlling unlocking of at least a predetermined function out of at least one first and at least one second processing function for execution based on the validation data,

wherein the at least one first processing function is for adjusting profile parameters for a selected dose adjustment profile, and

the at least one the second processing function for stepwise adapting the dose of insulin based at least on the selected dose adjustment profile and thereby determining the value for the dose of insulin to be set based on received blood glucose value data,

wherein the profile parameters for each different dose adjustment profile comprise a specific initial dose value, a specific time interval for increasing the dose, a specific dose increase step and a low blood glucose threshold value."

Claim 14:

"*A computer program product comprising a computer-readable medium bearing computer program code embodied therein for use with a computer, wherein the computer program code comprises the computer program according to claim 13.*"

In the following, the claims referred to are those of the main request.

VI. The **appellant's arguments** relevant for the present decision can be summarised as follows.

Sufficiency of disclosure

The invention as claimed in the main request was not sufficiently disclosed. The claims encompassed a situation in which only the first processing function, and not the second processing function, was unlocked for execution. In such a situation, information for glycemic control still had to be provided, since this was the purpose of the claimed device and method as stated in the opening lines of the independent claims.

As put forward at the oral proceedings before the Board, this applied in particular to the method of claim 8 since, in line with the established interpretation of the term "for" in the expression "method for", providing information for glycemic control formed an integral part of the claimed method.

However, the contested patent did not disclose how such information could be provided when only the first processing function was unlocked, i.e. without executing the second processing function.

Novelty in view of D3

The subject-matter of claim 1 was not novel in view of D3.

D3 disclosed that a plurality of infusion profiles were stored in the device, such as the basal profiles disclosed in Figures 15 to 18. These profiles could be regarded as dose adjustment profiles.

D3 further disclosed that user data including a blood glucose target and personal limits were entered by a user immediately before the basal profile was edited (see the lower part of Figure 30A showing steps y.2.1, y.2.4 and y.3). This at least implicitly anticipated a specific low blood glucose threshold value as part of the profile.

Therefore, D3 disclosed profile parameters for different dose adjustment profiles each comprising a specific low blood glucose threshold value.

Moreover, the wording of claim 1 required neither that the specific low blood glucose threshold value be different for each dose adjustment profile, nor that a specific low blood glucose threshold value be stored separately for each profile. Thus, claim 1 encompassed the case of a specific low blood glucose threshold value stored once in the device and applicable to all dose adjustment profiles. Thus, the blood glucose data entered in steps y.2.1 and y.2.4 as part of the user data were in any event novelty-destroying since they applied to all dose adjustment profiles.

A similar objection applied to the further independent claims.

Inventive step starting from D3

In any case, the subject-matter of claim 1 lacked an inventive step starting from D3, either considered alone or in combination with the common general knowledge, for example as reflected in D11 or D12.

D3 already disclosed that many relevant parameters of the dose adjustment profiles could be edited by the

user. In view of this, the person skilled in the art starting from D3 and faced with the technical problem of further personalising the dose adjustment profiles would have found it obvious to add a specific low blood glucose threshold value to the list of editable parameters of each dose adjustment profile.

This was further supported by the common general knowledge, as exemplified by D11 and D12. The different low blood glucose threshold values disclosed in these documents suggested that there was no consensus on a precise specific low blood glucose threshold value to be used, and that this threshold value had to be adapted to the patient at hand, thereby suggesting to add a specific low blood glucose threshold value to the list of editable parameters of each profile.

Hence, the person skilled in the art starting from D3 would have arrived at the subject-matter of claim 1 without inventive skill.

In a further line of argument, the appellant reiterated that claim 1 covered a situation in which the specific low blood glucose threshold value was the same for all profiles. In that case, storing this value separately in each profile had no technical effect; rather, it amounted to a degraded version of the disclosure of D3. It followed that claim 1 was at least not inventive over its whole scope.

The same reasoning applied to the further independent claims.

Inventive step starting from D2

The subject-matter of claim 1, which differed from D2 by the same distinguishing feature as from D3, also lacked an inventive step starting from D2.

D2 disclosed controlling the delivery of insulin by an insulin infusion device in accordance with one of a plurality of profiles, or "basal infusion patterns", stored in a storage unit of the device (see Figure 2 and page 15, lines 12-13). These patterns constituted dose adjustment profiles.

D2 further disclosed evaluating the suitability of the various profiles "based on data representative of deviations of a user's glucose level from a target zone" (page 12, lines 11-13) or based on "deviations from the blood glucose (BG) target zone" (page 17, line 9). This constituted a motivation to tailor the target zone to individual users and to include it in the set of editable parameters. Since the lower limit of the target zone constituted a low blood glucose threshold value, this would have motivated the person skilled in the art starting from D2 and faced with the problem of further personalising the dose adjustment profiles of D2 to implement a (specific) low blood glucose threshold value as an additional editable parameter for each profile.

Moreover, for the same reasons as discussed for the inventive-step objection starting from D3, the common general knowledge, as reflected for example by D11 and D12, would have likewise provided such motivation.

The person skilled in the art starting from D2 would therefore have arrived at the subject-matter of claim 1 without inventive skill. A similar objection applied to the further independent claims.

VII. The **respondent's arguments** relevant for the present decision can be summarised as follows.

Sufficiency of disclosure

The invention as claimed in the main request was sufficiently disclosed. Information for glycemic control, namely a dose of insulin to be set, was provided by the claimed device and method only when the second processing function was unlocked and executed.

Novelty in view of D3

The subject-matter of claims 1, 8, 13 and 14 was novel in view of D3. D3 failed to disclose that each of the different dose adjustment profiles comprised a specific low blood glucose threshold value.

Inventive step starting from D3

The subject-matter of claim 1 involved an inventive step starting from D3. Similar considerations applied to the further independent claims.

The distinguishing feature that each of the different dose adjustment profiles was provided with a specific low blood glucose threshold value solved the technical problem of providing an improved medical device for safe and personalised titration of insulin.

Starting from D3, the person skilled in the art would have had no motivation to implement such a feature, even when considering D11 and D12. In fact, the disclosure in D12 of a single specific low blood glucose threshold value of 72 mg/dl applicable to two

different algorithms pointed away from providing each dose adjustment profile with its own specific low blood glucose threshold value.

Inventive step starting from D2

The subject-matter of claim 1 likewise involved an inventive step starting from D2, for essentially the same reasons as for the objection based on D3. The same applied to the other independent claims.

Reasons for the Decision

1. Subject-matter of the contested patent

1.1 The contested patent relates to a medical device for providing information for glycemic control, namely a dose of insulin to be set (claim 1), and to a corresponding method (claim 8), computer program (claim 13) and computer program product (claim 14).

1.2 The device is intended to assist a user in achieving good glycemic control, which usually requires increasing the insulin dose from an initial dose to a final dose over a certain period of time until a specific blood glucose value, typically the fasting blood glucose (FBG) value, has reached a target range (see paragraphs [0005] to [0007]). This process of adjusting the dose until a desired result is achieved is known as titration.

1.3 For this purpose, as defined in the claims, profile parameters for different dose adjustment profiles, each comprising 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, are stored in the device.

According to the description (see paragraphs [0007], [0095] to [0098] and [0131]), a specific low blood glucose threshold value is a threshold value against which a blood glucose value measured for the patient, such as the FBG value, is compared. Its purpose is to take account of low blood glucose values when determining whether the insulin dose should be increased as part of the titration process, since increasing the insulin dose when the patient already has a low blood glucose value may increase the risk of hypoglycemic events. Hence, if the patient's blood glucose value is below this specific low blood glucose threshold value, specific rules, also referred to as "low FBG rules" or "hypoglycemic rules", may be applied. These rules may result, for example, in the insulin dose to be administered not being increased for the time being. This specific low blood glucose threshold value can typically be set at around 70 mg/dl or below (see paragraphs [0095] to [0097]).

According to the claims, a specific low blood glucose threshold value is stored as part of each of the different dose adjustment profiles (see paragraphs [0032], [0033] and [0036] to [0038]).

1.4 Furthermore, the device comprises data processing means arranged to execute:
- a first processing function for adjusting profile parameters for a selected dose adjustment profile, and
- a second processing function for stepwise adapting the insulin dose based at least on the selected dose adjustment profile and thereby determining the value

for the insulin dose to be set based on received blood glucose value data.

In order to prevent an unauthorised person from modifying the device, in particular by modifying the dose adjustment profiles, or using it in a manner which could be harmful to the user, the device is configured to allow the execution of at least one predetermined function out of the first and second processing functions only after successful validation of security data, such as an activation key or a password (see paragraphs [0157] and [0192] to [0193]). To this end, the device further comprises validating means arranged to validate received security data and to provide validation data corresponding to the validation of the received security data, and safety means arranged to unlock at least one predetermined function of the first and second processing functions for execution based on the validation data.

2. Sufficiency of disclosure

2.1 The Board agrees with the respondent that the contested patent discloses the invention as claimed in the main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2.2 The appellant argued that in a situation in which only the first processing function, and not the second processing function, was unlocked for execution - which is encompassed by the claims, as is common ground - information for glycemic control was still provided, since this was the purpose of the claimed device and method, as stated in the opening lines of the independent claims. As submitted by the appellant at the oral proceedings before the Board, this was in

particular the case for the method of claim 8 since, in line with the established interpretation of the term "for" in the expression "method for", providing information for glycemic control formed an integral part of the method. However, the appellant contended, the patent failed to disclose how such information could be provided when only the first processing function was unlocked, i.e. without executing the second processing function.

2.3 This is not convincing.

As already set out in T 862/20, Reasons 6.4, the person skilled in the art understands that information for glycemic control, namely a dose of insulin to be set, is provided by the claimed device and method only after successful validation of received security data and unlocking of the second processing function. In such a case, an insulin dose is determined by executing the second processing function. When only the first processing function is unlocked, the device or method may allow adjustment of profile parameters by executing the first processing function, but it does not provide information for glycemic control in the sense of determining a dose of insulin to be set.

Contrary to the appellant's view, this applies even if the wording "for providing information for glycemic control" requires the method of claim 8 to provide such information. Indeed, this wording does not require that such information be provided irrespective of whether the second processing function by which it is determined has been unlocked. Rather, the provision of this information by executing the second processing function is conditional upon the second processing

function being unlocked for execution based on the validation data.

Therefore, contrary to the appellant's argument, the claimed invention does not encompass any situation in which information for glycemic control, namely a dose of insulin to be set, is provided otherwise than by executing the second processing function. The invention as claimed in the main request is thus sufficiently disclosed.

3. Main request - novelty in view of D3

3.1 The Board agrees with the respondent that the subject-matter of claims 1, 8, 13 and 14 is novel in view of D3.

3.2 D3 discloses controlling a drug delivery system in accordance with a drug infusion profile, or basal profile, which specifies the infusion rate over time at which the drug, such as insulin, is to be delivered (see page 14, first paragraph; page 17, line 10). The appellant referred in particular to the (weekly and daily) basal profiles shown in Figures 15 to 18 (see, for example, Figure 15 reproduced below).

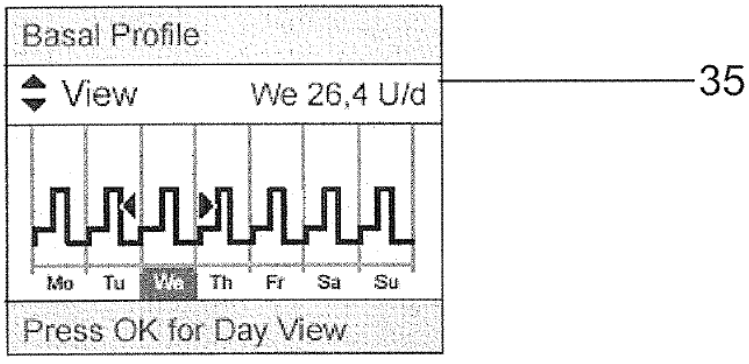

Fig. 15

3.3 Even if, to the appellant's benefit, such basal profiles are regarded as dose adjustment profiles, D3 does not directly and unambiguously disclose profile parameters for different dose adjustment profiles each comprising a specific low blood glucose threshold value, as required by claim 1.

3.4 The appellant relied in this respect on the lower part of Figure 30A of D3, reproduced below.

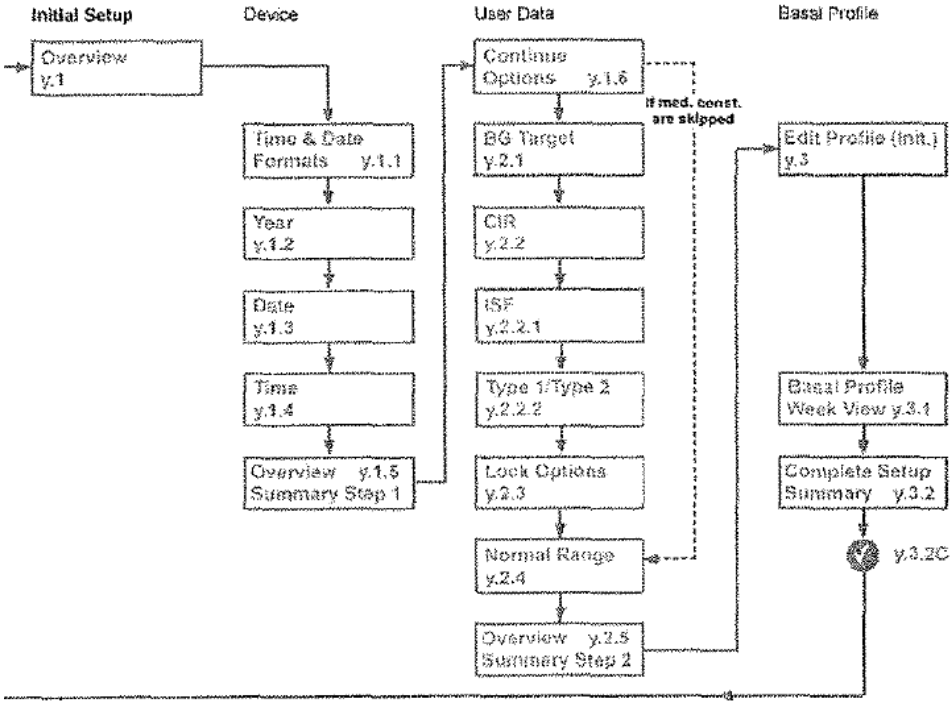

Fig. 30A

This figure discloses that a blood glucose target (see "BG Target" in step y.2.1), and what the appellant referred to as personal limits (see "Normal Range" in step y.2.4), are entered in the device as part of user data before a basal profile is edited (see "Edit Profile" in step y.3 in the right column "Basal Profile").

According to the appellant, the blood glucose data entered in steps y.2.1 and y.2.4 included what could be regarded as a specific low blood glucose threshold value. Moreover, since the basal profile was edited immediately after entering the user data (see the arrow linking the columns "User Data" and "Basal Profile"), this blood glucose value became part of the basal profile itself. Accordingly, this at least implicitly anticipated a specific low blood glucose threshold value as part of the basal profile.

This is not convincing. The lower part of Figure 30A discloses, at most, that certain user data are entered in the device, before a basal profile is then edited separately. Contrary to the appellant's argument, this time sequence does not make the user data become part of the basal profile edited subsequently. This holds irrespective of whether the edited basal profile is regarded as a weekly profile as a whole or as comprising a plurality of daily profiles. Claim 1 requires that each dose adjustment profile stored in the device comprises, among other features, a specific low blood glucose threshold value, i.e. that each dose adjustment profile is provided with its own specific low blood glucose threshold value assigned to it. As submitted by the respondent, there is no direct and unambiguous disclosure of such a feature in D3, neither for the basal profile to be edited in accordance with the lower part of Figure 30A, nor, more generally, for any basal profile disclosed in D3.

3.5 The appellant further argued that the wording of claim 1 required neither that the specific low blood glucose threshold value be different for each dose adjustment profile, nor that a specific low blood

glucose threshold value be stored separately for each profile. Thus, according to the appellant, a specific low blood glucose threshold value entered once in the device and applicable to all dose adjustment profiles, as was the blood glucose data entered in steps y.2.1 and y.2.4 in D3, was in any event novelty-destroying.

This argument is also not persuasive. Claim 1 requires, as stated above, that each of these dose adjustment profiles is provided with its own specific low blood glucose threshold value assigned to it. While the Board agrees with the appellant that the specific low blood glucose threshold values of the various dose adjustment profiles stored in the device need not be different, claim 1 still allows them to differ. Therefore, a threshold value entered once as general user data and merely applicable to all profiles, which would not allow this possibility, does not directly and unambiguously disclose this feature.

3.6 At least for these reasons, the subject-matter of claim 1 is novel in view of D3.

3.7 This reasoning applies correspondingly to independent claims 8, 13 and 14, the subject-matter of which is therefore also novel in view of D3.

4. Main request - inventive step starting from D3

4.1 The appellant further contended that, if the feature that each of the different dose adjustment profiles comprises a specific low blood glucose threshold value were to be found novel in view of D3, it would not, in any case, render the subject-matter of claim 1 inventive starting from D3, either considered alone or

in combination with the common general knowledge. The same applied to the further independent claims.

The Board disagrees and concurs with the respondent that the subject-matter of claims 1, 8, 13 and 14 involves an inventive step starting from D3, even when considering D11 and D12.

4.2 In a first line of argument, the appellant formulated the objective technical problem to be solved by this distinguishing feature as being to further personalise the dose adjustment profiles.

The appellant then argued that the person skilled in the art starting from D3 and faced with this technical problem would have found it obvious, already in view of D3 alone, to add the specific low blood glucose threshold value to the list of editable parameters of each dose adjustment profile, since D3 already disclosed that many relevant parameters of the dose adjustment profiles could be edited by the user.

According to the appellant, this modification was also supported by the common general knowledge, as exemplified by D11 and D12. Indeed, the different low blood glucose threshold values disclosed in these documents (70 mg/dl in Figure 1 of D11; 72 mg/dl in the legend of Table 1 of D12) showed that there was no consensus on a precise specific low blood glucose threshold value to be used and that this threshold value had instead to be adapted to the patient at hand (see D11, page 194, middle column, "for every patient").

Even when accepting this formulation of the objective technical problem, the appellant's argument is not persuasive.

D3 itself does not suggest that the editing of the basal profile in step y.3 may include an additional specific low blood glucose threshold value associated with the profile. Furthermore, the fact that D11 and D12 may suggest that different specific low blood glucose threshold values may be used in different clinical contexts at most supports the idea of allowing a user to edit a specific low blood glucose threshold value, for example adapted to the patient at hand. This could lead the person skilled in the art to add such a specific low blood glucose threshold value to the list of editable parameters which are edited as part of the user data in accordance with the lower part of Figure 30A, column "User Data".

However, claim 1 does not merely require that a specific low blood glucose threshold value be stored in the device and edited. Rather, it requires that each of the different dose adjustment profiles stored in the device be provided with its own specific low blood glucose threshold value. Contrary to the appellant's argument, neither D3 alone nor the common general knowledge as exemplified by D11 and D12 would have prompted the person skilled in the art to implement this feature in the device of D3.

As argued by the respondent, the disclosure in D12 of a single specific low blood glucose threshold value of 72 mg/dl applicable to two different algorithms (see Table 1) in fact teaches away from providing each dose adjustment profile with its own specific low blood glucose threshold value.

4.3 In a further line of argument, the appellant reiterated that claim 1 covered a situation in which the specific low blood glucose threshold value was the same for all profiles, and argued that in such a case, storing this value separately in each profile had no technical effect and in fact amounted to a degraded version of the disclosure of D3. It followed, according to the appellant, that claim 1 was at least not inventive over its whole scope.

This argument is also not persuasive. It incorrectly conflates the possibility of selecting the same specific low blood glucose threshold value for several or all dose adjustment profiles - a situation admittedly covered by claim 1 - with the absence of profile-specific parameters. However, this possibility is merely a possible concrete realisation of the distinguishing feature that each dose adjustment profile comprises a specific low blood glucose threshold value as one of its profile parameters. In the situation referred to by the appellant, the same threshold value would, under the claim, still be provided as a profile parameter of each dose adjustment profile. This possibility does not prevent the distinguishing feature from generally allowing increased personalisation, as put forward by the appellant in the first line of argument.

4.4 Therefore, the person skilled in the art starting from D3 would not have arrived at the subject-matter of claim 1 in an obvious manner, and without hindsight, either on the basis of D3 alone or in combination with the common general knowledge as exemplified by D11 and D12.

4.5 This reasoning applies correspondingly to the further independent claims.

5. Main request - inventive step starting from D2

5.1 The Board agrees with the respondent that the subject-matter of claims 1, 8, 13 and 14 involves an inventive step starting from D2, even in view of the common general knowledge exemplified by D11 and D12.

5.2 At the oral proceedings before the Board, the parties recognised that the issue of inventive step starting from D2 raised considerations similar to those discussed for the objection starting from D3. They did not provide any further comments on this issue but referred to their written submissions. Therefore, the Board saw no reason to deviate from its preliminary opinion set out in point 5 of its communication under Article 15(1) RPBA, which is reiterated below.

5.3 D2 discloses controlling the delivery of insulin by an insulin infusion device in accordance with one of a plurality of profiles, or "basal infusion patterns", stored in a storage unit of the device (see page 15, lines 12-13). Figure 2, reproduced below, shows several examples of such profiles, each representing changes in infusion rate from an average basal rate as a function of time.

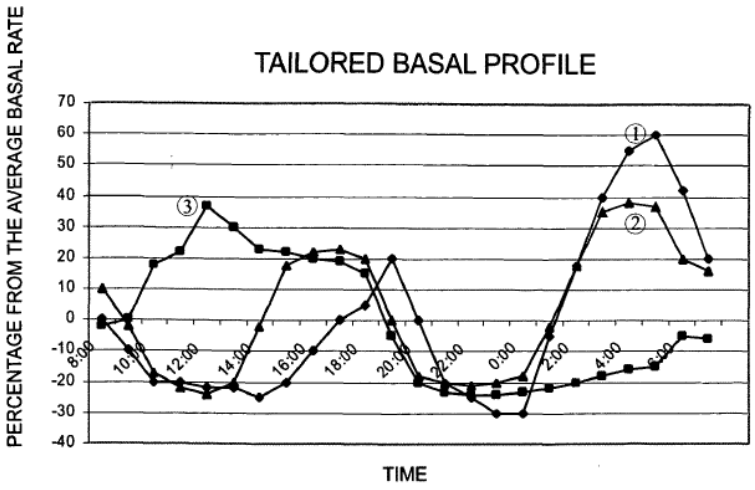

FIG. 2

5.4 Even if, to the appellant's benefit, such profiles are regarded as dose adjustment profiles, it is common ground that D2, like D3, does not disclose profiles each comprising a specific low blood glucose threshold value, as required by claim 1.

5.5 The appellant pointed out that D2 disclosed evaluating the suitability of the various profiles "based on data representative of deviations of a user's glucose level from a target zone" (page 12, lines 11-13) or based on "deviations from the blood glucose (BG) target zone" (see page 17, line 9). According to the appellant, this constituted a motivation to tailor the target zone to individual users and to include it in the set of editable parameters. Since the lower limit of the target zone constituted a low blood glucose threshold value, this would have led the person skilled in the art starting from D2 and faced with the problem of further personalising the dose adjustment profile of D2 to implement a specific low blood glucose threshold value as a parameter for each profile.

5.6 This is not persuasive, essentially for the same reasons as discussed above for the inventive-step objection starting from D3. Nothing in D2 suggests providing each of the infusion profiles or patterns with its own low blood glucose threshold value. This is all the more so if this threshold value is used in the way discussed by the appellant to evaluate the suitability of the various profiles, which seems rather to rely on comparing profiles against a common reference value, such as the lower boundary of the blood glucose target zone on the basis of which the evaluation is carried out.

As set out above in relation to D3, D11 and D12 do not provide such a motivation either.

Therefore, for this reason alone, the person skilled in the art starting from D2 would not have arrived at the subject-matter of claim 1 in an obvious manner and without hindsight.

5.7 This reasoning applies correspondingly to the further independent claims.

6. Conclusion

It follows from the foregoing that none of the appellant's objections prejudices the maintenance of the contested patent on the basis of the main request, i.e. in the form found allowable by the opposition division in the decision under appeal. The appeal is therefore to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated