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Datasheet for the decision of 29 January 2026

Case Number: T 0339/24 - 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. 52(2)(c), 54, 56

Keyword:
Main request - method for performing mental acts (yes)
Novelty - auxiliary request (yes)
Inventive step - auxiliary request (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0339/24 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 29 January 2026

Appellant: (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)
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)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 January 2024 concerning maintenance of the European Patent No. 2393415 in amended form.**

Composition of the Board:

Chairman	A. Martinez Möller
Members:	S. Böttcher
	Y. Podbielski

Summary of Facts and Submissions

I. Both the opponent and the patent proprietor filed an appeal against the interlocutory decision of the opposition division sent on 2 January 2024 that the patent could be maintained on the basis of auxiliary request 10 filed on 14 September 2023.

II. Oral proceedings before the Board took place on 29 January 2026.

III. The appellant-patent proprietor requested that the decision be set aside and that the patent be maintained as granted or on the basis of one of auxiliary requests 1 to 14 filed with the statement of grounds of appeal.

The appellant-opponent requested that the decision be set aside and that the patent be revoked.

IV. This decision refers to the following documents.

D2 WO 2009/001349 A1
D3 WO 2007/000427 A1
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., "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, Vol. 10, 2008, pp. 387-399

V. Claim 1 of the patent as granted (main request) 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 main request 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 main request 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. Claims 1, 9 and 17 of auxiliary request 1 are identical to the claims above, except that the beginning of claim 1 is amended as follows.

"A computer-implemented method for configuring (...)"

VII. The appellant-patent proprietor's arguments may be summarised as follows.

Main request - method of performing a mental act

A method for "configuring a process for determining a dose" as recited in claim 1 could not be carried out exclusively as a mental act. It was rather a technical process that had to be carried out by technical means, i.e. by a computer. Further, the steps of "defining", "storing", "adapting" and "personalising" were technically implemented steps. In particular, the step of "storing the different dose adjustment profiles" manifested itself physically outside the human brain.

Hence, claim 1 did not relate to a method of performing a mental act and was therefore not excluded from patentability (Article 52(2)(c) EPC).

Auxiliary request 1 - novelty in view of D2

D2 failed to disclose the feature of "wherein each of the different dose adjustment profiles is based at least on […] a specific low blood glucose value".

D2 did not disclose that the personalisation of the selected profile was done by defining a user specific target blood glucose value.

Hence, the subject-matter of claim 1 of auxiliary request 1 was novel in view of D2.

Auxiliary request 1 - novelty in view of D3

D3 disclosed "a user input device for programming a parameter profile for a drug delivery system" (page 2, lines 33-34).

The lower part of Figure 30A of D3 merely showed a box containing the expression "BG Target y.2.1". There was no disclosure in Figure 30A or elsewhere in D3 of this being a specific target blood glucose value used to personalise a selected dose adjustment profile. Indeed, if the lower half of Fig. 30A showed that a blood glucose target could be set, it would appear from Fig. 30A that such a blood glucose target was set during an "initial setup".

Contrary to the opposition division's view, the feature of "wherein each of the different dose adjustment profiles is based at least on (...) a specific low blood glucose threshold value" was not implicitly disclosed in D3. The vague reference on page 12, lines 15-16 to "entering personal limits" left it open to which limits they referred. There was no disclosure in D3 that the BG thresholds referred or were part of the dose adjustment profiles identified by the opponent.

Hence, the subject-matter of claim 1 of auxiliary request 1 was novel in view of D3.

Auxiliary request 1 - inventive step in view of D2

The distinguishing features had the technical effect of allowing for the dose adjustment profiles to be better tailored to an individual user.

The problem to be solved by the present invention might be defined as to provide a method for configuring a

process for determining a dose of insulin to be administered for glycemic control leading to a better controlled and well-defined result.

The common general knowledge exemplified by D14 and D15 would not have prompted the person skilled in the art to modify the method disclosed in D2 to incorporate "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 low blood glucose threshold value".

Thus, the subject-matter of claim 1 was inventive in view of D2.

Auxiliary request 1 - inventive step in view of D3

The technical effect resulting from the distinguishing features resided in a more controlled and well-defined diabetes therapy.

The problem to be solved by the present invention might thus be defined as to provide a method for configuring a process for determining a dose of insulin to be administered for glycemic control leading to a better controlled and well-defined result.

The common general knowledge would not prompt the person skilled in the art to add the lower BG threshold to the dose adjustment profile of the device of D3. D3 also did not suggest to personalize the profile after it had been selected.

Hence, the subject-matter of claim 1 involved an inventive step in view of D3.

VIII. The appellant-opponent's arguments may be summarised as follows.

Main request - method of performing a mental act

Claim 1 related to a method of performing mental acts. All method steps could be carried out by a human being without using a computer/processor. In particular, the different dose adjustment profiles could be memorized, and all defining/selecting and personalizing steps could be performed by a human brain.

"Configuring a process" merely meant that the user decided using his/her brain which steps were to be performed. This could be performed without any technical means.

Hence, claim 1 was excluded from patentability under Article 52(2)(c) EPC.

Auxiliary request 1 - novelty in view of D2

D2 also disclosed the feature "the selected profile is personalized by defining a user specific target blood glucose value" as the existence of a blood glucose level target zone (mentioned on page 12, lines 10 to 16) inherently required that a target value had been set or amended. D2 even mentioned that the evaluation of the suitability might be based on data representative of "a user's hemoglobin A1C levels", meaning that the evaluation was done based on user specific blood glucose target levels.

D2 also disclosed the feature that each of the patterns was based on a specific low blood glucose value. The lower value of the target zone could be regarded as the

specific low blood glucose value. Claim 1 did not require that the specific low blood glucose value had to be different for each profile.

Therefore, the subject-matter of claim 1 lacked novelty in view of D2.

Auxiliary request 1 - novelty in view of D3

The basal profile disclosed in Figures 15 to 18 could be regarded as a dose adjustment profile for adapting a dose.

It was mentioned on page 12, lines 15 to 17, that personal limits of the user could be entered in the system. This implied that the profile was personalized by defining a specific target blood glucose value.

The top right of the lower part of Figure 30A referred to the "Basal Profile". From the box below that label it was apparent that the basal profile was the one which could be edited after the user data was entered. Such user data included blood glucose target and personal limits and therefore at least implicitly anticipated a specific low blood glucose threshold value as part of the profile. Furthermore, Figure 31A disclosed that the blood glucose target could be edited or redefined.

Hence, the subject-matter of claim 1 lacked novelty in view of D3.

Auxiliary request 1 - inventive step in view of D2

When starting from D2, the skilled person already got the hint to evaluate the suitability of a selected

pattern based on user's glucose level relative to a target zone. D2 also provided the information that the suitability was to be checked based on user specific A1C levels (page 12, lines 10 to 16). It was common general knowledge that A1C levels represented glycemic goal or target levels.

The common general knowledge exemplified by D14 provided a clear teaching that the glycemic goal or target level should be tailored for every patient. D15 confirmed that working with target blood glucose values was well known (Table 1, "target FBG"). Based on this teaching and being faced with the objective technical problem of better tailoring the dose adjustment profile to the user, the person skilled in the art would use the user specific glycemic target or goal as one parameter for tailoring the dose adjustment profile. In doing so the skilled person would arrive at the solution of claim 1 without exercising any inventive skills.

Hence, the subject-matter of claim 1 did not involve an inventive step in view of D2.

Auxiliary request 1 - inventive step in view of D3

The technical effect of the features "each dose adjustment profile is based on a specific low blood glucose threshold value" might be regarded as better tailoring a dose adjustment profile to a user.

Starting from the fact that D3 already disclosed to include many parameters, like BG target, into the editable dose adjustment profiles and faced with the problem how to further personalize the dose adjustment profile, it would have been obvious for the skilled

person to add the specific low blood glucose threshold value to the list of editable parameters.

This was further confirmed by the common general knowledge as exemplified by D14 and D15. The different low blood glucose thresholds described in D14 (70 mg/dl in Fig. 1) and D15 (72 mg/dl below Table 1) provided a motivation for the person skilled in the art to include this parameter into the list of editable parameters because it showed that the person skilled in the art was well aware that there was a need for being able to work with different threshold values.

Accordingly, starting from D3 the person skilled in the art would have arrived at the claimed solution without exercising any inventive activity, based on D3 alone as well as starting from D3 in view of common general knowledge as exemplified by D14 and D15.

Hence, the subject-matter of claim 1 did not involve an inventive step in view of D3.

Reasons for the Decision

1. Subject-matter of the patent

The patent relates to the glycemic control of patients with diabetes.

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.

Claim 1 of the present patent 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. Each of the different dose adjustment profiles is 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.

Claim 9 relates to a system for configuring a process for determining a dose of insulin to be administered comprising means to carry out the steps of claim 1.

Claim 17 relates to a computer program for configuring a process for determining a dose of insulin to be

administered comprising code for carrying out the steps of claim 1.

2. Main request (patent as granted) - exclusion from patentability under Article 52(2)(c) EPC

2.1 The method defined in claim 1 includes the steps of defining different dose adjustment profiles (each being based on certain parameters), storing the different dose adjustment profiles, selecting one of the different dose adjustment profiles and personalising the selected dose adjustment profile (by assigning a further parameter to this profile).

2.2 As submitted by the opponent, all these steps could be performed mentally by a user. The different dose adjustment profiles could be made up and then memorized in the user's mind. Hence, contrary to the patent proprietor's view, the step "storing the different dose adjustment profiles" does not manifest itself physically outside the human brain, as it neither requires any activity performed by a body part nor any technical means such as a computer.

2.3 Likewise, the Board does not concur with the patent proprietor that "configuring a process" is a technical process that has to be carried out by technical means. It can as well mean that the user decides using his/her brain which steps are to be performed.

2.4 The Board therefore concurs with the opponent that claim 1 as granted relates to a method for performing mental acts as such, which is excluded from patentability pursuant to Article 52(2)(c) EPC.

3. Auxiliary request 1 - exclusion from patentability under Article 52(2)(c) EPC

Claim 1 of auxiliary request 1 explicitly stipulates that the method is "computer-implemented". The method has therefore a technical character and is not excluded from patentability under Article 52(2)(c) EPC. This was not contested by the opponent.

4. Auxiliary request 1 - novelty in view of D2

4.1 D2 relates to controlling "delivery of basal insulin according to a predetermined basal infusion pattern, the basal infusion pattern selected from a plurality of predetermined basal infusion patterns" (page 3, lines 17 to 19). Thus, D2 is concerned with insulin infusion rates for an infusion device. Figure 2 discloses graphs exemplary of three initial basal insulin infusion rate distributions (i.e. patterns). These patterns are stored in a storage unit. Upon starting operation of the infusion device, one of the patterns is selected (page 15, lines 4 to 26). This pattern can be personalised to a specific patient, e.g. by shifting it in time (Figure 3b, page 16, lines 1 to 5) or by adjusting the magnitude of the infusion rate (Figure 4, page 16, lines 12 to 18).

4.2 Assuming, for the sake of argument, that the patterns of Figure 2 can be regarded as dose adjustment profiles for stepwise adapting a dose, the question is whether D2 discloses that each of these patterns is based on a specific low blood glucose threshold value.

The opponent argued that, as described on page 17, lines 7 to 10, the lower value of the target zone defined a lower limit and could be regarded as the

specific low blood glucose threshold value.

However, even if this were true, there is no disclosure in D2 that a specific low blood glucose threshold value belongs to each of the patterns (from which one is selected at the beginning of the infusion treatment).

In this context, the Board agrees with the opponent that the specific low blood glucose threshold value does not have to be different for each profile. It is however required, that each profile has an identifiable specific low blood glucose threshold value assigned to it such that this parameter can (together with the other parameters mentioned in the claim) form the basis of the selection.

4.3 The opponent further argued that the existence of a target zone as mentioned on page 12, lines 10 to 16, inherently required that blood glucose target levels had been set for a specific user. Hence, D2, by its reference to "a user's haemoglobin A1C levels", also disclosed the step of defining a specific target blood glucose value for a specific user.

However, even if the target level of D2 was defined specifically for a user, D2 does not disclose that this was done in order to personalise the selected pattern, i.e. after the pattern was selected.

4.4 Thus, D2 does not disclose that each of the defined dose adjustment profiles is based on a specific low blood glucose threshold value and that the selected profile is personalised by defining a specific target blood glucose value for a specific user. The subject-matter of claim 1 is therefore novel in view of D2.

5. Auxiliary request 1 - novelty in view of D3

5.1 D3 discloses "a user input device for programming a parameter profile for a drug delivery system" (page 2, lines 33-34) and disclosed a "basal profile" used for infusion (see e.g. Figures 15 to 18).

5.2 According to the opponent, the basal profile could be regarded as a dose adjustment profile for adapting a dose. Figure 30A disclosed that a blood glucose target could be entered as user data and that the basal profile could be edited after the user data was entered. Thus, D3 at least implicitly disclosed that a specific low blood glucose threshold value could be set as a part of the profile and that a specific target blood glucose value for a specific user could be defined.

5.3 The opponent's argument is not convincing. As submitted by the patent proprietor, it cannot be derived from D3 that any of the basal profiles shown in Figure 15 has a specific low blood glucose threshold value assigned to it. Furthermore, even if Figure 30A disclosed that a blood glucose target value could be set, D3 does not disclose that such a target value is set after selecting one of the stored profiles with the aim to personalise it.

5.4 Thus, D3 does not disclose that each of the defined dose adjustment profiles is based on a specific low blood glucose threshold value and that the selected profile is personalised by defining a specific target blood glucose value for a specific user. The subject-matter of claim 1 is therefore novel in view of D3.

6. Auxiliary request 1 - inventive step starting from D2

6.1 The technical effect of the distinguishing features mentioned above may be regarded as better tailoring a dose adjustment profile to a user.

6.2 According to the opponent, it was common general knowledge exemplified by D14 and D15 that the glycemic goal or target level should be tailored for every patient. Based on this knowledge it would have been obvious for the person skilled in the art to use the specific glycemic target as a parameter for tailoring the dose adjustment profile, thus arriving at the solution of claim 1 without exercising inventive skill.

6.3 The Board does not agree. If D14 and D15 taught to tailor a dose adjustment profile to a user, the person skilled in the art would probably do this by defining certain target values for the specific user. However, the person skilled in the art would not be prompted to define, in advance of the treatment, several different dose adjustment profiles each being based on a specific low blood glucose threshold value. The skilled person would also not be prompted to personalise, after selecting one of the profiles, this profile by defining a specific target blood glucose value for a specific user. Hence, the specific way of tailoring the dose adjustment profile for a specific user defined in claim 1 is not rendered obvious by the common general knowledge exemplified by D14 and D15.

The subject-matter of claim 1 therefore involves an inventive step in view of D2 in combination with the common general knowledge exemplified by D14 and D15.

7. Auxiliary request 1 - inventive step starting from D3

7.1 The opponent argued that, starting from D3, it would have been obvious for the person skilled in the art to add the specific low blood glucose threshold value and the specific target blood glucose value to the editable parameters.

7.2 However, just adding these two parameters to the (possibly) editable parameters mentioned in D3 would not result in a method according to claim 1. The claimed method requires that each of the pre-defined dose adjustment profiles from which the user can select is provided with a specific low blood glucose threshold value and that in a step which is performed after one profile has been selected a specific target blood glucose value is assigned to the selected profile. Neither D3 alone nor the common general knowledge of certain low blood glucose thresholds disclosed in D14 and D15 would prompt the person skilled in the art to implement these features in the method described in D3.

7.3 Hence, the subject-matter of claim 1 also involves an inventive step in view of D3 alone or in combination with the common general knowledge as exemplified by D14 and D15.

8. Auxiliary request 1 - further independent claims

The considerations set out above for claim 1 apply by analogy to claims 9 and 17.

9. Conclusion

None of the objections raised by the opponent prejudices the maintenance of the patent on the basis

of auxiliary request 1.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:
- claims 1-18 according to auxiliary request 1 filed with the statement of grounds of appeal
- paragraphs [0001] to [0277] of the patent specification
- Figures 1-36 of the patent specification.

The Registrar: The Chairman:

A. Chavinier-Tomsic A. Martinez Möller

Decision electronically authenticated