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Datasheet for the decision of 13 December 2024

Case Number: T 1492/22 - 3.2.02

Application Number: 15174910.8

Publication Number: 3111831

IPC: A61B5/00, A61B5/145

Language of the proceedings: EN

Title of invention:
A PORTABLE DEVICE AND A METHOD FOR PROCESSING CONTINUOUS MONITORING DATA INDICATIVE OF AN ANALYTE IN A BODILY FLUID, A MEDICAL SYSTEM AND A COMPUTER PROGRAM PRODUCT

Applicant:
Roche Diabetes Care GmbH
F. Hoffmann-La Roche AG

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA 2020 Art. 11

Keyword:
Inventive step - (yes)
Amendments - added subject-matter (no)

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Case Number: T 1492/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 December 2024

Appellant: (Applicant 1)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Appellant: (Applicant 2)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Bittner, Thomas L. Boehmert & Boehmert Anwaltspartnerschaft mbB Pettenkoferstrasse 22 80336 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 25 February 2022 refusing European patent application No. 15174910.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	C. Schmidt

Summary of Facts and Submissions

I. The appeal is against the Examining Division's decision to refuse European patent application No. 15174910.8. The Examining Division found that the subject-matter of claim 1 of each of the requests then on file lacked an inventive step.

II. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed on 18 November 2024, or, in the alternative, that a patent be granted on the basis of one of auxiliary requests 1 to 4, filed on 9 June 2022 as main request and auxiliary requests 1 to 3, respectively.

The appellant requested oral proceedings as an auxiliary measure if the board did not grant a patent or did not remit the case to the Examining Division.

III. Claim 1 of the **main request** reads as follows:

"A portable device (1) for processing continuous monitoring data indicative of an analyte in a bodily fluid, comprising
- a data interface device (3), configured to receive a stream of continuous monitoring data from a body worn sensor, the continuous monitoring data being indicative of a continuous glucose monitoring in a bodily fluid,
- a storage device (5), configured to store at least part of the continuous monitoring data, and
- a control device (4), configured to process the continuous monitoring data and, at least for data

exchange, functionally connectable to the data interface device (3), and the storage device (5), wherein
- the control device (4) is further configured to switch, according to a predefined operation condition, between a first and a second mode of operation during a sensor session of the body worn sensor, the first mode of operation comprising providing video data indicative of the continuous monitoring data for outputting the video data by a display device (6), and the second mode of operation comprising storing the continuous monitoring data in the storage device (5) and blocking displaying of the continuous monitoring data on the display device (6), and
- the predefined operation condition is a glucose threshold for hypoglycemia or hyperglycemia."

IV. The following documents are relevant to the present decision:

D1 US 2014/0200426 A1
D2 US 2012/0108934 A1
D3 US 2014/0148659 A1

V. The appellant's arguments of relevance to the present decision can be summarised as follows.

Main request - inventive step

The subject-matter of claim 1 was inventive over D1 in view of common general knowledge. D1 did not disclose switching the mode of operation according to a predefined operation condition, this condition being a glucose threshold for hypoglycaemia or hyperglycaemia. This allowed better adaptation to the needs of patients regarding hypoglycaemia and hyperglycaemia. For

example, in the event of a value falling below a hypoglycaemia threshold, the control device could switch to the first mode to provide video data and to allow a quick response to the glucose values.

D1 provided no connection between the alarm of paragraph [0213] and the Masked Mode. D2 and D3 did not provide any further pertinent teaching.

Reasons for the Decision

1. Patent application

1.1 It is sometimes desired not to disclose to the user or patient the monitoring information of a monitored analyte such as blood glucose. This "blinded" mode of operation may be used for example by healthcare professionals who prefer to derive therapy adaptations based on measured patterns which are not altered by behavioural changes on the part of the patient if monitoring information is disclosed to the patient.

1.2 Claim 1 of the main request relates to a portable device for processing continuous monitoring data indicative of an analyte in a bodily fluid. The device comprises a data interface device, a storage device, a control device and a user interface device. The control device is configured to switch between a first (un-blinded) mode of operation and a second (blinded) mode of operation according to a predefined operation condition that is a glucose threshold for hypoglycaemia or hyperglycaemia.

2. Main request - admittance

2.1 The main request constitutes an amendment to the appellant's appeal case after notification of a communication under Article 15(1) RPBA. This communication raised new objections under Article 123(2) EPC against the then auxiliary request 3. The main request *prima facie* overcomes these objections. The board considers these to constitute exceptional circumstances within the meaning of Article 13(2) RPBA. Therefore, the board decided to admit the main request into the proceedings.

3. Main request - Article 123(2) EPC

3.1 Claim 1 of the main request substantially corresponds to claim 1 of auxiliary request 3 considered in the appealed decision, with deletion of the user interface device and of the last two features of the claim. The Examining Division did not raise any objection under Article 123(2) EPC against that request.

3.2 The board is satisfied that the requirements of Article 123(2) EPC are complied with. The basis for independent claims 1 and 10 of the main request is provided in original claims 1 and 11 and on page 9, lines 8 to 11 and 20 to 23 of the application as filed (the passages providing a basis for the feature specifying that the predefined operation condition is a glucose threshold for hypoglycaemia or hyperglycaemia). Claims 2 to 9 and 11 of the main request correspond to original claims 3 to 10 and 12 respectively.

4. Main request - Article 56 EPC

4.1 In the appealed decision, claim 1 of the then auxiliary request 3 was found not to involve an inventive step over D1 in combination with common general knowledge.

4.2 D1 discloses a portable device for processing continuous monitoring data indicative of an analyte in bodily fluid. It discloses in paragraphs [0262] and [0480]-[0484] a "Masked Mode option" that enables manual activation or deactivation of a Masked Mode. When the Masked Mode is disabled, sensor glucose data is displayed to the user, and when it is enabled, sensor glucose data is hidden from the user but that data is still stored (see also figures 10A, 10C and 47). A disabled Masked Mode corresponds to the "first mode of operation" within the meaning of claim 1 and an enabled Masked Mode corresponds to the "second mode of operation".

4.3 The subject-matter of claim 1 differs from the device of D1 in that switching between the two modes is carried out according to a predefined operation condition, this predefined operation condition being a glucose threshold for hypoglycaemia or hyperglycaemia. In D1, switching between the two modes is carried out manually by a user.

4.4 The Examining Division considered the glucose threshold for hypoglycaemia or hyperglycaemia to be a non-technical requirement specification, and found that the person skilled in the art faced with the task of avoiding manual setting of modes by the user when a hypoglycaemia or hyperglycaemia event occurs would automate mode switching.

4.5 The board reaches a different conclusion. As put forward by the appellant, if, for example, the glucose value falls below a hypoglycaemia threshold, the device may be switched to the first mode of operation in order to provide video data allowing a quicker and better informed response to the condition, with the continuously monitored glucose values then being displayed. The control device being configured to switch between the two modes of operation according to a glucose threshold for hypoglycaemia or hyperglycaemia is based on technical considerations and contributes to solving the problem of providing a safer device for the patient. The feature therefore cannot be considered a mere non-technical requirement specification and thus cannot be included in the objective technical problem.

4.6 It is true that D1 discloses issuing an alarm when the level of the analyte is at or near a threshold (paragraph [0213]) or when the level of the analyte exceeds a threshold (paragraph [0214]), for example to alert to a hypoglycaemic or hyperglycaemic glucose level. However, issuing an alarm is independent of the mode of operation (masked/unmasked). D1 does not disclose or suggest enabling or disabling the Masked Mode according to a glucose threshold for hypoglycaemia or hyperglycaemia. There is also no evidence on file showing that this belongs to common general knowledge.

4.7 It follows that the subject-matter of claim 1 is inventive over D1 in combination with common general knowledge.

4.8 D2 and D3 were cited in the European Search Opinion but not relied upon in the appealed decision. These documents disclose a masked mode (blinded mode in paragraphs [0070] and [0071] of D2; masked mode in

paragraphs [0006] and [0033] to [0036] of D3) but do not suggest the claimed solution. Hence, even if these documents were to be consulted when starting from D1 and faced with the problem of providing a safer device for the user, they would not lead to a device anticipating the device of claim 1.

4.9 Since the board cannot rule out there being other reasons for not granting a patent on the basis of the main request, there are special reasons within the meaning of Article 11 RPBA for remitting the case to the Examining Division.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

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

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated