Internal distribution code:

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

Datasheet for the decision of 10 May 2021

Case Number: T 2313/18 - 3.5.05

Application Number: 11770355.3

Publication Number: 2628106

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
UPDATABILITY OF STRUCTURED BLOOD GLUCOSE TESTS ON HANDHELD DIABETES MANAGEMENT DEVICES

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

Headword:
Non-modifiable firmware/ROCHE

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

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 2313/18 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 10 May 2021

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 18 April 2018 refusing European patent application No. 11770355.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	F. Blumer

Summary of Facts and Submissions

I. The appeal is against the examining division's decision to refuse the application on the grounds that the sole request did not meet the requirements of Article 56 EPC in view of the following document:

D2: US 2010/212675 A1

II. With their statement setting out the grounds of appeal, the appellants maintained the sole request on which the decision under appeal was based as their main request and filed first to third auxiliary requests. They requested that the decision be set aside and that a patent be granted on the basis of one of these requests. They requested oral proceedings as an auxiliary measure.

III. In its preliminary opinion issued in preparation for the oral proceedings, the board raised objections under Article 56 EPC and informed the appellants that it was minded not to admit the auxiliary requests filed with the statement setting out the grounds of appeal.

IV. Oral proceedings were held before the board, during which the appellants withdrew their auxiliary requests.

V. Claim 1 of the sole request reads as follows:

"A handheld diabetes management device (104) having improved updatability of entry, adherence, and exit criteria for a structured blood glucose test, the handheld diabetes management device (104) comprising:

- a blood glucose (bG) measurement engine (508) that measures a bG level in a sample of blood of a user and that generates sample data indicative of the bG level;
- memory (532);
- firmware stored in a non-modifiable portion of the memory (532), the firmware including a subroutine for each different type of a structured bG test, wherein each of the subroutines is a submodule of a firmware module (536) in the non-modifiable portion of the memory (532);
- a display (408); and
- a processor module (504), in communication with the bG measurement engine (508), the display (408), and the memory (532), that:
    - executes the firmware for performing operations to carry out a structured bG test;
    - selectively retrieves entry, adherence, and exit criteria stored in a modifiable portion of the memory (532) for individual bG samples expected to be input for the structured bG test;
    - selectively retrieves entry, adherence, and exit criteria stored in the modifiable portion of the memory (532) for bG sample groups expected for the structured bG test; and
    - retrieves entry, adherence criteria, and exit criteria from the modifiable portion of the memory (532) for the structured bG test;

wherein the subroutines point to where test configuration data associated with the structured bG test and the entry, adherence, and exit criteria associated with the structured bG test are stored in the modifiable portion of the memory (532); and
wherein the test configuration data and the entry, adherence, and exit criteria associated with the structured bG test and stored in the modifiable portion

of the memory (532) are changeable without changing the firmware stored in the non-modifiable portion of the memory (532)."

Reasons for the Decision

1. First and foremost, the appellants contested the examining division's assertion that the embodiment disclosed in paragraph [0074] of D2, according to which "software 34 is implemented primarily in hardware logic using, for example, hardware components such as application specific integrated circuits (ASICs)", was "equivalent to [...] firmware". They argued that this assertion was based on an incorrect interpretation that it was the possibility of being implemented in hardware logic that qualified a particular piece of software as being "firmware". They further argued that the software 34 in D2 would not qualify as firmware in view of paragraphs [0056] and [0062] of D2, which explicitly indicated that the software 34 can be loaded onto and executed on different types of electronic device. This meant that the software 34 was not device-specific in the sense that firmware would normally be understood; however, both in their written reply to the board's preliminary opinion and at the oral proceedings, the appellants clarified that they did not contest that a device such as the collection device 24 from D2, which is a blood glucose meter or a continuous glucose monitor, should have some kind of firmware. Instead, they argued that D2 did not explicitly refer to or discuss this firmware.

2. With regard to the entry, adherence and exit criteria 226, 224 and 228 in D2, the appellants submitted that D2 did not disclose these being stored in the same

memory as the firmware. Since D2 does not explicitly refer to or discuss the firmware of the collection device 24, the board agrees that it can only be concluded with certainty that its firmware should be stored somewhere on the collection device 24, but not necessarily in the same memory as the criteria listed above; however, the present application as filed also does not support the argument that storing the firmware and these criteria in "the same memory" would have any unexpected effect compared with storing them in different memories (see e.g. page 13 of the description, lines 13 to 16, which mentions an alternative implementation in which the firmware is not in the same memory 532, but in a separate one 542).

3. Claim 1 requires the firmware to be stored in a "non-modifiable portion of the memory", but requires the entry, adherence and exit criteria to be stored in a "modifiable portion of the memory". In its preliminary opinion, the board noted that this wording required some interpretation. In particular, the word "portion" was not a specific technical term used in memory hardware or memory management, such as "cell" or "segment", but instead was a broad generalisation. Therefore, the board understood any arbitrary part of a memory, including precisely the portion in which a particular file is stored, to be a "portion of the memory". With regard to "non-modifiable", this was understood in this context to refer to the access rights or file permissions given to users (a patient or clinician). Since the appellants emphasised that the same memory had a "modifiable portion" and a "non-modifiable portion", this could not be a feature of the hardware. This was also supported by the second paragraph on page 13 of the description, which gives "NAND type flash or another type of re-writable

memory" [emphasis by the board] as an example of the memory 532. The appellants explained at the oral proceedings that "modifiable portion" and "non-modifiable portion" were indeed broad definitions in terms of function which may be implemented by different means.

4. Since D2 does not explicitly refer to or discuss the firmware of the collection device 24, as a matter of fact, it also cannot disclose the access rights associated with it; however, it is well known that users are not normally given the permission to modify firmware, let alone access it. This was indeed one of the appellants' arguments in their statement setting out the grounds of appeal against the examining division's assertion that the software 34 in D2 was firmware. The appellants submitted in this statement that "changing the firmware of a device [...] may rarely or never be done during the lifetime of the device. Some firmware memory devices are permanently installed and cannot be changed after manufacture" (see the statement setting out the grounds of appeal, B.2.2, third paragraph); however, it would then be obvious to define the file permissions of any firmware that the collection device 24 of D2 has as being "non-modifiable", thus storing them in a "non-modifiable portion of the memory".

5. For these reasons, the subject-matter of claim 1 does not involve an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

L. Stridde A. Ritzka

Decision electronically authenticated