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**Datasheet for the decision  
of 24 June 2021**

**Case Number:** T 2472/18 - 3.5.05

**Application Number:** 10717918.6

**Publication Number:** 2419848

**IPC:** G06F19/00

**Language of the proceedings:** EN

**Title of invention:**

THERAPY MANAGEMENT DEVELOPMENT PLATFORM

**Applicant:**

Baxter International Inc  
Baxter Healthcare SA

**Headword:**

First and second levels of access/BAXTER

**Relevant legal provisions:**

EPC Art. 123(2)  
RPBA Art. 12(4)

**Keyword:**

Amendments - allowable (no)  
Auxiliary requests - diverging versions of claims



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Case Number: T 2472/18 - 3.5.05

**D E C I S I O N**  
**of Technical Board of Appeal 3.5.05**  
**of 24 June 2021**

**Appellant:** Baxter International Inc  
(Applicant 1) One Baxter Parkway  
Deerfield, IL 60015 (US)

**Appellant:** Baxter Healthcare SA  
(Applicant 2) Thurgauerstrasse 130  
8152 Glattpark (Opfikon) (CH)

**Representative:** Potter Clarkson  
The Belgrave Centre  
Talbot Street  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 2 May 2018  
refusing European patent application No.  
10717918.6 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chair** A. Ritzka  
**Members:** E. Konak  
E. Mille

## Summary of Facts and Submissions

- I. The appeal is against the examining division's decision to refuse the application on the ground that the then main request and then auxiliary requests 1 and 2 did not meet the requirements of Articles 123(2) and 56 EPC.
- II. With their statement setting out the grounds of appeal, the appellants filed a main request and auxiliary requests 1 to 5. 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, *inter alia*, Article 123(2) EPC and with regard to the admissibility of the auxiliary requests filed with the statement setting out the grounds of appeal (Article 12(4) RPBA 2007).
- IV. The appellants did not reply in substance but withdrew their request for oral proceedings and requested partial reimbursement of the appeal fee. The scheduled oral proceedings were thus cancelled.
- V. Claim 1 of the main request reads as follows:
- "A therapy management development platform (100) for facilitating development of a therapy management system, the therapy management system including:
- (i) a medical device capable of providing therapy management comprising a pump controller (102) coupled to a pump input/output interface (112); and

(ii) an interface module (104) including an interface module controller (122) and a module-sensor input/output interface (128), the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and

the interface module controller customizably programmed to receive data from a sensor (106) coupled to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto,

characterised in that:

the therapy management development platform is configured to allow a user to modify the operation of the medical device;

the therapy management development platform is configured to provide a first level of access relative to the medical device prior to modification of the medical device using the therapy management development platform to provide for the use of sensors and/or control algorithms to permit testing to occur;

the therapy management development platform is configured to receive an indication of approval to provide a second level of access relative to the medical device after modification of the medical device using the therapy management development platform to provide for the use of additional or different sensors and/or control algorithms to permit further testing to occur; and

the therapy management development platform is configured to provide the second level of access in response to the received indication of approval."

VI. Claim 1 of auxiliary request 1 reads as follows:

"A therapy management development platform (100) for facilitating development of a therapy management system, the therapy management system including:

(i) a medical device capable of providing therapy management comprising a pump controller (102) coupled to a pump input/output interface (112); and

(ii) an interface module (104) including an interface module controller (122) and a module-sensor input/output interface (128), the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and

the interface module controller customizably programmed to receive data from a sensor (106) coupled to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto,

characterised in that:

the therapy management development platform is configured to provide a first level of access to a non-therapeutic use of sensors and/or control algorithms of the platform to permit testing to occur;

the therapy management development platform is configured to receive an indication of approval to provide a second level of access to a non-therapeutic use of additional or different sensors and/or control algorithms of the platform to permit further testing to occur; and

the therapy management development platform is configured to provide the second level of access in response to the received indication of approval."

VII. Claim 1 of auxiliary request 2 reads as follows:

"A therapy management development platform (100) for facilitating development of a therapy management system, the therapy management system including:

(i) a medical device capable of providing therapy management comprising a pump controller (102) coupled to a pump input/output interface (112); and

(ii) an interface module (104) including an interface module controller (122) and a module-sensor input/output interface (128), the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and

the interface module controller customizably programmed to receive data from a sensor (106) coupled to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto,

characterised in that:

the therapy management development platform is configured to allow a user to modify the operation of the medical device;

the therapy management development platform comprises a development toolkit configured to permit a program to be written by a user through the manipulation of a GUI in combination with a library of standardized input commands, output commands, and procedure commands;

the therapy management development platform is configured to provide a first level of access relative to the medical device prior to modification of the medical device using the therapy management development platform to provide for the use of sensors and/or control algorithms to permit testing to occur;

the therapy management development platform is configured to receive an indication of approval to

provide a second level of access relative to the medical device after modification of the medical device using the therapy management development platform to provide for the use of additional or different sensors and/or control algorithms to permit further testing to occur;

the therapy management development platform is configured to provide the second level of access in response to the received indication of approval."

VIII. Claim 1 of auxiliary request 3 reads as follows:

"A therapy management development platform (100) for facilitating development of a therapy management system, the therapy management system including:

(i) a medical device capable of providing therapy management comprising a pump controller (102) coupled to a pump input/output interface (112); and

(ii) an interface module (104) including an interface module controller (122) and a module-sensor input/output interface (128), the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and

the interface module controller customizably programmed to receive data from a sensor (106) coupled to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto,

characterised in that:

the therapy management development platform is configured to facilitate modification of the operation of the medical device (i) to use a prototype sensor; (ii) to make changes to the operation of a control

algorithm used by the medical device to control therapy management; or (iii) both (i) and (ii);

the therapy management development platform is configured to provide a first level of access relative to the medical device prior to modification of the medical device using the therapy management development platform to provide for the use of sensors and/or control algorithms to permit testing to occur;

the therapy management development platform is configured to receive an indication of approval to provide a second level of access relative to the medical device after modification of the medical device using the therapy management development platform to provide for the use of additional or different sensors and/or control algorithms to permit further testing to occur; and

the therapy management development platform is configured to provide the second level of access in response to the received indication of approval."

IX. Claim 1 of auxiliary request 4 reads as follows:

"A therapy management development platform (100) for facilitating development of a therapy management system, the therapy management system including:

(i) a medical device capable of providing therapy management comprising a pump controller (102) coupled to a pump input/output interface (112); and

(ii) an interface module (104) including an interface module controller (122) and a module-sensor input/output interface (128), the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and

the interface module controller customizably programmed to receive data from a sensor (106) coupled



to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto,

characterised in that:

the therapy management development platform includes a development toolkit facilitating programming of the module controller of the interface module by selection of commands from a library of standardized input, output and procedure commands, the development toolkit permitting a user, via manipulation of a graphical user interface, to compose a program which is converted by the development toolkit into a set of commands executable by the module controller, wherein the standardized commands include commands for establishing data channels to receive signals from the sensor, the pump controller, and the input/output interface and scaling sensor readings according to minimum and maximum voltage outputs for the sensor, implementing filtering algorithms on sensor and pump controller data, and/or programming a control algorithm for the pump controller;

the therapy management development platform is configured to allow a user to modify the operation of the medical device;

the therapy management development platform is configured to provide a first level of access relative to the medical device prior to modification of the medical device using the therapy management development platform to provide for the use of sensors and/or control algorithms to permit testing to occur;

the therapy management development platform is configured to receive an indication of approval to provide a second level of access relative to the medical device after modification of the medical device using the therapy management development platform to

provide for the use of additional or different sensors and/or control algorithms to permit further testing to occur; and

the therapy management development platform is configured to provide the second level of access in response to the received indication of approval."

X. Claim 1 of auxiliary request 5 reads as follows:

"A therapy management development platform (100) for facilitating development of a therapy management system, the therapy management system including:

(i) a medical device capable of providing therapy management comprising a pump controller (102) coupled to a pump input/output interface (112); and

(ii) an interface module (104) including an interface module controller (122) and a module-sensor input/output interface (128), the module-sensor input/output interface having at least one standardized input port, at least one standardized output port and at least one standardized power connection, and

the interface module controller customizably programmed to receive data from a sensor (106) coupled to the module-sensor input/output interface and from the pump controller and to provide instructions to the pump controller to vary the operation of a pump coupled thereto,

characterised in that:

the therapy management development platform is configured to allow a user to modify the operation of the medical device;

the therapy management development platform is configured to provide a first level of access relative to the medical device prior to modification of the medical device using the therapy management development

platform to provide for the use of sensors and control algorithms to permit testing to occur;

the therapy management development platform is configured to receive an indication of approval to provide a second level of access relative to the medical device after modification of the medical device using the therapy management development platform to provide for the use of additional or different sensors and control algorithms to permit further testing to occur; and

the therapy management development platform is configured to provide the second level of access in response to the received indication of approval."

## **Reasons for the Decision**

1. Main request

1.1 The amendments to claim 1 of the main request to the effect that the claimed platform provides "a first level of access relative to the medical device prior to modification of the medical device using the therapy management development platform to provide for the use of sensors and/or control algorithms to permit testing to occur" and "receive[s] an indication of approval to provide a second level of access relative to the medical device after modification of the medical device using the therapy management development platform to provide for the use of additional or different sensors and/or control algorithms to permit further testing to occur" contain subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC). The appellants gave paragraph [0075] of the description as filed as the basis for these amendments. However, this paragraph does not refer anywhere to "level[s] of access" but to "a first functionality" and

"*a second functionality*". Functionality and access levels are different concepts. Furthermore, paragraph [0075] refers neither to "*receiving an approval*" nor to any "*testing*" or "*further testing*". Therefore, these amendments are not directly and unambiguously derivable from the application as filed.

- 1.2 The board raised this objection in its preliminary opinion to which the appellants did not reply in substance. Under these circumstances, the boards sees no reason to change its preliminary opinion. Thus, the main request does not meet the requirements of Article 123(2) EPC.
  
2. Admissibility of the auxiliary requests (Article 12(4) RPBA 2007)
  - 2.1 The appellants filed a number of new requests with their statement setting out the grounds of appeal, including the new main request discussed above and new second to fifth auxiliary requests. The main request on which the contested decision was based was refiled as first auxiliary request, thus changing its sequence.
  
  - 2.2 The board noted in its preliminary opinion that the auxiliary requests on file did not represent a convergent development, increasingly limiting the subject-matter of claim 1 of the main request in the same direction (see Case Law of the Boards of Appeal of the European Patent Office, Ninth Edition, July 2019, V.A.4.12.4). Rather, they entailed different lines of development incorporating different features. For example, the feature that "*the therapy management development platform is configured to allow a user to modify the operation of the medical device*" in claim 1 of the main request did not appear in auxiliary

requests 1 and 3. The wording "*relative to the medical device prior to modification of the medical device using the therapy management development platform for the*" and "*relative to the medical device after modification of the medical device using the therapy management development platform to provide for the*" in claim 1 of the main request disappeared in auxiliary request 1 and then reappeared in auxiliary request 2. The "*development toolkit*" feature in claim 1 of auxiliary request 2 disappeared in auxiliary request 3, then reappeared in auxiliary request 4 to finally disappear again in auxiliary request 5. Therefore, it was doubtful whether the auxiliary requests were admissible.

2.3 The appellants did not reply to this objection either, and the board sees no reason to change its preliminary opinion. Therefore, the board exercises its discretion under Article 12(4) RPBA 2007 and does not admit the auxiliary requests.

3. Request for partial reimbursement of the appeal fee

3.1 According to Rule 103(4)(c) EPC, the appeal fee is to be reimbursed at 25% if any request for oral proceedings is withdrawn within one month of notification of the communication issued by the board of appeal in preparation for the oral proceedings and no oral proceedings take place.

3.2 In this case, the communication in preparation for the oral proceedings was despatched on 7 June 2021 and thus notified on 17 June 2021. The withdrawal of the request for oral proceedings was received on 21 June 2021, i.e. within the time limit established in Rule 103(4)(c) EPC. Thus, the appeal fee has to be reimbursed at 25%.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The appeal fee is reimbursed at 25%.

The Registrar:

The Chair:



K. Götz-Wein

A. Ritzka

Decision electronically authenticated