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Datasheet for the decision of 30 September 2019

Case Number: T 2139/14 - 3.2.02

Application Number: 08022100.5

Publication Number: 2198902

IPC: A61M5/142, G06F19/00

Language of the proceedings: EN

Title of invention:
Portable drug administration device switchable between two different administration modes

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

Headword:

Relevant legal provisions:
EPC Art. 84, 123(2), 111(1)

Keyword:

Claims - clarity - main request (no) - auxiliary request 1 (no) - auxiliary request 3 (yes)
Amendments - added subject-matter - auxiliary request 2 (yes) - auxiliary request 3 (no)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

Catchword:

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 2139/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 30 September 2019

Appellant: (Applicant 1)	F. Hoffmann-La Roche AG Grenzacherstraße 124 4070 Basel (CH)
Appellant: (Applicant 2)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Rentsch Partner AG Bellerivestrasse 203 Postfach 8034 Zürich (CH)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 27 June 2014 refusing European patent application No. 08022100.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	S. Böttcher
	P. L. P. Weber

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division to refuse European patent application No. 08022100.5 because claims 1, 3 and 4 of the main request did not meet the requirements of Article 84 EPC and claims 1, 4 and 8 of the main request did not meet the requirements of Article 123(2) EPC. Furthermore, at least one claim of each of auxiliary requests 1 to 15 did not meet the requirements of Articles 84 and/or 123(2) EPC. The written decision was dispatched on 27 June 2014.

II. Notice of appeal was filed on 11 August 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 24 October 2014.

III. The Board summoned the appellant to oral proceedings and provided its provisional opinion on the issues of clarity and added subject-matter in a communication of 7 June 2019.

IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or one of auxiliary requests 1 to 3 filed with the letter dated 7 August 2019. In this letter, the appellant announced that it only planned on attending the oral proceedings if neither the main request nor any of the auxiliary requests 1 to 3 were considered to meet the requirements of Articles 84 and 123(2) EPC.

V. With a communication dated 22 August 2019, the appellant was informed that the oral proceedings had been cancelled.

VI. Claim 1 of the main request reads as follows:

"A portable drug administration device with a replaceable drug cartridge and a replaceable power cell, comprising

- a pump,
- a controller (34) configured to control operation of the pump according to a standard administration mode and a special operation mode which differs from the standard administration mode, the standard operation mode including the administration of drug boli according to a bolus administration profile and according to a superimposed basal administration profile, the special operation mode including temporarily suspending drug administration, characterized in that
- the controller (34) is configured
  - to detect the occurrence of an event trigger, the event trigger being generated by the controller (34) upon occurrence of the beginning of a maintenance action by a device user, the maintenance action being the replacement the power cell, when being exhausted, or of the drug cartridge, when being empty,
  - to store, in response to the event trigger, administration data, the administration data comprising all information characterizing a current administration according to both bolus administration profiles and basal administration profiles at a time of occurrence of the event trigger, automatically in a memory (35),
  - and to switch the device from the standard administration mode to the special operation mode, and
  - the controller (34) is further configured to detect the occurrence of a restoring trigger, the

restoring trigger being generated upon completion of the maintenance action, and to retrieve, in response to the restoring trigger, the administration data from the memory (35), and to switch the device from the special operation mode to the standard administration mode and to control the pump to resume administration according to the retrieved administration data."

VII. Claim 1 of each of auxiliary requests 1 to 3 corresponds to claim 1 of the main request.

VIII. Dependent claim 3 of the main request reads as follows:

"The drug administration device according to one of the preceding claims, wherein the controller (34) is configured, in response to the restoring trigger, to selectively control the pump to resume administration according to a default administration profile."

IX. Dependent claim 3 of auxiliary request 1 corresponds to claim 3 of the main request.

X. Dependent claim 3 of auxiliary request 2 reads as follows:

"The drug administration device according to one of the preceding claims, wherein the controller (34) is configured to control the device to switch to a stop mode - where administration of any bolus according to a bolus administration profile as well as any temporary modification of the administration are cancelled - on the occurrence of a timeout in the special operation mode."

XI. The arguments of the appellant relevant for the present decision may be summarised as follows:

Clarity (Article 84 EPC)

The omission of the feature "backup power cell" in claim 1 of the main request did not violate Article 84 EPC since this feature was not essential to the definition of the invention. There were several ways to ensure power supply to the controller and the memory if the main power cell was exhausted. Providing a backup power cell was only one possibility for achieving this result. Alternatively, the circuitry could have been designed such that a separate backup power cell was not necessary.

Claim 3 of the main request required that the controller according to claim 1 was further configured to selectively control the pump according to a default administration profile. Hence, the combination of claim 1 and claim 3 defined a system where administration might either be resumed in accordance with the data stored in the memory or in accordance with the standard profile.

The wording of claim 1 concerning the specific configuration of the controller did not exclude that the controller might, in addition, be configured to operate differently in a specific situation.

As a result, the definition in claim 3 did not involve a contradiction to the definition of claim 1. Therefore the requirements of Article 84 EPC were met.

Disclosure in the application as filed (Article 123(2) EPC)

Since the backup power cell was not to be considered an essential feature, its omission did not constitute an impermissible intermediate generalisation. Therefore,

claim 1 met the requirements of Article 123(2) EPC.

Claim 3 of auxiliary request 2 included a definition of the stop mode, namely, "where administration of any bolus according to a bolus administration profile as well as any temporary modification of the administration are cancelled" which was supported by the passage on page 2, lines 15 to 26. Although this passage referred to the outcome of the stop mode in prior art devices, it would have been clear to the skilled person that this definition was also applicable to a stop mode in a device according to the invention. The fact that the condition "occurrence of a time out" mentioned in claim 3 was not discussed in this paragraph, did not affect this finding. Consequently, the introduction of the definition of the stop mode in claim 3 of auxiliary request 2 did not infringe Article 123(2) EPC.

Reasons for the Decision

1. The appeal is admissible.

2. Subject-matter of the application

The application relates to a portable drug administration device (e.g. an insulin pump) comprising a controller configured to detect an event trigger, namely, according to claim 1, the beginning of the replacement of the battery or the drug cartridge. In response to this event trigger, current administration data is stored, and the device is switched into a special operation mode (i.e. drug administration is suspended). Upon detection of a restoring trigger that is generated upon completion of the replacement of the battery or the drug cartridge, the controller retrieves the administration data from the memory and resumes drug administration according to the

retrieved administration data.

3. Main request - clarity (Article 84 EPC)

3.1 The Examining Division considered the omission of the feature "backup power cell" in claim 1 to infringe Article 84 EPC since this feature was essential to the definition of the invention.

The Board does not agree with this opinion. It is clear from the description of the present application (page 16, line 32, to page 17, line 8) that the backup power cell is provided to ensure power supply to the controller and the memory if the main power cell is removed for replacement and if this removal is the event that triggers the storing of the administration data. It is further stated in the above-mentioned paragraph that powering the main power cell by the backup power cell is advantageous in this case. However, this is only one way of ensuring that administration data can be stored if the exhausted main power cell is removed for replacement. The same paragraph indicates an alternative measure of the data being stored continuously and "frozen" upon occurrence of an event trigger. Hence, for the skilled person, alternative ways of achieving data storage would have been conceivable which do not require an additional power cell. This is further confirmed on page 14, lines 3 to 5, where it is stated that the backup power cell is only a preferred feature.

Hence, it cannot be derived from the description of the application that the provision of a backup power cell is essential to the definition of the invention.

Claim 1 therefore meets the requirements of Article 84

EPC.

3.2 Claim 3 specifies that the controller is configured to selectively control the pump to resume drug administration according to a default administration profile. It is clear from the description (page 7, lines 25 to 34) that the default administration profile is applied as an alternative to the stored administration profile applied according to claim 1. Hence, there is a contradiction between claim 1 and claim 3. Claim 1 already defines that every time the restoring trigger is detected, the administration is resumed on the basis of the stored and retrieved data. Thus, it is paradoxical that according to claim 3, which is dependent on claim 1, the detection of the same restoring trigger should result in administration according to a different data scheme, namely the default administration profile.

The appellant referred to the fact that claim 3 specifies that the controller selectively controls the administration according to the default profile. Therefore, in the appellant's view, claim 1 and claim 3, in combination, defined a system where administration may be resumed in accordance with either the stored data or the default administration profile.

The Board cannot concur with this view. Since claim 3 is dependent on claim 1, claim 3 can merely define an additional configuration of the controller according to claim 1 but not an alternative configuration. An alternative configuration would have to be compatible with the configuration defined in claim 1.

The Board therefore agrees with the appellant that the wording of claim 1 does not exclude that the controller may have additional configurations. However, the wording

of claim 1 excludes that the controller has an alternative configuration, such as defined in claim 3.

Consequently, claim 3 of the main request lacks clarity (Article 84 EPC).

4. Main request - Added subject-matter (Article 123(2) EPC)

In the Examining Division's view, the omission of the - allegedly essential - feature "backup power cell" from the embodiment in which the replacement of the exhausted main power cell generated the event trigger constituted an unallowable intermediate generalisation. Hence, claim 1 did not meet the requirements of Article 123(2) EPC.

As established above, the Board does not consider the feature "backup power cell" to be an essential feature to the definition of the invention. Furthermore, it is mentioned on page 14, lines 3 to 5 of the description, that the backup power cell is a preferred feature in this embodiment. Therefore, the omission of this feature does not constitute an unallowable intermediate generalisation. Claim 1 of the main request meets the requirements of Article 123(2) EPC.

5. Auxiliary request 1 - Clarity (Article 84 EPC)

Claim 3 of this request corresponds to claim 3 of the main request. Since the Board found that this claim lacks clarity, auxiliary request 1 is not allowable.

6. Auxiliary request 2 - Added subject-matter (Article 123(2) EPC)

Claim 3 of this request corresponds to claim 4 of the request on which the impugned decision was based.

The Examining Division considered the explanation of the stop mode as "where administration of any bolus according to a bolus administration profile as well as any temporary modification of the administration are cancelled", which had been introduced in claim 3 during the examination proceedings, to add subject-matter that extended beyond the content of the application as originally filed, contrary to Article 123(2) EPC.

The Board agrees with the Examining Division that the passage referred to by the applicant (page 2, lines 15 to 26) relates to the general description of the prior art. In this paragraph, the operation of the stop mode in prior art devices is explained. However, it cannot be derived directly and unambiguously from this passage how the stop mode of the controller of the claimed device is defined. Hence, the amendment made to the claim introduces added subject-matter.

The appellant argued that the technical meaning of a stop mode would have been known to the person skilled in the art. Hence, the skilled person would have understood that the stop mode of the device according to claim 3 would be the same as the stop mode of the prior art devices referred to on page 2, lines 15 to 26, irrespective of the fact that the conditions that cause the device to switch into the stop mode mentioned in the claim were different from the ones referred to in this passage.

The Board does not concur with this view. The skilled person might have understood from the passage that if a known device is switched into the stop mode, the bolus profile and any temporary modification of the administration are cancelled, and that therefore the stop mode requires a dedicated user input (e.g. re-programming

of the bolus administration profile) to put the device back into run mode. However, the skilled person would not have got any direct and unambiguous information about the stop mode of the device according to claim 3, i.e. according to the invention.

It follows that claim 3 of auxiliary request 2 includes subject-matter that extends beyond the content of the application as originally filed, contrary to Article 123(2) EPC.

7. Auxiliary request 3

Claim 1 of auxiliary request 3 corresponds to claim 1 of the main request and therefore meets the requirements of Articles 84 and 123(2) EPC.

Dependent claims 2 to 4 correspond to claims 2, 6 and 7 of the request on which the decision was based. The Examining Division did not raise any objections under Articles 84 or 123(2) EPC against these claims. The Board has no objections under Articles 84 or 123(2) EPC either.

As the claims of auxiliary request 3 have not been examined with regard to novelty and inventive step, the case is remitted to the Examining Division for further prosecution pursuant to Article 111(1) EPC, as requested by the appellant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated