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Datasheet for the decision of 24 October 2018

Case Number: T 0298/14 - 3.2.02

Application Number: 06809836.7

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Title of invention:
MODULAR PORTABLE INFUSION PUMP

Patent Proprietors:
Roche Diagnostics GmbH
F. Hoffmann-La Roche SA

Opponent:
Sanofi-Aventis Deutschland GmbH

Headword:

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

Keyword:
Amendments - extension beyond the content of the application as filed (no)

Decisions cited:
T 1018/02, T 0197/10

Catchword:

Europäisches Patentamt
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Beschwerdekammern

Boards of Appeal

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Case Number: T 0298/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 October 2018

Appellant: (Patent Proprietor 1)	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Appellant: (Patent Proprietor 2)	F. Hoffmann-La Roche SA Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Peterreins Schley Patent- und Rechtsanwälte Hermann-Sack-Strasse 3 80331 München (DE)
Respondent: (Opponent)	Sanofi-Aventis Deutschland GmbH Brüningstrasse 50 65929 Frankfurt am Main (DE)
Representative:	Cohausz & Florack Patent- & Rechtsanwälte Partnerschaftsgesellschaft mbB Bleichstraße 14 40211 Düsseldorf (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 January 2014 revoking European patent No. 1945285 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	E. Dufrasne
Members:	S. Böttcher
	D. Ceccarelli

Summary of Facts and Submissions

I. The patent proprietors lodged an appeal against the Opposition Division's decision, dispatched on 27 January 2014, to revoke European patent No. 1 945 285.

II. The patent was opposed on the grounds of lack of novelty and lack of inventive step (Article 100(a) EPC), insufficient disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. The Opposition Division held that claim 1 of the main request as amended during opposition proceedings and claim 1 of the first to thirteenth auxiliary requests, as filed during opposition proceedings, contained subject-matter extending beyond the content of the application as filed. As a consequence, the ground for opposition according to Article 100(c) EPC prejudiced the maintenance of the patent as granted or on the basis of one of the first to thirteenth auxiliary requests.

IV. Notice of appeal was received on 7 February 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 24 February 2014.

V. The Board summoned the parties to oral proceedings.

VI. Oral proceedings took place on 24 October 2018.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request and auxiliary requests 1 to 6 filed with letter dated 25 May 2012, auxiliary

requests 7 to 13 filed with letter dated 25 October 2013 and auxiliary request 14 filed with letter dated 24 February 2014. It also requested remittal to the department of first instance for further prosecution.

The respondent requested that the appeal be dismissed.

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

"A medical infusion system (1000) for providing sustained infusion with controlled rate injection of a fluid into a body of a patient, the system comprising:
a first separate reusable unit (I), comprising:
a controller (101) for managing operations,
a transceiver for communication,
an engine (103) for generating motion for a fluid transfer system, and
a first portion (105) of the fluid transfer system, the fluid transfer system becoming operative for transfer of the fluid when the first portion (105) is operatively coupled to a secondary portion of the fluid transfer system;
a second separate depletable unit (II), comprising:
a secondary portion (207) of the fluid transfer system, for operative coupling to the first portion (105),
a reservoir (203) for holding the fluid to be infused,
a tube (205) to enable fluid communication between the reservoir and the body of the patient, and
at least one source of energy (201) for delivery of power to the first unit (I) when the first unit (I) is operatively coupled to the second unit (II);
a third separate unit (III), comprising:

a cannula (305) for insertion into the body of the patient,
a trocar (303) fitted to the cannula; and
a fourth separate remote control unit (IV), comprising:
a transceiver (405) for communication with the first separate reusable unit,
at least one memory (403) for storing at least one of one or more computer programs, data, and instructions,
a control module (401) coupled to the at least one memory (403) and to the transceiver (405), and operative for receiving, executing, and emitting data and instructions, and
an I/O user interface for communication of data with a user and for sending instructions from the user to the controller (101),
wherein the controller (101) for managing operations is configured in such a manner that upon:
emission of appropriate instructions from the fourth separate remote control unit (IV),
operatively coupling the first separate reusable unit (I) and the second separate depletable unit (II), and
the cannula (305) being disposed in the body,
power is supplied to the engine (103) for generating motion for the fluid transfer system, and fluid is transferred from the reservoir (203) to the body."

VIII. The appellant's arguments are essentially those underlying the reasons for this decision.

IX. The respondent's arguments where relevant for the present decision may be summarised as follows:

The replacement of *liquid* with *fluid* in claim 1 violated Article 123(2) EPC.

In the description, the term "liquid" was always used in relation to the injection of a medicament. Therefore, the replacement of *liquid* with *fluid*, in particular in the last part of claim 1, where the fluid transfer from the reservoir to the body was specified, introduced subject-matter that was not derivable from the application as filed.

The insertion of the feature *separate* with regard to the third unit in claim 1 introduced added subject-matter, since it created an inconsistency between claim 1 and claim 3. Figures 18 and 19 showed a system including a rotatable member as defined in claim 3. However, as could be derived from those figures, in this embodiment the third unit was not separate.

The wording *the controller for managing operations is configured in such a manner that...* in claim 1 meant that the controller supplied power to the engine only when the three requirements (i) (emission of instructions), (ii) (coupling of the first and second units) and (iii) (insertion of the cannula) were fulfilled.

This required the controller to be configured to check the fulfilment of these three conditions. In particular, the controller had to be configured to check whether the cannula was disposed in the body, e.g. by means of a sensor. Since such a configuration had not been disclosed in the original application documents the claim included added subject-matter, contrary to the requirements of Article 123(2) EPC.

Paragraphs [0013], [0022] and [0025] of the description could not be considered as a basis for the amendment since they distinguished between preconditions that related to the controller, namely the emission of instructions and the coupling of the units, corresponding to requirements (i) and (ii) in claim 1, and the precondition "insertion of the cannula", corresponding to requirement (iii) in the claim, which related to the transfer of liquid in the body and had no influence on the controller. In contrast, in claim 1, all three requirements were under the control of the controller.

Furthermore, paragraphs [0013], [0022] and [0025] disclosed the coupling of the first, second and third units and their disposal on the skin of the patient, whereas in the claim it was mentioned only that the first and the second units were coupled.
Moreover, in paragraph [0013], it was mentioned that the fluid transfer system was controlled by the controller and the transceiver, whereas in claim 1 it was only the controller that was configured to supply power to the engine.

Hence, if paragraphs [0013], [0022] and [0025] were considered as a basis for the amendment, the claim would include an inadmissible intermediate generalisation.

According to decision T 1018/02, the description could not be used to give a different meaning to a claim feature which in itself imparted a clear, credible technical teaching to the skilled reader. In the present case, interpreting the claim to mean that the controller had to be configured to check whether the cannula was inserted was neither illogical nor

technically meaningless since this could be done by means of a sensor.
Moreover, according to T 197/10, if the claims were clear, it was not necessary to consult the description in order to interpret them.

Reasons for the Decision

1. The appeal is admissible.

2. The invention relates to a medical infusion system comprising four separate units, namely:
   - a first reusable unit I comprising a controller and an engine
   - a second depletable unit II comprising a medicament reservoir and a source of energy
   - a third injection unit III comprising a cannula for insertion into the body
   - a fourth remote control unit IV.

   For an injection the user chooses a desired type of unit II and couples this unit to the reusable unit I. The user then selects a type of unit III and couples this unit to unit II to establish fluid communication therewith. The assembled units are placed on the skin, with the cannula inserted into the skin. Upon command from the remote control unit, the engine of unit I is powered and liquid is dispensed from the reservoir and subsequently forwarded through the cannula to the skin.

3. Claim 1 of the main request is based on claim 20 as originally filed, including the following amendments:

a) The term *liquid* has been replaced with *fluid* throughout the claim.

b) The third unit is now denoted as a third *separate* unit.

c) The wording "*the controller for managing operations is configured in such a manner that*" has been introduced before the passage "upon emission of appropriate instructions from the fourth unit, operatively coupling the first unit and the second unit, and the cannula being disposed in the body, power is supplied to the engine (...) and fluid is transferred (...) to the body."

4. Amendment a)

4.1 The Board acknowledges that the term *fluid* may also include gases and is therefore broader than *liquid*. However, in the medical field, the term *fluid* is often used as a synonym for *liquid*. Accordingly, the Board observes that the terms *liquid* and *fluid* are used interchangeably in the description and claim 20 as originally filed. Hence, in the Board's view, the replacement of *liquid* with *fluid* in claim 1 does not violate Article 123(2) EPC.

4.2 The respondent argued that in the description the term *liquid* was always used in relation to the injection of a medicament.

The Board cannot accept this line of argument. The injection of fluid into the body is explicitly mentioned in paragraph [0061] ("...management of fluid injection..."), and the dispensing or ejection of fluid from the reservoir is mentioned in paragraphs [0001]

("...dispensing of fluids..."), [0014] ("...to eject fluid"), [0017] ("...flow of fluid..."), [0058] ("...fluid dispensing device.") and [0062] ("...transfer of fluid..."). Hence, in the Board's view, there is ample basis for this amendment.

5. Amendment b)

5.1 The basis for the introduction of the term *separate* in connection with the third unit can be found in paragraph [0058] of the description, which mentions that all four units are preferably separate units.

5.2 The Board does not share the respondent's view that there is an inconsistency between claim 1 and claim 3. Figures 18 and 19 show a system that includes a rotatable member as defined in claim 3, with a separate third unit (denoted as "III", in contrast to the second unit "II") which is coupled to the second unit. In fact, claim 3 requires the second unit to comprise a rotatable member (rotary fastener 61) for receiving the third unit. Hence, it is clear that the third unit is a separate unit that can be introduced within the rotary fastener (paragraph [0127]). Thus, there is no inconsistency between claim 1 and claim 3; they both relate to a separate third unit.

Furthermore, since the first, second and fourth units are defined as separate in claim 1, the third unit inevitably has to be separate, too. Consequently, the introduction of the term *separate* does not amount to added subject-matter.

6. Amendment c)

6.1 Support for this amendment can be found in paragraphs [0013], [0022] and [0025] of the description. Each of these paragraphs mentions that, upon fulfilment of the requirements for emission of instructions from the fourth unit and operatively coupling the first and second units (requirements (i) and (ii) as denoted by the parties), power is supplied to the engine for generating motion for the fluid transfer system and, after insertion of the cannula (requirement (iii)), liquid is transferred to the body, under control of the controller.

6.2 According to the respondent, the wording "*the controller for managing operations is configured in such a manner that*" in claim 1 required the controller to have been configured to check whether the three conditions were actually fulfilled.

However, the Board takes the view that the controller is only configured to supply power to the engine, and requirements (i) to (iii) have to be fulfilled in order to enable the entire system to operate in the intended manner. As defined in requirement (i), the instructions are sent out by the remote control, and the controller reacts to these instructions by supplying power to the engine. The coupling of the first unit and the second unit defined in requirement (ii) has to be performed so that the controller and the engine can receive power from the battery.

In the Board's opinion, it cannot be derived from the contested wording that the fulfilment of any of these requirements is reflected in the configuration of the controller. In particular, the claim wording does not require the controller to have been configured to check

whether the cannula has been disposed in the body of a patient.

It follows that, as also confirmed by paragraphs [0013], [0022] and [0025] of the description, the wording "*the controller for managing operations is configured in such a manner that*" can only be construed to mean that power is supplied to the engine and fluid is transferred to the body once the three requirements are fulfilled. It does not however require any of requirements (i) to (iii) to be actively checked.

6.3 In the respondent's opinion, paragraphs [0013], [0022] and [0025] distinguished between preconditions that related to the controller, namely the emission of instructions and the coupling of the units, corresponding to requirements (i) and (ii) in claim 1, and the precondition "insertion of the cannula", corresponding to requirement (iii) in the claim, which related to the transfer of liquid in the body and had no influence on the controller. In contrast, in claim 1, all three requirements were under the control of the controller.

The Board agrees with the respondent that the controller is involved in requirements (i) and (ii) to the effect that the controller has to receive the instructions and can supply power to the engine only when the second unit (comprising the source of energy) is connected to the first unit (comprising the engine). In contrast, the insertion of the cannula in the body (requirement (iii)) does not require any interaction with the controller. This is only a prerequisite for fluid to be transferred from the reservoir to the body, as required by the last feature of claim 1.

However, in the Board's view, neither the wording of claim 1 nor the wording of paragraphs [0013], [0022] and [0025] can be understood to mean that the supply of power by the controller is dependent on the fulfilment of any of these three requirements.

6.4 The respondent pointed out that claim 1, unlike paragraphs [0013], [0022] and [0025], does not explicitly specify that all three units are operatively coupled.

However, the Board holds that this does not amount to an inadmissible intermediate generalisation, since the part of the claim relating to the coupling of the units is unchanged compared to original claim 20.

6.5 Furthermore, the Board does not concur with the respondent that paragraphs [0013], [0022] and [0025] could not be considered as a basis for the amendment since they referred to the "controller and transceiver".

The Board observes that the transceiver mentioned in paragraphs [0013], [0022] and [0025] is already included in claim 1. It is clear that this transceiver is necessary for the communication between the first unit and the fourth unit, and paragraphs [0013], [0022] and [0025] do not imply anything else.

6.6 Hence, paragraphs [0013], [0022] and [0025] can be regarded as a basis for the introduction of the wording "*the controller for managing operations is configured in such a manner that*" in claim 1.

6.7 For the Board, unlike the respondent, the decisions T 1018/02 and T 197/10 do not appear to be applicable in

the present case. In the Board's view, claim 1 does not impart a clear and unambiguous technical teaching to the skilled reader to the effect that the controller has to be configured to check the fulfilment of any of requirements (i), (ii) and (iii).

7. Therefore, claim 1 of the main request does not include subject-matter extending beyond the content of the application as filed. It follows that the requirements of Article 123(2) EPC are fulfilled.

8. The remaining grounds for opposition have not been dealt with by the Opposition Division. Accordingly, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC and remit the case to the department of first instance for further prosecution, as requested by the appellant. The respondent has not objected to the remittal.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

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

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated