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**Datasheet for the decision
of 1 October 2019**

Case Number: T 1911/14 - 3.2.02

Application Number: 02784823.3

Publication Number: 1406540

IPC: A61B5/00, H04L12/28

Language of the proceedings: EN

Title of invention:

METHOD AND SYSTEM FOR CONTROLLING DATA INFORMATION BETWEEN TWO
PORTABLE MEDICAL APPARATUSES

Patent Proprietor:

NOVO NORDISK A/S

Opponents:

Roche Diabetes Care AG
Roche Diagnostics Deutschland GmbH
Sanofi-Aventis Deutschland GmbH

Headword:

Relevant legal provisions:

EPC Art. 56
RPBA Art. 12(4)

Keyword:

Late-filed evidence and auxiliary requests - admitted (yes)
Inventive step - (no)

Decisions cited:

Catchword:



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Case Number: T 1911/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 1 October 2019

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
18 July 2014 concerning the maintenance of
European Patent No. 1406540 in amended form**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
 M. Stern

Summary of Facts and Submissions

- I. The patent proprietor, opponent 2 and opponent 3 have appealed against the Opposition Division's decision that, account being taken of the amendments according to auxiliary request 2 made by the proprietor during the opposition proceedings, European patent No. 1 406 540 and the invention to which it relates met the requirements of the EPC.

The written decision was despatched on 18 July 2014.

The patent was opposed by three opponents on the grounds of insufficient disclosure, added subject-matter, exception to patentability of methods of treatment of the human body by therapy, lack of novelty and lack of inventive step.

- II. The appellant/patent proprietor (hereinafter "the proprietor") filed notice of appeal and paid the appeal fee on 23 September 2014. The statement setting out the grounds of appeal was received on 27 November 2014.
- III. The appellant/opponent 2 (hereinafter "opponent 2") filed notice of appeal and paid the appeal fee on 15 September 2014. The statement setting out the grounds of appeal was received on 14 November 2014.
- IV. The appellant/opponent 3 (hereinafter "opponent 3") filed notice of appeal and paid the appeal fee on 26 September 2014. The statement setting out the grounds of appeal was received on 27 November 2014.
- V. Oral proceedings took place on 1 October 2019.

The proprietor 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, 3, 2 and 4 to 17 submitted by letter dated 12 June 2015, in that order.

Opponent 2 and opponent 3 requested that the decision under appeal be set aside and that the patent be revoked.

The party as of right/opponent 1 submitted no requests.

VI. The following documents are mentioned in the present decision:

D2_01: WO-A-00/74753;
D3_01: WO-A-00/10628;
D1_03: EP-A-1 048 310;
D18_03: Excerpt from "Specification of the Bluetooth System", v1.0B, 1 December 1999, pages 3, 4, 19 and 143;
D18A_03: "Specification of the Bluetooth System", v1.0B, 1 December 1999;
D19_03: WO-A-00/19877.

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

"A method of controlling data information between two portable medical apparatuses (101; 102), the use of the apparatuses including a first operation and a second operation, said portable apparatuses comprising a first apparatus (101) for performing the first operation and a second apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing, transmitting, receiving, processing and displaying data

information, and where the two apparatuses have a number of interrelated positions during normal use, wherein the method comprises the steps of:

- automatically storing at least first data information relevant to said first operation in said first apparatus (101),
- automatically storing at least second data information relevant to said second operation in said second apparatus (102), and
- automatically transmitting, via short-range communications means (117; 118), data information relevant to at least one of said first and second operations between said first and second apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions, wherein said second apparatus is a drug administration device,

characterized in that the step of automatically transmitting data information between said first and second apparatuses comprises one or more of the following: checking a unique and individual apparatus identification number for each apparatus, and pairing the first apparatus and the second apparatus by linking their individual and unique identification numbers."

Claim 1 of auxiliary request 1 reads as claim 1 of the main request except that the final part of the claim reads as follows (the differences compared with claim 1 of the main request have been highlighted by the Board):

"characterized in that the step of automatically transmitting data information between said first and second apparatuses comprises ~~one or more of the~~ following: checking a unique and individual apparatus identification number for each apparatus, and pairing

the first apparatus and the second apparatus by linking their individual and unique identification numbers".

Claim 1 of auxiliary request 3 reads as claim 1 of auxiliary request 1 except that the passage defining the step of automatically transmitting data information reads as follows (the differences compared with claim 1 of auxiliary request 1 have been highlighted by the Board):

"...automatically transmitting, via Bluetooth ~~short-range RF~~ communications means (117; 118), data information relevant to at least one of said first and second operations between said first and second apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions...".

Claim 1 of auxiliary request 2 reads as claim 1 of auxiliary request 1 except that the final part of the claim reads as follows (the differences compared with claim 1 of auxiliary request 1 have been highlighted by the Board):

"and wherein ~~characterized in that~~ the step of automatically transmitting data information between said first and second apparatuses comprises the following: checking a unique and individual apparatus identification number for each apparatus, and pairing the first apparatus and the second apparatus by linking their individual and unique identification numbers, characterized in that the one of said number of interrelated positions is obtained when said first apparatus is fitted onto said second apparatus".

Claim 1 of auxiliary request 4 reads as claim 1 of

auxiliary request 1 except that the final part of the claim reads as follows (the differences compared with claim 1 of auxiliary request 1 have been highlighted by the Board):

"characterized in that the step of automatically transmitting data information between said first and second apparatuses comprises the following: checking a unique and individual apparatus identification number for each apparatus, and pairing the first apparatus and the second apparatus by linking their individual and unique identification numbers,
and that said first and second operations are selected from the group of: injection of medication, measurement of a body fluid, administering a number of carbohydrates, and performing a physical activity".

The independent claim of auxiliary request 5 reads as follows:

"A system for controlling data information between two portable apparatuses (101; 102), the use of the apparatuses including a first operation and a second operation, said portable apparatuses comprising a first apparatus (101) for performing the first operation and a second apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing, transmitting, receiving, processing and displaying data information, and where the two apparatuses have a number of interrelated positions during normal use, wherein

- said first apparatus comprises storage means for automatically storing at least first data information relevant to said first operation.
- said second apparatus comprises storage means for automatically storing at least second data information

relevant to said second operation, and

- that said first and second apparatuses comprise short-range communications means (117;118) for automatically transmitting data information relevant to at least one of said first and second operations between said first and second apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions, wherein said second apparatus is a drug administration device, characterized in that the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of at least one apparatus comprises information relating to pairing the first apparatus and the second apparatus by linking their individual and unique identification numbers."

The independent claim of auxiliary request 6 reads as follows (the differences compared with the independent claim of auxiliary request 5 have been highlighted by the Board):

"A system for controlling data information between two portable medical apparatuses (101; 102), the use of the apparatuses including a first operation and a second operation, said portable medical apparatuses comprising a first medical apparatus (101) for performing the first operation and a second apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing, transmitting, receiving, processing and displaying data information, and where the two apparatuses have a number of interrelated positions during normal use, wherein

- said first medical apparatus comprises storage means

for automatically storing at least first data information relevant to said first operation.

- said second medical apparatus comprises storage means for automatically storing at least second data information relevant to said second operation, and
- that said first and second medical apparatuses comprise short-range communications means (117;118) for automatically transmitting data information relevant to at least one of said first and second operations between said first and second medical apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions, wherein said second medical apparatus is a drug administration device, characterized in that the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of ~~at least one apparatus~~ each of the first and the second medical apparatuses comprises information relating to pairing the first medical apparatus and the second medical apparatus by linking their individual and unique identification numbers."

The independent claim of auxiliary request 7 reads as the independent claim of auxiliary request 6 except that the final part of the claim reads as follows (the differences compared with claim 1 of auxiliary request 6 have been highlighted by the Board):

~~"characterized in that~~ and wherein the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of at least one apparatus ~~each of the first and the second medical apparatuses~~ comprises information relating to pairing the first medical apparatus and the second medical apparatus by linking their individual

and unique identification numbers,
characterized in that the one of said number of
interrelated positions is obtained when said first
medical apparatus is fitted onto said second medical
apparatus".

The independent claim of auxiliary request 8 reads as follows (the differences compared with the independent claim of auxiliary request 5 have been highlighted by the Board):

"A system for controlling data information between two portable medical apparatuses (101; 102), the use of the apparatuses including a first operation and a second operation, said portable medical apparatuses comprising a first medical apparatus (101) for performing the first operation and a second medical apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing, transmitting, receiving, processing and displaying data information, and where the two apparatuses have a number of interrelated positions during normal use, wherein

- said first medical apparatus comprises storage means for automatically storing at least first data information relevant to said first operation.
- said second medical apparatus comprises storage means for automatically storing at least second data information relevant to said second operation, and
- that said first and second medical apparatuses comprise Bluetooth RF ~~short-range communications means~~ (117;118) for automatically transmitting data information relevant to at least one of said first and second operations between said first and second medical apparatuses when said apparatuses are mutually positioned in one of said number of interrelated

positions,
wherein said second medical apparatus is a drug administration device,
characterized in that the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of ~~at least one apparatus~~ each of the first and the second medical apparatuses comprises information relating to pairing the first medical apparatus and the second medical apparatus by linking their individual and unique identification numbers."

The independent claim of auxiliary request 9 reads as follows (the differences compared with the independent claim of auxiliary request 5 have been highlighted by the Board):

"A system for controlling data information between two portable medical apparatuses (101; 102), the use of the apparatuses including a first operation and a second operation, said portable apparatuses comprising a first apparatus (101) for performing the first operation and a second apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing, transmitting, receiving, processing and displaying data information, and where the two apparatuses have a number of interrelated positions during normal use, wherein

- said first medical apparatus comprises storage means for automatically storing at least first data information relevant to said first operation.
- said second medical apparatus comprises storage means for automatically storing at least second data information relevant to said second operation, and
- that said first and second medical apparatuses comprise short-range communications means (117;118) for

automatically transmitting data information relevant to at least one of said first and second operations between said first and second medical apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions, wherein said second apparatus is a drug administration device, characterized in that the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of at least one apparatus comprises information relating to pairing the first medical apparatus and the second medical apparatus by linking their individual and unique identification numbers, and that said first and second operations are selected from the group of:

- injection of medication,
- measurement of a body fluid,
- administering a number of carbohydrates, and
- performing a physical activity."

Claim 1 of auxiliary request 10 reads as claim 1 of the main request except that the final part of the claim reads as follows (the differences compared with claim 1 of the main request have been highlighted by the Board):

"characterized in that the step of automatically transmitting data information between said first and second apparatuses comprises one or more of the following: checking an unique and individual apparatus identification number for each apparatus, and pairing ~~the~~ a first apparatus and ~~the~~ a second apparatus by linking their individual and unique identification numbers".

Claim 1 of auxiliary request 11 reads as claim 1 of

auxiliary request 1 except that the final part of the claim reads as follows (the differences compared with claim 1 of auxiliary request 1 have been highlighted by the Board):

"characterized in that the step of automatically transmitting data information between said first and second apparatuses comprises the following: checking an unique and individual apparatus identification number for each apparatus, and pairing ~~the~~ a first apparatus and ~~the~~ a second apparatus by linking their individual and unique identification numbers".

Claim 1 of auxiliary request 12 reads as claim 1 of auxiliary request 2 except that the final part of the claim reads as follows (the differences compared with claim 1 of auxiliary request 2 have been highlighted by the Board):

"wherein the step of automatically transmitting data information between said first and second apparatuses comprises the following: checking an unique and individual apparatus identification number for each apparatus, and pairing ~~the~~ a first apparatus and ~~the~~ a second apparatus by linking their individual and unique identification numbers,
characterized in that the one of said number of interrelated positions is obtained when said first apparatus is fitted onto said second apparatus".

Claim 1 of auxiliary request 13 reads as claim 1 of auxiliary request 3 except that the final part of the claim reads as follows (the differences compared with claim 1 of auxiliary request 3 have been highlighted by the Board):

"characterized in that the step of automatically transmitting data information between said first and second apparatuses comprises the following: checking an unique and individual apparatus identification number for each apparatus, and pairing the a first apparatus and the a second apparatus by linking their individual and unique identification numbers".

The independent claim of auxiliary request 14 reads as the independent claim of auxiliary request 5 except that the final part of the claim reads as follows (the differences compared with the independent claim of auxiliary request 5 have been highlighted by the Board):

"characterized in that the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of at least one apparatus comprises information relating to pairing the a first apparatus and the a second apparatus by linking their individual and unique identification numbers".

The independent claim of auxiliary request 15 reads as follows (the differences compared with the independent claim of auxiliary request 6 have been highlighted by the Board):

"A system for controlling data information between two portable medical apparatuses (101; 102), the use of the apparatuses including a first operation and a second operation, said portable ~~medical~~ apparatuses comprising a first ~~medical~~ apparatus (101) for performing the first operation and a second apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing,

transmitting, receiving, processing and displaying data information, and where the two apparatuses have a number of interrelated positions during normal use, wherein

- said first medical apparatus comprises storage means for automatically storing at least first data information relevant to said first operation.
- said second medical apparatus comprises storage means for automatically storing at least second data information relevant to said second operation, and
- that said first and second medical apparatuses comprise short-range communications means (117;118) for automatically transmitting data information relevant to at least one of said first and second operations between said first and second medical apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions, wherein said second ~~medical~~ apparatus is a drug administration device, characterized in that the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of each of the first and the second medical apparatuses comprises information relating to pairing ~~the~~ a first ~~medical~~ apparatus and ~~the~~ a second ~~medical~~ apparatus by linking their individual and unique identification numbers."

The independent claim of auxiliary request 16 reads as follows (the differences compared with the independent claim of auxiliary request 7 have been highlighted by the Board):

"A system for controlling data information between two portable ~~medical~~ apparatuses (101; 102), the use of the apparatuses including a first operation and a second

operation, said portable ~~medical~~ apparatuses comprising a first ~~medical~~ apparatus (101) for performing the first operation and a second apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing, transmitting, receiving, processing and displaying data information, and where the two apparatuses have a number of interrelated positions during normal use, wherein

- said first ~~medical~~ apparatus comprises storage means for automatically storing at least first data information relevant to said first operation.
- said second ~~medical~~ apparatus comprises storage means for automatically storing at least second data information relevant to said second operation, and
- that said first and second ~~medical~~ apparatuses comprise short-range communications means (117;118) for automatically transmitting data information relevant to at least one of said first and second operations between said first and second ~~medical~~ apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions, wherein said second ~~medical~~ apparatus is a drug administration device, and wherein the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of at least one apparatus comprises information relating to pairing ~~the~~ a first ~~medical~~ apparatus and ~~the~~ a second ~~medical~~ apparatus by linking their individual and unique identification numbers, characterized in that the one of said number of interrelated positions is obtained when said first ~~medical~~ apparatus is fitted onto said second ~~medical~~ apparatus."

The independent claim of auxiliary request 17 reads as follows (the differences compared with the independent claim of auxiliary request 8 have been highlighted by the Board):

"A system for controlling data information between two portable ~~medical~~ apparatuses (101; 102), the use of the apparatuses including a first operation and a second operation, said portable ~~medical~~ apparatuses comprising a first ~~medical~~ apparatus (101) for performing the first operation and a second ~~medical~~ apparatus (102) for performing the second operation, where each apparatus has means for one or more of the following: storing, transmitting, receiving, processing and displaying data information, and where the two apparatuses have a number of interrelated positions during normal use, wherein

- said first ~~medical~~ apparatus comprises storage means for automatically storing at least first data information relevant to said first operation.
 - said second ~~medical~~ apparatus comprises storage means for automatically storing at least second data information relevant to said second operation, and
 - that said first and second ~~medical~~ apparatuses comprise Bluetooth RF communication (117;118) for automatically transmitting data information relevant to at least one of said first and second operations between said first and second ~~medical~~ apparatuses when said apparatuses are mutually positioned in one of said number of interrelated positions,
- wherein said second ~~medical~~ apparatus is a drug administration device,
characterized in that the storage means of each apparatus comprises a unique and individual apparatus identification number and that the storage means of each of the first and the second ~~medical~~ apparatuses

comprises information relating to pairing ~~the~~ a first medical apparatus and ~~the~~ a second medical apparatus by linking their individual and unique identification numbers."

VIII. The arguments of the proprietor, where relevant to the present decision, may be summarised as follows:

Main request - novelty and inventive step

D2_01 concerned a sensor system in communication with an infusion device. Considering the sensor system as a first medical apparatus and the infusion device as the second medical apparatus within the meaning of claim 1, D2_01 did not disclose that the two apparatuses had a number of interrelated positions during normal use. Furthermore, it did not disclose automatic transmission of data between the apparatuses when they were positioned in one particular position. Finally, D2_01 disclosed neither the checking of unique apparatus identification numbers nor the pairing of the apparatuses by linking such unique identification numbers.

In normal use the relative position of the sensor system and the infusion device on a patient was fixed, as shown in Figure 2 of D2_01.

The transmission of data between the sensor system and the infusion device of D2_01 occurred periodically, as disclosed, for example, on page 13, line 30 to page 14, line 2. It did not occur automatically in response to the specific positioning of the two apparatuses in one of the number of interrelated positions.

D19_03, referred to on page 63, lines 6 to 13 of D2_01,

had been wrongly admitted into the opposition proceedings by the Opposition Division in so far as its teachings concerned the telemeter monitor transmitter of the sensor system disclosed in D2_01 and the pairing of the sensor system and the infusion device by linking their unique identification numbers. Since D19_03 was cross-referenced in D2_01, the opponents could have submitted the document in due time, and not only two working days before the oral proceedings at first instance. Moreover, D19_03 was prima facie not relevant as it disclosed several embodiments of a telemetered monitor transmitter and was unclear about which of these different embodiments should be employed in the sensor system of D2_01, and it did not disclose two ID numbers, one for the sensor system and one for the infusion device. In any case, the ID code of the telemetered monitor transmitter of D19_03 was used for an entirely different purpose than the unique ID number of the claimed system: it was utilised to control a time window based synchronisation scheme for data exchange (page 15, line 28 to page 16, line 17), and not for communication with the infusion device.

While page 34, line 29, to page 35, line 2 of D2_01 discussed a sensor system which transmitted a message including an ID code, it was not disclosed for which purpose such a code was used. The reference to D3_01 on page 64, lines 3 to 14 of D2_01 was not specific, since D3_01 was only one of a number of citations. Moreover, D3_01 disclosed several infusion devices, among which only one included a unique ID number. A combination of the sensor system with this last infusion device was a non-obvious selection from a list. In any case, there was no teaching to pair the sensor system and the infusion device by linking their individual and unique identification numbers. D3_01 disclosed communication

between sensor systems and an optional RF programmer (Figure 2). Page 63, lines 19 to 22 of D2_01 disclosed that the sensor system simply received a hand-shake signal from the infusion device, indicating that information had been received correctly.

The technical effect of the distinguishing features of the subject-matter of claim 1 was explained in paragraphs [0015] and [0018] of the patent: a given first apparatus could only exchange data information with a second apparatus of a single corresponding set, and the data was exchanged automatically. That solved the problem of ensuring the maintenance of a valid and complete logbook of the use of the apparatuses, which was not addressed in the cited prior art.

It followed that the subject-matter of claim 1 of the main request was novel and inventive.

Auxiliary requests - admissibility

All the auxiliary requests should be admitted, as they were submitted with the reply to the statements of grounds of the opponents and addressed their objections.

Auxiliary requests 5, 10 and 14 - novelty and inventive step

The same arguments brought forward in relation to the main request applied to the subject-matter of claim 1 of auxiliary request 10, and to the subject-matter of the independent claim of each of auxiliary requests 5 and 14, directed to a system instead of a method.

Auxiliary requests 1, 6, 11 and 15 - novelty and inventive step

The same arguments brought forward in relation to the main request applied to the subject-matter of claim 1 of each of auxiliary requests 1 and 11, being more specific than the subject-matter of claim 1 of the main request in the definition of the step of automatically transmitting data, and to the subject-matter of the independent claim of each of auxiliary requests 6 and 15, directed to a system instead of a method.

Auxiliary requests 3, 8, 13 and 17 - novelty and inventive step

The subject-matter of claim 1 of each of auxiliary requests 3 and 13, and of the independent claim of each of auxiliary requests 8 and 17, comprised the feature that the automatic transmission took place via Bluetooth RF communication.

D2_01, even in combination with D3_01 and D19_03, did not disclose this feature.

The technical problem solved by this feature was how to provide a valid exchange of data and still enable easy coupling of the first and second apparatuses to common office equipment.

D19_03 taught a specific communication protocol (Table 1 on page 17). There was no reason why the skilled person would have replaced such a communication protocol by Bluetooth RF communication. Although it was not disputed that a Bluetooth standard was known at the priority date of the patent in suit, that standard was not an obvious choice at that date, since it required

continuous communication involving high power consumption. No Bluetooth profile had been developed for medical devices at that date.

Document D18A_03, on which the opponents relied, should not be admitted into the appeal proceedings, as it had been filed unjustifiably late and was not more relevant than the other prior art already on file.

Auxiliary requests 2, 7, 12 and 16 - novelty and inventive step

D1_03 disclosed a glucose monitor and an electronic pen which could be considered, respectively, as the first and the second apparatus within the meaning of claim 1 of each of auxiliary requests 2 and 12, and of the independent claim of each of auxiliary requests 7 and 16.

D1_03 disclosed neither automatic transmission of data between the two apparatuses, nor checking unique identification numbers to pair the apparatuses.

The technical problem solved by these distinguishing features was to provide improved data quality.

D3_01 concerned a completely different system having two apparatuses in communication with each other. The two apparatuses were not intended to be fitted one onto the other. Moreover, the communication between the two apparatuses was manually initiated and did not involve the checking of unique identification numbers of both apparatuses.

Hence, the subject-matter of claim 1 of each of auxiliary requests 2 and 12, and of the independent

claim of each of auxiliary requests 7 and 16, was novel and inventive.

Auxiliary requests 4 and 9 - novelty and inventive step

The same arguments brought forward in relation to the main request applied to the subject-matter of claim 1 of auxiliary request 4, being more specific than the subject-matter of claim 1 of the main request in the definition of the first and second operations, and to the subject-matter of the independent claim of auxiliary request 9, directed to a system instead of a method.

- IX. The arguments of the opponents, where relevant to the present decision, may be summarised as follows:

Main request - novelty and inventive step

D2_01 disclosed a method of controlling data information between two portable medical apparatuses, comprising all the features of claim 1 of the main request. More specifically, it disclosed a first medical apparatus in the form of a sensor system (10, 28 and 30 in the figures) and a second medical apparatus in the form of an infusion device (14 and 24 in the figures). During normal use the two apparatuses were worn on the body of a user and could be freely moved into different interrelated positions. Data transmission between the two apparatuses occurred periodically (page 13, line 30 to page 14, line 2 and page 41, lines 20 to 25), hence it was automatic. Claim 1 did not require the transmission to take place in only one of the number of interrelated positions. D2_01 also disclosed that the step of automatically transmitting data information included the checking of

unique apparatus identification numbers of the sensor system (page 34, line 32 to page 35, line 2 of D2_01, and page 16, lines 9 to 15 of D19_03) and of the infusion device (page 13, lines 4 to 27 of D3_01), and the pairing of the apparatuses by linking such unique identification numbers (hand-shake disclosed on page 63, lines 19 to 22 of D2_01).

D3_01 and D19_03 were incorporated by reference in D2_01 (page 63, lines 6 to 13 and page 64, lines 3 to 14). Their disclosure completed that of D2_01. For this reason D19_03 had to be admitted into the appeal proceedings.

If it was concluded that D2_01 did not disclose the claimed pairing of the apparatuses, the problem solved by this feature did not relate to the maintenance of a logbook, but concerned the provision of a system in which two devices safely communicate the way it is intended, without confusion. The pairing of the devices by linking their unique identification numbers, in a manner analogous to the pairing of an infusion device with its RF programmer as disclosed in D3_01, page 13, lines 4 to 20, was obvious.

It followed that the subject-matter of claim 1 of the main request was neither novel nor inventive.

Auxiliary requests - admissibility

The auxiliary requests had been filed late, did not address the objections raised by the opponents, and could have been filed during the first-instance proceedings. They should not be admitted into the appeal proceedings.

Auxiliary requests 5, 10 and 14 - novelty and inventive step

The same arguments brought forward in relation to the main request applied to the subject-matter of claim 1 of auxiliary request 10, and to the subject-matter of the independent claim of each of auxiliary requests 5 and 14, directed to a system instead of a method.

Auxiliary requests 1, 6, 11 and 15 - novelty and inventive step

The same arguments brought forward in relation to the main request applied to the subject-matter of claim 1 of each of auxiliary requests 1 and 11, and to the subject-matter of the independent claim of each of auxiliary requests 6 and 15, directed to a system instead of a method. D2_01 disclosed both the checking of a unique and individual apparatus identification number for each apparatus and the pairing of the apparatuses by linking their unique and individual apparatus identification numbers.

Auxiliary requests 3, 8, 13 and 17 - novelty and inventive step

The feature of the Bluetooth RF communication for the transmission of data information, as defined in claim 1 of each of auxiliary requests 3 and 13, and in the independent claim of each of auxiliary requests 8 and 17, was not disclosed in D2_01.

The distinguishing feature merely addressed the technical problem of providing a near-field communication protocol to implement the transmission of data information as disclosed in D2_01. In this

respect, Table 1 on page 17 of D19_03 did not disclose a communication protocol, but a message format which could be sent by different communication protocols.

At the priority date of the patent in suit, Bluetooth was a commonly used communication protocol in medical technology, as derivable from pages 19 and 893 of D18A_03 which explained that the Bluetooth system was operating in the Industrial Scientific Medicine (ISM) band. Its implementation for the transmission of data information in D2_01 was obvious.

Whether Bluetooth involved high power consumption was of little relevance, as this alleged disadvantage had been accepted in the patent in suit without an indication of any measure to compensate for it.

D18A_03 was the complete Bluetooth specification, of which D18_03, filed with the notice of opposition of opponent 3, was an excerpt. Its filing did not alter the case. D18A_03 had to be admitted into the appeal proceedings.

Auxiliary requests 2, 7, 12 and 16 - novelty and inventive step

D1_03 disclosed a first medical apparatus in the form of a glucose monitor and a second medical apparatus in the form of an electronic pen. These apparatuses were used in a method according to claim 1 of each of auxiliary requests 2 and 12, and built up a system according to the independent claim of each of auxiliary requests 7 and 16, with the difference that no checking of unique identification numbers to pair the apparatuses was involved.

Paragraphs [0021] and [0022] of D1_03 disclosed automatic transmission of data between the glucose monitor and the electronic pen.

The objective technical problem solved by the distinguishing feature of claim 1 of each of auxiliary requests 2 and 12, and the independent claim of each of auxiliary requests 7 and 16 was to ensure that transmission of data only takes place between the intended apparatuses, for example belonging to the same user. It was merely a security issue.

D3_01 taught the pairing of two apparatuses by linking their unique identification numbers in order to prevent wrong information from being transmitted. The skilled person would have implemented the teaching of D3_01 in the method and system of D1_03 for solving the objective technical problem, thereby arriving at the subject-matter of claim 1 of each of auxiliary requests 2 and 12, and the independent claim of each of auxiliary requests 7 and 16, in an obvious way.

Auxiliary requests 4 and 9 - novelty and inventive step

The same arguments brought forward in relation to the main request applied to the subject-matter of claim 1 of auxiliary request 4 and to the subject-matter of the independent claim of auxiliary request 9, directed to a system instead of a method. D2_01 disclosed that the first operation was the measurement of a body fluid and the second operation was the injection of medication.

Reasons for the Decision

1. The appeals are admissible.
2. The invention

The invention relates to a method and a system for controlling data information between two portable medical apparatuses.

The two medical apparatuses comprise a first apparatus for performing a first operation and a second apparatus for performing a second operation. The apparatuses have a number of interrelated positions during normal use. According to paragraph [0076] of the patent, in a preferred embodiment, depicted in Figure 1a reproduced below, the first apparatus (101) is a protective cap unit comprising a blood glucose monitor, and the second apparatus (102) is an insulin administration device.

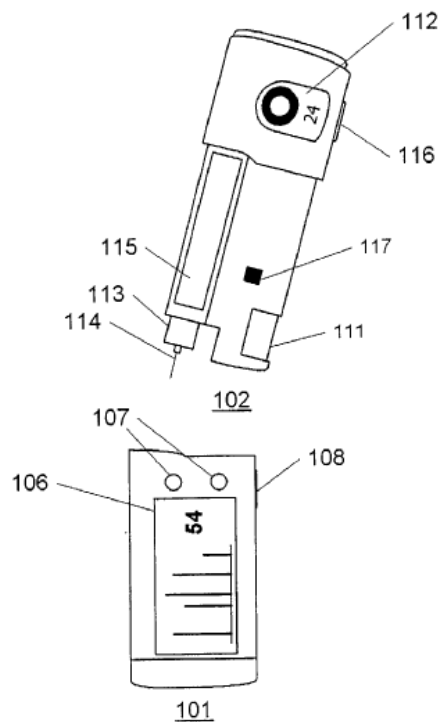


Figure 1a

Each apparatus has means for one or more of "storing, transmitting, receiving, processing and displaying data information". According to the preferred embodiment, the protective cap and the insulin administration device can store, transmit and receive data information between each other.

Data information relevant to the respective operations is stored in the respective apparatuses. Data information relevant to at least one of the two operations is transmitted via short-range communication means between the two apparatuses when they are mutually positioned in one of the interrelated positions, after pairing the apparatuses by checking and linking unique identification numbers. According to the preferred embodiment, the transmitted data information could be the measured glucose level and the time of the measurement (paragraph [0088]), and the amount and type of medication administered with the insulin administration device (paragraph [0082]).

According to the patent, advantages of the invention are the automatic creation and maintenance of a log-book (paragraph [0080]), important for the treatment of diabetes, and patient assistance for performing an individual treatment by providing recommendations about the amount of insulin to be injected when needed (paragraph [0120]).

3. Main request - novelty and inventive step

3.1 As a preliminary remark the Board notes that the scope of claim 1 of the main request is very broad compared with the disclosure of the preferred embodiment. While the preferred embodiment is specific to the treatment of diabetes and involves the use of an insulin

administration device and a glucose sensor housed in a cap of the administration device, claim 1 of the main request specifies nothing about the operations performed by the two medical apparatuses, the interrelated positions during normal use, and the transmitted data information.

3.2 The opponents argued that the subject-matter of claim 1 lacked novelty, in particular over D2_01.

D2_01 concerns a closed loop system for controlling insulin infusion. As visible in Figures 2 and 3 reproduced below, the system comprises a first apparatus for performing a first operation consisting of obtaining the blood glucose level in the body, the first apparatus including a sensor (26), a sensor set (28), a sensor cable (32) and a telemetered characteristic monitor (30), and a second apparatus for performing a second operation consisting of the administration of insulin, the second apparatus being in the form of a drug administration device including an infusion device (34) and a controller (12).

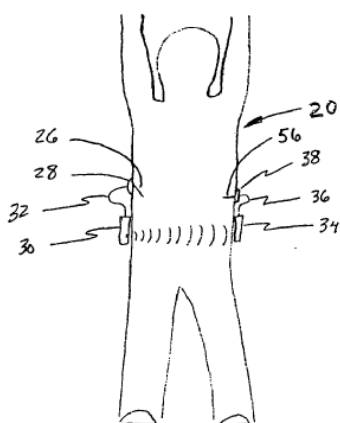


Fig. 2

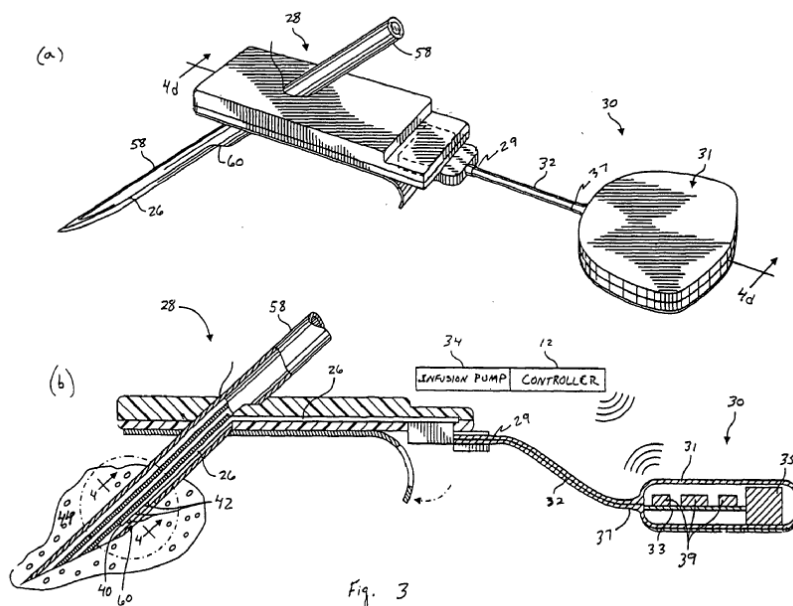


Fig. 3

The general method of operation of these apparatuses is disclosed on page 12, lines 10 to 17, in conjunction with Figure 1. The first apparatus, denominated glucose sensor system in that passage, generates a sensor signal and transmits it to the controller. The controller receives the sensor signal and generates commands for infusing insulin. It follows that the first apparatus comprises means for transmitting data information, and the second apparatus comprises means for receiving data information within the meaning of claim 1 of the main request.

The two apparatuses are worn by a patient as shown in Figure 2. Although they are represented in a fixed relative position, as the proprietor argued, the two apparatuses, during normal use, can be moved relative to each other, not only depending on the patient's movements but also because they can be repositioned onto different locations of the patient's body. Hence, the apparatuses have a number of interrelated positions during normal use, within the meaning of claim 1 of the main request.

The glucose sensor system automatically stores sensor values in a memory, for periodically sending those values, via short-range communication means (page 13, lines 10 to 13), to the controller of the second apparatus (page 13, line 30 to page 14, line 2).

- 3.3 As far as the details of the drug administration device are concerned, D2_01 incorporates by reference four documents of the prior art, amongst which is D3_01 (page 64, lines 3 to 12). D2_01 expressly states that the infusion devices of those documents are used in its preferred embodiments.

The proprietor argued that combining a specific infusion device described in D3_01 with the rest of the system of D2_01 would amount to a selection from a list, which included all the infusion devices disclosed in the four documents incorporated by reference. The Board does not accept this argument. In the context of the system disclosed in D2_01, specifying a few infusion devices that can be employed in that system amounts to a direct and unambiguous disclosure of each of the different resulting systems as separate embodiments.

According to an embodiment illustrated in Figure 1 of D3_01, the infusion device has a memory that stores historical data (page 8, lines 24 to 27) comprising patient infusion history and pump activity (page 3, lines 16 to 17). Inherently, such storage has to be automatic at least during a certain period of time, since the data to be stored varies continuously during operation.

As already explained above, D2_01 discloses that the

glucose sensor system periodically transmits data to the controller of the drug administration device (page 12, lines 10 to 17). This periodic transmission takes place via short-range communication means (page 13, lines 8 to 13) while the glucose sensor system and the drug administration device are worn by the user in any of the interrelated positions within the meaning of claim 1 of the main request. Since no user intervention is required for the transmission to take place, the latter qualifies as automatic within the meaning of the claim. As regards the proprietor's argument that the transmission did not occur in response to a specific positioning of the two claimed apparatuses in one of the number of interrelated positions, the Board notes that this is simply not required by the claim wording.

It follows that D2_01, with the added teaching of D3_01 incorporated by reference, discloses all the features of the preamble of claim 1 of the main request.

- 3.4 On page 63, lines 6 to 13, D2_01 makes specific reference to D19_03, incorporating it by reference, for the features of the telemetered characteristic monitor (30) of the glucose sensor system.

The proprietor argued that D19_03 had been filed late and should not be admitted in the proceedings.

D19_03 was admitted into the opposition proceedings by the Opposition Division in so far as its teachings concerned the telemeter monitor transmitter of the glucose sensor system disclosed in D2_01, and the pairing of the glucose sensor system and the drug administration by linking respective unique identification numbers (point 1.3.3 of the Reasons of the impugned decision). The Board sees no valid reason

to overturn the discretionary decision of the Opposition Division in that respect. In particular, the prima facie relevance of D19_03 is given since the disclosure of this document concerning the telemeter monitor transmitter, being provided with a unique identification number, is more specific than that of D2_01.

On page 34, line 29 to page 35, line 2, D2_01 discloses that the glucose sensor system may transmit a serial number or an ID code. D19_03 is more precise in that respect, since it discloses that the telemetered characteristic monitor of the glucose sensor system may transmit "a unique ID code that uniquely identifies each telemetered characteristic monitor transmitter" (page 16, lines 9 to 15). This amounts to a disclosure of a unique and individual identification number of the glucose sensor system, within the meaning of claim 1 of the main request.

D3_01 discloses that the drug administration device of D2_01 may also have a unique identification code, used "to substantially avoid interference with other external infusion devices" in the context of data communication between the drug administration device and a remote commander (page 4, lines 6 to 11 of D3_01). This amounts to a disclosure of a unique and individual identification number of the drug administration device, within the meaning of claim 1 of the main request.

Moreover, D2_01 (page 63, lines 19 to 22) discloses pairing of the glucose sensor system and the drug administration device:

"...the telemetered characteristic monitor transmitter

includes a receiver to receive updates or requests for additional sensor data or to receive a confirmation (a hand-shake signal) indicating that information has been received correctly."

Such a hand-shake between the two apparatuses is one way of pairing the two apparatuses within the meaning of claim 1, in the Board's view.

- 3.5 The proprietor argued that D2_01 does not directly and unambiguously disclose checking the unique and individual identification numbers of the two medical apparatuses or pairing the apparatuses by linking these numbers.

Accepting the proprietor's argument, the Board does not see any inventive step in carrying out the pairing disclosed as such; by linking the unique and individual identification numbers, which are provided in and can be transmitted by the two medical apparatuses of D2_01. It would have been an obvious possibility for the skilled person who had to physically implement the disclosed pairing. The problem formulated by the proprietor, relating to the maintenance of a logbook, is not accepted as it is not solved by the specific claimed way of pairing the two medical apparatuses.

- 3.6 It follows that, even in the most favorable approach for the proprietor, the subject-matter of claim 1 of the main request is not inventive (Article 56 EPC).

Hence, the patent cannot be maintained on the basis of the main request.

4. Auxiliary requests - admissibility

The opponents objected to the admissibility of the auxiliary requests. The Board notes that those requests were submitted with the proprietor's reply to the statements of grounds of opponent 2 and opponent 3. While the Board retains a discretion not to admit requests which could have been presented in the first-instance proceedings, under Article 12(4) RPBA this is the exception, rather than the rule. The Board admits the auxiliary requests into the appeal proceedings, as it considers that they were filed as a fair attempt to address the objections raised by the opponents in appeal.

5. Auxiliary requests 5, 10 and 14 - novelty and inventive step

5.1 The subject-matter of claim 1 of auxiliary request 10 is not inventive (Article 56 EPC) over D2_01 for the reasons explained under points 3.1 to 3.6 above, as it does not differ in substance from the subject-matter of claim 1 of the main request.

For the same reasons the subject-matter of the independent claim of each of auxiliary requests 5 and 14, drafted as system claims instead of method claims, does not involve any inventive step (Article 56 EPC) over D2_01.

5.2 Hence, the patent cannot be maintained on the basis of any of auxiliary requests 5, 10 and 14.

6. Auxiliary requests 1, 6, 11 and 15 - novelty and inventive step

6.1 The subject-matter of claim 1 of each of auxiliary requests 1 and 11 is not inventive (Article 56 EPC) over D2_01 for the reasons explained under points 3.1 to 3.6 above, in consideration of the fact that pairing the two medical devices by linking their unique and individual identification numbers implies the checking of those numbers.

For the same reasons the subject-matter of the independent claim of each of auxiliary requests 6 and 15, drafted as a system claim instead of a method claim, does not involve an inventive step (Article 56 EPC) over D2_01.

6.2 Hence, the patent cannot be maintained on the basis of any of auxiliary requests 1, 6, 11 and 15.

7. Auxiliary requests 3, 8, 13 and 17 - novelty and inventive step

7.1 The subject-matter of claim 1 of each of auxiliary requests 3 and 13, and of the independent claim of each of auxiliary requests 8 and 17 includes that the automatic transmission of data is done via Bluetooth RF communication.

While D2_01 discloses RF communication (page 13, lines 10 to 13), it does not disclose Bluetooth.

It is common ground, however, that a Bluetooth standard was known at the priority date of the patent in suit. This can be derived from, in particular, D18A_03.

7.2 The admittance of document D18A_03, filed by opponent 3 with the statement of grounds, was objected to by the proprietor. However, the Board is convinced that the filing of D18A_03, at the earliest stage of the appeal proceedings, to complete D18_03 is an appropriate and foreseeable reaction to the impugned decision. Hence, under Article 12(4) RPBA, D18A_03 is part of the appeal proceedings.

7.3 Faced with the problem of physically implementing the communication in the RF communication means of D2_01, the skilled person would have considered the known Bluetooth standard as an obvious possibility, in particular because that standard operated in a frequency band dedicated to medical applications (pages 19 and 893 of D18A_03).

The proprietor's argument that D19_03 already taught a specific communication protocol on page 17, Table 1, is not accepted by the Board. As the opponents submitted, that table does not disclose any communication protocol, merely a message format.

Whether the Bluetooth standard known at the priority date of the patent involved high power consumption is not decisive either, since it was implemented in the patent in suit without an indication of any measure to compensate for the alleged disadvantage and without any surprising advantage. As regards the advantage of facilitating the communication with other equipment such as office equipment, alleged by the proprietor, the Board notes that facilitating such communication is the purpose of any communication standard.

In conclusion, the subject-matter of claim 1 of each of auxiliary requests 3 and 13, and of the independent

claim of each of auxiliary requests 8 and 17 does not involve any inventive step (Article 56 EPC) over D2_01 in combination with D18A_03.

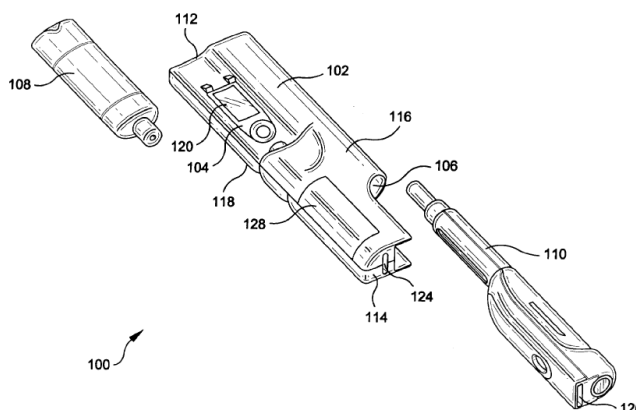
7.4 Hence, the patent cannot be maintained on the basis of any of auxiliary requests 3, 8, 13 and 17.

8. Auxiliary requests 2, 7, 12 and 16 - novelty and inventive step

8.1 The opponents argued that the subject-matter of claim 1 of each of auxiliary requests 2 and 12, and of the independent claim of each of auxiliary requests 7 and 16, lacked an inventive step when starting from D1_03 as the closest prior art.

8.2 D1_03 concerns an integrated diagnostic and medication delivery system comprising a medication delivery pen and a blood monitoring device, as shown in particular in Figure 2 reproduced below.

FIG. 2



The system comprises a first apparatus in the form of a glucose monitor for monitoring glucose in blood (housing 102), and a second apparatus in the form of an

insulin pen for delivering insulin to a patient (insulin pen 110).

It is common ground that the apparatuses have a number of interrelated positions during normal use.

In use, there is communication of data information between the glucose monitor and the insulin pen, via short-range communication means, when the glucose monitor is fitted onto the insulin pen (column 5, lines 35 to 38 and Figure 1).

The glucose monitor automatically stores the blood glucose level measured (column 5, lines 25 and 26). Also, the insulin pen, in an embodiment according to which it is in the form of an electronic pen, automatically stores information relevant to its operation (column 5, lines 30 to 44).

The proprietor argued that D1_03 did not disclose automatic transmission of data between the glucose monitor and the insulin pen.

However, in the Board's view, if this feature is not implicitly disclosed in D1_03, it is at least obvious in view of the passage in column 5, lines 45 to 53:

"In those embodiments of the invention that employ a mechanical delivery pen, the display located on the housing may be configured so that it automatically switches between two modes. In the first mode, when the pen is installed in the compartment 106 the display displays the blood glucose data. When the pen is removed from its compartment, the display switches to a mode that allows information from the medication delivery pen to be manually entered."

Although this passage refers to an embodiment comprising a mechanical delivery pen, it teaches automatic recognition of the presence of the pen in its compartment. Since, in the embodiment comprising an electronic pen, information is transmitted from the pen to the glucose monitor as explained above, it would have been obvious to perform the transmission upon recognition of the presence of the pen in its compartment - hence automatically - in analogy with the embodiment comprising a mechanical delivery pen.

8.3 D1_03 does not disclose checking a unique and individual apparatus identification number for each apparatus, and pairing the first apparatus and the second apparatus by linking their individual and unique identification numbers.

Pairing the two apparatuses before transmission of data information ensures that the transmission only takes place between the intended apparatuses. Therefore exchange of wrong data, for example between a glucose monitor and an insulin pen belonging to different users of the same family, is prevented. This addresses the objective technical problem of enhancing the security of use of the system.

As the opponents argued, D3_01 teaches the pairing of an infusion device and a RF programmer by linking their unique identification numbers (page 13, lines 4 to 19). This is to prevent transmission of wrong information which could pose a security problem.

In view of this teaching and the objective technical problem, the skilled person would have implemented the pairing disclosed in D3_01 in the system disclosed in

D1_03 without any inventive activity.

Whether D3_01 concerns a different system comprising two medical apparatuses which are not intended to be fitted onto each other, as the proprietor argued, is of little relevance, since the same objective technical problem is addressed and the difference is not related to that problem.

8.4 In conclusion, the subject-matter of claim 1 of each of auxiliary requests 2 and 12, and of the independent claim of each of auxiliary requests 7 and 16, does not involve an inventive step (Article 56 EPC) over D1_03 in combination with D3_01.

8.5 Hence, the patent cannot be maintained on the basis of any of auxiliary requests 2, 7, 12 and 16.

9. Auxiliary requests 4 and 9 - novelty and inventive step

9.1 The subject-matter of claim 1 of auxiliary request 4 is not inventive (Article 56 EPC) over D2_01 for the reasons explained under points 3.1 to 3.6 above, in consideration of the fact that according to D2_01 the first operation is obtaining the blood glucose level in the body and the second operation is the administration of insulin.

For the same reasons the subject-matter of the independent claim of auxiliary request 9, drafted as a system claim instead of a method claim, does not involve an inventive step (Article 56 EPC) over D2_01.

9.2 Hence, the patent cannot be maintained on the basis of either auxiliary request 4 or auxiliary request 9.

10. Since there is no allowable request, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated