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D E C I S I O N
of 15 January 2003

Case Number: T 0398/99 - 3.2.2

Application Number: 94913723.6

Publication Number: 0696924

IPC: A61M 5/145

Language of the proceedings: EN

Title of invention:
Syringes and syringe pumps

Applicant:
AstraZeneca AB

Opponent:

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Headword:

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Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty and inventive step (yes, after amendments)"

Decisions cited:

-

Catchword:

-



Case Number: T 0398/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 15 January 2003

Appellant: AstraZeneca AB
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Representative: Billington, Lawrence Emlyn
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 3 December 1998
refusing European patent application
No. 94 913 723.6 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
U. J. Tronser

Summary of Facts and Submissions

I. European patent application No. 94 913 723.6 (PCT publication No. WO 94/25089) was refused by the Examining Division on the grounds of both lack of novelty and inventive step vis-à-vis the prior art documents D1 or D2, having regards to the common general knowledge of a person skilled in the art.

D1: WO-A-91/04759

D2: DE-A-4 020 522.

II. The appellant (applicant) lodged an appeal against this decision on 1 February 1999 and filed a statement of grounds on 31 March 1999 along with two sets of claims according to a main and an auxiliary request, respectively.

III. In a communication dated 25 July 2002 the appellant was informed by the Board that a patent based on the auxiliary request would be acceptable, provided that the description be adapted correspondingly.

IV. The appellant replied favourably by letter dated 6 September 2002, submitting fair copies of the application documents incorporating the required amendments.

V. The appellant requested, finally, that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claims: 1 to 29 submitted with letter dated
6 September 2002.

Description: pages 1, 7 to 8, 10 to 11, 14 to 20 of the PCT application as filed.
page 2 (amended sheet) filed on 26 April 1995 (see International Preliminary Examination Report).
page 9 submitted with letter dated 23 October 1997.
pages 3 to 6, 6a, 12 to 13, 13a, 21 to 23 submitted with letter dated 6 September 2002.

Drawings: Sheets 1/5 to 5/5 according to the PCT application as filed.

VI. Independent claims 1, 21, 28 and 29 read as follows:

"1. A syringe having readable data carrier means (2c) therewith to carry data relating to a medicament contained or to be contained in the syringe, wherein the data carrier means (2c) comprises a device which is electrically and/or magnetically operable to be activated by a suitable field applied by an external means and, in response to said activation, to emit said data it is carrying, the device being a resonant device adapted to resonate at at least one predetermined frequency when activated as aforesaid, thereby to emit medicament-related data represented by the value or values of said at least one predetermined resonant frequency."

"21. A syringe pump (6) cooperable with a syringe according to claim 1, and comprising activation means (32) operable to emit a field suitable to cause the resonant electrically and/or magnetically operable device with the syringe to resonate and thereby emit

data it is carrying, the syringe pump (6) further comprising receiving means for receiving the data thus emitted by being operable to detect the value or values of the at least one predetermined resonant frequency at which said resonant electrically and/or magnetically operable device resonates, drive means (13) for operating the syringe to deliver to a patient medicament when contained in the syringe, and control means (7) coupled to said receiving means and to said drive means (13) to operate the drive means taking into account data received from the data carrier means by the receiving means."

"28. A method for automatically identifying a medicament or a property of a medicament, comprising providing with a syringe which contains or is to contain the medicament, data carrier means comprising a device which is electrically and/or magnetically operable to be activated by a suitable field applied by an external means and, in response to said activation, to emit said data it is carrying, the device being a resonant device adapted to resonate at at least one predetermined frequency when activated as aforesaid, thereby to emit medicament-related data represented by the value or values of said at least one predetermined resonant frequency."

"29. A partially disassembled prepackaged syringe comprising a barrel (1), a plunger (4) and a finger grip (2) in an assembled state with the plunger (4) fitting closely within the barrel (1) and the finger grip (2) being present in an open end of the barrel (1), there being a plunger rod (3) provided separately from the plunger (4), and the syringe being provided with data carrier means (2c) to carry data relating to

a medicament contained or, to be contained in the syringe, wherein the data carrier means (2c) comprises a device which is electrically and/or magnetically operable to be activated by a suitable field applied by an external means and, in response to said activation, to emit said data it is carrying, the device being a resonant device adapted to resonate at at least one predetermined frequency when activated as aforesaid, thereby to emit medicament-related data represented by the value or values of said at least one predetermined resonant frequency."

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments*

The four independent claims were appropriately reworded in the one-part-form, in accordance with Rule 29(1) EPC.

Claim 1 is based on original claims 1 and 2 and on the following passages of the PCT application as filed: page 6, lines 3 to 13; page 14, lines 1 to 7 and 28 to 31; page 20, lines 11 to 18.

Claims 2 to 20 are based on original claims 3 to 7 and 9 to 22, respectively.

Claim 21 is based on original claim 23 supplemented by additional features supported by the application as filed, page 6, lines 11 to 13 and page 18, last paragraph.

Claims 22 to 27 are based on original claims 24 to 29, respectively.

Claim 28: The method claim is based on original method claim 30, supplemented by features picked up from the present claim 1 to provide consistency.

Claim 29 is based on original claim 31, supplemented as well by features picked up from the present claim 1.

The description was adapted in accordance with the independent claims. Moreover, non-resonant systems illustrated by Figures 3 and 4 were clearly excluded from the invention.

Therefore, all amendments are clear and fairly supported by the application as filed, in accordance with the requirements of Article 84 and 123(2) EPC.

3. *Novelty and inventive step*

Independent claims 1, 21, 28 and 29 are all consistent and specify each that the device used as data carrier means is a resonant device for emitting the data it is carrying when activated by a suitable external field, the resonant frequency of which represents the medicament-related data. The Board, therefore, finds it appropriate to limit its examination to these essential features for the assessment of novelty and inventive step of the claimed subject-matter.

3.1 Novelty

Document D1 referred to in the application as filed is regarded as the closest prior art. It discloses an

infusion pump having a computer to control the dispensing of a medicament contained in a replaceable syringe to be mounted in an housing provided in the infusion pump. A motor is connected to the syringe plunger to drive it axially in order to expel the medicament from the syringe towards a patient. The syringe is provided with a bar code 32, in label form, mounted on it, indicating the prescription prepared by the physician. The infusion pump is provided correspondingly with a bar code reader 30 to input the prescription data to the pump computer.

Although not expressly mentioned in document D1, the bar code reader is an optical system of a conventional type, in which the bar code on the label is simply and passively read by reflection of light. A bar code needs not be activated to be read since there is no emission of data within the meaning of the present invention. As reported in document D1 (cf. page 3, lines 9 to 14), "the bar code reader reads the bar code when the syringe is inserted in the housing and inputs the prescribed data to the pump computer". Alternatively (cf. page 6, last paragraph), other machine-readable indicia such as magnetic strips or tags may generally be contemplated. However, those alternatives and the functioning thereof are not otherwise detailed so that their disclosure is anyway insufficient and, therefore, inoperant.

The subject-matter of the independent claims differs from document D1 in that said data carrier means comprises a device operable to be activated by a suitable field in order to emit the data it is carrying. Further, in that the device resonates when activated, so as to emit medicament-related data

represented by the resonance frequency. Consequently, the subject-matter of the independent claims is novel within the meaning of Article 54 EPC.

3.2 Inventive step

A drawback in document D1, as submitted by the appellant, is that an optical bar code surface pattern or a magnetic strip represents an unsafe way of providing data, which can be misread if incorrectly placed or subjected to contamination by foreign material. Such a technical problem is also derivable from the advantages of the invention enumerated in the description as originally filed (cf. from page 6, lines 34 to page 7, line 12).

The solution to this problem is given by the features mentioned above, which are not disclosed in document D1. More specifically, the data carrier means is a resonant device which resonates when activated by a suitable magnetic or electric field, the resonant frequency of which is predetermined to represent a medicament-related data (e.g. identification or concentration). The carrier means, therefore, emits the data it is carrying. The resonant frequency is then detected and processed in the pump computer, which outputs a signal for driving the plunger of the syringe. With this arrangement, any error due to incorrect positioning or physical contamination of the bar code or of the associated reader used in the previous systems, can be avoided.

As already noticed, the optical bar code reader used in document D1 is a passive system since the data of the pattern are not emitted. Rather, they are read by

reflection of light without need of any external activation field. The same is true with passive magnetic strips, which are not comparable to active magnetostrictive devices such as those used in the present application (Figures 6 to 9), which rely on resonant magnetically biased materials suitably activated by an external magnetic field.

By the incorporation in all independent claims of the features specifying that the data carrier means is a resonant device adapted to resonate when activated by a suitable field applied by an external means, thereby to emit medicament-related data represented by the resonant frequency, the claimed subject-matter has been restricted to features not envisaged by document D1. Therefore, the specific solution as now claimed is neither disclosed nor suggested by document D1.

Document D2 discloses a system for identifying the type and size of a syringe to be accommodated in the recess of a syringe holder. An identification resistance 4 having a predetermined value is applied to the holder. When the holder accommodating the syringe is mounted on the pressure infusion apparatus an electrical contact is established with a second resistance 8 which forms with the previous identification resistance a voltage divider circuit for detecting the voltage and, therefore, identifying the syringe. Also this known system makes use of passive components such as electrical resistances, which necessitate direct contacts. The use of a resonant device for emitting data it is carrying in response to an external activating field is, therefore, not suggested by document D2, either.

As stated in the present application, fundamental or harmonic resonance systems are known from other documents and have already been proposed for other applications such as goods labelling, luggage sorting at airports, security and access control or remotely reading of gas or electricity meters. However, the specific adaptation of these known principles to the identification of a medicament contained in a syringe for controlling its administration to a patient are not suggested by the above-cited documents. Therefore, the combination as claimed of all the features, which just represents such an adaptation, implies an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of the documents listed in section V above.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß