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D E C I S I O N
of 5 July 1995

Case Number: T 0300/93 - 3.2.2

Application Number: 85101770.7

Publication Number: 0192786

IPC: A61M 5/14

Language of the proceedings: EN

Title of invention:
Processor-controlled angiographic injector device

Patentee:
Medrad Incorporated

Opponent:
Siemens AG

Headword:
-

Relevant legal provisions:
EPC Art. 123(2, 3), 52(1), 54, 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 0300/93 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 5 July 1995

Appellant:
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Representative: -

Decision under appeal: Decision of the Opposition Division of the
European Patent Office dated 15 January 1993
revoking European patent No. 0 192 786 to
Article 102(1) EPC.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: C. G. F. Biggio
M. K. S. Auz Castro

Summary of Facts and Submissions

- I. European patent No. 192 786 was granted on 7 February 1990, on the basis of application No. 85 101 770.7 filed on 18 February 1985.

- II. On 30 October 1990, an opposition was filed by the Respondent on the ground of Article 100(a) EPC, alleging lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC). The Opponent relied on the following documents:

E1 = US-A-3 701 345,
E2 = Siemens Bedienungsanleitung "SIMTRAC C, Mikroprozessor gesteuerter Angiographie-Hochdruck-Impulsinjektor",
E3 = DE-A-2 410 868, and
E4 = US-A-4 146 029.

- III. The Opposition Division held that the subject-matter of Claim 1, as filed on 4 October 1991 (Request A), and of Claim 1, as filed at the Oral Proceedings held on 30 November 1992 (Request B), was obvious in the light of the teachings disclosed by the documents E1 and E2, and revoked the patent by its decision issued on 15 January 1993.

- IV. The Appellant (Patentee) lodged an appeal, received on 25 May 1993, against said decision of the Opposition Division, paying the appeal fee on the same day. The Statement of Grounds was filed on 25 May 1993.

- V. The following further prior art documents were mentioned in the appeal procedure:

E5 = K. Block et al: "Einführung in die Elektronik, Kontaktlose Signalverarbeitung", 1981, pages 508-509, 538 (by the Respondent on 27 September 1993), and
E6 = US-A-4 006 736 (by the Appellant on 5 March 1995).

On 1 March 1995, the Appellant filed an additional set of claims, to be considered as a further auxiliary request (Request C).

VI. On 8 March 1995, oral proceedings were held at the request of both parties.

At the oral proceedings, the Appellant filed two newly amended sets of claims (Request D and Request E), to be considered as further auxiliary requests.

VII. Claim 1 according to the Requests A to E are set out below, the subdivision and identification of the individual features having been made by the Board.

(i) Request A (main request) reads:

"An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising

- a) means (204) for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,
- b) drive means (24) for effecting discharge of said media through said discharge port,
- c) receiving means for receiving at least one injection control parameter which includes at least one parameter selected from a group including flow rate of contrast media, volume of contrast media during an

injection, pressure limit of said contrast media, X-ray photo delay, inject delay and flow rise/fall time of pressure of contrast media, and

- d) processor control means (10) for generating at least one injection control signal as a function of said at least one injection parameter supplied thereto and for supplying said control signal to said drive means (24) thereby to effect controlled discharge of said media,
- e) wherein said drive means (24) and processor control means (10) comprise a closed loop servo system responsive to a position command signal produced by said processor control means (10), **characterized by**
- f) memory means (18) for storing a set of injection parameters,
- g) means for producing an identification tag for association with each set of at least one injection parameters and for storing said tag with said set in said memory means,
- h) recall means responsive to a given tag for recalling from said memory means an associated set of injection parameters to said receiving means thereby to enable quick recall of routine sets of injection parameters without operator input prior to the injection".

- (ii) Request B (1st auxiliary request)
Claim 1 differs from Claim 1 according to Request A in that the features (g) and (h) are amended to read:

- g') means for producing an identification tag, including a program number and a title field, for association with each set of said at least one injection parameters and for storing said tag with said set in said memory means,
- h') recall means responsive to a given tag for recalling from said memory means an associated set of injection parameters, for displaying the title field, and for supplying said recalled set of injection parameters to said receiving means thereby to enable quick recall of routine sets of injection parameters without operator input prior to the injection.

(iii) Request C (2nd auxiliary request)

Claim 1 differs from Claim 1 according to Request A in that its characterising portion contains the following additional feature:

- i) "further including mechanical stop controller means (26) responsive to a pre-established forward limit of said piston to inhibit said drive means for discharging media from said syringe, said forward limit being determined by said processor control means".

(iv) Request D (3rd auxiliary request) reads:

"An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

- a') means (204) for holding a reservoir comprising a syringe having a piston and containing contrast media and including a discharge port through which the media is discharged,

- b) drive means (24) for effecting a discharge of said media through said discharge port,
- c) receiving means for receiving at least one injection control parameter which includes at least one parameter selected from a group including flow rate of contrast media, volume of contrast media, duration of an injection, pressure limit of said contrast media, X-ray photo delay, inject delay and flow rise/fall time of pressure of contrast media, and
- d) processor control means (10) for generating at least one injection control signal as a function of said at least one injection parameter supplied thereto and for supplying said control signal to said drive means (24) thereby to effect controlled discharge of said media,
- f) memory means (18) for storing a set of injection parameters,
- g) means for producing an identification tag, including a program number, for association with each set of said at least one injection parameters and for storing said tag with said set in said memory means,
- h) recall means responsive to a given tag for recalling from said memory means an associated set of injection parameters and for supplying said recalled set of injection parameters to said receiving means thereby to enable quick recall of routine sets of injection parameters without operator input prior to the injection,

- e) wherein said drive means (24) and processor control means (10) comprise a closed loop servo system responsive to a position command signal produced by said processor control means (10), **characterized in that**
- g") the means for producing an identification tag further includes a title field,
- h") the recall means further displays the title fields upon recalling of the associated set of injection parameters,
- i) further includes mechanical stop controller means (26) responsive to a pre-established forward limit of said piston to inhibit said drive means for discharging media from said syringe, said forward limit being determined by said processor control means,
- j) wherein said mechanical stop controller means (26) comprises a stop member (212) and a d.c. stop motor (241) operatively connected to said stop member, means (66) for monitoring the position of said piston, means (74) for producing a stop command signal when the position of said piston reaches said forward limit, and means responsive to said command signal to actuate said stop motor which, in turn, advances said stop member to mechanically prevent forward movement of said piston, and
- k) wherein said processor control means includes control means (110) for establishing said pre-established forward limit of said stop member in dependence on the value of an injection parameter supplied thereto".

- (v) Request E (4th auxiliary request)
Claim 1 differs from Claim 1 according to Request D in that its characterising portion contains the following additional features:
- 1) "further includes safety relay means (28, 44) for alternatively enabling one of said drive means and said mechanical stop controller means thereby to prevent movement of said drive means while said mechanical stop controller is actuated".

VIII. During the oral proceedings of 8 March 1995 and in writing, the parties made the following submissions.

Document E2 was unanimously considered as representing the closest prior art on file.

- (i) As to Claim 1 of the Request (A)
The Appellant admitted that E2 disclosed features a) to d) and f), but submitted that said document did not disclose **either** "drive means and processor control means comprising a closed loop servo system responsive to a position command signal produced by said processor control means" (feature e)), **or** the features mentioned in the characterising clause of Claim 1, **especially**: "means for producing an identification tag for association with each set of said at least one injection parameters and for storing said tag with said set" (feature g)) and, consequently, "recall means responsive to a given tag for recalling...an associated set of injection parameters..." (feature h)). In particular, it was submitted that, since the device according to E2 comprised only five memory positions for storing therein sets of injection parameters, the identification tag for association with a set of

injection parameters did not need not to be stored with said set; the operation of recalling a stored set could, in fact, be carried out by merely addressing each of said five memory positions. The user could place a manually written "code word" on an identification field, which "code word" would enable the user to recognise the stored injection program. The invention, however permitted the user to generate an identification tag which was stored together with the sets of the injection parameters in a non-volatile memory. The feature e) was known from document E1, but not in combination with the other features of Claim 1, in particular not with the features f) to h).

The Respondent, on the contrary, submitted that the person skilled in the art would have considered the above features e), g) and h) as also disclosed by E2, at least by implication. In particular, it was submitted that, in such a device as that according to E2,

- the use of a closed loop servo system responsive to a position command signal produced by the processor control means was a compulsory necessity, at least in order to insure that the patient to be treated with said device would never be exposed to the physical damages possibly resulting e.g. from too high an injection pressure and/or a too high a volume of the contrast medium,
- the feature of producing an identification tag for association with a set of injection parameters and storing it with said set, was also a necessity, since the specific memory position, in which a given set of injection parameters was stored, was randomly chosen

among the five available memory positions, so that it would be impossible to recall a stored set of injection parameters, without using its own associated identification tag, which must, therefore, be stored together therewith.

(ii) As to Claim 1 of Request (B)

The Appellant submitted that "means for producing an identification tag, including a program number and a title field" (feature g')) and, consequently, "means...for displaying the title field" (feature h')) were not disclosed by E2. Reference was made to page 1-4 (headline 113) of E2, to show which was the effective nature of the information contained in the "title field 113" according to said document, and it was submitted that said information had nothing to do with the information contained in the "title field" according to the patent at issue (see: Figure 8C, top left side, the branch "yes" starting off the field "store button pressed?"); the latter information being, moreover, "freely or randomly" determined by the user, which did not appear to be possible in the device according to E2. It was further pointed out that the keyboard of said device showed only numerical keys, so that it was impossible, with such a keyboard, to produce an identification tag comprising not only "one or more numbers", but also "words or alphanumeric combinations" (see patent at issue: col. 12 lines 5 to 8).

The Respondent, on the contrary, submitted that a person skilled in the art would have considered the disputed features g') and h') as disclosed by E2, at least by implication. Reference was made

to page 1-4 (headline 113) of E2, in comparison with the above-quoted disclosure of the patent at issue (Figure 8C, top left side, the branch "yes" starting off the field "store button pressed?"; col. 12 lines 5 to 8), and it was pointed out that neither said disclosure, nor the wording of Claim 1 specified either the nature of the information stored in the "title field", according to the patent at issue or the fact that said information was "freely or randomly" determinable by the user. This allowed the person skilled in the art to arrive at the above consideration.

In response to a question from the Board, the Appellant admitted that, in the patent at issue, the identification tag was associated with a set of injection parameters - constituting a piece of information- and stored together therewith, in a manner which might be considered as analogous to that according to the well-known MS-DOS procedure.

(iii) As to Claim 1 of Request (C)

The Appellant admitted that mechanical stop means, to be manually positioned by an operator, were known in E6; submitting, however, that mechanical stop controller means according to feature i) were not disclosed by said document, nor rendered obvious by the combination of E2 and E6, even when taking into account E1.

It was pointed out that the mechanical stop controller means according to feature i) had the purpose of insuring that a patient, to be treated with the device according to the patent at issue, would never be exposed to the physical damages possibly resulting from an erroneous manual

positioning, by the operator, of the mechanical stop means according to E6; such a purpose, and even the possible necessity of such a safety device as according to feature i) being unknown in E2.

The Respondent submitted that a person skilled in the art, having regard to the stated purpose of the mechanical stop controller means according to feature i), would have considered it obvious to incorporate that feature in a device according to E2, at the light of the combined teachings of E2, E6 and E1.

In support of this submission, it was pointed out

- that, since the mechanical stop means according to E6 were to be manually positioned by an operator, the danger of an erroneous positioning by the latter was obvious, so that the stated purpose of the mechanical stop controller means according to feature i) was also obvious,
- that E1 disclosed electromechanical stop controller means, which, similarly to those according to feature i), were responsive to a preestablished forward limit of the piston movement to inhibit the drive means thereof, under the control of processor control means,
- that the claimed features i) merely resulted from the association of the mechanical stop means according to E6 with drive means and processor control means comprising a closed loop servo system responsive to a position command signal produced by said processor control means, and
- that said drive means and closed loop servo system were analogous, if not identical to those according to feature e), already known

in E2, so that the person skilled in the art, in order to achieve the stated purpose of automatically positioning mechanical stop means of the kind known in E6 and thereby avoiding the danger of an erroneous positioning by the operator, did not need to design a fully new closed loop servo system, but merely to duplicate an already known one.

(iv) As to Claim 1 of Request (D)

Both parties concentrated their submissions on the features which differentiate the subject-matter of Claim 1 according to Request (D) from that of Claim 1 according to the Request (C), i.e. on features g"), h"), j) and k).

The Appellant submitted that features g"), and h") were not disclosed by E2, while features j) and k) were not disclosed by any of the prior art documents considered.

It was further pointed out that, since the device according to the patent at issue comprised features j) and k), the latter necessarily comprised a second drive motor expressly provided for servo-positioning the mechanical stop controller means; such a second drive motor being neither disclosed nor even suggested by any of the prior art documents considered.

The Respondent pointed out that features g") and h") merely resulted from the fact that features g') and h') of Claim 1 according to the Request (B) had been split into features g) and g"), respectively h) and h"), in Claim 1 according to Request (D) and, consequently, maintained the submission that said features g") and h") were disclosed by E2, at least by implication.

It was, moreover, submitted that the effective technical meaning of said features was unclear. In respect of features j) and k), submissions analogous to those made in respect of feature i) of Request (C) pointed out further that the problem to be solved was the obvious one of rendering fully reliable the possibly unreliable mechanical stop means according to E6, this by replacing the possibly unreliable "human actuator" of said mechanical stop means according to E6 by a fully reliable "mechanical actuator" (motor) under the control of a position servo-control system resulting from the duplication of the already existing position servo-control system responsible for the positioning of the syringe piston.

(v) As to Claim 1 of Request (E)

The Appellant submitted that feature 1) was neither disclosed nor even suggested by any of the prior art documents considered, taken alone or in combination.

It was, moreover, submitted that a person skilled in the art, well aware of the extremely precise positioning of a mechanical element (piston or stop means) which may be obtained with closed loop servo-systems, would have never envisaged that it could be suitable to provide such closed loop servo-systems with additional safety means (relay 28, 44), as according to feature 1).

The Respondent admitted that feature 1) was neither disclosed nor even suggested by any of the prior art documents considered, taken alone or in combination.

It was, however, submitted that the person skilled in the art would have considered feature

1) as an obvious feature, in order to ensure that the mechanical stop means was effectively positioned and locked on the wanted preestablished forward limit position of the subsequent piston movement, prior to enabling the piston drive motor to effect said subsequent movement of the piston, i.e. in order to ensure the independence of the drive motor positioning the piston from that positioning the mechanical stop means; such an independence being only achievable with the additional safety means (relay 28, 44, as according to feature 1), or with other means acting in an analogous manner and providing for the same specific claimed effect, i.e. alternatively enabling the piston drive motor and the mechanical stop controller drive motor, thereby preventing movement of the piston while the mechanical stop controller was actuated.

- IX. The Appellant requested that the appealed decision be set aside and the patent maintained
- as Main Request (Request A), on the basis of: Claims 1 to 54 filed on 4 October 1991, the description of the patent as granted with the amendments in column 1, lines 1 to 16, filed during the oral proceedings, and column 1, line 17, to column 2, line 25, filed on 4 October 1991, and Figures 1 to 8D as granted;
 - as First Auxiliary Request (Request B), on the basis of: Claim 1 filed on 30 November 1992, otherwise as Request A;
 - as Second Auxiliary Request (Request C), on the basis of: Claims 1 to 53 filed on 1 March 1995 and description and figures according to Request A;

- as Third Auxiliary Request (Request D), on the basis of: Claims 1 to 51 filed during oral proceedings and description and figures according to Request A;
- as Fourth Auxiliary Request (Request E), on the basis of: Claims 1 to 50 filed during oral proceedings and description and figures according to Request A.

The Respondent requested that the appeal be dismissed.

- X. The oral proceedings was closed. It was announced that the decision would be issued in writing.

Reasons for the Decision

1. The appeal is admissible.

2. *Formal aspects*

2.1 Amendments

Claim 1 of Request A is a combination of the features of originally filed Claims 1, 2, 13 and 17 or of Claims 1 and 17 of the patent as granted.

Claim 1 of the Request B comprises, in addition to the features of Claim 1 of Request A, the features that the identification tag includes a program number and a title field and that the recall means comprise means for displaying the title field.

The information that the means for producing an identification tag can produce a program number and a title field is disclosed in the algorithm of figure 8C of the application as filed and of the patent as granted (see: top left side, the branch "yes" starting off the field "store button pressed?"). According thereto, the

identification tag can comprise a program number from 1 to 99 and a title field.

Moreover, on page 22, lines 16 to 24 of the application as filed and in column 11 line 64 to column 12 line 10 of the patent specification, the information is given that one or more numbers or words, or alphanumeric combinations, can be used as an identification tag. Page 23, lines 1 and 2 or column 12 lines 10 to 14, together with a part of the algorithm shown in Figure 8D (see: the branch "yes" starting off the field "recall button pressed?") give the information that the recall means comprise means for displaying the title field.

Claim 1 of Request C comprises, in addition to the features of Claim 1 of Request A, the features mentioned by the originally filed Claim 5, which corresponds to granted Claim 5.

Claim 1 of Request D comprises, in addition to the features of Claim 1 of Request B, the features mentioned by the originally filed Claims 5, 6 and 7, which correspond to granted Claims 5, 6 and 7.

Claim 1 of Request E comprises, in addition to the features of Claim 1 of Request D, the features mentioned by the originally filed Claim 8, which corresponds to granted Claim 8.

The amendments in columns 1 and 2 of the specification of the patent at issue comply with the requirements of Rule 27(1)b and c EPC.

From the above it follows that the patent at issue has not been amended in such a way that it contains subject-matter which extends beyond the content of the application as filed or beyond the protection conferred (Article 123(2) and (3) EPC).

2.2 Interpretation

According to the description of the patent at issue (column 11, line 59, column 12, line 14, and Figure 8C and 8D) the information identifying a prestored set of injection parameters which is entered in the angiographic injector device can be numeric or alphabetical information. From this it follows that the identification tag can be a program number and/or a title field. The features g) and g") according to the Requests B, D, and E therefore, have to be interpreted in the sense that the **means for producing an identification tag is a means for producing a program number and/or a title field as an identification tag.**

3. *Prior art*

The documents E1, E2 and E6 disclose the relevant prior art, with respect to the subject-matter of Claim 1 according to the main and auxiliary requests.

- 3.1 E1 concerns an angiographic injector control system for delivering a controlled volume of injection fluid substantially comprising the features a) to e) of Claim 1 according to Request A, but not the features f), g) and h) of said Claim 1.

According to the description (see column 6 lines 1 to 61; column 18, line 52 to column 19, line 6; Figure 1) and to Claims 1 to 5, 12, 13, 16 and 17 of E1, the angiographic injector there disclosed comprises the following features:

- a control means responsible for a stop command signal, derived from a position command signal and from a preestablished forward limit depending on the volume of contrast media to be injected, for inhibiting the

piston drive means for discharging the contrast media from the syringe and preventing said piston from discharging further volume of contrast media from said syringe;

- the actual positions of the syringe piston is monitored;
- said stop command signal is produced when the monitored position of the piston reaches said preestablished forward limit;
- further forward movement of the piston is prevented in response to said stop command signal which triggers an arm-disarm circuit (84) to terminate the injection and prevent further operation of the system;
- a microswitch (27) is additionally installed to detect the forward movements of a pin (22) - which is free to move along the shaft (18) of the drive means (12) for discharging contrast media from the syringe during the operation thereof - and to trigger said arm-disarm circuit (84) to terminate the injection and prevent further operation of the system, when all the contrast media contained in the syringe has been injected.

3.2 E2 concerns operating instructions for an angiographic injector device for injecting contrast media into the vascular system of a patient. It has been common ground that the features a) to d) and f) of Claim 1 according to all requests can be derived therefrom.

According to page 3 (chapter "Anwendung"), complete injection programs are stored in the memory means and numerous parameters can be programmed. The permanent control of all relevant parameters before and during the injection and the recording of all parameters provides greatest safety for the patient (error control and error signal). The duration, flow rate and pressure of contrast media requires a most exact control of all parameters to prevent injury to the patient receiving

the injection. Such a control is warranted by a closed loop servo system as specified in feature e), since this system permits a quick comparison between the wanted value of an injection parameter and the actual measured value thereof for determining the "error" and acting in such a way that this "error" is made equal zero. The known device, therefore, implicitly comprises also this feature.

According to page 4-1, five different set parameters can be stored in the memory. A number is associated with each of these sets upon storage (see procedure described on page 4-2). This program number is produced by the keyboard 108 (see page 4-2), and is stored together with the set of parameters in order to allow recalling of the set (see page 4-3). Consequently, the program number constitutes an identification tag and keyboard 108 together with the processor is a means for producing an identification tag for association with each set of injection parameters and for storing the tag with the set in said memory means (feature g)).

The set of parameters can be recalled in **E2** following the procedure described on page 4-3. According thereto, key 116 is hit, the program number entered through keyboard 108, and key 110 hit. The set of parameters is then loaded in the processor, where it can be used directly for an injection of contrast media. It is even possible to change one or all parameters before starting the injection and to supply the recalled set of injection parameters, without operator input prior to an injection (feature h)).

The Appellant argued that E2 did not disclose means for producing an identification tag since, he argued, E2 comprises five different memory places, one for each set of parameters, so that no identification tag would need to be assigned to one of these memories.

This could not be accepted by the Board since the program number enables the processor to identify the location in the processor memory where the corresponding set of parameters is stored. This program number fulfils thus the function of an identification tag. The fact that this identification tag is only numerical and not alphanumeric is irrelevant since, for example, Claim 1 according to requests "A" and "C" does not call for the tag to be alphanumeric. Moreover, the recall means of E2 comprises the display field 113 on which the program number (see recall procedure of pages 4-3) and alphanumeric dialogue messages such as operation and working conditions, parameters etc. (p. 1-4) are displayed.

The person skilled in the art arrives at this conclusion on the basis of the analogy existing between the identification tag according to the patent at issue, and a "filename" made up by two alphanumeric words and randomly determinable by the operator, according to the well-known MS-DOS procedure, as admitted by the Appellant.

According to said MS-DOS procedure for storing pieces of information ("computer files", in the language of data processing), an identification tag ("filename" in the language of data processing) is associated to each "computer file" and stored together therewith; said "filename" being made up by two alphanumeric words and being randomly determinable by the operator.

3.3 E6 discloses an angiographic injector for injecting contrast media by means of a syringe having a piston (70) and comprises a motor (150), drive components, and a control unit. This unit includes the mechanism for selecting delivery parameters, and circuitry for controlling the delivery of the contrast media.

E6 also describes (see column 20, line 34 to column 21, line 29; Claims 24 to 27) a mechanism for limiting the forward movement of the piston (70). This mechanism comprises a rigid block (534), which is able to follow the movement of piston (70), and a solid abutment block (512) which can be moved, by manually rotating a command lever (516), and prepositioned at a predetermined forward limit position - corresponding to a desired volume of contrast media to be injected -, where it is locked by mechanical means 26, 518 and 522.

Upon completion of the injection of the desired volume of contrast media, the follower block (534) contacts the abutment block (512), thereby provoking the actuation of a microswitch (530) which disables the motor (150) driving piston (70) and, accordingly, prevents further forward movement of piston (70).

Thus, the solid abutment block (512) is positioned at the wanted predetermined forward limit position by an "actuator" represented by an human operator, which "actuates" said solid abutment block (512) prior to the beginning of an injector operation, i.e. prior to the actuation of the motor (150) driving the syringe piston (70).

4. *Novelty*

The examination as to whether the subject-matter of Claim 1 according to the Requests A to E is new results in the following:

4.1 *Requests A and B*

From above point 3.2 follows that E2 discloses an angiographic injector device which comprises all features of Claim 1 according to the Requests A and B.

Therefore, the subject-matter of these Claims cannot be considered new within the meaning of Article 54 EPC.

4.2 *Requests C to E*

4.2.1 The subject-matter of Claim 1 according to the Requests C to E differs from the device according to E2 in that

- the feature i) has been added (Request C);
- the features i) to k) have been added (Request D);
- the features i) to l) have been added (Request E).

4.2.2 None of the other documents mentioned above (E3, E4, E6) discloses all the features of Claim 1 according to the requests C to E.

4.2.3 Novelty of the subject-matter of Claim 1 according to Requests C to E is thus to be recognised.

5. *Inventive step*

On the question of whether or not the cited prior art could suggest the subject-matter of Claim 1 according to the requests C to E the following should be observed:

5.1 *Request C*

Feature i) concerns a mechanical stop controller means which mechanically prevents the piston of a syringe from further movement, when a given amount of contrast media has been injected. The principle of providing mechanical stop controls means which limit the movement of the piston of a syringe is already known (see above point 3.3).

It is therefore obvious to the person skilled in the art to apply this known principle to the device according to E2, if the safety of a patient should be enhanced. Since this device has all the means for storing many different parameters and for generating different control signals, it is in the common knowledge of the person skilled in the art to determine also the stop position of the piston on the basis of injection information supplied to the device by the processor control means.

The subject-matter of Claim 1, therefore, does not involve an inventive step within the meaning of Article 56 EPC.

5.2 *Request D*

As it can be seen from above point 5.1, feature i) does not contribute to the inventive step involved by the device according to Claim 1, since such a device is disclosed by E2, at least by implication.

As to features j) and k), the Board, bearing in mind - the analogy which exists between the drive means driving the piston of the syringe and the drive means driving the mechanical stop controller means according to feature i), and

- the fact that the mechanical stop controller means according to E6 are "driven" by an "actuator" represented by an human operator,

holds that the person skilled in the art would have considered as obvious to use analogous, if not identical actuator means for driving both the piston and the mechanical stop controller means; both said drive means comprising a drive motor.

Since the purpose of said mechanical stop controller means is indeed that of inhibiting the drive means of said piston from moving the latter over said forward limit and thereby preventing it from further discharging an unwanted volume of media from said syringe, the person skilled in the art would have considered that this purpose might only be achieved if the drive means of the piston, or of the mechanical stop controller means, were such that they would act in total independence from each other. The person skilled in the art would have considered as obvious the use of a second motor for driving said mechanical stop controller means; said motor being independent from that driving the piston, but controlled in a manner and by closed loop servo control means, which are analogous, if not identical to those used for driving the piston of the syringe.

The Board, thus, concludes that the subject-matter of Claim 1 according to Request (D) is not patentable pursuant to Article 52(1) EPC, for reason of lack of an inventive step pursuant to Article 56 EPC.

5.3 Request (E)

The Board agrees with the Appellant that, having regard to his general knowledge about the performances which may be obtained with closed loop servo-systems, a person skilled in the art would have, prima facie, considered it superfluous to provide such closed loop servo-systems with additional safety means (relay 28, 44), as according to feature 1). But this only in cases where the safety of a patient had not to be ensured.

The principle, as such, of ensuring that the mechanical stop means is effectively positioned and locked on the wanted preestablished forward limit position of the subsequent piston movement, prior to allowing the piston drive motor to effect said subsequent movement of the piston, is known from document E6, where the mechanical stop means are positioned by a human operator, prior to initiating the actuation of the piston.

It follows that the person skilled in the art, trying to avoid the dangers connected with the action of said human operator, would have maintained the same principle in a system intended automatically to execute the task of a human operator and, accordingly, arranged the piston drive motor and the mechanical stop controller drive motor in such a manner as to ensure, beyond any possible failure, that the mechanical stop means is effectively positioned and locked on the wanted preestablished forward limit position of the subsequent piston movement, prior to allowing the piston drive motor to effect said subsequent movement of the piston.

According to his general knowledge, said person skilled in the art would have also considered that the most efficient manner for implementing said principle was the incorporation, in a system intended automatically to

execute the task of said human operator, of means suitable for positively preventing movement of the piston while the mechanical stop controller is actuated, i.e. means for enabling the mechanical stop controller drive motor, but not the piston drive motor and vice-versa, thus for alternatively enabling the piston drive motor and the mechanical stop controller drive motor.

The Board, thus, concludes that the subject-matter of Claim 1 according to Request (E) is not patentable pursuant to Article 52(1) EPC, for reason of lack of an inventive step pursuant to Article 56 EPC.

6. Since the subject-matter of Claim 1 according to each of the Appellant's requests A, B, C, D and E is not patentable pursuant to Article 52(1) EPC, the patent at issue cannot be maintained.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:



S. Fabiani

The Chairman:



H. Seidenschwarz

