

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 7 October 2004

Case Number: T 1194/01 - 3.4.1

Application Number: 95936338.3

Publication Number: 0789603

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:

Electrotransport system with remote telemetry link

Applicant:

ALZA CORPORATION

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 123(2)

Keyword:

"Inventive step - yes, after amendment"

Decisions cited:

-

Catchword:

-



Case Number: T 1194/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 7 October 2004

Appellant: ALZA CORPORATION
1900 Charleston Road
Mountain View, CA 94043 (US)

Representative: Tomlinson, Kerry John
Frank B. Dehn & Co.,
European Patent Attorneys
179 Queen Victoria Street
London EC4V 4EL (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 21 May 2001
refusing European application No. 95936338.3
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. Davies
Members: R. Q. Bekkering
M. G. L. Rognoni

Summary of Facts and Submissions

I. European patent application 95 936 338.3 (publication No. EP-A-0 789 603) was refused by a decision of the examining division dispatched on 21 May 2001, on the ground that the subject-matter of claim 1 then on file lacked an inventive step (Articles 52(1) and 56 EPC).

II. The appellant (applicant) lodged an appeal against the decision on 30 July 2001 and paid the appeal fee on the same day. The statement of the grounds of appeal was received on 1 October 2001.

Oral proceedings were requested as an auxiliary measure.

III. The following documents were taken into consideration:

D1: US-A-5 224 928

D2: WO-A-92 21307

D3: FR-A-2 695 566

D4: US-A-4 281 664

IV. Oral proceedings were held on 7 October 2004.

The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the following documents filed during the oral proceedings:

Claims: No. 1 to 12

Description: pages 1 to 26

Drawings: figures 1 to 4

V. Claim 1 reads as follows:

"An electrotransport system (100) for delivering a therapeutic agent through a body surface of a patient, the system including a delivery unit (130) having a pair of electrodes (132, 134), at least one of the electrodes (132, 134) containing the therapeutic agent to be delivered, a source of electrical power electrically connectable to the electrodes (132, 134), sensor means (174) for sensing a predetermined patient body parameter condition or a predetermined delivery unit parameter condition, the sensor means (174) providing a sense signal; and a control unit (102) generating a control unit signal for controlling the delivery unit (130); the delivery unit (130) being adapted to be worn on the patient's body and being physically separate from the control unit (102); the control unit (102) and the delivery unit (130) communicating via a telemetry communication link (120, 122) by means of a radiated energy signal between transmitter means and receiver means; characterised in that the transmitter means and receiver means comprise first security code transmitter means (152, 154), in said control unit (102), programmed to store a first predetermined unique code therein and transmitting said first predetermined unique code to said delivery unit

(130) in response to the logic state of said control unit signal;
second security code transmitter means (170, 166), in said delivery unit (130), programmed to store a second predetermined unique code, different from the first, therein and transmitting said second predetermined unique code to said control unit (102) in response to the logic state of said sense signal;
first security code receiver means (156, 158), in said control unit (102), programmed to store said second predetermined unique code therein;
second security code receiver means (168, 164), in said delivery unit (102), programmed to store said second predetermined unique code therein;
whereby said first security code receiver means (156, 158) is only responsive to receipt of said second predetermined unique code from said second security code transmitter means (170, 166), producing an output signal, the logic state of which reflects the logic state of said sense signal, to provide an indication of the sensed parameter condition; and
whereby said second security code receiver means (168, 164) is only responsive to receipt of said first predetermined unique code from said first security code transmitter means (152, 154), producing an output signal, the logic state of which reflects the logic state of said control unit signal, to cause delivery of said therapeutic agent".

VI. The appellant's submission in support of its request may be summarised as follows:

The security coding features defined in claim 1 for a telemetry communication link between a delivery unit

worn on a patient's body for the delivery of a therapeutic agent and a remote control unit, was not taught in the prior art. Where a number of electrotransport systems with remote control units were used simultaneously, such as in a hospital, there was a risk that the control signals sent out from the control units were received by the wrong delivery units and vice versa. This would endanger the patients, in that the patients could receive inappropriate treatment and the physician could receive incorrect information about the condition of the patients or the condition of their delivery devices. The claimed security coding features obviated these problems.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

2. *Amendments*

Claim 1 is based on originally filed claims 1 to 4, 14, 15 and 18 and the original description pertaining to the embodiment shown in figure 4. In particular, according to the original description the transmitter means are responsive to the logic state of their input signal and the receiver means produce an output signal having a logic state depending on the receipt of their respective unique codes (cf page 18, line 18 to page 24, line 22).

The dependent claims 2 to 12 are based on originally filed claims 5 to 13, 17 and 21, respectively, and the original description. In particular, regarding claim 5, the feature relating to the provision of different timing sequences for the control unit signal is derivable from the description page 9, lines 5 to 14 and page 25, lines 13 to 24. Claim 12 is also based on page 14, lines 10 to 18 of the originally filed description.

The board is thus satisfied that the amendments comply with the requirements of Article 123(2) EPC.

3. *Novelty*

The closest prior art is provided by document D3. From this document a system is known *inter alia* for percutaneous drug delivery by iontophoresis (cf page 2, lines 1 to 3) using electrodes containing the drug to be delivered connected to an electrical power source. The outputs of the system (22, 25, 26) are monitored by visual and acoustic monitors (30, 31) which, based on a parallel sampling of the electrical signal at the output, indicate its existence, frequency and amplitude (cf page 5, lines 10 to 17; figure 1). The visual and acoustic intensity of these monitors is a function of the impedance of the tissue, whereas their activation frequency depends on the frequency of the electrical signal. These monitors, thus, constitute sensor means for sensing a predetermined patient body parameter condition, namely tissue impedance, as defined in claim 1. Furthermore, they sense the existence and frequency of the electrical signal and as such

constitute sensor means for sensing a predetermined delivery unit parameter condition.

The system consists of a delivery unit to be worn on the patient's body (cf eg figures 4 to 8, 10 and corresponding description) physically separate from the control unit (33,133,233) (cf figures 1 to 3; page 5, lines 18 to 37). A duplex radio or optical telemetry communication link is provided between the control unit and the delivery unit, with corresponding transmitter and receiver means. The link is for communicating commands from the control unit to the delivery unit. Moreover, it is used for confirming that the commands relating to a phase of operation are accepted and that the phase of operation is assumed by the delivery unit, by communicating validation information from the delivery unit to the control unit (cf page 5, lines 32 to 37).

Accordingly, document D3 shows an electrotransport system according to the preamble of claim 1.

The system defined in claim 1 differs from the system known from document D3 in respect of the features provided in the characterising part of claim 1 concerning the transmission and receiver means of the telemetry communication link.

No further details are given in document D3 regarding the communication link. In particular, there is no mention in document D3 of the transmitters on either side each transmitting a respective unique code stored in the transmitter, and of the receivers on either side, each programmed to store the respective unique

code and being only responsive to the receipt of the respective unique code.

Although, as in substance argued in the decision under appeal, it may be held that for instance ordinary radio communication involves some kind of encoding at the transmitter side in the form of eg an analog or digital modulation of the carrier radio signal according to a predetermined scheme or "code", and a corresponding decoding at the receiver side, the system defined in present claim 1 is distinguished therefrom in that only the two different unique codes are transmitted between the control unit and the delivery unit, rather than some "encoded" signal.

Accordingly, the subject-matter of claim 1 is novel with respect to document D3 (Articles 52(1) and 54(1), (2) EPC).

It is, furthermore, also novel with respect to the remaining cited documents, disclosing more remote prior art.

In particular, document D4 discloses a two-way telemetry communication link between a medical device implanted in a patient, such as a pacemaker or a medication dispensing device, and an external terminal (cf column 1, lines 8 to 13 and lines 45 to 49). Digital data may be transmitted to the external terminal, where it may be decoded into numerals and characters using known terminal devices (cf column 2, lines 39 to 52 and column 8, lines 1 to 3). There is no disclosure of the transmission of a unique code,

programmed in both the transmitter and receiver, providing a secure transmission.

Document D2 discloses a two-way telemetry communication link between an ingestible capsule and a remote unit. No unique codes are involved.

4. *Inventive step*

In the system of the application in suit, a first unique code is programmed into the transmitter of the control unit and into the receiver of the delivery unit, and transmitted from the control unit to the delivery unit. A second, different unique code is programmed into the transmitter of the delivery unit and into the receiver of the control unit, and transmitted from the delivery unit to the control unit. The transmitters, in response to the logic state of their respective input signals, transmit the respective code and the receivers only produce a corresponding response when they receive the respective unique code for which they are programmed.

This arrangement provides additional security against falsely initiating the delivery of the therapeutic agent to the patient due to interference from other radiated energy sources (cf description, page 9, lines 25 to 29). Furthermore, it allows for the simultaneous operation of several of these systems, for instance in a hospital, without the risk of crosstalk between the systems. Moreover, the transmission of two different codes guarantees that the transmission of signals by the transmitter and the receipt of signals by the receiver of the same unit may be securely

differentiated (cf description, page 19, lines 22 to 24).

None of the cited documents is concerned with these problems relating to the telemetry communication link.

Furthermore, also the solution as defined in the characterising portion of claim 1 is not suggested in any of cited documents. Standard radio communication techniques for the transmission of signals, without security measures, are used in documents D2 to D4. Although the coded telemetry communication link as such is an off-the-shelf system, which was commonly available at the priority date of the application in suit, (cf description, page 19, lines 15 to 17), it provides a relatively simple but effective way of overcoming the interference and crosstalk problems mentioned above and, therefore, in the board's view an inventive step has to be recognised for its implementation in the specific claimed electrotransport system.

Accordingly, the subject-matter of claim 1 involves an inventive step (Articles 52(1) and 56 EPC).

Claims 2 to 12 are dependent on claim 1, providing further limitations. The subject-matter of these claims, therefore, also involves an inventive step.

5. The description has been brought into conformity with the amended claims.
6. The patent application with the amended documents according to the appellant's request also meets the

remaining requirements of the EPC, so that a patent can be granted on the basis of these documents.

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 following documents filed during the oral proceedings:

Claims: No. 1 to 12

Description: pages 1 to 26

Drawings: figures 1 to 4

The Registrar:

The Chairman:

R. Schumacher

G. Davies