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D E C I S I O N
of 10 July 2001

Case Number: T 0278/96 - 3.4.1

Application Number: 91907364.3

Publication Number: 0522043

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:
Iontophoretic delivery device

Applicant:
ALZA CORPORATION

Opponent:

-

Headword:

-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - (yes) after amendment"

Decisions cited:

-

Catchword:

-



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Boards of Appeal

Chambres de recours

Case Number: T 0278/96 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 10 July 2001

Appellant: ALZA CORPORATION
950 Page Mill Road
P.O. Box 10950
Palo Alto
California 94303-0802 (US)

Representative: Gutmann, Ernest
Ernest Gutmann - Yves Plasseraud S.A.
3, rue Chauveau-Lagarde
FR-75008 (FR)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 6 November 1995
refusing European patent application
No. 91 907 364.3 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. Davies
Members: U. G. O. Himmler
M. G. L. Rognoni

Summary of Facts and Submissions

I. The appellant lodged an appeal against the decision of the Examining Division to refuse European patent application No. 91 907 364.3.

II. In the contested decision, the Examining Division referred to the following prior art documents:

D1: US-A 4 414 359

D2: US-A 4 515 168

D3: GB-A 1 321 863

D4: US-A 4 250 878

D5: US-A 4 474 570

D6: US-A 4 340 047

III. During the oral proceedings held on 10 July 2001, the appellant filed new claims 1 to 17 with pages 1 to 15 of the description, as amended, and Figures 1 to 4, and requested that the decision under appeal be set aside and that a patent be granted on the basis of the above-mentioned documents.

Independent claim 1 has the following wording:

"1. An electrically powered iontophoretic delivery device for delivering an agent by iontophoresis including a source of electrical power (30) adapted to be electrically connected through a circuit means (60) to a pair of electrode assemblies (41, 43) for the

iontophoretic delivery of said agent to a patient, said circuit means comprising a current generating circuit (70) connected to said electrode assemblies and capable of providing an electric current suitable for the iontophoretic delivery of said agent to said patient,

characterized in that

said circuit means (60) also comprise an activation circuit (62) electrically connected to said source of electrical power (30) and also electrically connected to one of said electrode assemblies (41, 43), the other one of said electrode assemblies being connected to said source of electrical power (30), said activation circuit (62) being such as to be activated when electrically closed by placing the electrodes on the patient's skin, said current generating circuit (70) being itself connected to said activation circuit such as to be electrically connected to the power source (30) when said activation circuit is activated, to thereby automatically induce the production of said electric current suitable for said iontophoretic delivery by said current generating circuit, and to automatically interrupt said iontophoretic delivery when said activation circuit is no longer activated, said activation circuit drawing substantially no current from said power source, when in the inactivated state."

IV. The appellant's arguments can be summarized as follows:

The problem objectively formulated starting from the state of the art as disclosed in document D5 was to provide automatic activation and deactivation of the agent delivery depending on the electrodes' contact.

For the solution of this underlying problem, document D2 did not give any incentive as it referred to a nerve locator which was clamped on a syringe.

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. The Board is satisfied that the amended claims fulfil the requirements of Article 123(2) EPC.

Since none of the cited documents discloses a device comprising all the features recited in claim 1, the only matter to be considered is that of inventive step.

3. *Inventive step*
 - 3.1 Document D5 constitutes the closest state of the art and discloses the following features recited in the preamble of claim 1 (the numbers in parentheses refer to the reference signs of the drawings of document D5):
 - an electrically powered iontophoretic delivery device (1) for delivering an agent (4, 6) by iontophoresis including a source of electrical power (8) adapted to be electrically connected through a circuit means (5 and 9-7) to a pair of electrode assemblies (2, 3) for the iontophoretic delivery of said agent (4, 6) to a patient, said circuit means comprising a current generating circuit (5-8-9-7) connected to said electrode assemblies (2, 3) and capable of providing an

electric current suitable for the iontophoretic delivery of said agent to said patient; (cf. Figures 1 and 2 and the corresponding description, column 1, line 52 to column 2, line 58).

In the iontophoretic delivery device of D5 the pair of electrodes is connected to a battery so that a closed circuit is formed when the electrodes are applied to the patient's skin (D5, column 1, lines 63 to 66).

Therefore, document D5 does not disclose an **activation** circuit electrically connected to the source of electrical power, and to one of said electrode assemblies, and activated when the electrodes are placed on the patient's skin.

3.2 The claimed subject-matter is distinguished over the state of the art disclosed in document D5 in that:

- (a) said circuit means (60) also comprise an activation circuit (62)
 - electrically connected to said source of electrical power (30) and
 - also electrically connected to one of said electrode assemblies (41, 43),
 - the other one of said electrode assemblies being connected to said source of electrical power (30),
- (b) said activation circuit (62) being such as to be activated when electrically closed by placing the

electrodes on the patient's skin,

- (c) said current generating circuit (70) being itself connected to said activation circuit such as to be electrically connected to the power source (30) when said activation circuit is activated,
 - to thereby automatically induce the production of said electric current suitable for said iontophoretic delivery by said current generating circuit, and
 - to automatically interrupt said iontophoretic delivery when said activation circuit is no longer activated,
- (d) said activation circuit drawing substantially no current from said power source, when in the inactivated state.

3.5 Starting from the iontophoretic device known from D5, the underlying problem of the present invention can be seen in:

- providing an electrical circuit which does not drain current from the power source during storage time but only when the electrodes of the device are correctly placed on the skin of the patient, and
- avoiding the drawbacks of a manually operated switch which must be correctly engaged by either the patient, the physician or the medical technician, thus representing a potential source of error in drug delivery (cf. page 4, line 15 to

page 5, line 2 of the description).

To solve these two problems the application provides circuit means comprising an activation circuit and a current generating circuit as specified in the characterising portion of claim 1. The activation circuit is electrically connected to the power source and is responsive to the completion of a circuit between the electrode assemblies. Upon application of the electrode assemblies to the body, the activation circuit automatically activates the current generating circuit. The activation circuit draws substantially no current from the power source, when in the inactivated state, i.e. when the circuit between the electrode assemblies is open. The current generating circuit when activated by the activation circuit, automatically induces the production of the electric current suitable for the iontophoretic delivery of the drug and automatically interrupts the iontophoretic delivery when the activation circuit is no longer activated.

3.5 D2 relates to a nerve stimulator for locating a nerve and comprises means for automatically energizing a current pulse generator when the needle touches the patient's skin (cf. column 2, lines 4 to 6). However, as shown in particular in Figures 3 and 4, this document discloses a circuit especially designed to indicate when the tip of the needle approaches the nerve and not for the purpose of delivering a drug. In the Board's opinion, this is a first reason why the person skilled in the art would not have taken into consideration document D2 in solving the underlying problem of the present application.

A further reason is that the skilled person would not

have had any incentive to select parts of the circuit of Figure 4, namely the resistors R6, R7, R9, R10 together with the transistor Q2 and the diode CRI, and to modify them in such a way as to make them suitable to power on and off the current generating circuit (i.e. a battery) of an iontophoretic device as known from D5.

- 3.6 All other documents which were taken into consideration during the examination procedure are less relevant for solving the underlying problem of the present invention.

Document D1 describes an iontophoretic device with a circuit for preventing excessive voltage build up resulting in a surge of current accompanied by the dangers of shock and burns to the patient's skin. No activation circuit as claimed in present claim 1 is shown in this document.

Document D3 does not relate to an electro-medical device but is concerned with a touch-operated switching device which includes a solid-state current amplifier and a pair of contacts arranged in such a manner that, when the contacts are bridged, a current feed path to a first transistor of the amplifier is completed. As an example for the applicability of this switching device, a keyboard is mentioned.

Document D4 refers to a bioelectrode for an iontophoretic device and does not show any circuitry.

Document D6 provides an iontophoretic treatment device which includes a circuit for conducting direct current through the skin, periodically reversing the current

and conducting a short pulse of current through the skin in the opposite direction in order to avoid the undesirable formation of vesicles, bulla and reddening of the skin. The circuitry of this device does not have any relevance to the activation circuit claimed in claim 1.

- 3.7 For these reasons, in the Board's judgement, the cited prior art documents would not lead the person skilled in the art to the claimed subject-matter. The subject-matter of independent claim 1, therefore, involves an inventive step within the meaning of Article 56 EPC.

Each of claims 2 to 17 is dependent on claim 1 and therefore also fulfils the requirement of inventive step.

Order

For these reasons it is decided that:

1. The decision of the Examining Division 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:

Claims: 1 to 17 as filed during the oral proceedings of 10 July 2001;

Description: pages 1 to 15 as filed during the oral proceedings of 10 July 2001;

Drawings: Figures 1 to 4 as filed during the oral proceedings of 10 July 2001.

The Registrar:

The Chairman:

R. Schumacher

G. Davies