

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen

D E C I S I O N
of 13 October 2000

Case Number: T 0673/95 - 3.4.1

Application Number: 91114140.6

Publication Number: 0461680

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:

Programmable control and mounting system for transdermal drug applicator

Applicant:

Drug Delivery System Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 54

Keyword:

"Novelty (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0673/95 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 13 October 2000

Appellant: Drug Delivery Systems Inc.
292 Madison Avenue
New York
New York 100717 (US)

Representative: Patentanwälte
Ruff, Beier und Partner
Willy-Brandt-Strasse 28
D-70173 Stuttgart (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted on 15 March 1995
refusing European patent application
No. 91 114 140.6 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
H. K. Wolfrum

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal, received on 11 May 1995, against the decision of the Examining Division, dispatched on 15 March 1995, refusing the application No. 91 114 140.6 (publication No. 0 461 680). The fee for the appeal was paid on 11 May 1995 and the statement setting out the grounds of appeal was received on 18 July 1995.

II. In the decision under appeal, the Examining Division held, *inter alia*, that the subject-matter of claim 1 was not novel, having regard to the following document:

D1: US-A-4 406 658

III. With the statement of grounds of appeal, the appellant filed, *inter alia*, a new set of claims 1 to 14.

IV. The wording of the independent claim 1 reads as follows:

"1. A transdermal drug applicator for application to a living body for the delivery of at least one drug through the skin (144, 230, 278, 350) or mucous membrane comprising:

applicator means (134, 220, 280) including at least one drug reservoir (186, 226, 290, 292, 344) containing said drug for delivering said drug through said skin (144, 230, 278, 350) by an electrokinetic mass transfer of said drug;

mounting means removably mounted to said body for holding said applicator means (134, 220, 260) to said

skin (144, 230, 278, 350);

power means (166, 222, 279, 356) for powering the delivery of said at least one drug through the skin (144, 230, 278, 350);

circuit means for transmitting electrical power received from said power means (166, 222, 279, 356) to said applicator means (134, 220, 260) wherein an electric circuit is created between said applicator means (134, 220, 260) and said power means (166, 222, 279, 356) through the skin (144, 230, 278, 350); and

characterised by programmable computer means (158, 212, 250, 280) for receiving programmed instructions relative to said drug and for transmitting signals relative to said drug and said programmed instructions to said power means (166, 222, 279, 356) for regulating the generation of power and delivery of said drug through said skin (144, 230, 278, 350) and wherein said transdermal drug applicator includes two parts, a first disposable and replaceable part including said at least one drug reservoir (186, 226, 290, 292, 344), and optionally said power means (186, 222, 279, 356), and a second reusable part including said programmable computer means (158, 212, 250, 280)."

Claim 2 to 14 are dependent on claim 1.

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

Claims: Nos. 1 to 14 as filed with the statement of grounds of appeal;

Description: page 5 and 5a as filed with the statement of grounds of appeal, page 2 as filed with a letter dated 23 December 1994, received on 24 December 1994, pages 1, 3, 4, 6 to 33 as originally filed.

Drawings: Sheets 1/8 to 8/8 as originally filed.

Auxiliarily, the appellant proposed to draft claim 1 in the one-part form in which the term characterized by " would be replaced by the term "and".

VI. In a communication dated 18 May 1999, the Board acknowledged that D1 did not show all the features recited in claim 1, but drew the appellant's attention to the fact that the following document cited in the European search report:

D6: EP-A-0 060 452

appeared to disclose a transdermal drug applicator falling within the terms of claim 1.

VII. The appellant filed a request for oral proceedings with a letter dated 7 October 1999, but withdrew the same with a letter dated 14 January 2000.

VIII. The arguments of the appellant, who did not comment on the novelty objection raised by the Board, may be summarized as follows:

The present invention related to a two-part transdermal drug applicator configuration in which the first part

was disposable and replaceable and contained the drug reservoir as well as, optionally, the power means for powering the delivery of the drug through the skin. The second part was reusable and contained the programmable computer means. Thus, the claims were directed to a device in which the elements that could be exhausted relatively rapidly were located in the same disposable and replaceable first part. However, the relatively expensive and sensitive programmable computer means was located in the second part which was capable of being reused.

Furthermore, the computer means was not simply used for powering up and down the device and for controlling the drug delivery timing, but could be used to regulate the delivery of the drug, for instance, in reaction to the body needs.

Reasons for the Decision

1. The appeal is admissible.

2.1 The independent claims according to the main and auxiliary requests differ from the claim 1 refused by the Examining Division essentially in that the transdermal drug applicator includes two parts:

- a first disposable and replaceable part including said at least one drug reservoir (186, 226, 290, 292, 344), and
- a second reusable part including the programmable computer means (158, 212, 250, 280).

2.2 The above features are supported by the embodiment of Figure 12 of the application as originally filed and, thus, the amendments comply with Article 123(2) EPC.

3.1 D6, which is cited in the present application as originally filed (page 3, line 24) and claims as priority a US application corresponding to D1, relates to a transdermal drug applicator for application to a living body for the delivery of at least one drug through the skin or mucous membrane. The drug applicator shown in D6 (Figures 1, 2A, 2B and 3) comprises the following features recited in the preamble of claim 1 according to the main request:

- applicator means 25 ("electrode") including at least one drug reservoir 28 ("pad") containing said drug for delivering said drug through the skin by an electrokinetic mass transfer of said drug;
- mounting means 55 ("strap") removably mounted to said body for holding said applicator means 25 to said skin;
- power means 12 ("battery") for powering the delivery of at least one drug through the skin;
- circuit means 15 ("electronics package") for transmitting electrical power received from said power means 12 to said applicator means 25 wherein an electric circuit is created between said applicator means 25 and said power means 12 through the skin.

3.2 As to the features recited in the characterising part

of claim 1, it is specified in D6 that:

- the drug applicator comprises a reusable part ("casing and plate combination"; cf. page 4, lines 20 to 30, and
- a disposable and replaceable part ("adhesive electrode pads", page 3, lines 29 to 31 and page 4, lines 23 to 27);
- the reusable part may comprise a microprocessor (i.e. "programmable computer means") for functions such as automatic power up, power down, controlling daily dosages, etc. (page 37, lines 4 to 11).

Furthermore, Figures 1, 2A, 2B and 3 clearly show that the pads containing the drug can be easily applied to and removed from the electrode plates 20 and 21.

3.3 As to the appellant's argument that in the transdermal drug applicator according to the present application the computer means can be used to regulate drug delivery in reaction to the patient's needs, the Board notes that claim 1 is not limited to such a specialized use of the programmable computer means, but covers the same powering and drug delivery functions specified in D6 (page 37, lines 4 to 11).

4. As D6 discloses a transdermal drug applicator falling within the terms of claim 1 of the main request, the subject-matter of this claim is not new within the meaning of Article 54 EPC. The same applies to claim 1 of the auxiliary request which differs from claim 1 of the main request only in that the former is drafted in

the one-part form.

5. Since none of the appellant's requests is allowable, the present application has to be refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

G. Davies