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D E C I S I O N
of 19 March 2002

Case Number: T 0901/97 - 3.4.1

Application Number: 91911198.9

Publication Number: 0522092

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:
Iontophoretic drug delivery system with two-stage delivery profile

Patentee:
ALZA CORPORATION

Opponent:
Vyteris Inc.

Headword:
Iontophoretic drug delivery system with two-stage delivery profile/ALZA CORPORATION

Relevant legal provisions:
EPC Art. 54(1) and (2)

Keyword:
"Novelty (no; main and auxiliary requests)"

Decisions cited:
T 0082/93

Catchword:
-

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Case Number: T 0901/97 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 19 March 2002

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 1 July 1997 revoling European patent No. 0 522 092 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
G. Assi

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division, dispatched on 1 July 1997, revoking European patent No. 0 522 092. The notice of appeal was received on 26 August 1997 and the prescribed fee was paid on the same day. The statement setting out the grounds of appeal was received on 10 November 1997.

II. Pursuant to Article 100(a) EPC, the opposition was based *inter alia* on the ground of lack of novelty (Articles 52(1) and 54(1) and (2) EPC).

III. Oral proceedings were held on 19 March 2002.

IV. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of:

claims 1 to 15 filed on 19 February 2002, columns 1 to 9 of the description filed on 5 June 1997, and Figures 1 to 10 of the patent (**main request)** or

claims 1 to 15 filed on 19 February 2002 with the description and Figures as for the main request (**auxiliary request**).

V. The respondent (opponent) requested that the appeal be dismissed.

VI. As regards the issue of novelty, reference was made in the opposition and appeal proceedings to document:

D1: WO-A-88 / 08 729.

VII. Independent **claim 1** of the **main request** reads as follows:

"1. Apparatus for use in a iontophoretic method which allows an ionized therapeutic agent to be introduced into the body of a user and a desired steady-state therapeutic concentration level of said therapeutic agent to be obtained and maintained in said user's body, said apparatus comprising:

- at least two electrodes which can be applied on body tissue of said user for closing an electrical path for an iontophoretic current travelling from one electrode to the other through said body tissue;
- iontophoretic current generation means (E1, E2) adapted to automatically :
  - (i) drive a first level of iontophoretic current through said electrodes and the body tissue when said electrodes are attached to the body tissue, during a predetermined interval of time so timed as to allow a concentration of the therapeutic agent in the body to be obtained, which approximates the desired steady-state therapeutic concentration level during said first interval of time;
  - (ii) switching without the user's intervention [to] a second lower level of iontophoretic current to be driven and maintained through said electrodes and the associated body tissue beginning after said first interval of time,
- wherein said second lower current level of iontophoretic current is that which is adapted to

substantially maintain the desired steady-state therapeutic concentration level of the therapeutic agent in the user's body."

Independent **claim 2** of the **main request** is directed to a similarly defined apparatus for use in a iontophoretic method which allows an uncharged therapeutic agent to be introduced into the body of a user.

Independent **claims 1** and **2** of the **auxiliary request** differ from the corresponding claims of the main request by having in feature (i) the phrase "said first level being higher than that which is required to obtain and maintain said desired steady-state therapeutic concentration level of said ionized therapeutic agent within said body tissue" added after "attached to the body tissue", and the expression "during a predetermined interval of time" replaced by the phrase "said first level of iontophoretic current being applied for a first predetermined interval of time".

VIII. The appellant essentially relied on the following submissions:

The subject-matter of the independent claims of both requests on file related to an apparatus for use in a specific iontophoretic method which allowed to reach more quickly a desired steady-state therapeutic concentration of a therapeutic agent in the body of a user than it was possible with prior art devices. According to the invention, iontophoretic current generation means drove a first level of iontophoretic current through the body during a predetermined first

interval of time. The first level was chosen higher than that required to obtain and maintain the desired steady-state concentration of the therapeutic agent and the first interval of time terminated when said steady-state concentration was reached. The current generation means then switched automatically to a second, lower level of iontophoretic current which allowed to substantially maintain said steady-state therapeutic concentration level.

In distinction thereto, it was proposed in document D1 to operate an apparatus for iontophoretic delivery of a therapeutic agent in exceptional circumstances in such a manner that a very high current was driven through the body so as to quickly deliver a high, therapeutically effective dose of the agent. The high current was not terminated when a desired steady-state therapeutical concentration was obtained but continued until the majority of the agent present in one of the electrodes was delivered. Subsequently, the current was set to a much lower level than the normal operating level for delivery of the remainder of the therapeutic agent at a much lower dosage rate. Thus the second current level was lower than that required for maintaining a steady-state therapeutical concentration of the agent. In this context, it could be inferred from the specific structure of the electrodes shown in Figures 4, 4A and 4B of D1 that the total amount of agent to be delivered was indeed limited, so that after the termination of the high current regime, there was not left much of the agent to be delivered.

In terms of structural features, the inventive apparatus comprised *inter alia* a specific timer means allowing to time the first interval in a manner which

was not taught in the prior art according to document D1. The structural features of the apparatus according to the invention were defined in relation to the specific functions which they performed and which were not envisaged in the prior art. In this respect, an analogy could be drawn between the claimed subject-matter and a chemical compound which, according to Article 54(5), was to be regarded as a novel substance for a hitherto unknown therapeutical use.

IX. The respondent disputed the appellant's view, relying on the following arguments:

In the independent claims on file, an attempt was made to define an apparatus for iontophoresis by therapeutical effects occurring in the user's body. However, for the issue of novelty, only those features should be taken into consideration which defined the structural elements of the apparatus. Such features were the provision of electrodes and of current generation means which were capable of delivering a first iontophoretic current at a high level and of automatically switching to a second current of a lower level. Such an apparatus was known from document D1.

If, on the other hand, the claims on their proper interpretation, were considered to constitute hybrid claims encompassing features relating to physical entities as well as features relating to activities, the claimed subject-matter would contravene the provisions of Article 52(4) EPC having regard to methods of therapeutic treatment.

X. In the contested decision (cf. points 4.1 and 4.2 of the reasons), claims corresponding to claims 1 and 2 of

the present main request were held to define novel and inventive subject-matter for the reason that the specific relationship between the first and second current levels and the associated agent delivery profile could not be unambiguously derived from document D1. However, dependent claim 3, defining a different agent delivery profile, was held to be in contradiction to the definitions of the independent claims so that the provisions of Article 84 EPC were not met.

Reasons for the Decision

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

2. *Novelty (Articles 52(1) and 54(1) and (2) EPC)*

2.1 Interpretation of the subject-matter of the independent claims

The independent claims of both requests on file are directed to apparatuses for use in a iontophoretic method. Each apparatus is defined by its basic structural elements, such as two electrodes and iontophoretic current generation means. These elements are further specified in functional terms. Thus, the electrodes have to be applicable on body tissue for closing an electrical path for an iontophoretic current travelling through the body tissue. The current generation means have to be adapted to automatically drive a first level of iontophoretic current during a predetermined interval of time and then to switch without the user's intervention to a second, lower

level of iontophoretic current to be driven and maintained through the electrodes and the associated body tissue.

Moreover, the claims comprise features which further specify the duration of the time interval and the intensity of the second current. The time interval should be timed so as to allow a concentration of the therapeutic agent in the body to be obtained, which approximates the desired steady-state therapeutic concentration level, and the second current level should be adapted to substantially maintain said steady-state concentration level of the therapeutic agent in the user's body. Furthermore, claims 1 and 2 of the auxiliary request confirm that the first current level would be higher than that which is required to obtain and maintain the desired steady-state therapeutic concentration level.

It is evident that these further features relate to effects which the application of specifically selected and timed current levels should have on the concentration of the therapeutic agent within the body and thus to a specific, therapeutically desirable agent delivery profile, according to which a desired steady-state concentration level of the agent is quickly obtained by a suitably timed application of a first, high level current and maintained by the subsequent application of a second, lower level current. The respective timing and choice of current levels would depend for instance on the nature of the agent and physiological conditions and therefore cannot be regarded as features defining an iontophoretic apparatus as such.

As a matter of fact, in order to be regarded as constituting **pure** device claims (in distinction to **hybrid** claims comprising features relating to physical entities as well as physical activities), the independent claims on file have to be considered as defining an apparatus whether or not it is in use (cf. T 82/93 OJ 1996, 274, point 2.3 of the reasons).

It follows from the foregoing that the features relating to the specific agent delivery profile have to be considered as additional explanations, in the sense that they specify the capability of the structural elements to be operated in the desired manner. Hence, the independent claims have to be interpreted as defining apparatuses having two electrodes and iontophoretic current generation means suitable for automatically driving a first, high level current through the electrodes for a time interval of a predetermined duration (e.g. by making use of a programmable timer means) and subsequently switching to a second, lower current level for continued delivery of a therapeutical agent.

2.2 The prior art according to document D1

Document D1 (cf. Figures 1 to 4 with the corresponding description) shows an apparatus for use in a iontophoretic method which allows a therapeutic agent to be introduced into the body of a user. The apparatus comprises two electrodes to be attached to the patient's skin and iontophoretic current generation means for driving a iontophoretic current through the electrodes and the associated body tissue. The current generation means comprise a programmable power source which is controlled by a microprocessor. The

microprocessor is associated with programmable memories for storing information concerning particular process parameters of specific medication treatments. According to page 15, lines 19 to 29, "the microprocessor can be programmed so that when a patient is in an extremely painful state, the current level used for delivery can be set to an operating level initially which is much higher than would normally be used (e.g. 2 Io) so that a bolus of the medication can be delivered immediately. The current is then subsequently set at a much lower level than the normal operating level so that the remainder of the medication is delivered at a much lower dosage rate thereafter. Thus, a more immediate therapeutic effect is achieved for a patient in pain distress."

2.3 It is apparent that the known iontophoretic apparatus shows all device features identified in point 2.1 above. In particular, it is evident that, in a specific mode of operation, the microprocessor of the known apparatus assumes the function of timer means for automatically switching after a (predetermined) time interval from a (predetermined) first, high level current for delivery of a therapeutic agent at a high rate to a (predetermined) second, lower level current for continued delivery of the therapeutic agent at a low rate.

The differences which the patent proprietor sees between the invention and the known apparatus relate to an allegedly novel agent delivery profile, which was not disclosed by document D1. However, in the light of the foregoing interpretation of the subject-matter of the independent claims, a specific delivery profile and the associated physiological effects which it may have

on a patient cannot constitute distinguishing features for the apparatus as such. Since the known apparatus is capable of operating at any physiologically desirable current level as well as of producing any agent delivery profile and, moreover, includes in particular the means required for an automated switching, after a predetermined time interval, from a high level iontophoretic current to a lower level iontophoretic current, possible differences in the individual current levels and time intervals as well as in the associated physiological significance of agent concentration levels are immaterial for the definition of an apparatus whether or not it is in use.

2.4 Finally, as regards the appellant's argument that the claims on file should be considered purpose-related product claims defining a new medical purpose and thus novel subject-matter in analogy to the case foreseen by Article 54(5) EPC, it is noted that this regulation applies specifically to chemical substances and compositions and is not applicable to a device such as a iontophoretic apparatus, particularly as the apparatuses according to the patent and the prior art serve the same purpose, i.e. the iontophoretic delivery of a therapeutic agent.

2.5. For these reasons, the independent claims of the main request and the auxiliary request do not comply with the requirements of Articles 52(1) and 54(1) and (2) EPC.

3. The requests of the appellant are not allowable. The ground of opposition under Article 100(a) EPC prejudices the maintenance of the European patent.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher G. Davies