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# Datasheet for the decision of 23 June 2010

**Case Number:** T 0072/07 - 3.4.01

**Application Number:** 97946508.5

**Publication Number:** 0941085

**IPC:** A61K 31/165, A61K 47/02, A61K 47/18, A61N 1/30

**Language of the proceedings:** EN

**Title of invention:**
Device for electrically assisted delivery of agents such as lidocaine and epinephrine

**Patentee:**
ALZA Corporation

**Opponent:**
Vyteris Inc.

**Headword:**
-

**Relevant legal provisions:**
-

**Relevant legal provisions (EPC 1973):**
EPC Art. 56

**Keyword:**
"Inventive step (no)"

**Decisions cited:**
-

**Catchword:**
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0072/07 - 3.4.01

# D E C I S I O N
**of the Technical Board of Appeal 3.4.01**
**of 23 June 2010**

**Appellant**: (Patent Proprietor)
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**Decision under appeal:**
**Decision of the Opposition Division of the European Patent Office posted 13 November 2006 revoking European patent No. 0941085 pursuant to Article 102(1) EPC 1973.**

**Composition of the Board:**

**Chairman:** B. Schachenmann
**Members:** P. Fontenay
G. Assi

## Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division to revoke European patent No. EP-B-941 085. The decision was announced during oral proceedings held on 12 September 2006. It was dispatched on 13 November 2006.

In the notice of opposition, the opponent relied, firstly, on the grounds for opposition under Article 100(a) EPC 1973 of lack of novelty (Article 54 EPC 1973), lack of inventive step (Article 56 EPC 1973) and lack of patentability under Article 52(4) EPC 1973 and, secondly, raised an objection of insufficiency of disclosure of the claimed invention under Article 100(b) EPC 1973. The opponent further put forward that the granted patent contained added subject-matter and contravened thus to the requirements of Article 100(c) EPC 1973.

In the reasons for its decision the opposition division held that the subject-matter of claim 1 of the main request and auxiliary requests then on file was obvious in view of a combination of documents JP-A-64/11565 (cf. D2: a translation into the English language), and US-A-5 019 034 (D3), starting with either document as closest prior art.

II. The appellant (patentee) filed an appeal against said decision on 12 January 2007 and paid the prescribed appeal fee on the same day. Cancellation of the decision was requested insofar as it held that the main request and first and second auxiliary requests lack an inventive step. More specifically, the appellant

requested that the patent be maintained as granted or, alternatively, on the basis of the main request or auxiliary requests presented during the oral proceedings before the opposition division.

In the written statement setting out the grounds of appeal filed on 16 March 2007, the appellant, however, did not pursue the request for maintenance of the patent as granted. The appellant's requests thus consisted in the maintenance of the patent in amended form
- based on the set of claims 1 to 18 filed with letter dated 12 July 2006 as main request with claims 19 and 20 withdrawn in the oral proceedings of 12 September 2006 before the examining division or
- based on the set of claims 1 to 17 filed as first auxiliary request in the oral proceedings of 12 September 2006, or
- based on the set of claims 1 to 17 filed with letter dated 12 July 2006 as second auxiliary request with claims 18 and 19 withdrawn in the oral proceedings of 12 September 2006.

III. The statement of grounds further contained a detailed analysis of the prior art which, in the appellant's view, established that the objection of lack of inventive step relied upon by the opposition division to revoke the patent was not justified.

It was, in particular, stressed that the objection relying on document D3 as closest prior art was not correct since document D3 did not represent a valid starting point for deciding on the inventive merits of the claimed invention. In the appellant's opinion,

document D3 disclosed electroporation devices which were not, as such, conceived for the same purpose as the claimed invention, i.e. to transport pharmaceutical compounds by iontophoresis. It was underlined, in this respect, that document D3 merely mentioned iontophoresis in passing but did not disclose an iontophoresis device per se.

IV. In a facsimile dated 30 July 2007, the respondent (opponent) requested that the decision of the opposition division be upheld and underlined that, as a consequence of the amendments made during the opposition proceedings, the subject-matter of claim 1 according to the main request and auxiliary requests on file lacked clarity under Article 84 EPC. The view that the claimed subject-matter was not sufficiently disclosed and that the patent contained added subject-matter was upheld. Finally, the respondent also reiterated its view that the claimed subject-matter was not new (main request) or at least was rendered obvious by the available prior art (main request and auxiliary requests).

V. At the request of the parties, the Board issued a summons to attend oral proceedings scheduled to take place on 23 June 2010.

In a communication pursuant to Article 15(1) Rules of Procedure of the Boards of Appeal (RPBA) dated 21 April 2010, the Board expressed its provisional opinion with regard to the requests on file. It was, in particular, noted that the Board was not convinced by the arguments provided by the respondent in relation with the issues of clarity, added subject-matter and sufficiency of

disclosure. According to a preliminary analysis of the prior art referred to by the respondent, the Board likewise indicated that it did not share the respondent's view regarding lack of novelty of the subject-matter of claim 1 of the main request.

Concerning the issue of inventive step, the Board indicated that, in its provisional opinion, both documents D2 and D3 could potentially be considered to illustrate the closest prior art. The attention of the parties was further drawn to various issues to be elucidated during the oral proceedings in relation with the actual teaching of document D3.

VI. By letters dated, respectively, 5 May 2010 and 19 May 2010, the appellant and the respondent indicated that they withdrew their requests for oral proceedings and would not be represented therein should they nevertheless take place. With these letters, both parties also confirmed their respective previous requests.

The oral proceedings were held before the Board on 23 June 2010 in the absence of the parties.

VII. Claim 1 of the main request reads:

" 1. An iontopheresis (sic) device for delivering an agent by iontophoresis through a body surface, said device including a pair of electrode assemblies, at least one of the assemblies comprising the agent to be delivered; a source of electrical power having a cell voltage, and adapted to be electrically connected to the pair of electrode assemblies, and circuit means connecting the pair of electrode assemblies and the

source of electrical power, the circuit means including an iontophoresis current generating circuit for generating iontophoresis current for delivering the agent, and an activation circuit for activating the current generating circuit,

the activation circuit being responsive to the resistance of the body surface after placement of the electrode assemblies thereon, whereby the activation circuit activates the current generating circuit when the body surface resistance is less than a threshold resistance value;

wherein the activation circuit applies a pulsed voltage across the electrode assemblies when the body surface resistance is equal to or greater than the threshold resistance value, the pulsed voltage having a magnitude which is greater than the cell voltage of the power source, the pulsed voltage being effective to reduce the resistance of the body surface to a value less than the threshold resistance value."

Claim 1 of the first auxiliary request reads as follows:

"1. An iontophoresis device for delivering an agent by iontophoresis through a body surface, said device including a pair of electrode assemblies, at least one of the assemblies comprising the agent to be delivered; a source of electrical power having a cell voltage, and adapted to be electrically connected to the pair of electrode assemblies, and circuit means connecting the pair of electrode assemblies and the source of electrical power, the circuit means including an iontophoresis current generating circuit for generating iontophoresis current for delivering the agent, and

an activation circuit for activating the current generating circuit,
wherein, upon applying the device to the body surface, the activation circuit:
a. detects the body surface resistance between the electrode assemblies; and then either
b. activates the current generating circuit when the body surface resistance is less than a threshold resistance value, the threshold resistance value being less than the initial resistance of the body surface; or
c. applies a pulsed voltage across the electrode assemblies when the body surface resistance is equal to or greater than the threshold resistance value, the pulsed voltage having a magnitude which is greater than the cell voltage of the power source, such that the pulsed voltage reduces the body surface resistance to less than the threshold resistance value; and then activates the current generating circuit.

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the reference to an agent has been specified and replaced by a reference to a local anaesthetic.

Claims 2 to 18 of the main request and claims 2 to 17 of the two auxiliary requests are dependent claims.

VIII. This decision is issued after the entry into force of the EPC 2000 on 13 December 2007. Reference is thus made to the relevant transitional provisions for the amended and new provisions of the EPC, from which it may be derived which Articles of the EPC 1973 are still

applicable to the present application and which Articles of the EPC 2000 are to apply.

Where Articles or Rules of the former version of the EPC apply, their citations are followed by the indication "1973" (cf. EPC, Citation practice, pages 4-6).

## Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 EPC 1973 and Rule 64 EPC 1973. It is, thus, admissible.

2. *Main request*

2.1 *Prior art*

Reference is made in this decision to the following prior art publications:

D1: W0-A-98/14235;
D2: English translation of JP-A-64-11565;
D3: US-A-5 019 034.

2.2 *Novelty - Article 54 EPC 1973*

2.2.1 Contrary to the view expressed by the opposition division in its decision (cf. point 3.1 of the Reasons), it appears that the device disclosed in document D1, which is prior art in the sense of Article 54(3)(4) EPC 1973, comprises an activation circuit responsive to the resistance between the patch electrodes (the load).

According to document D1, an activation circuit provided in the iontophoresis delivery device periodically delivers a pulse voltage when the measured resistance is indeed greater than a threshold resistance value, that is, as long as the patch incorporating the electrode assemblies is not positioned on the body skin (cf. D1, page 13, lines 11-21). It is noted, in this respect, that the pulse current delivered by the power means in document D1 is necessarily accompanied by a corresponding pulse voltage across the load. Furthermore, although the pulsed voltage (current) is intended to determine whether the patch is applied to the skin, and fulfils as such a different purpose than in the present application, it would in effect permit to identify any variation of the resistance across the electrode assemblies independently of the load's nature.

However, the feature according to which the pulsed voltage applied across the electrode assemblies when the measured resistance is greater than a threshold value (cf. D1, page 13, lines 11-13; Figure 6A) has a magnitude greater than the cell voltage of the power source is not disclosed in D1. Moreover, in document D1, the threshold resistance value is chosen so as to distinguish between the open state of the circuit, wherein the electrodes are for example separated by air, and a state of the circuit in which the body surface would close the circuit. This implies that the threshold resistance value specified in document D1 is higher than the expected resistance of the body surface. Thus, in the case of the electrode assemblies being brought in contact with the body skin, the generated pulsed voltage cannot be considered to have

the effect of reducing the resistance of the body surface to a value below the threshold resistance, as recited in independent claim 1 of the main request, since this condition is already fulfilled as a mere consequence of the contact being established between the electrode assemblies and the body surface.

2.2.2 As acknowledged by the opposition division and reiterated by the appellant in the statement of grounds, the iontophoresis device of document D2 is controlled in an automatic manner so as to initiate iontophoresis following a pretreatment comprising application of a high voltage during a predetermined period controlled by a dedicated timer. The device of document D2 is thus not responsive, as such, to the skin resistance, as required in independent claim 1 of the main request.

2.2.3 Document D3 relates, quite generally, to the transport of molecules across human or animal skin taking advantage of the technique of electroporation to increase the skin permeability (cf. column 4, lines 3-8). The transport of molecules may be achieved by driving forces resulting, for example, from concentration differences, temperature differences or hydrostatic pressure (cf. column 2, lines 31-35; column 4, lines 21-26). According to another embodiment in document D3, the transport of molecules is alternatively achieved by iontophoresis (cf. column 4, lines 21-23; column 11, line 66 - column 12, line 24).

As a matter of fact, the whole paragraph bridging columns 11 and 12 in document D3 relates to a process combining electroporation and iontophoresis. Although this passage does not provide details as to the actual

reduction to practice of the corresponding system, it provides sufficient evidence that an arrangement is indeed contemplated in document D3, which would be able to deliver ionic agents into the body by means of an electric current. Such a system or arrangement therefore qualifies as iontophoresis device for delivering an agent by iontophoresis through a body surface, in accordance with the general understanding of the terms "iontophoretic" and "iontophoresis", as reproduced in paragraph [0025] of the patent specification. It necessarily comprises the features inherent to this kind of apparatuses: a pair of electrode assemblies wherein at least one of them comprises the agent to be delivered; a source of electrical power having a cell voltage and being adapted to be electrically connected to the pair of electrode assemblies; and circuit means connecting the pair of electrode assemblies and the source of electrical power wherein the circuit means includes an iontophoresis current generating circuit for generating iontophoresis current for delivering the agent.

Moreover, the indication in column 12, lines 19-24 that "*When the pores have retracted to a size at which the transport rate drops below a selected level, the continuous, low voltage field for the iontophoresis is temporarily interrupted or is maintained and a new electrical pulse having the characteristics to induce electroporation is applied*" implies that an activation circuit responsive to the resistance of the body surface after placement of the electrode assemblies thereon is also provided.

This statement further establishes that the activation circuit applies a pulsed voltage across the electrode assemblies when the body surface resistance is equal to or greater than a threshold resistance value since the retraction of the pores size is directly associated with a corresponding increase of the skin resistance. The indication that the new electrical pulse has the characteristics to induce electroporation implicates that the pulsed voltage is also effective to reduce the resistance of the skin to a value less than the threshold resistance value.

Although the sentence reproduced above implies some kind of coordination between the iontophoresis unit and the electroporation unit and thus rules out that the iontophoresis device and electroporation device be independent, as submitted by the appellant, it is as such insufficient to ascertain whether these functionalities are indeed performed by one and the same device, as recited in claim 1 of the main request.

There is also no indication to be found in the passage referred to above that the activation circuit is responsive to the resistance of the body surface following placement of the electrode assemblies thereon, whereby the activation circuit activates the current generating circuit when the body surface resistance is less than a threshold resistance value

A further difference between the claimed subject-matter and the embodiment of document D3 referred to above resides in the fact that the pulsed voltage applied by the activation means according to the invention has a

magnitude which is greater than the cell voltage of the power source.

2.2.4 It follows from the above analyses that the subject-matter of claim 1 of the main request is new in view of documents D1, D2 and D3.

2.3 *Inventive step - Article 56 EPC 1973*

2.3.1 The Board rejects the appellant's arguments according to which document D3 does not constitute a valid starting point in order to assess the inventive merits of the claimed invention. While it is accepted that the closest prior art should disclose subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, the Board opines that these criteria have to be applied to each concrete disclosure within a document and not to the possibly more abstract teaching resulting from the document considered as a whole.

In the Board's judgement, the fact that document D3 focuses on an aspect (electroporation), which is not corresponding to the actual main functionality of the claimed device (iontophoresis), is no bar for a specific disclosure within this document being considered to reflect the closest prior art. In the Board's view, a different conclusion would be contrary to the approach developed by the boards of appeal of an objective assessment of inventive step which implicates that each item of prior art be assessed on its own merits. To avoid any misunderstanding, it should nevertheless be reminded that this appraisal does not

question the general principle according to which a specific concrete disclosure within a document should be interpreted in its context, i.e. in the light of the whole document.

In the present case, the passage bridging columns 11 and 12 in D3 discloses a process and, implicitly, a "system" (cf. point 2.2.3 above) combining iontophoresis and electroporation processes. Whether the system of D3 should be dubbed as an electroporation system with an iontophoresis facility or as an iontophoresis system with an electroporation facility is, in this respect, irrelevant since what actually matters is what the system objectively performs. Consequently, since the system discussed above under section 2.2.3 shares with the claimed invention the purpose of transporting drugs by iontophoresis and, additionally, combines this functionality with electroporation which is similarly initiated on the basis of the measured body surface resistance, it satisfies the criteria to qualify as closest prior art.

2.3.2 As established above under section 2.2.3, the claimed device differs from the system discussed in the paragraph bridging columns 11 and 12 in document D3 in that:

(i) the iontophoresis and electroporation units are incorporated in one and the same device,

(ii) the activation circuit is responsive to the resistance of the body surface after placement of the electrode assemblies thereon, whereby the activation circuit activates the current generating circuit when the body surface resistance is less than a threshold resistance value,

(iii) the pulsed voltage applied by the activation circuit has a magnitude which is greater than the cell voltage of the power source.

In the Board's judgement, the three distinguishing features provide various effects solving different technical problems. Their inventive contribution is therefore to be analysed separately.

2.3.3 The technical effect achieved by feature i) regarding the integration of the iontophoresis and electroporation units within one and the same device is to make the system easier to handle.

Starting from document D3 and faced with the choice of combining the iontophoresis and electroporation units as separate units within a system or as integrated parts of a single device, the skilled person would immediately recognize that the first solution would be particularly inconvenient for a system to be positioned and fixed on a body surface. This is all the more true, in the present case, since the electroporation process has to be carried out at about the same location as where iontophoresis is to be later carried out. The skilled person would hence opt, as a straightforward measure, for an integration of the electroporation and iontophoresis units in one single device.

Distinguishing feature ii) permits a more efficient use of the claimed device since iontophoresis can be immediately activated following contact of the electrode assemblies with the body surface if said surface is already in a state permitting higher

transport rates without recurring to the preliminary application of an electroporation pulse.

For the Board, the teaching in column 12, lines 19-24 in document D3 according to which "*When the pores have retracted to a size at which the transport rate drops below a selected level, ... a new electrical pulse having the characteristics to induce electroporation is applied*" directly hints at this additional functional limitation. While it is acknowledged that this statement does not explicitly, nor implicitly, establish whether a first electroporation is applied before beginning iontophoresis, it nevertheless teaches, more generally, to apply electroporation pulses when actually required. It would thus be obvious to apply this teaching in the situation immediately following placement of the electrode assemblies on the body surface to improve the efficiency of the iontophoresis device.

Concerning feature iii), the Board notes, in the absence of any further indication in the description, that it primarily serves the purpose of generating a pulse the amplitude of which is effective to reduce the resistance of the body surface. It is, however, known that the electrical potentials actually required to significantly decrease the skin resistance are substantially higher than those normally applied during iontophoresis (cf. D3, column 12, lines 1-6; D2, page 2, lines 47-55). The actual reduction to practice of the corresponding circuit results from the application of normal design procedure for which the presence of an inventive step is to be denied.

2.3.4 In conclusion, the Board is unable to identify in the distinguishing features of claim 1 of the main request any inventive contribution to the prior art. It follows that none of these distinguishing features can justify the presence of an inventive step in the sense of Article 56 EPC 1973.

3. *First auxiliary request*

Claim 1 of the first auxiliary request has been worded so as to more clearly define, in terms of functional limitations, the process actually carried out by the activation circuit. More specifically, the amended wording clarifies that the activation circuit, firstly, detects the body surface resistance and, secondly, depending on the results on whether or not the detected resistance is less than a threshold value, activates the current generating circuit to provoke iontophoresis or, alternatively, preliminarily applies a pulsed voltage to reduce the resistance of the body surface.

Since the analysis carried out in relation with claim 1 of the main request is based on precisely this interpretation of the claimed device, the conclusions reached above in relation with the novelty and inventive step issues apply *mutatis mutandis* to claim 1 of the first auxiliary request.

In consequence, the subject-matter of claim 1 of the first auxiliary request is not inventive in the sense of Article 56 EPC 1973.

4. *Second auxiliary request*

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that it specifies that the agent delivered by the iontophoresis device is a local anaesthetic.

The Board cannot identify any reason to diverge from the conclusions it reached in relation with claim 1 of the main request.

In particular, the arguments presented by the appellant in the statement of grounds relating to particular requirements linked to the delivery of lidocaine are not relevant when deciding on the obviousness of a device used, more generally, for the transport of a local anaesthetic.

Moreover, the delivery of local anaesthetics by way of iontophoresis is well known in the art, as acknowledged by the patentee in paragraph [0009] of the patent specification or confirmed in document D2 (cf. D2, page 3, lines 16-19). The specific reference to a local anaesthetic does not therefore add anything inventive to the subject-matter of claim 1 of the main request which conclusions thus also apply to claim 1 of the second auxiliary request.

## Order

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar | The Chairman

R. Schumacher | B. Schachenmann