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## DECISION of 24 November 2005

Case Number:	T 0646/01 - 3.4.01
Application Number:	92120924.3
Publication Number:	0547482
IPC:	A61N 1/30

Language of the proceedings: EN

## Title of invention:

Iontophoresis system having features for reducing skin irritation

#### Patentee:

Vyteris, Inc.

## Opponent:

ALZA CORPORATION

### Headword:

Iontophoresis system switching from a controlled constant direct voltage made of operation to a controlled constant direct current mode

### Relevant legal provisions:

EPC Art. 100(a), 54(1)(2), 56, 123(2) and (3)

## Keyword:

"Amendments to the patent (admissible, main request)" "Novelty and inventive step (yes, main request)"

Decisions cited:

-

Catchword:

-



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Beschwerdekammern

Boards of Appeal

Chambres de recours

**Case Number:** T 0646/01 - 3.4.01

## DECISION of the Technical Board of Appeal 3.4.01 of 24 November 2005

Appellant: (Proprietor of the patent)	Vyteris, Inc. 13-01 Pollitt Drive Fair Lawn New Jersey 07410-2700 (US)	
Representative:	Lawrence, Peter Robin Broughton GILL JENNINGS & EVERY Broadgate House 7 Eldon Street London EC2M 7LH (GB)	
<b>Respondent:</b> (Opponent)	ALZA CORPORATION 950 Page Mill Road P.O. Box 10950 Palo Alto California (US)	
Representative:	Brown, Fraser Gregory James fJ Cleveland 40-43 Chancery Lane London WC2A 1JQ (GB)	
Decision under appeal:	Decision of the Opposition Division of the European Patent Office posted 16 March 2001 revoking European patent No. 0547482 pursuant to Article 102(1) EPC.	

Composition of the Board:

Chairman:	в.	Schachenmann
Members:	н.	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 16 March 2001, revoking European patent No. 0 547 482.

> The notice of appeal was received on 15 May 2001 and the prescribed fee was paid on the same day. On 16 July 2001 a statement of grounds of appeal was filed.

- II. Pursuant to Article 100(a) EPC, the opposition was based on the grounds of lack of novelty and inventive step (Articles 52(1), 54(1) and (2) and 56 EPC).
- III. In response to a communication of the Board of Appeal dated 7 October 2005, the appellant filed by letter of 16 November 2005 amended patent documents including new claim versions according to a main and two auxiliary requests.
- IV. Oral proceedings were held at the request of the parties on 24 November 2005.

In the oral proceedings the appellant further amended its main request.

In view of amendments made to the patent, the debate in the appeal proceedings concentrated on the issue of inventive step. In support of its submission, the respondent (opponent) made reference to the following prior art documents :

**E1**: WO-A-91/09645,

E3: US-A-4 141 359,

- E4: US-A-4 292 968, and
- E9: United States Statutory Invention Registration H-516, published on 6 September 1988.
- V. The appellant requested that the decision under appeal be set aside and the patent be maintained in amended form according to a **main request** on the basis of the following documents:
  - claims: 1 to 8, filed in the oral proceedings;
  - description: pages 2 to 10, filed in the oral
    proceedings;
  - drawings: figures 1 to 5 and 5A of the patent as granted; figures 6 and 7, filed in the oral proceedings.

Alternatively, the appellant requested maintenance of the patent in amended form on the basis of one of the sets of claims filed as **first** and **second auxiliary requests** by letter of 16 November 2005.

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

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VII. Independent claim 1 of the appellant's main request reads as follows :

> "1. An operable iontophoretic drug delivery system comprising a drug reservoir (21) adapted to be attached to the skin of an animal, wherein said drug reservoir (21) contains an ionic compound selected from the group consisting of therapeutic compounds, diagnostic compounds and drugs, a first electrode (22) in said drug reservoir (21), a second electrode (25) adapted to be brought into electrical connection with said animal, an electrolyte reservoir (23) adapted to be placed in communication with the skin of the animal, said second electrode (25) being positioned within the electrolyte reservoir, circuit means for providing electrical communication between said first and second electrodes (22, 25), said circuit means including means for connecting to a source of electrical power, said circuit means comprising a first supply means for supplying controlled voltage between said electrodes (22, 25) when the system is activated, said circuit means further comprising a second supply means for providing controlled current to one of said electrodes (22), said circuit means further including means for monitoring the current through said one of said electrodes (22), and switching means in said circuit means,

characterised by

said switching means being operable for switching from a first mode wherein said first supply means supplies said controlled voltage as a controlled constant direct voltage ranging between 3 and 30 Volts to a second mode wherein said second supply means provides said controlled current as a controlled constant direct current, when said current monitored by said monitoring means reaches a predetermined value."

Claims 2 to 8 are dependent claims.

Claims 1 of the two auxiliary requests are further amended by the introduction of additional limiting features.

VIII. The appellant essentially relied on the following submissions:

The amendments made to the main request with respect to the patent as granted aimed at limiting the operability of the drug delivery system according to the invention to a constant direct voltage and direct current operation, respectively, in distinction to pulsed modes of operation, and at removing ambiguities as to the interpretation of the claim definitions, by deleting embodiments, such as those of Figures 5B and 8, no longer intended to fall within the scope of the claims.

A system according to amended claim 1 of the main request was neither known from nor rendered obvious by any of the cited prior art documents.

Document E1, against the teaching of which claim 1 was delimited, could be considered an appropriate starting point for the skilled person in that it was concerned with the same problem as the present invention, *ie* the desire to minimise irritation and skin damages by iontophoretic treatments. Document E1, however, concerned systems operating with a pulsed iontophoretic current where the transition from constant voltage to constant current occurred within kHz pulses and thus on a time scale considerably shorter than the switching according to claim 1 when an initially high skin resistance had dropped to a low value. In particular, E1 solved the problem referred to above by using dual segment kHz pulses, wherein the first segment had a controlled average voltage amplitude and the second segment had a controlled average current amplitude. Hence E1 taught a different solution to the problem of minimizing irritation and skin damages.

Document E4 referred to a system for ion therapy which was solely suitable for an anti-bactericidal treatment of wounds by elemental silver ions liberated from a silver electrode which was in direct contact with infected tissue. In order to avoid electrolysis leading to tissue damage, the known system combined a constant current source with a voltage limiter, which provided a shunt for the current delivered to the electrodes and thus limited the inter-electrode voltage to a very low level below 1.1 Volt. The system known from E4, lacking electrodes within a drug reservoir and electrolyte reservoir, respectively, as well as circuit means including a power supply means for supplying a constant voltage in the range of 3 to 30 Volt, as specified in claim 1 of the main request, was not capable of performing iontophoretic treatments by which complex ionic compounds were efficiently delivered through intact skin tissue having a much higher electrical resistance than wound tissue. For these reasons, E4 was totally irrelevant for the claimed invention so that its teaching would not have been taken into consideration by a skilled person for improving systems

capable of iontophoretic drug delivery through healthy skin.

But even if the skilled person had consulted E4, he would not have learned from the document a structure having functions as those of the patent in suit. E4 foresaw a normal operation in a constant current mode and was concerned with patient protection against overvoltages associated with an unforeseen rise in the - normally low - impedance of the load between the electrodes. The system of E4, when activated, would start with operating in the constant current mode and, by monitoring the inter-electrode voltage, change into a mode of operation with a limited constant voltage only when the voltage at the electrodes exceeded a certain preset upper limit. The function of the known system was thus exactly opposite to that of the claimed system which monitored the current through the electrodes and set out with operating in a controlled constant voltage mode when initially the skin resistance was high and switched to a constant current mode when the skin impedance had decreased and thus the monitored current had reached a predetermined value.

Document E9, although relating to a iontophoretic system of the type defined in claim 1, did not teach the invention either. The system known from E9 directly applied the voltage of a power source to the electrodes and slowly turned on the current in the circuit. No current monitoring was foreseen. The voltage at the electrodes inevitably dropped with a decreasing skin resistance. The known system thus neither possessed a constant voltage supply means nor active switching means for switching from a controlled constant voltage mode of operation to a controlled constant current mode when the current monitored reached a predetermined limit. Lacking the claimed control means and switching means, the known system was less efficient in drug delivery.

IX. The respondent's submissions may be summarised as follows:

> The admissibility of the amendments made to claim 1 of the main request was contested as the term "supplying", replacing the former term "providing" in the definition of the first supply means, was isolated from the description of a specific embodiment. Its incorporation in the general definitions according to claim 1 thus resulted in an intermediate generalisation for which the originally-filed application documents did not provide a basis of disclosure. Furthermore, the amendments concerning the definitions of a constant voltage or current mode of operation were derived from a comparison with the teaching of document E1 but had no proper basis in the application documents as filed.

> Regarding the claim interpretation, the definitions in the form of "means for" were vague and should be given a broad meaning in particular in view of the fact that the embodiment of Figure 8 of the patent in suit did not show any switches or any circuitry monitoring the current. Moreover, even after amendment, claim 1 of the main request, which was silent as to the time scales in which the switching between the two modes would occur, did not unambiguously exclude an operation with constant direct current or voltage pulses. Thus, document E1, which disclosed a iontophoretic drug

delivery system operating with DC pulses that had a first part of constant voltage followed by a second part of constant current and thus taught the claimed solution on a small time scale, had still to be considered detrimental to the patentability of the claimed subject-matter.

Even if claim 1 was considered to be limited to a drug delivery system operating with non-pulsed currents, its subject-matter was rendered obvious by the teachings of documents E9 and E4, either taken alone or in combination.

Document E9 showed circuit means which started iontophoresis with a substantially constant voltage and switched then to a constant current mode of operation. In particular in view of the embodiment of Figure 8 of the patent in suit, which did not show any switches, means for monitoring the current or separate first and second power supply means for a constant voltage mode and a constant current mode of operation, respectively, the systems according to the invention and according to the teaching of E9 functioned in identical manner. If there were any differences related to the circuitry, eg concerning the nature of the voltage source, these constituted straightforward workshop modifications, like providing a voltage limiter or a constant voltage power supply which did not provide any real technical effect or improvement.

Moreover, the use of a voltage limiter was known from document E4, which disclosed a drug delivery system that was capable of functioning in the same manner as the claimed system and solved the same problem as the present invention. When during use of the system known from E4 the impedance between the electrodes increased so that the voltage at the electrodes would exceed a predetermined upper limit, part of the constant current supplied to the electrodes was immediately shunted away so as to keep the voltage constant at said limit. Contrary to the appellant's allegations, the teaching of E4 was by no means limited to the treatment of wounds or to the delivery of a certain drug so that the known system would also be applicable to skin having normal impedance values. Moreover, there was no basis for the conjecture that the system taught by E4 would always start in a constant current mode. In fact, when attaching the known system to normal skin, the power supply circuit would limit the applied voltage to the predetermined level immediately after activation and continue to operate in a constant voltage mode. It was thus irrelevant that E4 did not explicitly describe the function of the circuit upon start-up of the system. On the other hand, the phrase "when the system is activated" in claim 1 under consideration did not necessarily imply that the system always started in the constant voltage mode. Therefore, the only differences to the claimed subject-matter concerned the structure of the electrodes. Electrodes being placed in a drug or electrolyte reservoir, respectively, were however absolutely conventional and known from each of documents E1, E3 and E9.

Thus, even if claim 1 was construed narrowly, and if E9 was considered not to show a constant voltage supply, the claimed subject-matter would be rendered obvious by the combined teachings of documents E9 and E4.

## Reasons for the Decision

- The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
- 2. Admissibility of the amendments according to the main request
- 2.1 Apart from a rearrangement of features in the two part form and minor editorial amendments with respect to claim 1 of the patent as granted, the following highlighted features have been added to claim 1 of the main request:
  - (i) the drug reservoir contains an ionic compound selected from the group consisting of therapeutic compounds, diagnostic compounds and drugs;
  - (ii) the first supply means supplies a controlled constant direct voltage between the electrodes;
  - (iii) the voltage ranges between 3 and 30 Volts; and
  - (iv) the second supply means provides a controlled constant **direct** current to one of the electrodes.
- 2.2 Feature (i) is disclosed on page 5, lines 2 and 3, of the published application and is included in originally-filed claim 2.

The fact that according to feature (ii) the first means "supplies" the constant voltage is explicitly disclosed on page 5, line 47, and page 6, line 1, of the published application.

Means for supplying or providing **direct** voltage and current according to features (ii) and (iv), respectively, in distinction to **pulsed** voltage and current, are explicitly disclosed on page 10, lines 46 to 49, of the published application.

Finally, the claimed range of voltages according to feature (iii) is disclosed on page 11, lines 41 to 42 and 46 to 48, of the published application, as well as in originally-filed claim 16.

In view of these findings, the Boards sees no evidence which would support the respondent's allegation that amendments made to claim 1 concerned features isolated from their proper context of disclosure and thus constituted a impermissible intermediate generalisation.

2.3 Further amendments concern the deletion of Figures 5B and 8 and the corresponding parts of the description, of claims directed to a system operating in a constant power mode (claims 3, 8 and 13 of the patent as granted), of claims directed to the embodiment of Figure 8 (claims 11 and 12 of the patent as granted), and of claims concerning a method for iontophoretic drug delivery (claims 14 and 15 of the patent as granted) as well as a corresponding adaptation of the description.

- 2.4 The amendments to the claims do not extend the protection conferred.
- 2.5 The Board is thus satisfied that the amendments made according to the appellants main request comply with the requirements of Articles 123(2) and (3) EPC and are thus admissible.
- 3. Interpretation of claim 1 of the main request
- 3.1 The opposed patent is concerned with the problem to optimize iontophoretic delivery of ionic compounds from a drug reservoir through the skin of an animal while minimizing irritation and skin damages (see page 2, lines 6 to 23 of the patent as granted). It is based on the recognition that the resistivity of the skin will initially be high but significantly drop under the influence of the iontophoretic current. Thus, keeping the iontophoretic current at its desired level would initially require to apply excessively high voltages to the electrodes which would entail the risk of undesirable sensations or even shocks and burns. The solution according to claim 1 under consideration avoids these risks by providing circuit means which cause the iontophoretic drug delivery system, when it is activated, to supply, in a first mode of operation, a controlled constant direct voltage to the electrodes via a first supply means. The circuit means further comprise means for monitoring the current flowing through one of the electrodes and switching means for switching from the first mode of operation to a second mode of operation wherein second supply means provide a controlled constant direct current to the electrodes,

when the monitored current has reached a predetermined value.

3.2 The patent as granted encompasses with the example of Figure 8 an embodiment consisting of a constant current source the two outputs of which are shunted by a Zener diode. The embodiment thus does not show circuit means comprising separate supply means for constant voltage and current, respectively, current monitoring means and switching means for actively switching from a constant voltage mode to a constant current mode of operation. Morever, the patent as granted shows in Figure 5B an embodiment according to which the system is operated with pulsed direct voltage and current.

> These two embodiments having been deleted according to the main request under consideration, the Board does not see any reason not to attribute to the wording of amended claim 1 its narrower, literal meaning of defining a system with circuit means which have separate supply means for constant direct voltage and current, commence iontophoretic drug delivery in a constant voltage mode, monitor the current provided to the electrodes, and, by the use of active switching means, switch to a constant current mode when, due to the drop in resistivity of the skin, the current generated by the applied voltage has reached its desired value.

- Novelty and inventive step of the subject-matter of claim 1 of the main request
- 4.1 According to the appellant, document E1 was an appropriate starting point for the present invention in

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that it addressed the same problem but taught a different solution. The two-part form of claim 1 was thus based on E1.

According to the respondent, the claimed subject-matter was, if not known, at any rate rendered obvious by the teaching of document E1.

4.1.1 Document E1 indeed shows a iontophoretic drug delivery system comprising all the features set out in the preamble of claim 1 under consideration (see in particular Figure 1; and page 15, line 16, to page 16, line 31). In particular, the presence of a drug reservoir and an electrolyte reservoir receiving the first and second electrode, respectively, is apparent from page 20, line 30 to page 21, line 11.

> The teaching of E1 starts from the observation that whilst iontophoresis with a constant DC mode of operation is more efficient than with a pulsed mode of operation, it tends to produce greater skin irritation (page 4, lines 9 to 27). E1 thus aims at improving drug administration and hence the therapeutic efficiency of the electrical energy applied in pulsed iontophoresis without compromising its desirably low skin irritation benefits (page 4, lines 28 to 32; page 5, lines 22 to 33). It is recognized that in pulsed iontophoresis, where a train of pulses at frequencies ranging between 0.5 kHz and 50 kHz is applied to the electrodes (page 14, line 17), the skin of a patient is equivalent to an electric load in the electric circuit, which load in turn is a reactive circuit comprising resistive and capacitive components (Figure 1 and the corresponding description on page 9). The improvement taught by E1

lies in the provision of circuit means which provide each individual pulse with a dual-segment waveform, the primary function of the first segment being the rapid charging of the capacitive component of the skin so as to allow for a more efficient ion transport over a greater proportion of the therapeutic pulse, the latter being the primary function of the second pulse segment (page 6, lines 12 to 27). In one embodiment, the first pulse segment has a predetermined or controlled average voltage amplitude ranging between 3 to 25 V, whereas the second segment has a predetermined or controlled average current amplitude ranging between 0.01 to 5 mA (page 6, line 32 to page 7, line 1; page 15, lines 16 to 33). For square or rectangular waveforms the average amplitude would correspond to the actual pulse amplitude (see in this respect page 11, lines 4 to 14; and page 23, line 32 to page 24, line 3).

4.1.2 Notwithstanding the reference in E1 to sensor-feedback means for sensing voltage and current and their use for controlling *inter alia* the relative duration of each pulse segment (page 16, lines 17 to 31), the switching in E1 from the constant voltage segment to the constant current segment apparently does not occur in reaction to a predetermined current level being reached but rather according to a preselected time interval for the first pulse segment. Hence, although according to E1 switching means are operable for switching from a first mode wherein first supply means provide a controlled constant voltage to a second mode wherein second supply means provide a controlled constant current to the electrodes, such switching occurs within each pulse at a frequency in the range of kHz corresponding to a cycle period in the order of milliseconds or lower,

which is substantially different from that during which physiological changes (such as a decrease of the skin impedance with ongoing iontophoresis) take place.

Therefore, since document E1 refers to a iontophoretic drug delivery system operating with pulsed voltages and currents, wherein switching between the constant voltage and constant current modes occurs within each kHz pulse according to a different criterion than that specified in claim 1, the teaching of E1 does not anticipate nor hints at the subject-matter of claim 1 of the main request.

- 4.2 According to the respondent, the claimed subject-matter was also rendered obvious by the teachings of documents E4 and/or E9.
- 4.2.1 Document E4 shows a system for ionic therapy delivering therapeutically active ions (in particular silver ions having a bactericidal effect) to an infected tissue to be treated by means of a controlled constant direct current (see claim 1; Figure 2; column 1, lines 9 to 50). For the purpose of a therapy with silver ions, the system comprises a silver or silver bearing anode (column 2, lines 5 to 11; column 3, lines 43 to 44). Moreover, it has a second electrode and circuit means for providing electrical communication between the electrodes. The circuit means comprise supply means (current generator 12) which provide to the electrodes a controlled constant direct current (eg 300 microampere; column 2, lines 24 to 25 and 43 to 48). The constant direct current mode is the normal mode of operation and is maintained until, due to an increasing load resistance, the voltage would reach a

predetermined maximum voltage, in which case the current supplied by the current generator is shunted through a voltage limiting circuit (voltage limiter 14) so that the voltage at the electrodes is effectively kept constant at the predetermined value (eg 0.9 Volt; column 1, lines 50 to 53; column 3, lines 10 to 23). By limiting the applied voltage to a value below 1.1 V, damage to the tissue due to electrolysis is avoided. The system further comprises means for monitoring and displaying the current passing between the electrodes (Figure 4; column 4, lines 12 to 23).

4.2.2 The subject-matter of claim 1 of the main request differs from the known system according to document E4 in several respects.

> Claim 1 refers to a different structure of the electrodes, namely those which are provided in a drug or electrolyte reservoir, respectively, and to a different range (*ie* 3 to 30 Volt) of the operating constant voltage. Moreover, the claimed circuit means for supplying voltage and current differ from the respective means of the known system in terms of structure and function.

The teaching of E4 is concerned with a specific type of controlled direct current source for releasing silver ions from an anode while avoiding electrode voltages sufficient to cause electrolysis. Nevertheless, since E4 also discloses supply means for a system used for iontophoresis with limited operating voltage at the electrodes, the appellant's submission is not convincing that E4 referred to a type of iontophoretic system and treatment which was irrelevant to the opposed patent and that the skilled person would not at all have taken E4 into consideration for the claimed type of iontophoretic drug delivery system.

Thus the question arises which conclusions the skilled person would have drawn from E4 in an attempt to solve the problem underlying the claimed subject-matter. In this context, the differences in structure and function of the circuit means are to be considered. Whereas the circuit means of the known system monitor and limit the voltage across the electrodes, the criterion for changing the mode of operation according to claim 1 under consideration is the monitored current. Moreover, E4 normally maintains a constant direct current mode for the iontophoretic treatment and passively limits the monitored voltage at the electrodes. The known circuit means are designed for a bactericidal treatment of infected tissue. In contrast thereto, the circuit means of the system according to claim 1 in suit are adapted for iontophoretic drug delivery to intact skin having a higher resistivity than that of infected tissue. Accordingly, the claimed system is in a constant voltage mode when it is activated, thereby applying to the electrodes, through a first supply means, a controlled constant direct voltage, and is switched to a constant current mode by applying, through a second supply means, a controlled constant direct current, when the monitored current through an electrode has reached a predetermined value.

It may be left open whether, as argued by the appellant, the claimed invention would indeed allow for a more efficient delivery of drug ions through intact skin, or whether, as argued by the respondent, the known system and circuit means, when hypothetically used at intact skin, would start operation and function in exactly the same manner as the claimed system. Based on the claim interpretation set out in paragraph 3.2. above, what matters, in the Board's opinion, is the fact that, in distinction to the known system, the claimed system and circuit means make use of separate supply means for constant direct voltage and current and of active switching means which are responsive to a different parameter, *ie* the monitored current reaching a predetermined value. Thus the claimed subject-matter constitutes a different, alternative solution, at which E4 does not provide any hint.

For these reasons, the Board considers the claimed subject-matter not to be rendered obvious by the teaching of E4.

4.2.3 From document E9 (see Figures 1, 6 and 7; column 3, lines 1 to 24) an operable iontophoretic drug delivery system is known which comprises a drug reservoir adapted to be attached to the skin of a patient, a first electrode in said drug reservoir, a second electrode adapted to be brought into connection with the patient, an electrolyte reservoir in which the second electrode is located and which is placed in communication with the skin, as well as circuit means providing electrical communication between the first and second electrodes and including means for connecting to a source of electrical power. The supply means comprise an 18 Volt battery, one pole of which is connected to one of the electrodes, and circuit means for providing a controlled constant direct current connected to the other electrode via the collectoremitter path of a transistor (Figure 7; column 4, lines 41 to 51; column 6, lines 24 to 48). When starting drug delivery, the known system gradually turns on said transistor (over a period of about a second) and, within the limits imposed by the impedance of the skin and the limited supply voltage, ramps up the current from zero until a desired maximum current value is reached (column 4, lines 43 to 47; column 6, lines 49 to 68). This gradual change of the current prevents burning, shocking or other unpleasant sensations (column 4, lines 29 to 34).

4.2.4 As convincingly argued by the appellant, in the known system the voltage at the electrodes starts from an initial value of 18 Volt and will gradually drop to a somewhat lower value with increasing current and decreasing skin resistance until the current has reached its desired level.

> In the Board's view, in distinction to the subjectmatter of claim 1 of the main request, the system known from E9 does not possess separate supply means for supplying constant voltage and current, respectively. In fact, its circuit means do not initially operate in a constant voltage mode in which a controlled constant direct voltage would be applied to the electrodes. Moreover, the circuit means of the known system do not comprise switching means and current monitoring means for actively switching to a controlled current mode of operation when the current monitored reaches a predetermined value.

Therefore, although the system according to document E9 allows for a iontophoretic delivery of ionic compounds with a controlled constant direct current and effectively limits the voltage which can appear at the electrodes, thus avoiding irritation and skin damages, it does not provide any hint at the claimed solution.

- 4.2.5 In conclusion, it has not been made plausible by the respondent, why the skilled person, in the absence from both documents of any hint as to circuit means having separate supply means for providing constant voltage and current as well as active switching means operative to a specific criterion based on the current monitored, would have devised without the benefit of hindsight a system having circuit means as specified in claim 1 under consideration.
- 4.2.6 Finally, document E3 refers to a iontophoretic drug delivery system having electrodes which are provided in a drug and electrolyte reservoir and circuit means which comprise a constant current source, an impedance checking circuit coupled to the electrodes and a safety-shutdown circuit coupled to said impedance checking circuit (see claim 1 and Figure 1 with the corresponding description). The document mentions 40 V as an upper limit of the voltage above which unpleasant sensations may occur (column 5, lines 42 to 43).

However, the known system does not foresee circuit means which would operate in a controlled constant voltage mode when the system is activated and would switch to a controlled constant direct current mode when the current monitored reaches a predetermined value. Therefore, its teaching, either taken alone or in combination with that of any other document of the available prior art, does not render obvious the subject-matter of claim 1 of the main request.

4.3 In summary, the subject-matter of claim 1 of the main request is novel and inventive and thus meets the requirements of Articles 54 and 56 EPC.

Dependent claims 2 to 8 relate to embodiments of the invention defined in claim 1.

5. Due to the amendments made to the description and drawings, the patent specification is in accordance with the subject-matter of the amended claims.

Accordingly, the Board has come to the conclusion that, taking into consideration the amendments made to the patent documents according to the respondent's main request, the patent and the invention to which it relates meet the requirements of the EPC.

# Order

# For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the following documents:
  - claims: 1 to 8, filed in the oral proceedings as main request;
  - **description:** pages 2 to 10, filed in the oral proceedings as main request;
  - **drawings:** Figures 1 to 5 and 5A of the patent as granted and Figures 6 and 7 filed in the oral proceedings.

The Registrar:

The Chairman:

R. Schumacher

B. Schachenmann