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D E C I S I O N
of 30 April 2002

Case Number: T 0026/98 - 3.4.1

Application Number: 91909992.9

Publication Number: 0527921

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:
Iontophoretic delivery device

Patentee:
ALZA CORPORATION

Opponent:
Société Nationale Elf Aquitaine (Production)

Headword:
-

Relevant legal provisions:
EPC Art. 56

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

Decisions cited:
T 0032/81, T 0176/84, T 0195/84, T 0222/86, T 0099/89

Catchword:
-

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Case Number: T 0026/98 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 30 April 2002

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 27 October 1997 concerning maintenance of European patent No. 0 527 921 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 19 December 1997, against the decision of the opposition division, despatched on 27 October 1997, maintaining the European patent No. 0 527 921 in amended form. The fee for the appeal was paid on 19 December 1997 and the statement setting out of the grounds of appeal was received on 26 February 1998.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, in particular, objections under Articles 52(1) and 56 EPC.

III. In the statement of grounds of appeal, the appellant referred to the following documents:

D1: WO-A-90/03825
D2: US-A-4 744 787
D3: US-A-4 303 748
D4: US-A-4 547 440
D5: US-A-4 578 326
D7: EP-B-0 098 772
D8: FR-A-2 469 202
D10: US-A-4 474 570.

IV. In response to a communication of the Board summoning the parties to oral proceedings and setting out the essential points to be discussed, the appellant announced by letter dated 22 March 2002 that they would not attend or be represented at the oral proceedings.

V. In accordance with Rule 71(2) EPC, oral proceedings were held on 30 April 2002 in the absence of the appellant.

VI. The appellant requested in writing that the decision of the opposition division be set aside and the patent revoked.

VII. The respondent (patentee) requested that the patent be maintained on the basis of the following documents:

main request: claims 1 to 19, filed in the oral proceedings;

columns 1, 2, 9 and 10 of the description as granted, and

columns 3 to 8 and 11 to 14 filed in the oral proceedings;

Figures 1 to 3 as granted;

auxiliary request: claim 1 filed in the oral proceedings;
claims 2 to 19, description and Figures as for the main request.

VIII. The wording of claim 1 according to the **main request** reads as follows:

"1. An electrically powered iontophoretic delivery device (10) including a donor electrode assembly (8), a counter electrode assembly (9) and a source of electrical power (27) adapted to be connected to the donor electrode assembly (8) and the counter electrode assembly (9), wherein the donor electrode assembly (8) includes an agent containing reservoir (15) adapted to be placed in agent transmitting relation with a body surface, and an electrode (11) adapted to be

electrically connected to the source of electrical power (27) and to the agent reservoir (15), the electrode (11) comprising a chemical species which is adapted to undergo oxidation or reduction during operation of the device; characterised in that:

(i) said chemical species is incorporated in the form of a particulate material in the amount of about 5 to 40 vol% in a polymer matrix,

(ii) and said polymer matrix further contains about 5 to 40 vol% of a conductive filler comprised of carbon and forming a conductive network through the matrix."

Claims 2 to 19 are dependent on claim 1.

Claim 1 of the **auxiliary request** differs from claim 1 of the main request in that the conductive filler is defined as being "comprised of carbon or graphite fibres".

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

Document D2 disclosed an iontophoretic delivery device comprising all the features recited in the preamble of claim 1 of the contested patent. The sacrificial electrode of such device, which was made of silver and had the form of a plate connected to an optional screen, was not entirely satisfactory because the metal plate lacked flexibility, delamination of the electrode embedded in the drug reservoir could occur and the cost of an electrode made of a silver plate was high.

The patent in suit overcame these problems by replacing the metal electrode of D2 with a composite electrode comprising a polymer matrix loaded both with a chemical species adapted to undergo oxidation or reduction and with a conductive filler.

When defining the prior art relevant to the present case, account should be taken of the fact that the development of an iontophoresis device involved complex technologies which required knowledge not only in physiology, pharmacology and skin biology but also in electrochemistry, chemistry and electronics. Thus, the notional person skilled in the art of iontophoresis was, in effect, represented by a team of experts, each specialised in one of the above fields (cf. T 99/89 and T 222/86, Case Law of the Boards of Appeal of the EPO, 4th. ed., para. 5.1.2). In particular, an electrochemist should be regarded as the expert responsible for improving the electrodes.

It was known from D1 that a polymer matrix loaded with a metallic powder, graphite powder or carbon fibres could be used as an electrode in an iontophoresis device. D10 showed an iontophoresis device having electrodes made of rubber loaded with carbon. D8 was concerned with improving electrochemical generators comprising at least two electrodes and taught, in particular, that the utilisation of composite electrodes reduced costs.

Documents D3, D4, D5 and D7 related to thin-film electrochemical generators which comprised at least one composite electrode constituted by a polymer matrix loaded with a conductive filler, such as carbon black, and with an electrochemically active species in the

form of a particulate material. In particular, D3 taught that a conductive filler mixed with the active chemical species facilitated the transfer of electric charges through the polymer matrix.

In the light of the teaching of D1, corroborated by the disclosures of D8 and D10, it would have been obvious to a skilled person, i.e. an electrochemist, to arrive at the conclusion that the active electrode shown in D2 could have been advantageously replaced by a composite electrode comprising the same active chemical species in the form of a particulate material dispersed in a polymer matrix. On the other hand, an electrochemist could not have ignored the state of the art represented by documents D3, D4, D5 and D7. These documents, in particular D3 and D7, taught that it was possible to obtain a very efficient active electrode by dispersing in a polymer matrix the active chemical species of the electrode in the form of a particulate material and by adding carbon powder or graphite in order to improve the conductivity of the composite electrode. On the basis of this consistent teaching, it would have been obvious to the electrochemist in the team of experts, who represented the person skilled in the field of iontophoresis, to arrive at the conclusion that adding carbon powder improved the transfer of charges in the composite electrode for an iontophoretic device suggested by the combination of D1 and D2.

In other words, the claimed invention resulted from an obvious application of the teaching of D1 and of teaching common to D3, D4, D5 and D7 to the iontophoretic delivery device known from D2, and, therefore, it did not involve an inventive step within the meaning of Article 56 EPC.

X. The respondent's arguments may be summarised as follows:

The present invention related to an iontophoresis device for wearing on the patient's body and addressed in particular the problems of improving the device's wearability on the part of the user and of avoiding skin irritation caused by pH shifts at the electrodes.

Document D2, which showed an iontophoresis device according to the preamble of claim 1 of the main request, taught to use an electrode comprising a chemical species adapted to undergo oxidation or reduction in order to avoid or minimize production of hydronium (H^+) ions. Thus, starting from D2, the problem addressed in the present patent could be defined as improving the wearability of the iontophoresis device known from D2. The solution consisted essentially in providing a composite electrode comprising a polymer matrix loaded with a redox agent and carbon as conductive filler, and in controlling the amounts of the conductive filler and of the active agent so as to maintain the functionality of the device of D2 and to improve its flexibility.

Document D1 did not teach to use as electrode for an iontophoresis device a polymer matrix loaded with a redox material, nor did it disclose mixing the redox material and carbon as conductive filler in a polymer matrix.

As to the definition of the skilled person, the teachings proper to the field of electrochemistry would not have been considered relevant at the time of the present invention. In fact, the problems normally

addressed by the person skilled in the field of iontophoresis were basically different and related to increasing the efficiency of the drug transport and to reducing the effects which might alter the drug to be delivered into the patient's body.

Furthermore, it should be pointed out that the electrochemical cells shown in documents D3, D4, D5, D7 and D8 included toxic materials and were not compatible with water-based applications. Hence, these documents were not relevant for the assessment of the inventive step of the present invention.

Since the prior art neither taught nor suggested to modify the iontophoretic delivery device of D2 by replacing the solid current distribution member and optional screen with a composite electrode incorporating both carbon as inert conductive filler and a particulate redox material, the subject-matter of claim 1 of the main request involved an inventive step within the meaning of Article 56 EPC.

Reasons for the Decision

1. The appeal is admissible.

Main request

2.1 Claim 1 according to the main request differs from claim 1 of the patent as maintained by the opposition division in that the conductive filler is specified as being "comprised of carbon".

2.2 As to the materials which can be used as conductive

filler, the description as originally filed contains the following statements:

(a) "The conductive filler preferably comprises electrically conductive fibres, such as graphite or carbon fibres" (emphasis added) (page 6, lines 9 to 11);

(b) "The conductive filler forming the conductive network in a polymeric matrix is preferably comprised of carbon or graphite fibres" (emphasis added) (page 8, lines 26 to 28).

2.3 According to the respondent, (b) contains a general reference to carbon as preferred conductive filler and, therefore, supports the above wording of claim 1.

In the opinion of the Board, the statement (b) could also be interpreted as meaning that the filler should be comprised either of **carbon fibres** or of **graphite fibres**. However, this interpretation may constitute an unnecessary limitation to the teaching of the contested patent since it is implicit to a skilled person that carbon need not be in the form of fibres to provide a conductive network within the polymer matrix. Thus, on balance, the Board accepts the respondent's interpretation of the original disclosure and considers that claim 1 of the main request is admissible under Article 123(2) EPC.

2.4 Further minor amendments to the dependent claims and to the description are meant to remove inconsistencies with the amended claim 1 and do not give rise to any objection under Article 123(2) EPC.

2.5 As claim 1 of the main request limits the protection conferred by the patent as granted to devices comprising carbon as conductive filler, it is admissible under Article 123(3) EPC.

3. The novelty within the meaning of Article 54 EPC of claim 1 of the patent as granted or of claim 1 of the patent as maintained by the opposition division has not been disputed by the appellant. Thus, novelty is not at issue in the present case.

4.1 Both the appellant and the respondent agree that D2, which shows an electrically powered iontophoretic delivery device comprising all the features recited in the preamble of claim 1 of the contested patent, represents the closest prior art.

D2 deals, *inter alia*, with the problem of reducing the formation of undesirable hydronium ions at the electrode and the contamination of the drug reservoir due to the oxidation of the electrode metal. This problem is solved by selecting an electrode comprising an electrochemically active (or sacrificial) component which, when oxidised or reduced during operation of the device, produces a species which immediately reacts with ions present in the electrode or available to the electrode in order to form an insoluble salt or neutral chemical compound. In particular, the iontophoretic device according to D2 (cf. the Figure) comprises a gel or a gel matrix 18 containing the ionic drug species which is to be transdermally introduced across the skin barrier. An electrode comprising a plate 23 in contact with an optional screen 22 is located inside the drug reservoir 18.

According to a first example, the anode made of silver is oxidised and reacts with the chloride ions present in the drug. Insoluble silver chloride is formed near the surface of the silver anode while the drug cations migrate from the reservoir into the body with greater efficiency.

According to a second example, the sacrificial electrode is a cathode of electrochemically active material such as chloridized silver. In operation, the AgCl on the surface of a silver cathode is decomposed into silver metal and chloride anions which are free to migrate, along with any anionic drug, into the patient's body. A sacrificial cathode of this generic type generally comprises a metallic salt in contact with a metal cathode.

4.2 In summary, D2 teaches:

- to locate the electrode inside the drug reservoir, whereby the drug reservoir comprises a gel or a gel matrix;

- to select a suitable sacrificial electrode/drug reservoir system in order to remove unwanted (charged) species from the system and to avoid or reduce the production of H^+ and thus minimise pH variation and O_2 production.

4.3 As pointed out by the respondent and not contested by the appellant, the electrode used in the device according to D2 has essentially the following drawbacks:

- the tab or plate (23) of the electrode lacks the

flexibility required in an iontophoretic device,

- the use of solid silver plates and/or screens is expensive considering that only the exterior surface of the silver is available for redox;

- if the electrode is used as an anode, a layer of silver halide which reduces the electrical efficiency of the iontophoresis device will build up on the metal surface;

- in case of the cathode, a higher electrical resistance is present at the outset because the surface is made of a silver halide; furthermore, the working life of the device is limited by the relatively thin layer of silver halide that can be deposited on the metal surface of the cathode;

- metal tabs, plates or screens can delaminate from the gel matrix of the drug reservoir.

4.4 The contested patent solves the above problems essentially by providing an electrode as specified in the characterising part of claim 1, i.e. an electrode which is formed by a polymer matrix containing:

- the chemical species adapted to undergo oxidation or reduction in the form of a particulate material in the amount of about 5 to 40 % vol and

- 5 to 40 % vol of conductive filler comprised of carbon and forming the conductive network through the matrix.

5.1 The appellant's arguments against the inventive step of

the subject matter of claim 1 is essentially based on the assumption that the skilled person starting from document D2 and wishing to improve the electrodes shown in this document would arrive at the following conclusions in the light of cited prior art:

(a) it is advantageous to replace an active metal electrode located in the gel matrix which constitutes the drug reservoir with the same active material dispersed in particular form in a polymer matrix;

(b) the electrical efficiency of the system could be improved by using a conductive filler, such as carbon, dispersed within the matrix.

According to the appellant, (a) would be suggested by document D1 together with D8 and D10, whereas (b) would reflect the teaching of D3, D4, D5 and D7.

5.2 According to the respondent, documents D3, D4, D5, D7 and D8 referred to by the appellant should not be considered as relevant prior art in the present case because they are concerned with electrochemical generators, and the person skilled in the art of iontophoresis cannot be expected to be familiar with documents published in such a specialised electrochemical field.

6.1 Hence, a question to be considered in the present appeal relates to the appropriate definition of the skilled person.

6.2 According to T 32/81 (OJ EPO 1982, 225), if the problem prompts the person skilled in the art to seek its

solution in another technical field, the specialist in that field is the person qualified to solve the problem. The assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability.

Decisions T 176/84 (OJ EPO 1986, 50) and T 195/84 (OJ EPO 1986, 121) addressed the problem of the relevant technical field, i.e. the question of the extent to which neighbouring areas beyond the specific field of the application might be taken into consideration when assessing inventive step. According to T 176/84, a skilled person would, as well as considering the state of the art in the specific technical field of the application, look for suggestions in neighbouring fields or in a broader general technical field if the same or similar problems arose and if he could be expected to be aware of such general fields. Furthermore, it is pointed out in T 195/84 that a non-specific (general) field dealing with the solution of any general technical problem which the application solved in its specific field should be added to the state of the art. Such solutions of general technical problems in non-specific (general) fields had to be viewed as forming part of the general technical knowledge which was to be attributed to those skilled persons versed in any specific technical field.

Sometimes, in particular when advanced technical fields are involved, the "skilled person" may be a group of people having different areas of expertise (cf. T 99/89 and T 222/86, *supra*).

6.3 Hence, as far as the definition of the skilled person is concerned, the following principles are generally

applied by the boards of appeal:

- if the problem prompts the person skilled in the art to seek its solution in another technical field, then the specialist in that field is the person qualified to solve the problem;

- the person skilled in the art can be expected to look for suggestions in neighbouring fields if the same or similar problems arise in such fields;

- the skilled person may be expected to look for suggestions in a general technical field if he or she is aware of such fields;

- in advanced technical fields the competent "skilled person" could be taken to mean a team of experts from the relevant technical branches;

- solutions of general technical problems in non-specific (general) fields are considered to be part of the general technical knowledge.

6.4 In the present case, the field of electrochemical generators cannot be considered as a neighbouring field of iontophoresis. Though both fields rely on electrochemical processes, such processes have substantially different purposes and applications and, consequently, have to satisfy different requirements. For instance, as pointed out by the respondent, the electrode materials shown in D3, D4,D5, D7 or D8 are designed for use in a dry environment which is very different from the wet environment next to a patient's skin or membrane.

Furthermore, the field of electrochemical generators is a highly specialised field and cannot be considered more general then the field of iontophoresis.

6.5 Although some of the problems identified in the device according to D2 appear to be common to the field of electrochemical cells, i.e. the cost of the metal electrode, the buildup of resistance when the active electrode is sacrificed and the lack of flexibility which may be critical in some cases (see e.g. D7, column 4, lines 50 to 62), there is no reason to believe that the person skilled in the art would look for a solution to such problems in D3, D4, D5, D7 or D8 which are essentially documents relating to the generation of electricity by electrochemical means, or that such person, confronted with the problem of improving the electrode configuration of a known iontophoretic device, would seek the advice of an expert in the art of electrochemical generators when documents in the field of iontophoresis already offer some viable solution (cf. D1 and D10).

6.6 Hence, the Board considers that of all the documents referred to by the appellant only D1, D2 and D10 constitute prior art relevant to the present case.

7.1 It is known from D1 (page 16, lines 24 to 26) to use in an iontophoretic delivery device electrodes comprising "a polymeric matrix loaded with metal powder, powdered graphite or carbon fibres, or any other electrically conductive material". This teaching is confirmed by D10 which shows an iontophoretic device having electrodes made of a rubber film comprising carbon (see "EXAMPLE 2").

7.2 The application of the teaching of D1 to the iontophoresis device known from D2 would prompt the skilled person to replace the anode electrode embedded in the gel matrix with a polymer matrix loaded with an appropriate amount of silver particles. On the other hand, if applied to the cathode electrode, the teaching of D1 would result in a polymer matrix loaded with particles of silver and silver chloride. In both cases, the straightforward combination of D1 and D2 would result in a device retaining the full functionality of the device of D2 with the added advantages of a polymer electrode which could be laminated on to the drug reservoir, accounted for improved wearability on the part of the user, due to its flexibility, and allowed better utilisation of the redox material because of the more favourable surface-area-to-volume ratio of the latter.

7.3 Thus, the Board agrees with the appellant that it would be obvious to a person skilled in the art to arrive at an iontophoretic device based on the combination of D2 and D1 (cf. item 5.1 of this decision).

7.4 Moreover, it may be argued that the person skilled in the art, having applied the teaching of D1 to D2, would easily realise that a further improvement could be achieved by replacing some of the silver particles with carbon in order to decrease the cost of the electrode and/or to increase its conductivity (cf. item, 5.1 of this decision).

However, in the opinion of the Board, it would not be fair, for the purpose of assessing the inventive step, to break down an invention into two or more **successive** improvements of the closest prior art and to examine

whether each improvement fulfils *per se* the requirement of Article 56 EPC. This is particularly so when, as in the present case, there is no suggestion in the closest prior art document, or in the teaching of the other relevant prior art, that a second improvement might be required or would be a necessary consequence of the first one. In fact, as pointed out above, replacing the silver electrode shown in D2 with a polymer loaded with silver particles results *a priori* in a viable iontophoretic device, the silver particles acting as the active chemical species and at the same time providing the electrically conductive network, and there is no reason to believe that the skilled person, starting from D2 and **not** from a device based on the combination of D2 and D1, would consider the addition of carbon as a conductive filler a further necessary (and obvious) measure to be taken as a consequence of the application of the teaching of D1.

8. For these reasons, the Board finds that, in the light of the known prior art, it was not obvious to a skilled person starting from D2 to arrive at an iontophoresis device falling within the terms of claim 1. Hence, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

Claims 2 to 19 are directly or indirectly dependent on claim 1 and, thus, their subject-matters also involve an inventive step.

9. In summary, the Board finds that the respondent's main request is allowable and that a patent can be maintained on the basis thereof. Consequently, there is no need to consider the respondent's auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the respondent's main request, as follows:

   Claims 1 to 19, filed in the oral proceedings;

   Columns 1, 2, 9 and 10 of the description as granted, and
   columns 3 to 8 and 11 to 14 filed in the oral proceedings;

   Figures 1 to 3 as granted.

The Registrar: The Chairman:

R. Schumacher G. Davies