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D E C I S I O N
of 26 November 2001

Case Number: T 0529/97 - 3.4.1

Application Number: 85307771.7

Publication Number: 0182520

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:
Apparatus for iontophoretic drug delivery

Applicant/Patentee:
ALZA CORPORATION

Opponent:
Vyteris Inc.
Société National Elf Aquitaine

Headword:
Apparatus for iontophoteric drug delivery/ALZA CORPORATION

Relevant legal provisions:
EPC Art. 123(2), 54(1) and (2), 56, 84

Keyword:
"Added subject-matter (no)"
"Novelty and inventive step (yes, after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0529/97 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 26 November 2001

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 10 March 1997 revoking European patent No. 0 182 520 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 10 March 1997, revoking European patent No. 0 182 520. The notice of appeal was received on 19 May 1997 and the prescribed fee was paid on the same day. The statement setting out the grounds of appeal was received on 21 July 1997 (a Monday).

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 and 56 EPC).

III. Oral proceedings were held on 26 November 2001.

IV. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 16, pages 1 to 3, 3a, and 4 to 25 of the description and Figure 1 filed in the oral proceedings.

V. The respondent 1 (opponent 1) did not object to the appellant's request.

VI. The respondent 2 (opponent 2) was not represented at the oral proceedings, as previously announced by a letter received on 22 October 2001, but requested in writing that the appeal be dismissed.

The written submissions of the respondent 2 did not address the subject-matter of any claim of the appellant's present request.

VII. In the appeal proceedings reference was made *inter alia* to the following documents:

D1: Samarin, *et al.*, Physicochemical Study of Iontophoresis, Voprosy Kurortologii, Fizioterapii i Lechebnoi Fizicheskoi Kul'tury, 1957, No. 4, pages 3 to 7, with English translation (pages 1 to 10);

D2: Chapter 12, "Iontophoresis", P.A. Rebinder, ed., pages 310 to 327, Moscow, USSR, Academy of Science, 1956, English translation (pages 1 to 30);

D4: US-A-4 474 570;

D5: US-A-4 383 529; and

D7: J. Allergy Clin. Immunol., vol. 52, No. 6, 1973, pages 328 to 333, R.H. Shereff *et al.*, "Effect of beta adrenergic stimulation and blockade on immediate hypersensitivity skin test reactions".

VIII. Independent **claim 1** reads as follows:

"1. An iontophoretic drug delivery apparatus comprising an iontophoretic drug delivery electrode assembly (10) itself comprising an electrode member (22,23) in electrical connection to a source (18,19,21) for an ionic drug species (19) to be delivered iontophoretically and for counterions therefor, said assembly containing at least one electrochemically active component which is oxidised or reduced during iontophoretic drug delivery or which oxidises or reduces other available species, in electrical connection to said source, and at least one of said electrochemically active component and said

counterions being such that in the operation of said assembly generation of ionic species at said electrode member is substantially avoided or ionic species generated at said electrode member are substantially entirely converted by species present or generated in or at said source and/or said electrochemically active component into species having lower susceptibility to iontophoretic delivery from said assembly,
characterised in that

said assembly comprises as said electrochemically active component said electrode member (22,23) which is a cathode which is silver chloride in contact with silver,

said counterions for said ionic drug species (19) present in said source comprise silver ions,

and said source comprises a gel reservoir containing therein the ionic drug species (19) to be delivered iontophoretically,

whereby during operation of said assembly water electrolysis at said electrode member is substantially avoided."

Independent **claim 4** is directed to an iontophoretic drug delivery electrode assembly having all the features included in the preamble of claim 1 and is characterised in that

" said assembly comprises as said electrochemically active component said electrode member (22,23) which is an intercalation compound or amalgam, whereby during operation of said assembly water electrolysis at said electrode member is substantially avoided."

Independent **claim 12** is directed to an iontophoretic drug delivery electrode assembly according to the preamble of claim 4 and is characterised in that

" said assembly comprises as said electrochemically active component said electrode member (22,23) which is a silver, tin, zinc, nickel or manganese anode, and said drug counterions comprise ferrocyanide or ferricyanide ions, whereby during operation of said assembly water electrolysis at said electrode member is substantially avoided."

Independent **claims 5** and **13** are directed to an iontophoretic drug delivery apparatus comprising an electrode assembly as claimed in claims 4 and 12, respectively.

IX. The appellant essentially relied on the following submissions:

The subject-matter of the amended claims was based on specific examples disclosed in the originally-filed claims and description. In particular, claim 1 was based on original claims 5 and 8, claim 4 was based on original claim 11, and claim 12 was based on technical information disclosed in the first paragraph of original page 11 of the description. Moreover, the claims were limited with respect in particular to claim 1 as granted.

The amendments clarified the nature of the electrochemically active component.

None of the documents of the cited prior art disclosed an apparatus or electrode assembly as defined in the

independent claims or gave the skilled person an incentive to devise the claimed subject-matter.

X. In the contested decision (cf. point 2.7 of the reasons), the opposition division had noted that a claim which corresponded to present claim 1 would fulfil the requirements of the EPC and that no objections had been raised during opposition against the subject-matter of independent claims which corresponded to present claims 4 and 12.

Reasons for the Decision

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

2. *Amendments*

In the view of the Board, the appellant's submission as to the basis of disclosure of the amended claimed subject-matter is correct. Moreover, the scope of protection of the present claims is indeed restricted with respect to claim 1 as granted.

Therefore, the Board is satisfied that the amended claims comply with the requirements of Articles 123(2) and (3) EPC.

3. *Clarity*

The Board is also satisfied that the amended claims comply with the requirements of Article 84 EPC in that they remove ambiguities as to the nature of the electrochemically active component included in former

claim versions.

4. *Novelty and inventive step*

4.1 An apparatus and electrode assembly according to the preambles of independent claims 1, 4 and 12, respectively, was known before the priority date of the present invention from each of documents D1, D2 and D7.

Moreover, from each of documents D4 and D5 it was known to use a gel reservoir in an iontophoretic drug delivery apparatus and electrode assembly.

4.2 However, none of the available prior art documents contains an indication as to the specific combination of a silver/silver chloride cathode with silver counterions as claimed in claim 1, the specific electrode materials, ie an intercalation compound or amalgam, as claimed in claim 4, and an anode selected from silver, tin, zinc, nickel or manganese in combination with ferrocyanide or ferricyanide drug counterions as claimed in claim 12.

Therefore, the claimed subject-matter is novel with respect to any of the prior art documents on file. Moreover, the Board sees no reason why any combination of the available prior art documents would have led the skilled person to the subject-matter of any claim on file.

4.3 For these reasons, the Board finds that the independent claims comply with the requirements of Articles 54 and 56 EPC having regard to novelty and inventive step.

5. The description has been adapted to the subject-matter

of the claims.

6. In summary, the Board finds the request of the appellant meets the requirements of the EPC and is allowable.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the first instance with the order to maintain the patent on the basis of the appellant's request.

The Registrar: The Chairman:

R. Schumacher G. Davies