BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal Yes / No

File Number: T 84/91 - 3.2.2

Application No.: 86 401 095.4

Publication No.: 0 246 385

Title of invention: Transcutaneous application of nicotine

Classification: A61M 37/00

D E C I S I O N
of 2 April 1992

Applicant: NEW MEXICO TECH RESEARCH FOUNDATION

Headword:

EPC Article 56

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

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 84/91 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 2 April 1992

Appellant : NEW MEXICO TECH RESEARCH FOUNDATION
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Decision under appeal : Decision of Examining Division of the European Patent Office dated 28 August 1990 refusing European patent application No. 86 401 095.4 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : P. Dropmann
Members : M. Noel
F. Benussi

Summary of Facts and Submissions

I. European patent application No. 86 401 095.4 (publication No. 0 246 385) was refused by decision of the Examining Division for the reason that the subject-matter of the claims did not involve an inventive step having regard to the documents:

(1) EP-A-0 171 800
(2) DE-A-3 438 284
(3) US-A-3 053 255
(4) Article "Transdermal administration of nicotine" by J.E. Rose, M.E. Jarvik and K.D. Rose, Drug and Alcohol Dependence, 13 (1984), pages 209 to 213, Elsevier Scientific Publishers Ireland Ltd.

II. The Appellant lodged an appeal against this decision on 26 October 1990, paying the appeal fee and submitting a Statement of Grounds in due time.

In reply to a communication informing the Appellant of the negative provisional opinion of the Board, the Appellant submitted a new set of amended claims.

III. Oral proceedings were held on 2 April 1992, during which the discussion turned, in addition, to document

(5) US-A-3 598 122

already mentioned in the European Search Report and reintroduced by the Board into the appeal proceedings (Article 114(1) EPC).

In the course of the proceedings, the Appellant submitted a new set of two amended claims, of which Claim 1 reads as follows:

"A device for administering nicotine for assisting a person to quit smoking or for the purpose of satisfying a nicotine habit while minimizing or eliminating side effects caused by absorbing nicotine through the lungs along with products of combustion of tobacco, comprising a pad (110) to be adhered to the skin and transdermally administering nicotine at a dosage rate sufficient to satisfy said nicotine habit, characterized in that said pad (110) is occlusive and comprises a nicotine-impermeable backing (112) defining a cavity (114) therein, and an inert fibrous material (122) having absorbed nicotine therein, within said cavity (114), said cavity being covered by a nicotine-permeable, porous, inert membrane (118)."

IV. The Appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

- Claims 1 and 2 as submitted during the oral proceedings, and

- adapted description and single figure as presented during the oral proceedings. In column 10, line 48 the term "Fig. 2" is to be replaced by "the drawing".

Reasons for the Decision

1. The appeal is admissible.

2. No formal objection can be raised under either Article 84 or Article 123(2) EPC since the amendments brought to the claims and to the description are clear and founded, and

do not extend beyond the content of the application as filed.

In particular in Claim 1 the term "an insert fibrous material having absorbed nicotine therein" is fairly supported by the application, column 7, lines 1 to 4 and column 10, Example 4, with reference to Figure 2. The term "said cavity being covered by a nicotine-permeable, porous, inert membrane" is derivable from the last paragraph at the bottom of column 6.

The subject-matter of Claim 2 is based on original Claim 7.

The amendments to the description serve to place the present invention in the proper perspective with respect to the prior art and to bring the disclosure in correspondence with the new claims. They are therefore acceptable.

3. Novelty

The subject-matter of Claim 1 must be regarded as novel since in none of the cited documents are all the features of Claim 1 mentioned in combination.

4. Closest prior art

The Board regards document (2), in agreement with the Appellant's view, as the closest prior art document since it suggests that a pad should be adhered to the skin which would contain nicotine for transdermal administration in order to satisfy a desire for nicotine at a daily dosage rate approximately the same as provided when absorbing nicotine by smoking, in accordance with the subject-matter of the precharacterising portion of Claim 1.

In addition to this, it is assumed in document (2) that depot plasters with a structure adapted for medicaments might also be used for administration of nicotine, which is, of course not to be considered as a medicament (cf. page 3 of the description, first paragraph).

However, document (2) discloses no structural feature relating to any kind of a pad, nor does it give any indication how the depot-plaster for nicotine should be produced and so fails to reduce to practice the suggested idea.

5. Problem and solution

Nicotine is highly toxic and due to its high skin permeability thus very dangerous. Since the manner of administration tentatively suggested in document (2) does not give any detail as to how the depot-plaster should be structured, there is a need for a pad specifically designed for nicotine only, which is safe and effective. For the Board, this represents the objective technical problem underlying the present application.

The solution is given by the features stated in the characterising portion of Claim 1, in particular:

- the pad is occlusive and comprises a nicotine-impermeable backing defining a cavity,

- the cavity is covered by a nicotine-permeable, porous, inert membrane, and

- the cavity contains an insert fibrous material having absorbed nicotine therein.

6. Inventive step

As mentioned in point 4 above, the teaching of document (2) invites the skilled person to search for a structure suitable for the administration of nicotine in documents dealing with plasters more particularly designed for medicaments.

6.1 Document (1) describes, as shown in Figure 2, an adhesive plaster comprising a recess 16 formed by a hermetic composite backing layer 14 and closed by a membrane 20 permeable to an active ingredient 18 which is embedded in the recess. However, there is no material for absorbing and retaining in the recess the active ingredient. The latter is a liquid or pasty medicament which gradually diffuses through the membrane and then into the skin.

6.2 Document (3) sets the problem of regulating and controlling the percutaneous absorption of a definite quantity of an active agent having toxic effects. The adhesive plaster described therein, however, differs widely both in structure and use from that of the present application. As shown in Figure 2 of document (3) the reservoir 6 contains an absorbent fibrous material having a capacity sufficient to take up a solvent which is free of active agent. The active agent itself is retained in a carrier 4 separated from the absorbent material by a non-permeable layer 3. The carrier is in communication with the reservoir through wicks 5 whereby the solvent contained in the reservoir is conveyed to the active agent carrier. Thus a definite quantity of diluted toxic active agent can penetrate through the skin.

The Board is of the opinion that neither of the embodiments described in documents (1) or (3) can be compared to the solution implementing the present

application, since nowhere in these documents is to be found an arrangement peculiar to Claim 1 whereby an absorbent material impregnated with a toxic substance is placed in direct contact with a permeable membrane to be applied to the skin.

6.3 In the present case, the direct combination of an absorbent material with a porous membrane is of primary importance, particularly when administering a pure nicotine base which is a substance highly toxic and readily absorbed through the skin.

By combining the regulating effects of both the absorbent material and the membrane, the delivery rate of nicotine can be controlled more precisely than otherwise, as was rightly observed by the Appellant. The absorbent material allows the pad to contain and retain a large amount of liquid nicotine which is thus uniformly distributed to the membrane. The membrane, in its turn, perfectly controls the dosage rate. Even if the membrane accidentally breaks or the absorbent material is squeezed out by external pressure on the pad, the absorbent material will retain most of the liquid nicotine so that the released small amount of nicotine would not be harmful to the user. Therefore the danger of misuse is also reduced.

6.4 Document (5) describes, with reference to the embodiment shown in Figure 2, a bandage for administering drugs and comprising a reservoir 12, an impermeable backing member 11 and a permeable adhesive layer 14 to be adhered to the skin. The reservoir can either be formed as a hollow drug container with the liquid drug trapped therein or take the form of an envelope made of material permeable to the drug so as to allow the drug to diffuse at first through the reservoir wall 13 and then into the adhesive layer 14. In this latter case, the reservoir wall acts as a porous

membrane with the dosage rate being controlled by the composition and thickness of the wall. However, it must be observed that the drug can pass by diffusion also through the side walls of the reservoir 12, as shown in Figure 2. This embodiment, therefore, does not form an occlusive pad in the sense of the present application which is having an impermeable backing provided with a recess for receiving a toxic substance and is liable to be hermetically closed.

As an alternative embodiment (cf. column 5, lines 70 to 71) the outer surface of the reservoir may be impermeable to the drug so that the backing layer 11 becomes unnecessary. It is questionable, however, whether said impermeable reservoir without backing could be compared with an impermeable backing defining a cavity such as specified in Claim 1. The Board is of the opinion that, neither in this case, an occlusive pad cannot be derived directly and unambiguously from document (5). In any event, an absorbent material within the cavity would still be missing.

According to a further embodiment described in document (5) (cf. column 4, lines 68 to 74 and Claim 3) the reservoir can be comprised of a solid matrix having the drug uniformly distributed therethrough. In this case the solid matrix can be compared with an absorbent material. Since, however, the matrix forms the reservoir itself, said absorbent cannot be said to be confined into a cavity. With this configuration an occlusive pad, in the sense of the application, is therefore also excluded. Further, since the drug rate is directly controlled by the matrix, the permeable adhesive layer does not act as a controlling membrane as is the case in the present application.

To sum up, it appears to the Board that the different embodiments described in document (5) suggest that a skilled person should make use of a reservoir acting either as a permeable membrane or as an absorbent material (matrix) for diffusing a drug at a controlled rate. However, document (5) does not suggest the use of the combination of a membrane and an absorbent material within a cavity according to the specific arrangement and effects as disclosed and claimed in the present application.

6.5 Document (4) is concerned with general considerations about the reduction of smoking by using transdermal administration of nicotine, diluted with a pharmaceutically acceptable vehicle. However, there is no suggestion of any specific structure for a suitable pad.

6.6 For the foregoing reasons, the person skilled in the art starting from document (2) and looking for a pad structure specifically designed for the administration of nicotine, in particular nicotine base, could not have found either in document (5) or in other citations taken isolated or in combination any indication leading him to the subject-matter of Claim 1. The Board, therefore, considers that the modifications which are necessary to adapt each of the pads described in respective documents (1), (3) or (5) so as to materialise the solution of principle disclosed in document (2) support the assumption of the inventive step of Claim 1, as required by Article 56 EPC.

6.7 As a consequence the dependent Claim 2 is also acceptable.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the documents listed in section IV above.

The Registrar: The Chairman:

S. Fabiani P. Dropmann

T. Wolf. 15.9.92

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