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D E C I S I O N
of 24 June 2005

Case Number: W 0004/05 - 3.2.2

Application Number: PCT/IB04/001974

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Title of invention:
Delivery device and method

Applicant:
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Opponent:
-

Headword:
-

Relevant legal provisions:
PCT Art. 17(3)a, 17(2)a
PCT R. 40.1, 40.2, 13.1, 13.3, 39.1(iv)

Keyword:
"Unity of invention "a posteriori" (yes)"

Decisions cited:
W 0005/85

Catchword:
-

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Case Number: W 0004/05 - 3.2.2

International Application No. PCT/IB04/001974

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 24 June 2005

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Subject of this decision: **Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 24 September 2004.**

Composition of the Board:

Chairman: T. K. H. Kriner
Members: R. Ries
S. Hoffmann

Summary of Facts and Submissions

I. The applicant filed an international application PCT/IB 2004/001974 with 58 claims. Independent product claims 1 and 37 read as follows:

"1. A delivery device for delivering substance to a mucosal surface within the oral cavity of a subject, the device comprising:
a mouthpiece unit to be gripped in the mouth of a subject, wherein the mouthpiece unit is configured such that, on exhalation or attempted exhalation by the subject, a pressure is developed in the oral cavity which is such as to close the oropharyngeal velum of the subject; and an outlet unit including at least one substance outlet from which substance is in use delivered to a mucosal surface within the oral cavity of the subject."

"37. A delivery device for delivering substance to a mucosal surface within the oral cavity of a subject, the device comprising:
a mouthpiece unit for fitting to the mouth of the subject; and
an oral outlet unit including at least one substance outlet from which substance is in use delivered to a mucosal surface within the oral cavity of the subject."

Independent claim 49 relates to a method for delivering substance (i.e. a vaccine or medicament) to a mucosal surface within the oral cavity of a subject (i.e. a patient).

Claims 2 to 36 which were directly or indirectly dependent on claim 1 relate to preferred embodiments of the delivery device according to claim 1.

Claims 38 to 48 which were directly or indirectly dependent on claim 37 relate to preferred embodiments of the delivery device according to claim 36.

Claims 50 to 58 which were directly or indirectly dependent on claim 49 relate to preferred embodiments of the method according to claim 49.

II. On 24 September 2004 the EPO, acting as International Search Authority (ISA), sent to the applicant an invitation to pay three (3) additional search fees pursuant to Article 17(3)(a) and Rule 40.1) PCT.

In the invitation, the ISA identified four (4) groups of inventions:

1. group (claims 1 to 4, 33 to 37):
a delivery device, comprising:
A) a mouthpiece unit
B) an oral outlet unit and
C) means for building up pressure in the oral cavity

2. group (claims 1, 5 to 21, 37, 44 to 48):
a delivery device, comprising:
A) a mouthpiece unit
B) an oral outlet unit and
D) an oral outlet unit positioner

3. group (claims 1, 22 to 28, 37, 38 to 43):

a delivery device, comprising:

A) a mouthpiece unit

B) an oral outlet unit and

E) a delivery unit

4. group (claims 1, 29 to 32)

a delivery device, comprising:

A) a mouthpiece unit

B) an oral outlet unit and

F) a nosepiece.

On the extra sheet of the invitation, the ISA referred to the documents cited in the International search report which disclosed the technical features A and B common to the claims of all groups. Given that the remaining features C, D, E and F in the claims of groups 1 to 4 had different purposes, the application was considered to encompass 4 different separate inventions, contrary to the requirements of Rule 13.1 PCT.

III. On 8 November 2004 the applicant paid three (3) additional fees under protest pursuant to Rule 40.2(c) PCT.

In support of the protest, the applicant submitted the following arguments:

The documents cited by the ISA all related to inhalation devices which were operated by inhalation through the mouthpiece rather than by exhalation. By contrast, the delivery device set out in claim 1 comprised a mouthpiece unit configured such that, on

exhalation or attempted exhalation by the subject, a pressure was developed to provide for closure of the oropharyngeal velum and for supply of a substance to the mucosal surface of the oral cavity. Consequently, the technical teaching given in the cited documents had no relevance whatsoever to the subject matter of claim 1 and of the dependent claims 2 to 36 which all related to a single invention.

When carrying out a search on the subject matter of claim 22 and of claims 23 to 28 dependent thereupon (called the "third group of inventions" by the ISA) merely defining the provision of a delivery unit, no additional effort was required since any prior art delivery device inevitably comprised such a substance delivery unit.

IV. In its notification regarding the review of the justification for the invitation to pay additional search fees according to PCT Rule 40.2(e) dated 7 January 2005, the Review Panel of the ISA confirmed that the finding of lack of unity was justified and invited the applicant to pay a protest fee.

As expressed by the ISA in part a) of the annex to the this notification, the device set out in claim 1 of the application was - contrary in the applicant's view - not unambiguously restricted to be operated exclusively by the patient's exhalation or attempted exhalation. Therefore, the device disclosed in particular in document

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was regarded as anticipating all the technical features of the device set out in independent claim 1 and likewise of that given in independent claim 37 which did not comprise the restriction to exhalation and therefore was even broader.

Although, according to part b) of the annex, the unity of invention "*a priori*" of claims 1 to 36 and 37 to 48 was admitted by the ISA, the present set of claims was nevertheless held to lack unity "*a posteriori*" having regard to the novelty objection for claims 1 and 37 based on the technical disclosure of document D1 and to the fact that the original single general inventive concept no longer existed.

V. On 7 February 2005, the applicant paid the required protest fee.

Reasons for the Decision

1. As the formal requirements of PCT Rule 40.2 (protest fee, reasoned statement) were met in due time, the protest is admissible.

2. In the present case the applicant paid three additional search fees for the groups of inventions identified by the ISA in claims 1 to 48. No comment on claims 49 to 58 all relating to a **method** for delivering a substance (vaccines, medicaments) to the mucosal surface within the oral cavity of a subject, i.e. to the treatment of the human or animal body by therapy was provided.

Following the provisions of PCT Rule 39.1(iv) in combination with PCT Article 17(2)(a)(i), the ISA correctly decided not to search the subject matter claimed in claims 49 to 58. The Board, therefore, has only to consider whether the ISA's reasoning with respect to the three additional groups of inventions is sufficient to substantiate a finding of lack of unity.

3. A lack of unity may become evident after having taken prior art into consideration, for instance a document showing that there is a lack of novelty of the subject matter of independent claim 1, and leaving two or more dependent claims without a single general inventive concept. This situation appears to apply to the present case. The Review panel of the ISA has argued in its notification referred to above that the delivery device set out in independent claims 1 and 37 was anticipated by the disclosure of document D1. It is thus apparent that the ISA made an "*a posteriori*" non-unity objection.

However, decision G 1/89 of the Enlarged Board of Appeal makes it clear that an objection of this kind can only be based **on a provisional opinion** on novelty and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination (cf. G 1/89, point 8.1 of the reasons). The Enlarged Board also held that charging of additional fees under Article 17(3)(a) PCT should be made only in clear cases (see also PCT International Search Guidelines, S06/1998(E) VII-12).

4. The Board has provisionally verified the novelty objection in particular with respect to the technical teaching given in document D1 and comes to the following conclusion:

4.1 Document D1 is concerned with a dry powder inhaler capable of dispensing reproducible doses of powdered medicament by offering performance independent of the patents aspiratory effort, manual dexterity, physical strength and ability to coordinate separate movements such as breathing and starting to squeeze or breathing and pressing a button or lever during administration. In order to receive the required dose of medicament, the patient simply inhales through the mouthpiece (cf. D1, column 2, line 66 to column 3, line 13). The advantages of the dry powder inhalation device are listed in D1, column 9, line 62 to column 10, line 37. It is indicated in point 8 referred to by the ISA that, as the aerosolization of the drug is not dependent on the air flow rate, the patient can be taught to inhale slowly, unlike most dry powder inhalers, thus reducing unwanted drug impaction on the back of the patient's throat. It is also apparent from Figures 1 to 3 that the drug is only administered when an air flow is generated by the patient's inhalation through the device and due to the fact that vane (31) ensures unidirectional flow of air from the exterior atmosphere via portal (27) to the patient port (4) by being displaceable in the forward direction only. Movement in the reverse direction upon the patient's exhalation is, however, prevented by the closure of vane (31) at stop (44) (cf. D1, column 13, lines 33 to 35; 54 to 58; column 15, lines 4 to 10).

4.2 By contrast, the delivery devices stipulated in claim 1 and the preferred embodiments set out in claims 2 to 36 of the present application provide for administering the medicament to the mucosal surface in the oral cavity when the oropharyngeal velum is closed by the patient's positive exhalation pressure. Consequently, the inhaler device disclosed in document D1 appears to be based on the totally different constructional conception of drug administration.

Moreover, the study of the description and the accompanying figures reveals that the single general inventive concept of the present invention appears to reside in a delivery device including means which effectively provides for closure of the oropharyngeal velum of the user. Thereby the oral cavity is isolated from the nasal cavity thus preventing the communication of substance (medicament) to the nasal cavity when the substance is delivered via the outlet unit directed to the mucosal surface within the oral cavity. The closure of the oropharyngeal velum can be achieved, inter alia, by a mouthpiece including a flow channel for providing a positive pressure in the oral cavity on exhalation, or a means for delivering a reflex inducing fluid to the patient's face, or by means for providing a reflex sucking action often referred to as the diving reflex etc. This concept is, however, not even remotely apparent from the disclosure of document D1.

Hence the subject matter of claim 1 would not be anticipated by the disclosure of document D1, and in consequence thereof, unity of invention for the delivery device set out in claim 1 and the preferred

embodiments thereof set out in the dependent claims 2 to 36 is given.

4.3 Contrary to claim 1 the delivery device according to independent claim 37 is, however, not necessarily operated by exhalation through the mouthpiece. Hence, this embodiment of the claimed device could be regarded as being anticipated by the powdered medication inhaler known from document D1, as has been argued by the ISA. In his statement, the applicant has not commented on that point. Given this situation, dependent claims 38 to 48 appear to be left without a single inventive concept.

4.4 However, it cannot be deduced from Rule 13 PCT and from the corresponding part of the Guidelines for International Search or the Administrative Instructions of the PCT that the mere existence of a prior art document which anticipates the subject matter of an independent claim inevitably prejudices the unity of the invention of the remaining subject matter of the application. Faced with a non-unity objection "*a posteriori*" arising from a prior disclosure resulting from an international search, the applicant has, during the later substantive examination according to PCT Chapter II various possibilities of restricting the claims without jeopardizing the unity of the invention. The restricted subject matter is normally defined on the basis of the dependent claims or the examples generally relating to the more preferred embodiments of the invention (see also W 5/85 dated 21 March 1986, point 10 the reasons).

5. It is further noted that if the search actually revealed relevant prior art (which is according to the position of the ISA in the present case document D1), it is indispensable for determining the unity of invention to define, on the basis of the disclosure of this prior art (i.e. D1) the technical problem(s) to be solved by the different inventions. Thus, unity of invention can be assessed only after having determined the technical problem(s) in such a manner.

In the present case, neither the annex to the ISA's invitation to pay additional fees of 24 September 2004 nor the finding of the Review Panel of 7 January 2005 comprised a detailed analysis of the technical problems underlying the four identified groups of inventions in view of both, the disclosure of the international application and document D1 as relevant state of the art. Rather, the novelty of the technical features set out in independent claims 1 and 37 was objected to vis-à-vis the disclosure of document D1, and it was argued that the technical features C), D) E) and F) in the four groups of inventions were different and had different purposes. This approach is, however, not sufficient to substantiate the objection of lack of unity between the four identified groups of inventions.

6. Hence, the Board is unable to concur with the reasoning in the ISA's invitation to pay three additional search fees on its finding that the subject matter of independent claims 1 and 38 was anticipated by document D1.

Order

For these reasons it is decided that:

Reimbursement of three additional search fees and of the protest fee is ordered.

The Registrar: The Chairman:

R. Schumacher T. K. H. Kriner