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D E C I S I O N
of 7 February 2003

Case Number: T 0399/01 - 3.2.2

Application Number: 92913029.2

Publication Number: 0585379

IPC: A61M 11/00

Language of the proceedings: EN

Title of invention:
Aerosol Inhalation Device

Patentee:
ABBOTT LABORATORIES

Opponent:
Trudell Medical International

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 83

Keyword:
"Sufficient disclosure (yes)"
"Novelty and inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0399/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 7 February 2003

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 29 November 2001 rejecting the opposition filed against European patent No. 0 585 379 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (opponent) filed an appeal against the decision of the opposition division to reject the opposition.

II. The Patent was opposed on the grounds of insufficient disclosure (Article 100b EPC), and of lack of novelty and inventive step (Article 100a EPC).

III. During appeal proceedings the appellant maintained all these grounds and based its objections on the following documents, already introduced during the opposition proceedings.

D1: US-A-4 641 644

D2: US-A-5 505 194

D3: Experimental tests by Dr Jolyon P. Mitchell and Mr Mark Nagel concerning: Performance of generic spacer devices having elliptical or circular cross-section

D4: US-A-3 994 421

With letter of 5 August 2002 the respondent submitted the document:

A1: E. Truckenbrodt, "Strömungsmechanik, Grundlagen und technische Anwendungen", Springer Verlag, 1968, pages 221, 223.

IV. Upon request of both parties, oral proceedings were held on 7 February 2003.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed or that the patent be maintained in amended form on the basis of the auxiliary request as submitted at the oral proceedings.

V. Claim 1 of the main request as granted reads as follows:

"An aerosol inhalation device (10) for maximizing delivery of medicament into the lung, said device (10) comprising an elongated expansion chamber (12) with a mouthpiece configuration (16) provided at one end thereof, an elongated canister housing (14) associated with said expansion chamber (12) for receiving a pressurized canister (46) of medicament having a valve stem (48) projecting from one end thereof, said canister housing (14) being telescopically slidable into said expansion chamber (12) and said canister housing (14) being pivotally connected to said expansion chamber (12) by connecting means further permitting axial movement of said canister housing (14) from a storage position telescoped within said expansion chamber (12) to an axially-aligned, fully extended position, said canister housing (14) being pivotal only when in said fully-extended position, into an operable position, said operable position being predetermined by interference means between said expansion chamber (12) and said canister housing (14), thereby limiting said relative pivotal movement therebetween, said canister housing (14) having a valve-stem-receiving portion (54), a laterally disposed

orifice passage (58) formed in said valve-stem-receiving portion (54) and intersecting a valve-stem-receiving bore (56) thereof with the axis of said orifice passage (58) being disposed at a first angle to the axis of said valve-stem-receiving bore (56) and with an exit end (60) of said orifice passage (58) being generally flared outwardly, said canister housing (14) being pivotal only through a second angle equal to or less than 90° into said operable position wherein the axis of said orifice passage (58) is disposed in axial alignment with a longitudinal axis of said elliptical expansion chamber (12), said first angle between said orifice passage (58) and said axis of said valve-stem-receiving-bore (56) being equal to or greater than 90°, characterized in that said expansion chamber (12) is elliptical in cross section."

VI. The appellant argued as follows.

The invention was not sufficiently disclosed for a skilled person in the field to be carried out. In particular, the patent did not contain any teaching about what was "sufficient", "maximized", or "high percentage of" (delivery of the medicament), see column 1, lines 7 to 16 of the description, and column 3, line 57, to column 4, line 28. Furthermore the disclosure did not contain any statement about the degree of eccentricity to delimit the term "elliptical" against the term "circular".

The subject-matter of claim 1 also embraced embodiments for which the major axis of the elliptical cross-section was directed vertical to the pivotal axis between the canister housing and the expansion chamber. According to the tests reported in document D2,

however, the desired favourable effect was only to be expected for a parallel alignment of the pivotal axis.

The subject-matter claim 1 was not novel having regard to document D4. Document D4 disclosed an expansion chamber having a circular cross-section. Being the circle a special case of an ellipse with the axes a, b having the same length, document D4 disclosed all the features of the invention.

In any case, the subject-matter of claim 1 did not involve an inventive step having regard to Document D4 and the general knowledge of the skilled person. Document D4 disclosed the benefits of administering the medicament at low velocity. Document A1 disclosed that the presence of a bend in a conduct caused the stream to develop a vortex slowing down the movement of the particles. The vortex effect increased with the eccentricity of the cross-section. In addition to the eccentricity, a bend in the flow path was also contributing to the proper functioning of the invention (see document D2, column 5, from line 57, and Table 2).

The results of the experimental tests contained in Table 3 of document D2 were not significant for the assessment of the inventive step being not directly representative for the invention because the tests were executed on elliptical cross-sections with the ratio between the horizontal axis a and the vertical axis b of the ellipse only equal or greater than 1, whereas the patent in suit concerned also the case where the ratio was smaller than 1.

VII. The respondent argued as follows.

The invention was feasible. Document D2 proved that starting from a circular cross-section it was possible to find an optimum for the delivery of the medicament by modifying the ratio a/b of the axes of the ellipsis. The results of the tests of document D2 were relevant to understand the invention and applicable to it. In particular it made no sense to distinguish the case where a > b from the case where a < b, because the two cases were perfectly symmetrical and therefore equivalent.

Document D4 did not disclose nor hint at using an elliptical cross-section for the expansion chamber in order to improve the vortex effect. On the contrary, it led away from the invention since it taught improving settling out of the fluid particles, see column 3, line 15; column 5, line 50. Document A1 was irrelevant, because there was no bend in the device of the invention and because it dealt with laminar and not turbulent flow.

Reasons for the Decision

1. The appeal is admissible.

2. *Sufficient disclosure*

Document D2, which is published after the priority date of the patent in suit, originates from the same inventors and concerns principally the same invention as the patent in suit. Therefore, the tests reported therein may be taken as a later filed expertise to assess the feasibility of the patent in suit. These tests are performed for the case only that the major

axis is directed parallel to the pivotal axis between the canister housing and the expansion chamber.

Document D2, in its claims and its general description, is, as the patent in suit, silent about the alignment of the pivotal axis with respect to the major axis of the elliptical cross-section of the expansion chamber. The manner of intended use of this hand-held apparatus and the geometry of the human mouth bring about that only the parallel alignment of these two axes is of practical importance. It is this alignment for which the tests disclosed in document D2 prove the feasibility. These tests are easy to perform by the skilled practitioner to find out those ratios and angles which optimise the delivery of a medicament.

The objections on the ground of Article 100(b) EPC, therefore, have no basis.

3. *Novelty*

Claim 1 is novel against the disclosure of document D4 and it differs therefrom in that the cross-section of the expansion chamber is elliptical.

It is true that according to the mathematical definition a circle is the particular embodiment of an ellipse, implying that positions of in the two focal points and the lengths of the two major axis coincide. In its normal technical meaning an ellipse is a flattened circle having a major axis and a minor axis transverse thereto. The fact that the figures of the patent in suit clearly disclose a cross-section which is not circular and the fact that the application for the present invention as originally filed recognizes as

disadvantageous the teaching of document D4, relying on a circular cross-section, see WO-A-92/20391, page 1, from line 15, clearly prove that the patent and its invention are founded on the latter technical definition of "elliptical" which excludes a circular cross-section.

Accordingly the subject-matter of claim 1 is novel against the disclosure of document D4.

4. *Inventive step*

Starting from the teaching of document D4, which has been unanimously accepted as representing the closest state of the art, the purpose of the invention consists in improving the delivery of a large percentage of medicament, especially a poorly absorbed drug as a peptide, to the deepest part of the patient's lung. To this purpose the velocity of the medicament particles has to be sufficiently slowed down so that to avoid an impact against the back of the throat, see patent in suit, column 1, lines 37 to 50.

The solution provided by the invention is to modify the circular cross-section of the expansion chamber of the known device of document D4 into an elliptical cross-section having a suitable axis ratio. The movement of the aerosolized medicament with this structural arrangement is a vortex movement which minimizes aggregation of the medicament particles and slows down their movement so as to minimize impaction of same against the back of the user's throat while maximizing the amount of the medicament delivered to the deepest portions of the lungs (see EP-B-585 379, column 4, lines 20 to 28).

Document D4 itself does not contain any hints which could lead the skilled person in the field to modify the device disclosed therein in the sense of the invention.

The additional consideration of the teaching of document A1 cannot lead to the invention in an obvious way either. Document Al, in its chapter "Richtungsänderungen", deals with the influence of direction changes (deviations) on stationary parallel streams of an incompressible homogenous fluid. For the cases of a rectangular and circular cross-section of a tube, the increased friction losses caused by a 90°-bend may result in the formation of secondary streams which together with the main stream deliver a spiralling stream picture.

The conditions of this idealised stationary model are far from the conditions existing at the operation of the inhalation device according to the patent in suit, where a first fluid is atomized into an initially resting second fluid which is accelerated thereby. Consequently, the Board cannot recognise that a person skilled in the art would possibly envisage to approximate the extremely non-stationary conditions prevailing during the operation of the device according to the invention by the model disclosed in document Al. Document A1 is therefore irrelevant for an evaluation of the invention.

The further documents of the state of the art are less relevant for the invention. In particular, document D1 deals with a device similar to that of the invention, but having a rectangular cross-section. Document D1 does not recognize the possible beneficial effect of a

particular cross-section. Document D3 deals with comparative tests which tend to show that a circular cross-section is better than the claimed elliptical cross-section, contrary to what is asserted in Table 3 of document D2. However, document D3 is silent regarding the geometry of the tested apparatus besides the expansion chamber, so that a meaningful comparison with the test results of document D2 is not possible.

Accordingly the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiß