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Datasheet for the decision of 5 October 2011

Case Number: T 0170/09 - 3.2.02

Application Number: 98924061.9

Publication Number: 0986413

IPC: A61M 15/08

Language of the proceedings: EN

Title of invention:
Inhaler for powdered medicaments

Patentee:
Direct-Haler A/S

Opponent:
Edward Tomlinson

Headword:
-

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0170/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 5 October 2011

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 10 November 2008 concerning maintenance of European patent No. 0986413 in amended form.

Composition of the Board:

Chairman: D. Valle
Members: M. Stern
A. Pignatelli

Summary of Facts and Submissions

I. The opponent filed on 20 January 2009 an appeal against the decision dated 10 November 2008 of the Opposition Division to maintain the patent in amended form. The fee for appeal was paid on the same day and the statement setting out the grounds for appeal was received on 20 March 2009.

II. Oral proceedings took place on 5 October 2011.

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the patent be maintained according to the main request or one of the three auxiliary requests all filed during the oral proceedings.

III. Following documents are relevant for the decision:

D1: DE-A-3018691
D6: WO-A-96/22802

IV. Claim 1 of the main request reads as follows:

"A device for applying a powdered or particulate substance to a mucous membrane within a nostril of a user of the device, said device comprising a tubular body defining an inner flow passage extending longitudinally between a nasal piece (12) at a first end of the tubular body to be inserted into the nostril of the user and an opposite second end of said body defining a mouthpiece (11) to be inserted between the

lips of the user, the length and the shape of the tubular body (10) being such that the nasal piece (12) and the mouthpiece (11) may at the same time be positioned in the nostril and between the lips, respectively, of the user, whereby the user may blow into the mouthpiece (11) end of the flow passage and transfer powdered or particulate substance arranged within the flow passage of the tubular body (10) to the nostril in a dispersed condition, the flow passage of said tubular body having a cross-sectional area not exceeding 75 mm^2, and said device further comprising restriction means for forming at least one cross-sectional restriction within the inner cavity of the tubular body, a dose (14) of powdered or particulate substance being arranged downstream of said restriction means before the device is used and said tubular body comprising an intermediate bendable section, characterized by said bendable section having turbulence-inducing means within the tubular body (10) in the form of adjacent, peripherally extending corrugations preferably having a substantially serrated outline when viewed in a longitudinal, axial section."

Claim 1 of the first auxiliary request reads as follows (amendments with respect to the main request underscored):

"A device for applying a powdered or particulate substance to a mucous membrane within a nostril of a user of the device, said device comprising a tubular body defining an inner flow passage extending longitudinally between a nasal piece (12) at a first end of the tubular body to be inserted into the nostril of the user and an opposite second end of said body

defining a mouthpiece (11) to be inserted between the lips of the user, the length and the shape of the tubular body (10) being such that the nasal piece (12) and the mouthpiece (11) may at the same time be positioned in the nostril and between the lips, respectively, of the user, whereby the user may blow into the mouthpiece (11) end of the flow passage and transfer powdered or particulate substance arranged within the flow passage of the tubular body (10) to the nostril in a dispersed condition, the flow passage of said tubular body having a cross-sectional area not exceeding 75 mm^2, and said device further comprising restriction means for forming at least one cross-sectional restriction within the inner cavity of the tubular body, a dose (14) of powdered or particulate substance being arranged downstream of said restriction means before the device is used and said tubular body comprising an intermediate bendable section, characterized by said bendable section having turbulence-inducing means within the tubular body (10) in the form of adjacent, peripherally extending corrugations preferably having a substantially serrated outline when viewed in a longitudinal, axial section, wherein the restriction means are yieldable so as to be movable between a first restricting position and a second position in which the restriction defined by the restriction means is substantially less or the restriction means comprise inwardly compressible or pinchable parts of the wall of the tubular body (10), the inwardly compressible or pinchable part being marked, for example by means of different colour, printing, knurling or roughening."

Claim 1 of the second auxiliary request reads as follows (amendments with respect to the main request underscored):

"A device for applying a powdered or particulate substance to a mucous membrane within a nostril of a user of the device, said device comprising a tubular body defining an inner flow passage extending longitudinally between a nasal piece (12) at a first end of the tubular body to be inserted into the nostril of the user and an opposite second end of said body defining a mouthpiece (11) to be inserted between the lips of the user, the length and the shape of the tubular body (10) being such that the nasal piece (12) and the mouthpiece (11) may at the same time be positioned in the nostril and between the lips, respectively, of the user, whereby the user may blow into the mouthpiece (11) end of the flow passage and transfer powdered or particulate substance arranged within the flow passage of the tubular body (10) to the nostril in a dispersed condition, the flow passage of said tubular body having a cross-sectional area not exceeding 75 mm^2, and said device further comprising restriction means for forming at least one cross-sectional restriction within the inner cavity of the tubular body, a dose (14) of powdered or particulate substance being arranged downstream of said restriction means before the device is used and said tubular body comprising an intermediate bendable section, characterized by said bendable section having turbulence-inducing means within the tubular body (10) in the form of adjacent, peripherally extending corrugations preferably having a substantially serrated outline when viewed in a longitudinal, axial section,

wherein the restriction means are yieldable so as to be movable between a first restricting position and a second position in which the restriction defined by the restriction means is substantially less, the restriction means being adapted to move from the first restricting position to their second, less restricting position when a user is blowing into the second end of the tubular body (10) so as to create a pressure difference between said first and second ends of the tubular body exceeding a predetermined value or the restriction means comprise inwardly compressible or pinchable parts of the wall of the tubular body (10) the inwardly compressible or pinchable part being marked, for example by means of different colour, printing, knurling or roughening."

Claim 1 of the third auxiliary request reads as follows (amendments with respect to the main request underscored):

"A device for applying a powdered or particulate substance to a mucous membrane within a nostril of a user of the device, said device comprising a tubular body defining an inner flow passage extending longitudinally between a nasal piece (12) at a first end of the tubular body to be inserted into the nostril of the user and an opposite second end of said body defining a mouthpiece (11) to be inserted between the lips of the user, the length and the shape of the tubular body (10) being such that the nasal piece (12) and the mouthpiece (11) may at the same time be positioned in the nostril and between the lips, respectively, of the user, whereby the user may blow into the mouthpiece (11) end of the flow passage and

transfer powdered or particulate substance arranged within the flow passage of the tubular body (10) to the nostril in a dispersed condition, the flow passage of said tubular body having a cross-sectional area not exceeding 75 mm^2, and said device further comprising restriction means for forming at least one cross-sectional restriction within the inner cavity of the tubular body, a dose (14) of powdered or particulate substance being arranged downstream of said restriction means before the device is used and said tubular body comprising an intermediate bendable section, characterized by said bendable section having turbulence-inducing means within the tubular body (10) in the form of adjacent, peripherally extending corrugations preferably having a substantially serrated outline when viewed in a longitudinal, axial section, wherein the restriction means are yieldable so as to be movable between a first restricting position and a second position in which the restriction defined by the restriction means is substantially less, and comprise a flap (24) which in said first position covers at least part of the cross-section of the inner cavity of the tubular body (10), the restriction means being adapted to move from the first restricting position to their second, less restricting position when a user is blowing into the second end of the tubular body (10) so as to create a pressure difference between said first and second ends of the tubular body exceeding a predetermined value or the restriction means comprise inwardly compressible or pinchable parts of the wall of the tubular body (10) the inwardly compressible or pinchable part being marked, for example by means of different colour, printing, knurling or roughening."

V. The appellant argued that the subject-matter of claim 1 of the main request did not involve an inventive step having regard to a combination of the teaching of D1 and D6. The auxiliary requests should not be admitted into the proceedings according to Article 13(3) of the Rules of Procedure of the Boards of Appeal because they contained new, unsearched subject-matter.

The respondent objected to the arguments of the appellant and argued in particular that D1 did not disclose a device having restriction means or that the dose of particulate substance was arranged downstream of the restriction means. The problem of the invention starting from D1 could not be to improve the bendability of the device, since the device according to D1 was already perfectly suitable to be bent at a desired angle. The device of D6 was not designed to have one end inserted in the lips and the other end inserted into the nose nor for blowing. By contrast, the device of D6 was designed for inhalation through the mouth or sniffing through the nose. The auxiliary requests did not contain subject-matter which had not yet been searched.

Reasons for the Decision

1. The appeal is admissible.

2. *Inventive step of the main request*

D1 discloses a device for applying a powdered or particulate substance to a mucous membrane within a nostril of a user of the device, said device comprising

a tubular body (1) defining an inner flow passage extending longitudinally between a nasal piece (page 6, paragraph 2) at a first end of the tubular body to be inserted into the nostril of the user and an opposite second end of said body defining a mouthpiece (page 6, paragraph 2) to be inserted between the lips of the user, the length and the shape of the tubular body being such that the nasal piece and the mouthpiece may at the same time be positioned in the nostril and between the lips, respectively, of the user, whereby the user may blow into the mouthpiece end of the flow passage and transfer powdered or particulate substance arranged within the flow passage of the tubular body to the nostril in a dispersed condition (page 5, paragraph 3, last sentence; page 6, paragraph 2), the flow passage of said tubular body having a cross-sectional area not exceeding 75 mm^2 (page 5, paragraph 3) and whereby said tubular body comprises an intermediate bendable section (page 6, last paragraph, elastic tube).

However, D1 does not disclose that said device further comprises restriction means for forming at least one cross-sectional restriction within the inner cavity of the tubular body, a dose of powdered or particulate substance being arranged downstream of said restriction means before the device is used and that said intermediate bendable section has turbulence inducing means within the tubular body in the form of adjacent, peripherally extending corrugations.

The problem to be solved by the invention can therefore to be seen in improving the suitability of the intermediate section to be bent and in improving the

dispersion of the powdered substance during delivery. The bending properties of the tubular body should in particular facilitate the positioning of one end of the tubular body between the lips and of the opposite end in the nostril. For this purpose the tubular body should be capable of being bent at a determinate angle and such angular position should be maintained without special further intervention. Contrary to the assertion of the respondent, a tubular body of uniform section such as that disclosed in D1 is not particularly suitable for this purpose because it does not present a special area particularly designed for bending.

In order to find a solution to the above set of problems, the person skilled in the art would consider D6, which belongs to the same field of the invention of inhalers of powdered medicaments, in particular for the nose, see page 8, lines 20-27.

D6, see in particular Figure 24, discloses an intermediate bendable section of the inhaler having corrugations similar to those of a drinking straw (see claim 8). This configuration - as is generally known - remarkably facilitates the angular positioning of the tubular body. Furthermore, these corrugations represent restriction means for forming at least one cross-sectional restriction within the inner cavity of the tubular body, a dose of powdered or particulate substance being capable of being arranged downstream of said restriction means before the device is used. These corrugations are adjacent and extend peripherally as in the claimed invention (compare Figure 24 of D6 with Figures 18 - 20 and page 4, lines 9-21 of the

invention). They also perform the function of turbulence-inducing means.

It is true, as the respondent pointed out, that D6 does not disclose specifically that the user "may" blow into the mouthpiece end of the flow passage and transfer the particulate substance to the nostril. The possibility of using the device in this way is however self-evident: page 8, lines 20-22 of D6 discloses that one end or the mouthpiece end of the tubular body may be adapted to be inserted into a nostril. That means that in the first alternative one end is adapted to be inserted into a nostril and the other end is adapted to function as mouthpiece end. In this case the user may blow into the mouthpiece end of the flow passage and transfer the particulate substance to the nostril.

It is also true that neither of the two relevant documents explicitly discloses that the dose of particulate substance is arranged downstream of the restriction means. However, the claim merely requires that a dose of powdered or particulate substance is arranged downstream of said restriction means before the device is used. This is a feature concerning the use of the device and does not restrict the claimed device. There is no doubt that the device is suitable for accommodating downstream of the corrugations (restriction means) a dose of the substance before use.

Accordingly, no inventive skills are necessary for combining the teaching of D1 with that of D6 in the form of the claimed invention and the subject-matter of claim 1 of the main request does not involve an inventive step.

3. *The auxiliary requests*

All the auxiliary requests 1 -3 contain in claim 1 the feature that the inwardly compressible or pinchable part is marked, for example by means of different colour, printing, knurling or roughening. This feature is essential for the evaluation of the inventive step of the claim but it was not contained in the original claims. It was introduced with letter of 5 September 2011, therefore after the date on which oral proceedings were arranged (10 June 2011), and had not been searched. It was therefore not possible to evaluate the inventive step of the claims without an additional search. This would have required an adjournment of the oral proceedings.

In consideration of the above, the auxiliary requests are not admitted into the proceedings on the basis of Article 13(3) of the Rules of Procedure of the Boards of Appeal, which states that amendments sought to be made after oral proceedings have been arranged shall not be admitted into the proceedings if they raise issues which the Board or the other party cannot reasonably be expected to deal without adjournment of the oral proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Hampe D. Valle