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**Datasheet for the decision
of 6 October 2020**

Case Number: T 1813/15 - 3.2.02

Application Number: 11191742.3

Publication Number: 2452715

IPC: A61M16/06, A61M16/08

Language of the proceedings: EN

Title of invention:

Patient interface

Applicant:

ResMed Pty Ltd

Headword:

Relevant legal provisions:

EPC Art. 54(1), 54(2), 56, 76(1), 84, 111(1), 123(2)
RPBA 2020 Art. 11, 12(2)

Keyword:

Novelty - main request and auxiliary request 1 (no)
Remittal to the department of first instance on the basis of
auxiliary request 2

Decisions cited:

Catchword:



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Case Number: T 1813/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 October 2020

Appellant: ResMed Pty Ltd
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 11 February
2015 refusing European patent application
No. 11191742.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: D. Ceccarelli
N. Obrovski

Summary of Facts and Submissions

- I. The applicant has appealed against the Examining Division's decision, posted on 11 February 2015, to refuse European patent application No. 11 191 742.3.

The application is a divisional application of European patent application No. 08 161 249.1.

- II. The Board summoned the appellant to oral proceedings by letter dated 23 April 2020. In the communication accompanying the summons the Board explained, *inter alia*, why, in its preliminary view, the subject-matter of claim 1 of the main request and of auxiliary request 1 appeared to lack novelty over the following document:

D1: US-A-2006/0283461

- III. Oral proceedings took place on 6 October 2020.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, one of auxiliary requests 1 to 6, all filed with the statement of grounds of appeal dated 22 June 2015.

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

"A patient interface (5010; 5610; 6010; 6510) for delivering breathable gas to a patient comprising:

a nasal pillows assembly (20; xx20) adapted to form a seal with a patient's nose; and

wherein the nasal pillows assembly (20; xx20) comprises

a pair of nasal pillows (24; xx24) and a gusset (25g-6), wherein each pillow (24; xx24) includes (i) a wall of pillow region (25g-1), (ii) an attachment of pillow to stalk region (25g-2), (iii) a stalk region (25g-3) and (iv) an attachment of stalk to platform region (25g-4), and wherein the gusset (25g-6) includes (v) a platform region (25g-8) and (vi) a gusset or base region (25g-6); and further wherein (i) the wall of pillow region (25g-1) is a flexing region, (ii) the attachment of pillow to stalk region (25g-2) is a flexing region, (iii) the stalk region (25g-3) is a flexing region, (iv) the attachment of stalk to platform region (25g-4) is a flexing region, (v) the nasal pillow assembly includes an additional flexing region (25g-5) located on the platform region (25g-8), wherein the additional flexing region (25g-5) is adapted to bend when the pillow is compressed, and wherein (vi) the gusset or base region (25g-6) is a flexing region."

Claim 1 of auxiliary request 1 reads as claim 1 of the main request, with the addition of the following wording at the end of the claim:

"wherein the attachment of pillow to stalk region (25g-2) is a first curved region and wherein the attachment of stalk to platform region (25g-4) is a second curved region, the second curved region (25g-4) having a reduced curvature compared to the first curved region (25g-2) and hence being stiffer than the first curved region (25g-2)".

Claim 1 of auxiliary request 2 reads as claim 1 of the main request, with the addition of the following

wording after the first occurrence of the term "gusset (25g-6)":

"adapted to provide contact with the patient's upper lip when worn".

V. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

The subject-matter of claim 1 of the main request was novel over D1. The two most relevant embodiments of a pillow assembly disclosed in this document, depicted in particular in Figures 33 to 34d and Figures 37 to 39, respectively, did not comprise a gusset within the meaning of claim 1. The term "gusset" implied a certain flexibility, which the base of the pillow assembly of the two embodiments of D1 did not have. Moreover, each of these embodiments only comprised two flexing regions. In particular, they did not comprise a gusset or base region which was a flexing region. A flexing region within the meaning of the claim had to be flexible in normal use of the pillow assembly. Such flexibility depended not only on the material, but also on the geometry of the pillow assembly.

The subject-matter of claim 1 of auxiliary request 1 was novel over the embodiment depicted in Figures 37 to 39 of D1. This embodiment did not comprise the same stalk region to which the wall of pillow region and the platform region were attached with respective curved regions having different curvatures. Moreover, the claim structure made it clear that the stalk region had to be between the wall of pillow region and the platform region. In the embodiment in Figures 37 to 39 a wall of pillow region directly transitioned into a further pillow region. It was not possible to define a

stalk region between the two pillow regions, or a radius of curvature between such a hypothetical stalk region and the pillow regions.

The subject-matter of claim 1 of auxiliary request 2 was novel over D1. D1 did not disclose a pillow assembly with a gusset region adapted to provide contact with the patient's upper lip when worn. The pillows in D1 were part of an oro-nasal mask. The presence of the mouth cushion of this mask made it impossible, in use, for the gusset region to be able to come into contact with the patient's upper lip, as expressly explained in paragraph [0249] of D1.

Reasons for the Decision

1. The invention

The invention relates to a patient interface for delivering breathable gas to a patient.

Patient interfaces as claimed are typically used in nasal masks for providing Continuous Positive Airway Pressure (CPAP) therapy to a patient. Such therapy consists in the delivery of pressurised air or oxygen-enriched air while the patient is sleeping, to avoid Obstructive Sleep Apnea (OSA). Patients suffering from this pathology stop breathing for some considerable time during sleep because their airway becomes blocked following the relaxation of throat and tongue muscles. The most common cause of OSA is excess weight and obesity, which is associated with soft tissue of the mouth and throat. OSA has a devastating impact on the quality of sleep and, as a consequence, on the quality of life in general. It can even be life-threatening, as

the patient may not resume breathing.

A patient on CPAP treatment, which potentially lasts for the entire life, is attached to a respirator every night. The comfort and effectiveness of the patient interface are of utmost importance.

The invention focuses on the structure of a nasal pillow assembly, comprising two nasal pillows, as depicted in Figures 27h, 25g and 28 reproduced below.

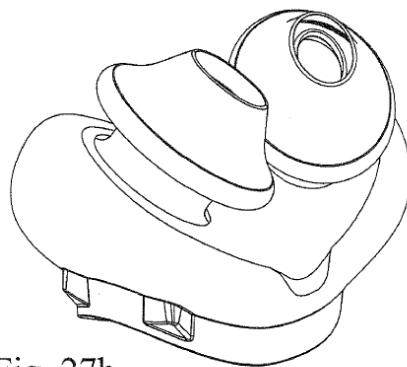
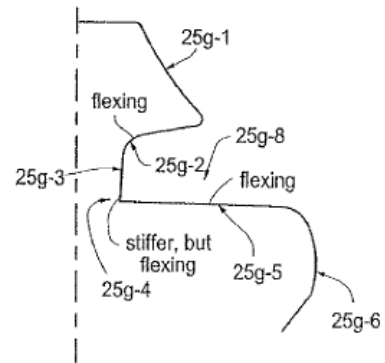


Fig. 27h



Present Example

Fig. 25g

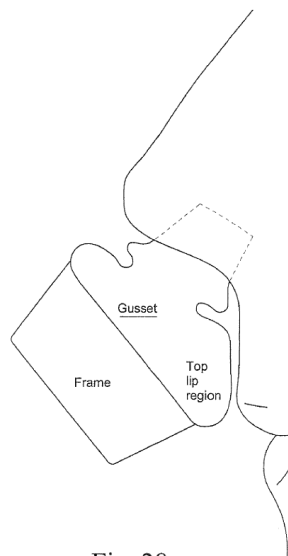


Fig. 28

More specifically, it concerns the design of each nasal pillow comprising a number of flexing regions, to

improve flexibility. In turn, this should ensure a tight fit of the pillows while maintaining a good comfort level when the patient moves during the night (paragraph [0006], for example).

The independent claims of all the requests concern the embodiments in Figures 23 to 30 and their related description on pages 43 to 51 of the application as filed.

2. Main request

The subject-matter of claim 1 of the main request is not novel over D1.

D1 concerns a mask system for delivering breathable gas to a patient in the context of CPAP treatment (paragraph [0003]). Such a system is depicted in Figure 1, reproduced below.

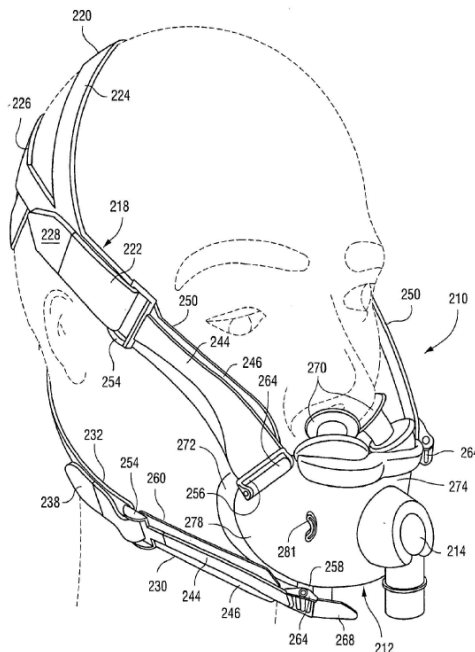


Fig. 1

The system comprises a patient interface for gas

delivery (212) in the form of a sealing assembly that provides a seal with both the mouth and the nasal passages (paragraph [0151]). The patient interface comprises a nasal pillows assembly (mouth cushion 272 together with nasal prongs 270, as disclosed in paragraphs [00185] and [00192]). The nasal pillow assembly of D1 is part of an oro-nasal mask; however such a mask is not excluded by claim 1 of the main request. In D1, the patient interface is illustrated alone in Figure 30, reproduced below.

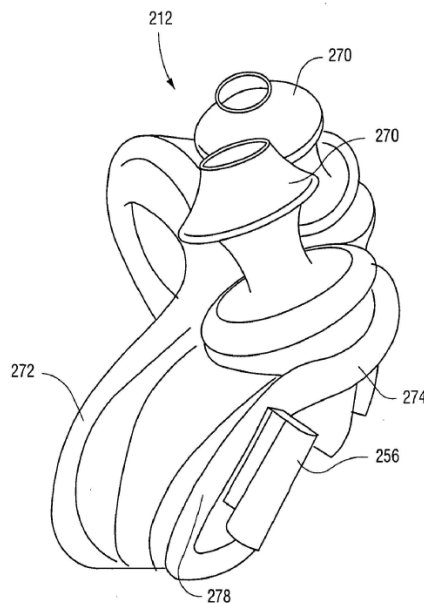


Fig. 30

The nasal pillows assembly is adapted to form a seal with a patient's nose and comprises a pair of nasal pillows (270). Two embodiments of the nasal pillows are of particular relevance. They are disclosed with reference to Figures 33 to 34d and Figures 37 to 39, respectively. Figures 34a and 37 are reproduced below.

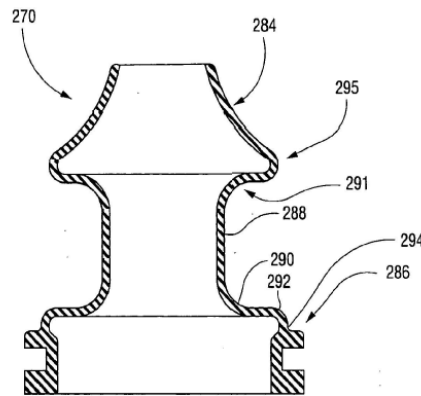


Fig. 34a

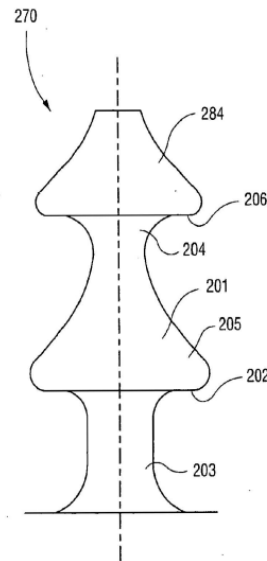


Fig. 37

The nasal pillows assembly further comprises a gusset (base portions 286 of each nasal pillow visible in Figure 34a, which are joined together as parts of a paired-prong arrangement disclosed in paragraph [0192]).

As regards the first embodiment, disclosed with reference to Figures 33 to 34d, each pillow includes a wall of pillow region (284), an attachment of pillow to stalk region (291), a stalk region (288) and an attachment of stalk to platform region (290).

Each pillow in the embodiment disclosed with reference to Figures 37 to 39 also includes several regions, from which a wall of pillow region (201), a stalk region (lower column 203), an attachment of pillow to stalk region (transition from region 201 to region 203) and an attachment of stalk to platform region (transition region 203 to the lowest region of the pillow shown in Figure 37) can be identified.

In both embodiments the gusset includes a gusset or base region (286, Figure 34a) and a platform region extending from the gusset or base region to the attachment of stalk to platform region (shown as 299 in Figure 34c-1). Although these regions are not shown in Figures 37 to 39, they must be present in the embodiment depicted in these figures in order to make it possible to couple the pillows to the rest of the assembly.

Claim 1 of the main request defines flexing regions. The appellant argued that D1 did not disclose a gusset or six flexing regions as claimed. However, the whole nasal pillows assembly in D1 is flexible. Paragraph [0191] expressly discloses that the mouth cushion and the nasal prongs may be made of silicone or a gel material. Paragraph [0193] discloses that the sectional thickness of all the regions of the nasal prongs, except base portion 286, is 0.75 mm. Although the sectional thickness of base portion 286 is disclosed to be larger, i.e. greater than 1.5 mm, this dimension does not make it rigid. Moreover, paragraph [0192] discloses that the base portion of the nasal prongs can be secured within a recess via a press-fit. This implies flexibility of this portion, which can be considered a gusset. The term "relatively rigid", used in paragraph [0200] in the description of stalk 288 and referred to by the appellant, implies general flexibility.

The appellant's argument that a flexing region within the meaning of the claim had a more limited meaning cannot be accepted, as the claim is very general in this respect. The claim does not define any specific functional feature in association with the flexing regions.

It follows that D1 anticipates the subject-matter of claim 1 of the main request. Hence, the main request is not allowable for lack of novelty (Article 54(1) and (2) EPC) of the subject-matter of claim 1.

3. Auxiliary request 1

The subject-matter of claim 1 of auxiliary request 1 is not novel over D1 either.

Claim 1 of auxiliary request 1 differs from claim 1 of the main request on account of the definition of the different curvatures of the attachment of pillow to stalk region and the attachment of stalk to platform region.

The embodiment in Figures 37 to 39 of D1 is of relevance to this additional feature.

In particular, in each pillow in this embodiment lower column 203 together with upper column 204 can be identified as a stalk region (paragraph [0208]). The attachment of pillow to stalk region can then be considered as the first curved region between the wall of pillow region (201) and upper column 204, while the attachment of stalk to platform region is the second curved region between lower column 203 and the lowest region of the pillow shown in Figure 37.

The second curved region has a reduced curvature (within the meaning of the present application) compared with the first curved region and hence is stiffer than the first curved region. The term "hence" in the claim makes the difference in flexibility only dependent on the difference in curvature.

The appellant argued that the embodiment in Figures 37 to 39 of D1 did not comprise the same stalk region to which the wall of pillow region and the platform region were attached with respective curved regions having different curvatures. This argument is not convincing. As explained in paragraphs [0208] to [0210] and as is evident from the geometry of the nasal pillows, lower column 203 and upper column 204, which are vertically aligned, together support wall of pillow regions 284 and 201. Hence, the lower and the upper column act as a single stalk and can be considered a stalk region within the meaning of the claim. In this respect, the Board notes that the term "region" is very general and does not exclude interruptions between different portions of the region.

Contrary to the appellant's view, the claim does not specify anything about the spatial sequence of the regions either. Whether the stalk region is between the wall of pillow region and the platform region in the specific embodiment of the description of the present application is not decisive, since the claim is a generalisation of this specific disclosure.

The argument that it was not possible to define a stalk region between wall of pillow regions 284 and 201 is not convincing either. According to Figure 37 and paragraph [0208] the wall of pillow regions transition into one another, through upper column 204. The definition of attachment regions and of a portion of the stalk region as parts of this transition is arbitrary. The attachment of pillow to stalk region is the part of the transition starting from wall of pillow region 201. Its curvature is clearly greater (within the meaning of the present application) compared with

that of the attachment of stalk to platform region.

It follows that D1 anticipates the subject-matter of claim 1 of the auxiliary request 1. Hence, auxiliary request 1 is not allowable for lack of novelty (Article 54(1) and (2) EPC) of the subject-matter of claim 1.

4. Auxiliary request 2

4.1 The subject-matter of claim 1 of auxiliary request 2 is based in particular on paragraphs [00345], [00365] and [00366], and Figures 25g and 28 of the parent application and the present application as filed (the description and drawings of these applications are identical). It follows that claim 1 complies with Articles 76(1) and 123(2) EPC.

It is the Board's view that claim 1 also fulfils the requirements of clarity as prescribed in Article 84 EPC (the features to which an objection has been raised under points 3.2 and 4.1 of the appealed decision for being unclear are not found in claim 1).

4.2 D1 does not disclose a gusset of a nasal pillow assembly which is adapted to provide contact with the patient's upper lip when worn. Each nasal pillow assembly disclosed in D1 comprises a mouth cushion which spaces the gusset from the upper lip when the nasal pillow assembly is worn (paragraph [0249]).

It follows that the subject-matter of claim 1 of auxiliary request 2 is novel (Article 54(1) and (2) EPC) over D1.

4.3 This distinguishing feature is for enhancing the seal of the nasal pillows, as explained in paragraph [00345]

of the application as filed. Therefore, it solves the objective technical problem of providing more effective CPAP therapy.

The person skilled in the art would not implement the distinguishing feature in the nasal pillow assemblies disclosed in D1, as its function is provided by the presence of the mouth cushion. Moreover, the implementation would require a complete re-design of the assemblies.

As a consequence, the subject-matter of claim 1 of auxiliary request 2 is also inventive (Article 56 EPC), when starting from D1.

5. Remittal to the Examining Division

The decision under appeal considered only claim 1 of the then pending requests, in view of the requirements of Articles 84 and 123(2) EPC and novelty over D1. This has been reviewed by the Board.

The decision did not deal with other requirements of the EPC, the consideration of which by two instances may be appropriate.

As regards the dependent claims and the description, for example, the Board notes that the claims are not based on claims of the parent application as originally filed, and that the description was adapted to claims of the parent application which are no longer present.

The appellant was also in favour of remitting the case.

For these reasons, and in view of the primary object of the appeal proceedings to review the decision under

appeal in a judicial manner (Article 12(2) RPBA 2020), the Board considers that special reasons within the meaning of Article 11 RPBA 2020 are present for remitting the case to the Examining Division for further prosecution, in accordance with Article 111(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated