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**Datasheet for the decision  
of 26 June 2007**

**Case Number:** T 1310/05 - 3.2.02

**Application Number:** 96937903.1

**Publication Number:** 0868156

**IPC:** A61F 2/20

**Language of the proceedings:** EN

**Title of invention:**

Voice prosthesis-cartridge assembly

**Patentee:**

Helix Medical, Inc.

**Opponent:**

Atos Medical AB

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 52(1), 56, 123(2)(3)

EPC R. 57a

**Keyword:**

"Allowability of amendments (yes)"

"Inventive step (yes)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 1310/05 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 26 June 2007

**Appellant:** Atos Medical AB  
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**Representative:** Asketorp, Göran  
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**Representative:** Findlay, Alice Rosemary  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
17 August 2005 concerning maintenance of  
European patent No. 0868156 in amended form.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** S. Chowdhury  
E. Dufrasne

## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division relating to European patent No. 0 868 156. The decision was dispatched on 17 August 2005.

The appeal and the fee for the appeal were received on 14 October 2005. The statement setting out the grounds of appeal was received on 19 December 2005.

The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step). The opposition division decided the claims of the main request, filed on 27 May 2005, met the requirements of the EPC, in particular those of Article 123(2) and (3) EPC and Article 52(1) EPC.

- II. The following documents were of particular interest in the appeal procedure:

D1: US-A-4 911 716

D2: US-A-5 314 470

D5: US-A-4 610 691.

- III. Oral proceedings were held on 26 June 2007.

The appellant requested that the decision under appeal be set aside and that European patent No. 0 868 156 be revoked.

The respondent (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or the

first or second auxiliary request, all filed with letter dated 25 May 2007.

IV. Independent claim 1 of the main request read as follows:

"A voice prosthesis for insertion into a fistula in a tracheoesophageal wall of a patient comprising in combination:

a hollow, tubular, flexible body (14, 100, 214) to be disposed in and to maintain said fistula open, said body having a first tracheal end and a second esophageal end and a wall between said ends;

a first flange (16) at the first end of the body;

a second flange (19) at the second end of the body;

said first and second flanges extending radially outward to a radially outer edge and said body, first flange and second flange being a unitary structure;

an elongated, hollow, rigid, cartridge (12, 92, 212) having an annular wall terminating in a tracheal face and an esophageal face (62);

said cartridge (12, 92, 212) received in said body (44, 100, 214) between said ends whereby the tracheal face and the esophageal face (62) of the cartridge (12, 92, 212) are disposed between the second flange (19) and the first flange (16);

means for retaining said cartridge in said body;

means on said esophageal face (62) for mounting a flapper valve (15);

a flapper valve (15) mounted on said cartridge (19, 92, 212) by said mounting means;

and means for seating said valve, said means comprising the esophageal face (62) of the cartridge (12, 92, 212)."

Claims 2 to 8 are dependent claims.

V. The parties argued as follows:

Appellant

Amendments: Objections arose under Article 123(2) and (3) EPC as well as under Rule 57a EPC as follows:

The change of the word "annular" to "tubular" increased the scope of protection since the former was a species within the genus of the latter, which encompassed triangular, square, etc. cross-sections. Moreover, this amendment was not occasioned by a ground for opposition.

The expressions "attached to" and "connected to" were more limiting than "unitary structure" and, moreover, the latter property was only disclosed together with a molded structure formed from a biocompatible elastomer. These amendments were also not occasioned by a ground for opposition.

Inventive step

D2 was the closest prior art document and it disclosed a two part voice prosthesis which had a similar use to that of the claimed device and needed little modification in order to reach the claimed device. The subject-matter of claim 1 differed from this prior art only by the features that the flapper valve of D2 had no means for mounting it on the cartridge (ring 14). The problem to be solved by these features was not known, but it could be that it enabled a different material to be used for the valve, but the person

skilled in the art would find this solution in D1 (Figure 19) and in D5.

Although D2 taught against a separate valve, the person skilled in the art would, nevertheless, consider providing a separate valve if there were some other advantage in so doing. The ring and valve seat were separate and could be made of an anti-bacterial material, and this advantage could be extended to the valve by making it separate.

Starting from the first embodiment of D1 (see Figure 2), the only differences were that, according to claim 1 the cartridge was rigid, the end faces of the cartridge were located between the flanges of the flexible body, and the esophageal face of the cartridge had means for mounting the flapper valve.

The person skilled in the art would look to Figure 19 of D1 and find these features. D1 disclosed four different bodies and two different cartridges. If one cartridge could be used with all the four embodiments then the person skilled in the art would see that the other cartridge could also be so used.

Respondent

Amendments:

The term "tubular" was narrower than "annular" since it also included the third dimension. The terms "connected to" and "attached to" implied separate flanges and were consequently less limiting than "unitary". This latter property related to the structure and was independent

of "molded", which related to the manner of manufacture, and "biocompatible elastomer", which related to the material. Moreover, the Figures showed a flexible body of unitary structure. The amendments, therefore, met the requirements of Article 123(2) and (3) EPC.

The amendments were made in order to clearly distinguish the claimed device from the D1 devices, and were, therefore, also in accordance with Rule 57a EPC.

Inventive step

D2 clearly taught away from the use of a separate flapper valve. Moreover, it did not disclose a cartridge because the ring 14 had neither the form nor the function of a cartridge as described in the patent.

The first embodiment of D1 described two devices, a permanent rigid implant, and a flexible voice prosthesis. The problem to be solved by the patent was that yeast growth on the valve could cause distortion of the shape of the valve which prevented the valve from closing. Leakage was also caused by distortion of the valve body adjacent to the seat of the valve and by yeast growth on the seat. These problems were solved by mounting a separate flapper valve on the end face of a rigid cartridge. These solutions were not available in the prior art.

## **Reasons for the decision**

1. The appeal is admissible.

2. *Amendments*

2.1 Granted claim 1 defines a hollow, annular, flexible body to be disposed in and to maintain the fistula open. This body, in addition to being annular, must also be elongate, in order to extend along the fistula and maintain it open. In other words, it is tubular. The description also consistently describes this body as being tubular.

All the voice prosthesis devices disclosed in the prior art have a substantially circular symmetry, as does the device of the patent in suit (see Figures 5, 11, and 13). Therefore, the flexible body of claim 1 must be a tubular body having a substantially circular cross-section. For these reasons "tubular" is both narrower than "annular" and also supported by the description.

The appellant's argument, that the word "tubular" also encompasses cross-sections such as triangular and rectangular is not realistic since, as shown, voice prosthesis devices are substantially circular in section and unlikely to have such exotic shapes.

2.2 The different properties of the body 14, as set out in column 4, lines 40 to 43 of the patent, are not linked together. The properties unitary, molded, and biocompatible elastomer relate, respectively, to the structure, manufacture, and material, which are independent of each other. Moreover, every embodiment of the patent shows a unitary structure of the flexible body. Therefore, it is in order to define the body as having a unitary structure.



It follows from the unitary construction of the flexible body that its flanges must be attached or connected to it. The Figures of the patent show the flanges as extending radially outward to a radially outer edge and said body.

For the above reasons the amendments questioned by the appellant comply with Article 123(2) and (3) EPC. Those amendments not questioned by the appellant are also allowable.

2.3 Lack of novelty was a ground of appeal and, in response to this attack the appellant made the above amendments in order to more clearly distinguish the claimed device from those of D1. For this reason the amendments are not objectionable under Rule 57a.

3. *Novelty*

The appellant withdrew its objection of lack of novelty at the oral proceedings, so this was no longer an issue to be decided.

4. *Inventive step - main request*

4.1 Document D1 is considered to be the closest prior art document since the embodiment of Figures 1 to 4 thereof discloses a two-part voice prosthesis comprising one tubular part received within the another.

4.2 The technical problems which the patent in suit addresses are set out in paragraphs 0009 and 0010. In particular, in prior art voice prostheses, yeast growth on the valve could cause distortion of the valve which

prevents the valve from closing. Leaking is also caused by distortion of the valve body adjacent to the seat of the valve and to yeast growth on the seat.

4.3 An essential combination of features of the claimed device for solving these problems is that the cartridge is an elongated, hollow, rigid body having an annular wall terminating in a tracheal face and an esophageal face, which latter face has means thereon for mounting a flapper valve, and a flapper mounted by the mounting means.

4.4 Because the cartridge is rigid, mounting the flapper valve on its esophageal face ensures that both the valve mounting and its seat are less prone to distortion than in a construction where the valve is mounted on a flexible tube. Therefore, there is less likelihood of leakage owing to distortion of the valve body and consequently less danger of yeast growth (cf the Patent, column 2, lines 34 to 36).

4.5 The prior art does not teach that a cartridge within a flexible body should be made rigid and a flapper valve mounted on its end face in order to solve these problems. In the first group of embodiments of D1 (described with reference to Figures 1 to 17) the valve is mounted on a pliable tube (see column 7, lines 11 to 15 and Figure 2).

As regards the second embodiment of D1 (described with reference to Figures 19 to 21), this does teach the use of a valve separate from the inner cartridge. However, this is in the context of an all-metal prosthesis (D1: column 10, line 66) wherein the valve is made of steel

and has a complicated structure (see the valve 508 in Figure 20). This embodiment does not teach a simple flap valve mounted on the end face of a cartridge.

D2 discloses a flap valve which is integral with a flexible tube (column 2, lines 31 to 33).

D5 is concerned with the problem that voice prostheses offer an unacceptably high resistance to air flow, which is also non-uniform, and the object of this patent is to overcome these drawbacks (D5, column 1, lines 33 to 36, 44 to 50, and 57 to 68). This problem is solved by the manner in which a flap valve is attached to a seat at the end face of a tubular body made of medical grade silicone material (column 3, lines 18 to 20). This material must be flexible to allow the prosthesis to be introduced into a fistula (Figure 1).

Therefore, none of D1, D2, and D5 teaches or suggests that a cartridge within a flexible body should be made rigid and a flapper valve mounted on its end face in order to solve the problem of valve distortion.

4.6 By virtue of these features alone the subject-matter of claim 1 involves an inventive step.

4.7 Furthermore, the rigid cartridge is received in the tubular body which must then necessarily be flexible to enable the cartridge to be inserted and removed from its seated position within it. The elongate cartridge affords support for the tubular body during use of the prosthesis.

The tubular body isolates the cartridge because the latter is located between the ends of the body. This feature not only protects the valve location from fungal growth but also the entire cartridge.

The feature, according to which means are provided on the esophageal face of the cartridge for mounting a flapper valve and a flapper valve mounted on the cartridge by the mounting means, means that the flapper valve may be made of a different material, which may be anti-bacterial, which property is relevant to the present technical problems.

As stated above (see point 4.5), D1 discloses the use of a separate valve, but only in an all-metal prosthesis having a complicated valve structure.

D5 discloses the use of a separate valve, but only in order to provide a low resistance to air flow, this document is not concerned with the question of using a different material for preventing yeast growth.

- 4.8 These other features of the claimed prosthesis also contribute to the simple manufacture of a voice prosthesis which is resistant to yeast growth.
- 4.9 The appellant also used document D2 as a starting point from which to attack claim 1. However, this document clearly states that the use of a separate valve is undesirable (column 1, lines 29 to 48) and it would go against the teaching of this document to provide a separate valve, which is an essential feature of claim 1.

Moreover, in D2 the ring 14 cannot be equated with the cartridge of claim 1. The cartridge of claim 1 is elongate in order to support the flexible outer body, so that by "elongate" is meant that the length must be a substantial proportion of the length of the prosthesis (see point 2.1 above). This is not the case with the ring 14 of D2. The stiffening ring would apparently only stiffen the flange 12 and/or the end of the cylindrical piece 10.

Thus, both the form and the function of the ring are different to those of the cartridge of claim 1, which is for supporting the outer tubular body within the fistula and for providing a robust valve mount. For these reasons D2 is not a suitable starting point from which to attack the claim.

- 4.10 For the above reasons the subject-matter of claim 1 of the main request involves an inventive step.

## 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 maintain the patent on the basis of the following documents:
  - Claims 1 to 8 filed as the main request with letter dated 25 May 2007;
  - Description columns 1 to 9 of the patent specification; and
  - Figures 1 to 14 of the patent specification.

The Registrar

The Chairman

V. Commare

T. K. H. Kriner