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D E C I S I O N
of 4 April 2006

Case Number: T 0216/04 - 3.2.02

Application Number: 95306158.7

Publication Number: 0700671

IPC: A61F 2/44

Language of the proceedings: EN

Title of invention:
Hydrogel intervertebral disc nucleus

Patentee:
Howmedica Osteonics Corp.

Opponent:
Mathys Medizinaltechnik AG

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Inventive step: confirmed"

Decisions cited:
-

Catchword:
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Case Number: T 0216/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 4 April 2006

Appellant: (Opponent)	Mathys Medizinaltechnik AG Güterstrasse 5 CH-2544 Bettlach (CH)
Representative:	Lusuardi, Werther Dr. Lusuardi AG Kreuzbühlstrasse 8 CH-8008 Zürich (CH)
Respondent: (Proprietor of the patent)	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah NJ 07430 (US)
Representative:	Hammond, Andrew David Valea AB Lindholmspiren 5 SE-41756 Gothenburg (SE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 16 January 2004 rejecting the opposition filed against European patent No. 0700671 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: M. Noël
M. Vogel

Summary of Facts and Submissions

I. Following an opposition filed by the appellant (opponent) against European patent No. 0700 671, the opposition division decided on 16 January 2004 to reject the opposition.

In the decision, the opposition division held that the grounds for opposition raised by the appellant (Article 100(a) and (b) EPC) did not prejudice the maintenance of the patent as granted.

II. The appellant lodged an appeal, received at the EPO on 9 February 2004, against this decision and paid the appeal fee on the same date. A statement setting out the grounds of appeal was filed on 7 April 2004.

III. Oral proceedings were held on 4 April 2006 during which the questions of novelty and inventive step were discussed with respect to the following prior art documents:

D1: EP-A1-0 453 393

D2: US-A-3 867 728

D7: US-A-5 192 326.

IV. At the end of the oral proceedings the requests of the parties were as follows:

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

The respondent (patentee) requested that the appeal be dismissed; auxiliary, that the patent be maintained on the basis of claim 1 of the first auxiliary request, or claims 1 to 20 of the second auxiliary request, all filed during the oral proceedings.

V. Claim 1 according to the main request (version as granted) reads as follows (identifying letters (a) to (e) added by the Board for ease of reference):

"(a) A prosthetic nucleus (10) for implantation in an intervertebral disc cavity (11), from which the natural nucleus has been removed, said cavity having a volume, wherein
(b) the prosthetic nucleus comprises at least one hydrophilic xerogel rod (10),
(c) said rod being in a form to allow it to be inserted through an opening (62) in the annulus of the disc and
(d) to be able to fold upon itself in the cavity,
(e) said rod further being of sufficient length and diameter that the hydrogel, when hydrated to its equilibrium water content when subjected to the constraints of the annulus and end plates of the disc, expands to essentially occupy said volume of the cavity."

VI. At the oral proceedings, the parties presented the following arguments:

(i) The appellant:

D7 represented the closest prior art. In the embodiment of Figure 14 the prosthetic nucleus 90 was made from hydrogel beads or particles sealed

within a semi-permeable membrane. When the hydrogel material was used in the dehydrated form, the nucleus occupied a reduced volume permitting it to be implanted into the cavity through a small window 104 in the annulus. To this end the membrane with its particulate hydrogel filler could be folded. During insertion, therefore, the membrane and its content took up the shape of the opening, i.e. the hydrogel had the form of a rod. The hydrogel could also be used in a semi-hydrated state. After implantation into the cavity the hydrogel nucleus slowly swelled so as to occupy the volume of the cavity. Therefore, D7 disclosed all the features recited in claim 1. As a result, the subject-matter of claim 1 was not novel.

Assuming, however, that the form of the xerogel rod was not implicitly disclosed by document D7, the subject-matter of claim 1 would anyway be obvious when considering the teaching of D7 in combination with the teaching of document D2 or D1:

D2 disclosed an embodiment (Figures 20, 21) in which an intervertebral prosthetic member 100 was made of a spirally-wound bar-like element 101, having elastic memory. For allowing insertion of the prosthesis into the cavity the spiral configuration was temporarily unwound into a smaller cross-sectional shape so that the bar-like element could be introduced through a small aperture having a similar shape. Since the prosthesis could be made in a variety of sizes and shapes depending on the specific disc to be

repaired, it was obvious for a person skilled in the art to select the most appropriate material and shape for the prosthetic member for it to be conveniently inserted into the cavity.

D1 disclosed (Figure 7) an intervertebral prosthesis made from an elastic strip spirally coiled about a valve within the cavity so as to facilitate adaptation of the prosthesis to the shape of the cavity. The valve and the strip were inserted into the cavity through a small opening by means of a tube. The circular cross-section of the tube, therefore, suggested the insertion of a prosthetic material in a form adapted to the shape of the tube, i.e. in the form of a rod.

(ii) The respondent:

None of the three embodiments described in D7 was concerned with the insertion of fully dehydrated xerogel in the form of a rod. In the embodiment of Figure 14 dehydrated hydrogel beads were sealed within a semi-permeable membrane and the filled membrane was then folded for implantation through a small window on the annulus. However, the prosthetic nucleus would actually unfold once inserted into the cavity. A xerogel rod folded upon itself within the cavity was, therefore, not disclosed.

Alternatively, the membrane could be inserted first and the hydrogel beads injected afterwards into the cavity by means of a tube, in a dehydrated or semi-hydrated state. Also in this

case the hydrogel was not implanted in the form of a rod but as beads or particles. Therefore, the subject-matter of claim 1 was new with respect to the teaching of D7.

Documents D1 and D2 made use of a non-swelling material and did not suggest the insertion of a material in the form of a rod. In D2 the material was inserted as a spirally-wound bar-like element through a small aperture having a similar cross-section, whereas in D1 a spirally-coiled elastic strip was inserted into the cavity so as to form a valve surrounded by a chamber for containing a fluid. In both cases, the material introduced into the cavity, therefore, had neither the form nor the properties of a rod of xerogel. As a result, the subject-matter of claim 1 was also not obvious vis-à-vis the state of the art.

Reasons for the Decision

1. The appeal is admissible.

2. *Interpretation of claim 1 as granted (main request)*

Claim 1 refers to "a prosthetic nucleus for implantation in an intervertebral disc cavity, from which the natural nucleus has been removed".

However, the features following the initial wording of claim 1 do not define such a prosthetic nucleus, but actually define the preparation of the prosthetic nucleus by using a hydrophilic xerogel as starting

material and inserting it in the form of a rod, in a sufficient amount, through an opening in the annulus of the disc, wherein at least one rod of xerogel is introduced into the cavity, as shown in Figures 3 to 6. In other words, claim 1 describes a device which is suitable for the formation of a prosthetic nucleus within an intervertebral cavity.

Therefore, the term "a prosthetic nucleus" in features (a) and (b) of claim 1 must be construed as meaning "a precursor of a prosthetic nucleus", knowing that a precursor is a substance (a product) from which another is formed (see Concise Oxford Dictionary). Moreover the term "said rod" (in features (c) and (e)) must be understood as implying one or several rods, wherein the term "a rod" necessarily implies an elongated piece of material, in accordance with the terms "tube" and "a long rod" referred to in the description of the present patent (see column 8, lines 10, 19 and 49).

3. *Novelty*

3.1 D7 which is a document of the proprietor of the present patent represents the closest prior art and is acknowledged as starting point at several places in the application as filed. Figures 10 to 15 show an embodiment of a precursor of a prosthetic nucleus 90 for implantation into an intervertebral disc cavity, having a predefined volume, from which the natural nucleus has been removed (see figure 13). Therefore feature (a) of claim 1 in suit is known from D7.

The precursor of the prosthetic nucleus is made from dehydrated synthetic hydrogel beads or particles sealed within a semi-permeable membrane (see Figures 10, 11 and column 7, lines 16 to 19). Since, according to the present patent, xerogel is the hydrated form of hydrogel, the beads used in document D7 are made of hydrophilic xerogel material, i.e. the precursor of the prosthetic nucleus comprises at least one piece of hydrophilic xerogel.

Because the volume of the prosthetic nucleus is largely reduced (80%) when the hydrogel beads contained in the semi-permeable membrane are in the dry form, the implant can be folded for insertion into the cavity through a small window 104 in the annulus of the disc (see Figure 14; column 8, lines 46 to 49 and paragraph bridging columns 8 and 9). The window 104 is also called opening (column 13, lines 42 to 46). Therefore, the features (b) and (c) of claim 1 are also disclosed by D7, with the exception that the precursor of the prosthetic nucleus does not comprise a rod.

Moreover, since the implant is folded (eventually upon itself) for its insertion through the opening into the cavity, it is not excluded that this configuration be temporarily retained after insertion and before expansion within the cavity. Therefore, feature (d) is also disclosed, the more so since the expression "to be able to" confers optionality to the following feature.

After implantation of the xerogel and expansion of the hydrated hydrogel, the hydrogel nucleus fills the volume of the cavity (see Figure 15; column 13, lines 46 to 49 and column 14, lines 7 to 10). This

implies that a sufficient amount of xerogel has been inserted, in the same way as in claim 1 under consideration the rod or rods of xerogel must be inserted with a desired and sufficient amount (through appropriate length and diameter) to occupy the volume of the cavity after re-hydration (see present patent, column 12, lines 14 to 17). Therefore, feature (e) is also known from D7.

3.2 It results therefrom that claim 1 as granted differs from the disclosure of D7 by the fact that the xerogel material is inserted in the form of a rod (feature (b)). The subject-matter of claim 1, therefore, is novel with respect to document D7.

4. *Inventive step*

4.1 The objective problem underlying the solution according to which the xerogel is inserted in the form of a rod, is to simplify the presentation of the material and to facilitate its implantation into the cavity. In fact, the form of the material is adapted to the circular form of the opening, which represents the simplest and easiest form to carry it out.

4.2 D7 discloses the insertion of dehydrated hydrogel either in bulk-form (Figures 1 to 6) with one or more larger pieces having together the shape of the cavity in a reduced scale, or as beads sealed within a flexible and deformable, semi-permeable membrane (Figures 10 to 18). Any other form of presentation of the hydrogel material is neither described nor suggested by D7, such that the provision of xerogel

having the form of a rod is not derivable from this document.

Moreover, the skilled person had no reason to modify the shape of the xerogel to be inserted since the solutions proposed in D7 turned out to be fully satisfactory at the time this document was filed. As a matter of fact, the beads of hydrogel could also be inserted directly into the cavity in a semi-hydrated state, by means of a tube (see column 16, lines 35 to 40). In the case of beads the hydrogel exhibits as a whole a surface area greater than the surface area provided by the hydrogel in the bulk form with, like the present invention, the advantage of time reduction for rehydration.

By using, according to the invention, a hydrogel material in the form of a rod or tube, the implantation is facilitated in that the material, which is easily and commercially available in that form as fully dehydrated xerogel, is actually inserted as partially hydrated hydrogel, due to environmental air humidity and the body fluids already present in the cavity. In this state, the rod of hydrogel can then easily be folded upon itself to fill the cavity as illustrated in Figures 3 to 6 of the present patent. This mode of implantation is neither disclosed nor suggested by D7.

4.3 Both documents D1 and D2 refer to a prosthetic nucleus formed by winding a band of non-swelling material within the cavity of an intervertebral disc. The band, rectangular in cross-section, is inserted through an opening of similar shape provided in the annulus.

In document D1 (see Figures 1 to 4) the prosthesis is made from a compact elastic strip which comprises several parts having progressively reduced cross-sections, one end of the strip-like parts being connected to a valve 3 for supplying an incompressible fluid into a chamber 1. A tube 27 (Figure 7) is introduced through the disc opening for successively implanting first the valve and then the strip-like parts into the cavity, whereby the strip-like parts are spirally coiled onto the valve up to the complete filling of the cavity. The chamber is then filled with an incompressible fluid. However, even if the insertion operation requires only a small opening, it remains that the material used as precursor is a non-hydrophilic and non-swellable material, and that it is not inserted in the form of a rod but of a rectangular cross-sectional strip, which is the most appropriate shape for forming a coil enclosing a fluid chamber (see column 2, lines 33 to 45).

In document D2 (see Figures 20 to 22) the prosthesis is made from a flat bar-like element 101 shaped into a spiral configuration so as to occupy the interior space of the cavity from which the natural nucleus has been removed. Before its insertion the spiral configuration is unwound into a smaller cross-sectional shape so that, again, the bar-like element can be introduced through a small aperture having a similar bar shape (see column 13, lines 29 to 36).

Consequently, there is nothing in the previous documents which suggests to the person skilled in the art to insert into the cavity of an intervertebral disc a hydrophilic and swelling material in the form of a

rod, i.e. in a form particularly suitable for it to be inserted over a length variable and adjustable to the volume of the cavity, while further offering the ability of being folded upon itself once in the cavity.

4.4 It results therefrom that the subject-matter of claim 1 as granted is not derivable from the prior art and involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner