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D E C I S I O N
of 10 May 2004

Case Number: W 0002/04 - 3.2.2

Application Number: PCT/IB 03/00713

Publication Number:

IPC: A61F 2/44, A61F 2/46, A61B 17/02

Language of the proceedings: EN

Title of invention:
Connectable Interbody Implant

Applicant:
Société de Fabrication de Matériel Orthopédique

Opponent:
-

Headword:
-

Relevant legal provisions:
PCT Art. 17(3)(a), 17(2)(a)
PCT R. 40.1, 40.2, 13.1, 39.1

Keyword:
"Unity of invention "a posteriori" (no, in part)"
"Unity of invention "a priori" (no)"

Decisions cited:
G 0001/89, W 0011/99

Catchword:
-

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Case Number: W 0002/04 - 3.2.2

International Application No. PCT/ IB 03/00713

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 10 May 2004

Applicant: Société de Fabrication de Matériel Orthopédique

Representative: Cabinet LAVOIX
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Decision under appeal: **Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated .**

Composition of the Board:

Chairman: W. D. Weiß
Members: R. Ries
B. J. Schachenmann

Summary of Facts and Submissions

I. The applicant filed an international application PCT/IB03/00713 with 25 claims. Independent product claims 1, 9, 15, 18, 20, 23 and method claims 24, 25 read as follows:

"1. Intersomatic implant for inserting and maintaining a bone graft in place in a receiving seat formed in a disc with a view to obtaining intervertebral fusion, characterized in that it consists of a plurality of parts provided with means for in situ connection of two consecutive parts."

"9. Instrument for in situ connection of a male intersomatic implant and a female intersomatic implant according to Claim 2, characterized in that it comprises two rods which are each equipped with means for fixing to the front face of the first part of an implant, and means for moving said rods towards one another while holding them in parallel positions."

"15. Instrument set for fitting an implant according to claim 14, characterized in that it comprises
- a rod provided with means, at one of its ends, for fixing said central part of the implant;
- and two tools formed by a sheath provided at one of its ends with means permitting one of the lateral parts of the implant to be maintained there, and a screwdriver arranged inside the sheath and provided with an impression which can cooperate with the screw."

"18. Tool to assist in introducing an intersomatic implant into a receiving seat formed in an intervertebral disc, characterized in that it comprises:
- a first part including a protector guide of which one end, intended to remain at the inlet of said receiving seat during said introduction, has a width "1" substantially equivalent to the height of said receiving seat and is equipped with stops intended to bear against the outer surfaces of the vertebrae;
- a second part including a distractor element placed at the end of a rod;
- a third part including a tubular element into which the rod of the second part can be inserted;
- and means permitting assembly of said three parts in a position permitting insertion of the end of the protector guide and the distractor element into said receiving seat, then disassembly of the three parts in such a way as to leave only said end of the protector guide in said receiving seat."

"20. An interbody implant for implanting between adjacent vertebrae, comprising:
a male implant having engagement protrusion extending therefrom;
a female implant defining a socket; and
wherein said protrusion of said male implant is engaged in said socket of said female protrusion."

"23. An interbody implant, comprising:
a central cage having apertures for receiving bone graft material, said central cage having a pair of obliquely angled end faces; and

a pair of lateral cages engaged with said pair of obliquely angled end faces, said lateral cages having apertures for receiving bone graft material."

"24. A method, comprising:
providing a male implant with an engagement protrusion and a female implant with a socket;
inserting the male implant and the female implant into a disc space defined between adjacent vertebrae; and
engaging the protrusion of the male implant with the socket of the female implant while in the disc space."

"25. A method, comprising:
providing a central cage with a pair of obliquely angled end faces and as pair of lateral cages;
inserting a central cage into a disc space defined between adjacent vertebrae; and
coupling the lateral cages to the obliquely angled end faces of the central cage while in the disc space."

Claims 2 to 8, 13, 14 which were directly or indirectly dependent on claim 1 related to preferred embodiments of the intersomatic implant.

Claims 10 to 12 which were directly or indirectly dependent on claim 9 related to an instrument for *in situ* connection of a two-part intersomatic implant.

Claims 16 and 17 which were directly or indirectly dependent on claim 15 related to a further instrument set for fitting a three-part intersomatic implant.

Claims 19 which was directly dependent upon claim 18 related to a tool to assist in introducing an

intersomatic implant into a receiving seat formed in an intervertebral disc.

Claims 21 and 22 which were directly dependent upon claim 20 related to preferred embodiments of the three-part implant set out in claim 20.

II. On 20 June 2003 the EPO, acting as International Search Authority (ISA) sent to the applicant an invitation to pay four (4) additional fees pursuant to Article 17(3)(a) and Rule 40.1 PCT.

In the invitation, the ISA identified five (5) groups of inventions:

1. Claims 1 to 8, 13, 14, 20 to 22: intersomatic implant;

2. Claims 9 to 12: instrument comprising two rods for connecting *in situ* a male and female part of an intersomatic implant;

3. Claims 15 to 17: instrument comprising a rod for fixing the central part of a three-part intersomatic implant and two tools permitting one of the lateral parts to be maintained and fixed to the central part;

4. Claims 18, 19: tool to assist introducing an intersomatic implant into the receiving set formed in an intervertebral disc;

5. Claim 23: an interbody implant comprising a central cage and a pair of lateral cages provided with apertures for receiving bone graft material.

The ISA specifically referred to document US 5861041 A (D1). In the ISA's view, this document disclosed an intersomatic implant for obtaining intervertebral fusion, the implant consisting of a plurality of parts provided with means for connecting the separate parts *in situ*, thus anticipating the subject matter of claim 1 and also of claim 2.

With respect to the remaining claims of the groups 1 to 5 of inventions and the technical features distinguishing these claims from the prior art D1, the ISA found that these technical features had nothing in common and solved different problems. Hence, the inventions defined by the claims of groups 1 to 5 were not considered as being linked by a common inventive concept and, consequently, the requirement of unity pursuant to Rule 13.1 PCT was not met.

III. On 17 July 2003 the applicant paid the additional fees under protest pursuant to Rule 40.2(c) PCT and requested that at least three (3) of the additional fees should be refunded.

In support of the protest, the applicant further referred to document US 5397364 (D2) and submitted the following arguments:

None of documents US 5861041 A (D1) and US 5397364 A (D2) discloses or suggests the two-part implant set out in claim 2 and, more specifically, the known

intersomatic implants are not formed by a "male" and "female" implant as claimed. Moreover, claims 9 to 12 relate to a specific instrument for connecting *in situ* the two parts of the implant described in claim 2. Consequently, the second group of inventions (claims 9 to 12) is linked to the first group of inventions (claims 2 to 8, 13, 14, 20 to 22).

Likewise, the third group of inventions (claims 15 to 17) relating to a tool for fitting an implant according to claim 14 (which forms another embodiment of the first group of inventions) is linked to the patentable matter set out in the first group. Contrary to the ISA's view, the implant stipulated in claim 14 is not anticipated by the one given in document D2 which discloses a different means for connecting the separate parts of the implant, that means not comprising tapped holes formed in the end faces of the central part of the implant and screws to be inserted into said tapped holes as claimed in claim 14.

The subject matter of claim 23 (fifth group of inventions) merely represents a preferred embodiment of the intersomatic implant given in claim 13 (first group) and, therefore, complies with requirements of unity of invention.

IV. On 6 November 2003, the Review Panel of the ISA confirmed that the finding of lack of unity was justified and invited the applicant to pay a protest fee.

V. On 27 November 2003, the applicant paid the required protest fee.

Reasons for the Decision

1. As all formal requirements of PCT Rule 40.2 (protest fee, reasoned statement) were met in due time, the protest is admissible.

2. It is apparent from independent claims 24 and 25 and from various parts of the description that the present application also resides in providing **an invasive surgical method** for inserting and engaging *in situ* a two-part or three-part implant into a disc space defined between adjacent vertebrae to provide spinal fusion.

Following the provisions of PCT Rule 39.1(iv) in combination with PCT Article 17(2)(a)(i), the ISA correctly decided not to search the subject matter claimed in the claims 24 and 25 which related to methods for treatment of the human or animal body by surgery or therapy. It, therefore, has to be examined whether a technical relationship, involving one or more of the same or corresponding special technical features, exists between the subject matter claimed in the remaining independent claims and to which extent these independent claims form a single general inventive concept so that the requirement of PCT Rule 13.1 is satisfied.

3. *Non-unity "a priori"*

3.1 In its statement of grounds for protest, the appellant did not comment on claims 18 and 19 (fourth group of inventions) which relate to a "tool to assist in

introducing an intersomatic implant". The Review Panel held that the tool set out in claims 18 and 19 aims at solving the problem of creating a safe pathway for the insertion of an implant into the receiving seat formed in an intervertebral disc, whereas the problem solved by the claimed implant (first group of inventions) is to maintain two adjacent vertebrae in a properly spaced-apart and stable position by fusing them together. The argument of the Review Panel that the tool set out in claim 18 does not exhibit a special technical relationship to the claimed implant is, therefore, undisputed by the applicant. Also in the Board's view, non-unity exists "*a priori*" between the tool according to the fourth group and the implants claimed in the first to third and fifth group of inventions since they address and solve different problems.

3.2 Although claim 23 is drafted as an "independent claim", the Board agrees with the appellant's view that the interbody implant set out in claim 23 actually represents a more preferred embodiment of the three-part implant stipulated in claim 13 which itself refers back to claim 1. Contrary to the arguments of the Review Panel (see point 6 of the annex to Form PCT/ISA 228 dated 06/11/2003), there is evidence given in the application on page 14, line 5 to page 16, line 30 and Figures 8 to 12 that the implant set out in claims 13 and 23 is provided with means to cooperate with the corresponding means of an instrument which is indispensable for manipulating and assembling the three parts in the intervertebral space. It is, therefore, concluded that unity exists between claims 13 and 23 (simply by understanding claim 23 as in fact dependent

on claim 13) and also between the claimed implant and the corresponding instrument for assembling the implant *in situ*.

4. *Non-unity "a posteriori"*

4.1 As stated in the decision G 1/89 of the Enlarged Board of Appeal (OJ EPO, 1991, 155), the ISA is empowered to raise an objection for lack of unity *"a posteriori"* i.e. after having taken the prior art into consideration. However, decision G 1/89 makes it clear that an objection of this kind can only be based **on a provisional opinion** on novelty and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination (cf. G 1/89, point 8.1 of the reasons). The Enlarged Board also held that charging of additional fees under Article 17.(3)(a) PCT should be made only in clear cases (see also PCT International Search Guidelines, S06/1998(E) VII-12).

Thus, a lack of unity may become evident after having taken prior art into consideration, for instance a document showing that there is a lack of novelty of the subject matter of independent claim 1, and leaving two or more dependent claims without a single general inventive concept. This appears to be the case in the present application since the objections by the ISA are based on document D1.

As to the first group of inventions, the ISA found that the subject matter of this group, in particular of claims 1 and 2, lacks novelty with respect to document US 5861041 A (D1) which discloses an intervertebral prosthetic disc system for installation intermediate to

two vertebrae, the system comprising a first disc segment having a male contour and a second disc segment having a female contour, the first and second segments having mutually interlocking configurations (cf. D1, claims 1 to 4).

The Board has verified the novelty objection in particular with respect to independent claim 1 finding that, in the light of the above teachings, the intersomatic implant set out in claim 1 comprising a plurality of parts and also the preferred embodiment comprising a male and female part set out in dependent claim 2 was already known from document D1. In particular, D1 discloses an intervertebral implant which comprises two parts having a male and female contour and a mechanical connector. The respective statement of the ISA in the international search report is therefore not objectionable as far as claims 1 and 2 are concerned. Besides, the lack of novelty of the subject matter of claim 1 vis-à-vis the implant disclosed in document D1 has not been disputed in the applicant's protest dated 17 July 2003. The Board is, therefore satisfied that claims 1 and 2 would not meet the requirement of novelty.

4.2 Given this situation, two separate preferred embodiments of implant would remain:

- a first two-part implant (claims 3 to 8, 20 to 22) and

- a second three-part intervertebral implant (claims 13, 14, 23).

It is discernable from the claims and the specification as a whole, that the first and second implant are different in that they

(a) exhibit a different structure (two parts; three parts),

(b) are provided with different fastening means for connecting the discrete implant parts *in situ* (cylindrical portion engaging elastic tabs or a socket for the two-part implant; screws inserted in tapped holes for connecting the central part with the lateral parts of the three-part implant) and

(c) require a separate instrument or instrument set specifically adapted to the structural design of each implant embodiment so that each type of implant can be positioned, manipulated and assembled *in situ* (the two part implant: claims 9 to 12; the three part implant: claims 15 to 17).

It goes without saying that the different types of implant could not be assembled *in situ* unless the matching instruments are provided with the special technical feature i.e. a means designed to be inserted and cooperate with the corresponding special technical feature of the implant, i.e. the receiving seats provided in the implant parts (cf. e.g. page 11, lines 14 to 22; page 14, line 30 to page 15, line 2). Thus instrument and implant interact in the same manner as a lock in which a key fits to open or close it.

4.3 Based on these considerations, three different groups of inventions can be identified on which the Board has carried out a **provisional** examination on the novelty:

group (1): an intersomatic implant consisting of two parts (present claims 3 to 8, 20 to 22) and the instrument specifically adapted for holding and connecting *in situ* the two parts (claims 9 to 12);

group (2): an intersomatic implant consisting of three part (present claims 13, 14, 23) and the instrument specifically adapted for holding and connecting *in situ* the three parts (claims 15 to 17); and

group (3): a spacer tool (present claims 18, 19) which maintains the space between the vertebrae concerned and aids in introducing the parts of a (any) intersomatic implant during the surgical treatment.

Compared with the implants disclosed in documents D1 or D2, the claims relating to the intersomatic implants set out in groups (1) and (2) and to the tool stipulated in the claims of group (3) appear to comprise patentable matter. For instance, the design of the cylindrical portion of the male implant set out in claims 3 and 5 would not be known from document D1. Moreover, the three part implant stipulated in claim 23 comprises obliquely angled faces and a pair of lateral cages not disclosed in document D2. Whether or not such patentable matter is present should, however, been examined in the later substantive examination procedure

according to PCT Chapter II. Only during that later procedure, the applicant has the possibility to overcome the objections raised by the examining division, for instance by restricting the claims (cf. W0011/99, point 4 of the Reasons, last sentence).

4.4 In the Board's view, only two additional fees are therefore justified.

5. Thus, the ISA's statement in its communication that the claims 1 to 25 comprise five (5) different inventions cannot be accepted as a sufficient reasoning in support of the finding of lack of unity of invention.

5.1 It follows from the above that the ISA's invitation to pay four additional fees was only partly justified. Hence, two additional search fees should be reimbursed.

5.2 Moreover, the Board finds that the applicant's protest was only in part justified. Given this situation, the protest fee cannot be refunded.

6. It is, however, noted that the Board's present assessment of unity of invention does not exclude the possibility that - in the later International Preliminary Examination under PCT Chapter II and based on other grounds - the issue of unity of invention may arise again with respect to parts of the application.

Order

For these reasons it is decided that:

Reimbursement of two additional search fees is ordered.

The Registrar: The Chairman:

V. Commare W. D. Weiss