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D E C I S I O N
of 5 March 1998

Case Number: T 0597/96 - 3.2.2

Application Number: 89907559.2

Publication Number: 0419564

IPC: A61F 2/00

Language of the proceedings: EN

Title of invention:
Threaded spinal implant

Applicant:
Michelson, Gary Karlin

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123, 84, 54, 56

Keyword:
"Claim 1 - clarity (yes)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0597/96 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 5 March 1998

Appellant: Michelson, Gary Karlin
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 14 February 1996
refusing European patent application
No. 89 907 559.2 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: D. Valle
J. C. M. De Preter

Summary of Facts and Submissions

- I. The appellant (applicant) lodged on 5 April 1996 an appeal against the decision of the Examining Division on the refusal of the application No. 89 907 559.2 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was received on 18 June 1996.
- II. The Examining Division held that
- claim 1 lacked clarity (Article 84 EPC);
 - the subject-matter of claim 1 lacked novelty (Article 54 EPC) with respect to the disclosure of document US-A-4 259 072 (D2),

or inventive step (Article 56 EPC) with respect to the teachings of the documents US-A-4 501 269 (D3) and DE-A-3 505 567 (D1).
- III. With letter of 5 February 1998, the appellant filed six sets of claims as main and auxiliary requests (Anlagen A to F) with adapted descriptions and Figures 1 to 5.
- IV. A third party filed observations on 15 May 1997 citing the document WO-A-8803781 (designated as D4 by the Board), whose Figures 14 and 15 including the corresponding description on page 8, paragraph 3 would be pertinent to claim 1.

V. Oral proceedings were held on 5 March 1998.

(i) The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims 1 to 8 filed during the oral proceedings, the description "Besch. V1" and the drawings (Figures 1 to 5) both filed with letter of 5 February 1998 (main request) or on the basis of the documents "Anlagen B to F" filed with letter of 5 February 1998 (auxiliary requests 1 to 5).

(ii) The wording of the claim 1 of the main request (Anlage A) is as follows:

"An artificial human spinal fusion implant (50) of the type consisting of an artificial rigid hollow cylindrical member of a material stronger than bone, the cylindrical member to be inserted into the space between two adjacent vertebrae (V) of the human spine such as to extend into and engage with said adjacent vertebrae (V) and to be filled with bone growth inducing material, the cylindrical member comprising a plurality of macro-sized openings (56) extending through its side wall so that through the openings (56) a bony fusion can take place between the bone growth inducing material in the cylindrical member and the adjacent vertebrae (V), characterized in that a series of threads (53) is provided on the exterior of the cylindrical member, and said macro-sized openings (56) are formed between said threads (53) and designed to

allow the bone growth inducing material to fill and extend through the openings (56) under compressed insertion of the bone growth inducing material into the cylindrical member".

The claims 1 according to the auxiliary requests 1 to 4 (Anlagen B to E) are combinations of the

- claims 1 and 2,
- claims 1 and 3,
- claims 1 to 3, and
- claims 1, 4 and 5

according to the main request.

Claim 1 according to the fifth auxiliary request (Anlage F) corresponds to a method for preparing an artificial human spinal fusion implant.

(iii) The appellant argued essentially in writing and orally as follows with respect to

- clarity:

The feature "material stronger than bone" which was one of the two features objected by the Examining Division and maintained in the new claims 1 of all requests, was to be regarded as unambiguously clear for the skilled person in the art - the spinal surgeon - and referred directly to whether or not the implant was constructed of a material stronger than the bone of the vertebrae. The Guidelines C-III, 4,5 referred to by the Examining Division could not be applied since the new claims 1 did not utilize the relative term "strong" isolation but made a comparison to a known material, namely bone. Therefore, the new claims 1 comply with Article 84 EPC.

- novelty:

Lack of novelty was only based on document D2, which concerned an endosseous implant for use in dental and orthopaedic treatment. This implant was a composite structure made of a combination of an outer ceramic member and an innerceramic core member bonded together by glass cement. Since none of these members could be used alone, the outer (cylindrical) ceramic member was not allowed to be regarded as an independent implant within the meaning of the present invention. Therefore the subject-matter of the claims 1 is novel within the meaning of Article 54 EPC.

- inventive step:

Document D3 concerned a method for implanting a smooth stainless steel basket in horses using an improvement to the well-known Cloward bone dowel technique and described an implant for use in the cervical spine of horses, not humans. This document did not contain any hint for modifying this implant in order to be applied to humans, in particular for providing threads on the exterior of the cylindrical member, which would be contrary to the teaching of document D3. Since according to the teaching of document D1 - which disclosed a cylindrical implant made of bone and provided with one thread cut into the exterior of the cylindrical implant - a thread is essential for stimulating the growing in of the implant to the surrounding bony tissue, this document did not give any idea how the person skilled in the art could have combined the teachings known from both documents D3 and D1. Therefore, the subject-matter of the new claims 1 did also involve an inventive step within the meaning of Article 56 EPC.

- Document D4:

This document disclosed an internal fixing device for osteosynthesis consisting of bone screws and a titanium osteosynthesis plate, which device was subjected to conditions

different to those governing an implant as defined in the new claims. Therefore, also this document could not prevent the grant of a patent on the basis of the new claims.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

2.1 The claims of the main request and the auxiliary requests 1 to 11 are based on the

claims: 1, 5 6, 8 to 10,

description: page 2. lines 2 to 9; page 9, lines 6 to 11; page 10, lines 14 to 17; page 14, lines 15, 16 18 to 29; page 16, lines 34 to 39; page 17, lines 8 to 12, 33 and 34;

Figures: 4, 4a to 4d and 5

of the application as filed.

The auxiliary request 5 can be derived from the application as filed:

- page 2. lines 2 to 9; page 9, lines 6 to 11;
page 10, lines 14 to 17; page 14, lines 15, 16 and 19 to 23; page 16, lines 30 to 39; page 17,

lines 33 to 34 and the Figures 4, 4a to 4d and 5.

2.2 The amendments to the description consist of the addition of the prior art according to document D1, the adaption to new claims 1 and mainly of correction of evident clerical errors, and to the figures of the insertion of missing reference numbers.

2.3 Therefore, the requirement of Article 123(2) EPC is met.

3. *Clarity*

3.1 As to the objection of the Examining Division in its decision that the feature stating that the outside diameter of the cylindrical member is larger than the disc space between two adjacent vertebrae to be fused was not clear, the following observations are made:

The feature is not present any more in any of the claims 1. However a new feature has been introduced which is equivalent to the previous one, namely that the cylindrical member extends into and engages with the two adjacent vertebrae, so that the Examining Division's objection should be dealt with.

The Examining Division supports its objection with the argument that the diameter of the member is defined by reference to the space between the vertebrae which is not defined itself because it varies broadly according for example to the age of the patient or the particular vertebra. The broad variability of a value is not however per se an impediment to the patentability as

far as a method is given to allow the skilled person in the field to establish the specific value required according to the particular circumstances. This condition is here met, since the skilled person is capable of ascertaining of the intervertebral space and of selecting an implant according for example to the age of the patient and to the particular vertebra to be fused.

The Examining Division's reference to Guidelines C-III, 4.8a is not relevant here because the dimensions of the spinal human bones are known, whereas the example cited in the Guidelines refers to a cassette whose dimensions are not known.

- 3.2 The Examining Division supports its objection concerning the clarity of the feature that the cylindrical member is stronger than bone by referring first to Guidelines, C-III, 4.5 where it is said that terms such "strong" should preferably not be used in the claims. However, the claim does not contain such term in isolation but compared with a known material, ie "stronger than bone". Having regard to the objection that such term is not clear because it is not specified which kind of strength is claimed it is referred to the description, page 9, lines 11 to 14, which clarifies that "stronger than bone" means that the device is capable of withstanding the forces generated within the spinal interface. At page 13, lines 17 and 18 it is specified that the preferred material is titanium. This information allows the person skilled in the art to choose the suitable material on the basis of the required strength. The Examining Division objects

finally that the required strength depends on the individual being to be considered. It is however evident that typical values of the strength of the vertebrae exist so that also from this point of view the term gives a sufficiently clear definition of the invention.

3.3 The new claims 1 fulfil, therefore, also the requirements of Article 84 EPC.

4. On the question of whether or not the cited prior art discloses or could suggest an artificial human spinal fusion implant according to claims 1 of the main request the following should be observed:

4.1 Novelty

Document D1:

This document discloses an autologous, homologous or heterologous bone graft for intersomatic cervical arthrodesis, which is completely made of bone material and which is provided with a thread cut into its circumferential surface.

The subject-matter of claim 1 differs from the above cited prior art in that

- the cylindrical member is of the type consisting of an artificial rigid hollow cylindrical member of a material stronger than bone,
- the cylindrical member extends into and engages with the adjacent vertebrae and is to be filled

with bone growth inducing material,

- the cylindrical member comprises a plurality of macro-sized openings extending through its side wall so that through the openings a bony fusion can take place between the bone growth inducing material in the cylindrical member and the adjacent vertebrae,
- a series of threads is provided on the exterior of the cylindrical member,
- the macro-sized openings are formed between the threads and designed to allow the bone growth inducing material to fill and extend through the openings under compressed insertion of the bone growth inducing material into the cylindrical member.

Document D2:

The disclosure of this document relates to an endosseous implant comprising a composite structural member having an outer ceramic member and an inner core member bonded together by glass cement. The outer member has a cylindrical shape and a cavity with micro-apertures on the outer surface thereof for permitting the penetration of a new bone and connective tissue therinto, and may be formed on its outer periphery with a series of threads.

The subject-matter of claim 1 is distinguished from this known implant in that

- it is an artificial human spinal fusion implant of a material stronger than bone,
- the cylindrical member is to be inserted into the space between two adjacent vertebrae of the human spine such as to extend into and engage with said adjacent vertebrae and to be filled with bone growth inducing material,
- the cylindrical member comprises a plurality of macro-sized openings extending through its side wall so that through the openings a bony fusion can take place between the bone growth inducing material in the cylindrical member and the adjacent vertebrae, whereby the macro-sized openings are formed between the threads and designed to allow the bone growth inducing material to fill and extend through the openings under compressed insertion of the bone growth inducing material into the cylindrical member.

Document D3:

This document - cited as the relevant back ground art in the application as filed (see page 4, line 24 to page 8, line 23) - concerns a process for immediate stabilization and subsequent promotion of bone-to-bone fusion in a human or animal joint where separation of the bones is restricted by surrounding ligaments or other soft tissue. It further discloses an implant which

- consists of an artificial rigid hollow cylindrical member of a material stronger than bone, an end of which includes a beveled outer surface (see column 3, lines 29 to 35);
- is inserted into the space between two adjacent vertebrae of the spine such as to extend into and engage with the adjacent vertebrae (see Figure 8);
- is filled with bone growth inducing material and comprises a plurality of macro-sized openings extending through the side wall so that through these openings a bony fusion can take place between the bone growth inducing material in the implant and the adjacent vertebrae (see column 2, lines 32 to 43; column 3, lines 43 to 51, column 4, lines 22 to 28).

Contrary to this known implant, the subject-matter of claim 1 comprises

- a series of threads on the exterior of the hollow cylindrical member, and
- openings between the threads being designed to allow the bone growth inducing material to be filled and to extend through these openings under compressed insertion of the bone growth inducing material into the cylindrical member.

Document D4:

This document relates to an internal fixing device for

osteosynthesis, in which bone screws are connected in a rigid and functionally stable manner with a pure titanium osteosynthesis plate. According to one embodiment, the bone screws are hollow and provided with openings in order to promote the growth of the bone tissue into the hollow screws (see page 8, lines 13 to 15; Figures 14 and 15). Therefore this prior art does not concern a human spinal fusion implant within the meaning of the subject-matter of claim 1.

From the above analysis follows that none of the documents D1 to D4 discloses all the features in any of the claims 1 according to the requests (Article 54 EPC).

4.2 Inventive step

4.2.1 The principle underlying the process as disclosed by document D3 is that of expansion - compression (or distraction - compression). The expansion occurs due to the tensioning of the surrounding ligaments attached to the bones forming the joint. The hollow cylindrical member is held in place between the bones by the compressive forces exerted on the bones and the hollow cylindrical member by the ligaments which resist expansion of the joint. The hollow cylindrical member takes up all slack in the surrounding ligaments created by the decreased thickness of the intervening cartilage which creates the problem being corrected.

This is achieved by driving the hollow cylindrical member into a transverse cylindrical opening bored

across contiguous bony surfaces of joints. The hollow cylindrical members includes at one end a beveled outer surface to facilitate said member's insertion between the contiguous bony surfaces, since the tapered end surface wedges the contiguous bony surfaces slightly apart as said member is driven between them (see column 2, lines 26 to 34; lines 52 to 55; column 3, lines 2 to 36; column 4, lines 17 to 21, 31 to 35; column 4, lines 54 to column 5, line 6; claim 1).

The process of pounding the hollow cylindrical member into its position is extremely dangerous and occurs directly over the spinal cord which is precariously vulnerable to percussive injury. Furthermore, the hollow cylindrical member is highly susceptible to forceful ejection which would result in great danger to the patient, since this member lacks any specific design features to secure it.

In contradiction to the teaching disclosed by document D3, where a smooth surface of the basket is necessary, the subject-matter of claim 1 of the application in suit relies on the principle of screwing the hollow cylindrical member into place by providing a series of threads on the exterior of the hollow cylindrical member. The series of threads permits a smooth, ie an atraumatical insertion of the hollow cylindrical into place and makes accidental dislodgement impossible.

4.2.2 According to the teaching of document D1, the thread formed by removal of bone from the bone graft facilitates and improves the insertion of the bone graft into the space between two contiguous bony surfaces and the growing in the adjacent bony tissue.

Since the prior art according to document D3 however requires a smooth and tapered hollow cylindrical member for being pounded into the place between two contiguous bony surfaces for obtaining the desired expansion-compression effect, the person skilled in the art would have no reason to depart from the principle underlying this prior art. In particular, because the implant according to document D1 is made of bone and not of a material stronger than bone. The thread itself is, therefore, also highly susceptible to fracture, which would render it useless for pounding this implant between two contiguous surfaces. Furthermore, the application of the teaching known from document D3 would not only involve the step from replacing the bony material of the thread by a material stronger than bone, but also the step of breaking up the thread into a series of threads and the step of providing the exterior of the hollow cylindrical member with this series of threads instead of cutting the threads into the wall of the hollow cylindrical member. This application could be done, however, only with the knowledge of the teaching of the application in suit, which hindsight is however not acceptable.

4.2.3 The devices according to the documents D2 and D4 are much further away from the implant as defined in claim 1 of the application in suit (see above point 4.1) than the other documents discussed in the paragraphs 4.2.1 and 4.2.2. Their teachings could, therefore, neither per se nor in combination with the teachings of the other documents lead the person skilled in the art to the subject-matter according to claim 1.

4.2.4 From the above follows that the subject-matter of claim 1 involves an inventive step (Article 56 EPC).

5. Consequently, the subject-matter according to the main request meets the requirements of the EPC for granting a patent.

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 grant a patent in the following version:
 - claims 1 to 8 filed during the oral proceedings;
 - description "Besch. V1" and drawings (Figures 1 to 5) filed with letter of 5 February 1998.

The Registrar:

The Chairman:

S. Fabiani

H. Seidenschwarz