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D E C I S I O N
of 8 October 1997

Case Number: T 0540/94 - 3.2.2

Application Number: 87850047.9

Publication Number: 0237505

IPC: A61C 8/00

Language of the proceedings: EN

Title of invention:
Anchoring member for permanent anchorage in bone tissue

Patentee:
The Institute for Applied Biotechnology

Opponent:
Aktiebolaget Astra Patent Department

Headword:
-

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

Keyword:
"Clarity and support - (yes, after amendment)"
"Inventive step (confirmed)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0540/94 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 8 October 1997

Appellant: (Opponent)
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Representative:
-

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 11 May 1994 concerning maintenance of the European patent No. 0 237 505 in amended form.**

Composition of the Board:

Chairman: H. Seidenschwarz
Members: M. G. Noël
J. C. M. De Preter

Summary of Facts and Submissions

I. In consequence of an opposition filed by the appellant against the European patent No. 0 237 505, the Opposition Division decided, in an interlocutory decision dated 11 May 1994, to maintain the patent in amended form.

II. The appellant lodged an appeal against the first instance's decision by letter received on 30 June 1994 and paid the appeal fee in due time. A statement of grounds of appeal along with new documents were filed subsequently by letter received on 7 September 1994.

In response to the respondent's reply (proprietor of the patent), the appellant still filed new documents to support its view.

III. In a communication dated 8 August 1997 accompanying the summons to oral proceedings, the Board informed the parties of a prima facie favourable opinion as to the first embodiment, according to Figures 1 and 2 of the patent in suit.

IV. Oral proceedings were held on 8 October 1997 in the course of which the respondent made amendments to claim 1 so as to remove a number of formal objections raised by the appellant in its letter dated 2 October 1997.

V. Claim 1 in suit, as filed during oral proceedings, reads as follows:

"1. Screw-shaped titanium anchoring member for permanent anchorage by osseo-integration in bone tissue,

(a) the member being adapted for permanent anchorage of artificial teeth or tooth bridges in the jaw-bone,

(b) comprising a cylindrical screw (1)

(c) having an outer cylindrical surface with a conical downwardly tapered tip portion and a bottom surface

(d) and at least two cavities (4, 8) directly communicating with at least two openings in the outer cylindrical and conical surface of the anchoring member so as to allow newly formed bone-tissue to grow into said cavities,

(e) said openings being symmetrically distributed about the periphery of the anchoring member,

(f) the edges (5, 10) formed by said cavities and the outer cylindrical surface forming cutting edges to provide self-tapping when the anchoring member is screwed into the bone tissue,

(g) said cavities (4, 8) being formed by through-holes (4) or volumes (8) made in the cylindrical surface and partially extending into the conical portion of the anchoring member,

(h) c h a r a c t e r i z e d in that said through-holes (4) or the comparatively deep bone material volumes (8), apart from said openings on the outer cylindrical and conical surface of the anchoring member, are closed,

(i) said openings have a longitudinal section with two straight edges,

(j) that the total volume of the cavities is adapted to the length of the anchoring member so that all the scraped-off bone material produced by self-tapping over the length of the anchoring member when the anchoring member is inserted in the jaw-bone is collected and housed within the anchoring member

(k) and that the bottom surface (6) of the anchoring member is unbroken without openings."

The identifying letters (a) to (k) added by the respondent, are maintained by the Board in the following, for ease of reference.

VI. The prior art documents considered by the Board in the present decision are as follows:

(2) DE-U-8 523 007

(3) GB-A-1 291 470

(7) Brånemark et al, Osseointegrated Implants in the Treatment of the Edentulous Jaw, Experience from a 10-year Period, Almquist & Wiksell International, Stockholm, 1977, pages 28 to 35.

(9) Orale Implantologie, volume 3, number 4, 1976, published by Deutschen Gesellschaft für zahnärztliche Implantologie e.V., page 44.

(10) Linkow - Cherchève, Theories and Techniques of Oral Implantology, The C.V. Mosby Company, Saint Louis, 1970, volume one, pages 156 to 158.

(11) Bechtol, Fergusson, Laing, Metals and Engineering in Bone and Joint Surgery, The Williams & Wilkins Company, Baltimore, 1959, chapter 5 (pages 92 to 126) and 9 (pages 152 to 171).

(13) US-A-4 414 966

(20) Brånemark et al, Intra-Osseous Anchorage of Dental Prostheses, II. Review of Clinical Approaches, Scand J Plast Reconstr Surg 4: pages 19 to 34, 1970.

VII. At the oral proceedings, the appellant argued essentially as follows:

- The subject-matter of claim 1 is not clear nor supported by the description (Article 84 EPC), in particular through the introduction of the expressions "at least two cavities", "openings in the conical surface", "are closed (cavities)", "two straight edges" and "self-tapping over the length of the anchoring member". In addition, some of these expressions, and in particular, the omission from the previous version of claim 1 of the last feature "in order to avoid unintentional penetration of the bone membrane" are such as to extend the claimed subject-matter beyond the content of the application as filed (Article 123(2) EPC).

- As to the first embodiment according to Figures 1 and 2 of the patent, document (7), which is close to document (3), represents the closest prior art. The implant described therein with reference to Figures 16 and 18 is self-tapping and has a central cavity, the volume of which is large enough to collect and contain all cut chips produced by self-tapping over the entire length of

the hole ahead of the implant. With respect to the subject-matter of claim 1, the only distinctive feature is that in document (7) the bottom surface of the implant is provided with an opening. However, it would be obvious for a person skilled in the art to close this opening, where necessary, ie to provide the implant with a solid bottom surface such as that disclosed in document (2). As a result, the first embodiment defined in claim 1 in suit is derivable in an obvious manner from the combination of the disclosures of documents (7) and (2).

- Linkow's self-tapping vent plants disclosed in document (10) are also provided with a hollow central cavity and an opened base. However, document (20) which can be used to complete and interpret the disclosure of document (10) refers to implants previously developed by Cherchève, which "closely resemble the Vent-Plant described below (Linkow), but lack the vent part...". The skilled person could thus find here a direct suggestion to close the bottom surface of the cavity so that, again, the first embodiment is not inventive.

- As to the second embodiment according to Figures 3 and 4 of the patent, document (2) represents the closest prior art. It relates to a close respondent's prior art design of a self-tapping, cylindrical, screw-shaped anchoring member, having a recess or volume extending in the outer cylindrical surface and in the conical surface thereof. The only difference is that the size and number of the chip-collecting volumes according to the patent's second embodiment are not directly derivable from this document. However, it would be quite natural for the skilled person to adapt the

total volume of the recess to the amount of material actually cut, the more because either of documents (11) or (13) recommends to form a plurality of volumes or flutes symmetrically distributed about the periphery of a self-tapping screw, so as to avoid unbalanced cutting forces. In addition, document (11) clearly discloses that the cutting flutes should be reasonably large to make a place for the chips to accumulate. Therefore, the second embodiment covered by claim 1 in suit is not inventive either, having regard in particular to the combination of the teachings of the documents (2) and (11).

- The respondent has not provided any evidence such as test results or statements by technical experts regarding the alleged improved success rate with the implants according to the patent. Therefore, it is quite impossible to determine whether the improved success rate, if any, actually can be ascribed to the features as set forth in the amended claim.

The respondent contested the appellant's submissions in all respects and set forth adverse arguments to support its view regarding both the formal and the substantive issues in relation to the subject-matter of claim 1 in suit.

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

The respondent requested that the appeal be dismissed and that the patent be maintained on the basis of

- claim 1 as filed during the oral proceedings

- claims 2 to 6, description and drawings according to the interlocutory decision.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

2.1 The patent seeks to cover two embodiments, which implies the invention to be defined in broads terms. This is the reason why claim 1 as originally filed was even then generally drafted, designating by cavities as well as housing formed inside the implant by communicating through-holes as recesses or volumes spaced on the outer cylindrical surface of the implant, but without inner communication.

According to the description of the first embodiment (Figures 1 and 2), the bone tissue material volume is formed by two through, perpendicular holes made in the cylindrical surface (column 3, lines 32 to 37 and column 4, lines 18 to 21). These through-holes are actually made of openings which form all together such a cavity that the scraped-off bone tissue material is accommodate within the cavity (column 4, lines 6 to 8). Therefore, by "cavity" is to be understood the total volume required for housing and storing all bone tissue material scraped-off over the length of the anchoring member (column 4, lines 28 to 32). However, in the Board's view, it is not excluded that said cavity be

formed with only two openings ("one or more openings", see column 3, lines 58 to 60), so that the first embodiment can be defined as well by two elementary cavities, each formed with one through-hole and two opposite openings.

In the second embodiment according to Figures 3 and 4, a cavity is more easily defined by providing the anchoring member with three separate volumes, symmetrically arranged about the periphery, but not going through (column 3, lines 37 to 41 and column 4, lines 43 to 47). Like in the first embodiment, these three elementary cavities have all together a total volume adapted to the implant length so that all scraped-off material can be housed within "the" cavity (column 4, lines 53 to 56).

Taking account of the difficulties encountered by the respondent trying to cover two embodiments in one main claim, the Board accepts that the term "cavity" be used also to define an elementary cavity in the sense explained above. Consequently, the expression "at least two cavities" introduced in claim 1 (feature (d)) applies equally to both embodiments and is regarded by the Board as validly supported by the application as filed.

2.2 The specification in claim 1 of the openings being present also in the conical surface of the anchoring member (feature (d)) is not open to objection by the Board since, in both embodiments, the openings partly defining the cavities extend in the conical tip portion of the implant. Therefore, although this feature is mentioned only in connection with the second embodiment (column 5, lines 5 to 7), it is also clearly disclosed by the drawings in connection with the first embodiment.

2.3 In the same way, it is clear from the drawings that, apart from said openings in the outer cylindrical and conical surface of the implant, the cavities are delimited by nothing more than the inner surfaces and the plane bottom surface of the implant, ie the cavities are closed. Thus, although the term "closed" is mentioned in the description only in connection with the first embodiment (column 4, lines 8 to 12), it obviously covers both of them and, therefore, can be validly maintained in claim 1 (feature (h)). In addition, as explained in the pre-cited paragraph of the description, the term closed "means that all scraped-off bone tissue material is collected within the cavity and is stored there", which clearly excludes any possibility for the scraped-off material to fall down inside the bone hole, ahead of the implant, while the latter is inserted.

The appellant submitted that the cavities will never be quite closed downwardly because of the distance between the lower edges of the cavities, at the apical end of the implant, and the wall of the bore hole since the inner diameter of the bore hole must be equal to or larger than the minor diameter (root of thread) of the implant (cf. Appendix A to the statement of grounds). The Board cannot accept this argument since, according to the very definition of the terms "closed cavity" recited in claim 1, all the surfaces concerned with openings (including in the conical surface) are excluded, which amounts to consider that said openings and therefore said distance do not exist any more. Moreover, in use, the gap between said lower edges of the cavities and said wall of the bore hole can only be very small since the conical tip portion of the implant is truncated over a short distance from the cylindrical portion. Therefore, keeping in mind the crude nature of the chips (spiral shaped segments mutually interlocking inside the cavity) produced by self-tapping when the

implant is screwed into the bone hole, it is quite unlikely that the shaped-off material is able to escape downwardly through such a narrow gap, which, again, confirms the above mentioned definition that the cavities are practically closed.

2.4 The Board also accepts that the expression "two straight edges" (feature i) be maintained in claim 1 without resulting in an extension of the subject-matter beyond the content of the application as filed, since said two straight edges do not necessarily form cutting edges such as the parallel, longitudinal edges 5 of the openings 4 contemplated in the first embodiment. Thus, the openings according to the second embodiment can also be formed with two straight edges of different types, in the present case one of which is formed by the positive cutting edge 10 and the other by the straight part 12b of the concave clearance.

2.5 As already mentioned above, according to the patent description (column 4, lines 28 to 32 and 53 to 56) the total bone volume of the cavity in the fixture (implant) is adapted to the fixture length so that all scraped-off bone tissue material can be housed in the cavity. Further (column 4, lines 5 to 6), the screw is self-tapping when anchored in the bone tissue. Therefore, essentially, feature (f) and (j) of claim 1 are supported by the above-cited passages of the description.

It is self evident that when the anchoring member is inserted (completely) in the jaw bone, self-tapping will occur over the entire length of the bone hole which is also the length of the anchoring member. Therefore, although the contested expression "by self-tapping over the length of the anchoring member" (feature (j)) is not to be found as such in the description, it represents a mere repetition, with

other words, of the teaching already contained in features (f) and (j), both fairly supported by the application as originally filed. Consequently, said expression is not detrimental to the clarity and can be maintained in claim 1.

2.6 The omission from claim 1 of the last feature "in order to avoid unintentional penetration of the bone membrane" is not objectionable under Article 123(3) EPC, since this feature, although present in the version as filed, was absent from the version as granted. As to Article 123(2) EPC, the omission also does not lead to an extension of the claimed subject-matter, since the feature under consideration is functional by nature, in the form of a result. Such a feature assists generally in clarifying the matter for which protection is sought, but remains optional. By contrast, the essential structural feature by means of which the result can be achieved, in the present case "that the bottom surface of the anchoring member is unbroken without opening" (feature (k)) is well present in the claim and this is sufficient. The omission of the contested feature, therefore, is of no consequence.

2.7 To sum up and in view of the above, the Board is satisfied that the wording of claim 1 as a whole, including also the amendments made at the appeal stage, fulfil all formal requirements of the EPC, in particular those based on Articles 84 and 123.

3. *Problem and solution*

3.1 As mentioned above, the subject-matter of claim 1 is generally worded, with broad terms, so as to cover two embodiments. Since, however, the two embodiments differ substantially in their structure, two different prior art documents can be taken up as starting point.

With respect to the first embodiment according to Figures 1 and 2, either document (3) or (7) is considered to represent the prior art which comes closer to the invention, as both of them disclose a cavity formed by transversal through-holes in communication with each other inside the implant.

With respect to the second embodiment according to Figures 3 and 4, document (2) is considered as representing the closest prior art since it discloses a cavity formed by a recess or volume machined at the periphery of the implant.

3.2 As stated in the introductory part of the patent in suit (column 3, lines 18 to 28) the anchoring member described in document (3) suffers from a major drawback in that the bottom surface of the cavity is open downwardly, so that scraped-off bone material can fall down onto the bottom of the bone hole and disturb the osseointegration of the base of the anchoring member. As to document (2), the single and shallow groove provided at the periphery of the implant is insufficient to lodge all bone material scraped-off by the cutting edge of the groove (cf. patent, column 2, lines 47 to 53).

Therefore, as generally stated in the patent (column 2, lines 54 to 58), one object of the invention is to achieve efficient bone-ingrowth of newly formed bone into the cavity. However, in view of the above-cited references, the more specific problem underlying the present patent is rather to simultaneously remove the major difficulties encountered with the prior art implants, so as to promote efficient osseointegration of the base of the anchoring member.

3.3 The solution is given by the feature combination recited in the characterising portion of claim 1, in particular by two essential characteristics:

- Firstly, the cavities must be **large enough** to accommodate all the scraped-off bone material produced by self-tapping (feature (j)). The functional nature of this feature is not objectionable since the total volume of the cavities can be easily determined by a person skilled in the art, in relation to the size of the anchoring member, which in turn depends on the specific application.

- Secondly, the cavities must be **closed** in the sense explained above (cf. point 2.3), which implies that the trapped bone material cannot escape and that the implant in which the cavities are formed by through-holes or deep volumes is provided with a solid bottom surface, without openings (features (h) and (k)).

4. *Inventive step*

4.1 First embodiment

As previously stated (cf. point 3.2) the implants described in documents (3) or (7) are not suitable since, while they are self-tapping and have a volume cavity sufficient for housing all scraped-off material, the cavity is opened downwardly so that the chips of material entering the cavity through the transversal openings can fall down into the bone hole, ahead of the implant base, and disturb osseointegration. Moreover, the cutting edges of the bottom opening of the implant can damage the bone membrane during insertion.

The various self-tapping vent-plants designed by Linkow in document (10)(cf. Figure 5-43) are also all provided with a cavity opened downwardly, since the vents are intended to be slipped over a bone core, machined in the bottom surface of the bone hole (cf. page 157, first paragraph). The opened bottom structure of the Linkow's implants is confirmed by document (20) where it is stated (cf. page 23, left column, lines 11 to 19) that "the most apical part of these implants consists of a ring with two small metal bars connecting it to the rest of the implant... . By drilling with this instrument (a hollow mill) a cylinder of bone is shaped at the intended site of the implant. This bony cylinder fits exactly into the vent when it is set". The Linkow's implants thus have the same disadvantages as those described in relation with documents (3) and (7).

At the oral proceedings, the appellant referred to the paragraph bridging pages 22 and 23 of document (20) and, in particular, to implants developed by Cherchève, prior to Linkow: "These implants closely resemble the vent-plant described below (Linkow), but lack the vent part, the flutes and have longer shafts". Hence, it was assumed that implants having the same structure as the Linkow's implants, but provided with a closed bottom surface, were already known at the same time. The Board cannot accept this argument because "vent part" is used in documents (10) or (20) to define the cavity as a whole and not only the opening in the base, so that the expression "but lack the vent part" means no cavity at all. Besides, there is no representation of the Cherchève implant in document (20). Contrary to that, document (9)(cf. page 44, Figure 8, letter d) shows unambiguously a Cherchève implant which, in the Board's view, corresponds to the definition given in document (20), ie a simple spiralled implant without any cavity and, therefore, without connection with the subject-matter of claim 1 in suit.

Starting from the implant described, for example, in document (7), which discloses a hollow cavity opened downwardly, the skilled person would not feel prompted to closing the bottom opening because the problem of retaining all scraped-off bone material as it is produced, within the cavity, is not addressed in this document, nor in any other document disclosing a similar structure. Neither the plane bottom surface shown in document (2) could lead the skilled person towards the claimed solution since the implant disclosed therein is not provided with any kind of hollow cavity in the sense of the first embodiment, so that the combination of two implants of different types is unlikely and inconsistent. Since no other document does suggest to close the inner cavity at the base of the implant by a solid bottom surface, without opening, in order to collect and house all scraped-off material, in the Board's judgement, the subject-matter of claim 1 including this feature is not obvious.

4.2 Second embodiment

The implant described in document (2) has only one small and shallow groove provided with cutting edges. But the volume of the recess is not intended for collecting and housing all scraped-off material. Therefore, it is insufficient for this purpose as the chips produced by self-tapping will necessarily fall down into the bone-hole, thus causing the difficulties previously mentioned.

Document (13) does not relate to an anchoring member for inserting in a jaw-bone, rather to a fixation pin for stabilizing fractures. It describes a plurality of grooves or flutes symmetrically arranged about the end of a screw shaft, so as to balance the cutting forces generated by self-tapping cutting edges, while the fixation pin is screwed. Moreover, like in the

invention, flutes are formed by longitudinally extending planar surfaces 24 and coextensive curved surfaces 26, intersecting each other at right angles, with the intersection constituting said self-tapping cutting edges. However, although it is likely that the total volume of the cavity formed by the flutes is sufficient to accommodate most of the bone chips produced by self-tapping, the problem of retaining the chips in the flutes is not addressed in this document. As a matter of fact, this problem cannot be solved with a fixture of this type, since the tip portion is not truncated, that is the conical end portion of the pin is progressively reduced towards the end of the pin. As a result, the gap between the lower ends of the flutes and the wall of the bone-hole as defined previously (cf. point 2.3) in relation to the second embodiment of the patent, is much greater with the implant described in document (13)(cf. end view of Figure 4) than in the present patent, so that the scraped-off material escapes through the wide gap and falls into the bone-hole. Hence, while the flutes disclosed in document (13) are substantially similar in form to the deep volume cavities according to the invention, the known flutes are not such as to form "closed cavities" in the sense of the patent in suit. Therefore, in the Board's view, document (13) does not either suggest the concept upon which the invention is based.

Document (11)(cf. chapter 9, pages 161 to 163) refers more particularly to the problem of cutting threads in bones by means of self-tapping flutes. The cutting flutes "should be reasonably large to make a place for the chips to accumulate" (cf. page 162, lines 18 to 19), however with an important limitation: "the chips which are cut in the bone must not fill the cutting flutes...since, if the flutes become filled with chips, there is increased chance of splitting the bone" (cf. pages 162, lines 3 to 5). This statement is clearly in

opposition to the requirements according to the implant of the invention, in which the cavities must lodge and retain all scrapped-off bone material. Moreover, document (11) describes two methods of making flutes (cf. page 162, line 35). Without going into details, the Board observes that in both cases, the chips are falling down in the hole ahead of the advancing screw (cf. page 163, lines 1 to 2 and 9 to 10) which, again, is contrary to the object of the present invention. It is thus obvious that the flutes generally proposed in document (11) are not suitable to retain all scraped-off material and, consequently, cannot suggest the cavities as defined in relation to the invention. In addition, document (11) does not refer to any dental application.

From the foregoing, it results that by combining the disclosures of documents (1) and (2), as was submitted by the appellant, the skilled person is not able to arrive at the claimed subject-matter.

4.3 The tests required by the appellant to determine whether the alleged success rate can actually be ascribed to the claimed features are, in the Board's judgement, neither useful nor necessary. At first, the onus is on the appellant to demonstrate that the invention is not patentable, for each party must carry the burden of proof for the acts it alleged. Next, even if it turned out that on the basis of some evidence provided by the respondent, the implants according to the patent were not so efficient as expected, such evidence would be irrelevant to the matter of inventive step. The requirements of the EPC are restricted to the criteria recited in Article 52(1), from which any

technical progress is excluded. Therefore, patentability can validly be recognised, even if the implants according to the patent were less efficient or of less successful than those produced in the prior art.

4.4 For all the foregoing reasons, the Board is satisfied that none of the two embodiments covered by claim 1 in suit can be derived in an obvious manner from the state of the art. Consequently, the subject-matter of claim 1 is inventive within the meaning of Article 56 EPC.

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 with claim 1 as filed during the oral proceedings and with claims 2 to 6, description and drawings according to the interlocutory decision.

The Registrar

S. Fabiani

The Chairman:

H. Seidenschwarz