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D E C I S I O N
of 6 July 1999

Case Number: T 0089/96 - 3.2.2

Application Number: 87112031.7

Publication Number: 0263274

IPC: A61C 8/00

Language of the proceedings: EN

Title of invention:

Improved submersible screw-type dental implant

Patentee:

V.P. Intellectual Properties, L.L.C.

Opponent:

Nobel Biocare AB

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56, 84

Keyword:

"Clarity (yes)"

"Novelty (yes)"

"Inventive step (yes - after amendment)"

Decisions cited:

T 0301/87

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0089/96 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 6 July 1999

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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 20 November
1995 concerning maintenance of European patent
No. 0 263 274 in amended form.

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. On 19 January 1996, the appellant (opponent) lodged an appeal against the decision of the Opposition Division stipulating the amended form in which the European patent No. 0 263 274 could be maintained and paid the fee for appeal on the same day. The statement setting out the grounds of appeal was received on 22 March 1996.

II. The Opposition division held that the grounds submitted by the opponent, namely those based on

(a) Article 100(a), that is lack of novelty having regard to document:

(D7) Theories and Techniques of Oral Implantology,
Leonard I. Linkow, Saint louis 1970, pages 1,
2, 9, 157

and lack of inventive step having regard to documents:

(D2) Osseointegration and its Experimental
Background, P-I Branemark, Sept. 1983

(D1) Osseointegrated Implants in the Treatment of
the Edentulous Jaw, P-I Branemark et al,
1977, pages 30 to 33,

or having regard to documents (D7) and (D2),

(b) Article 100(b) EPC (insufficient disclosure), and

(c) Article 84 EPC (lack of clarity)

did not prejudice the maintenance of the patent in amended form.

The opposition division found further that the amendments met the requirements of Articles 123(2) and (3) EPC.

III. On 8 August 1996 the respondent (patent proprietor) filed as "annex 3" the following document:

(D8) Theories and Techniques of Oral Implantology, Leonard I. Linkow, Saint Louis 1970, page 263 (originating from the same publication of document (D7)).

On 7 June 1999 the appellant filed the documents:

(D9) Lexikon der Technik, with a definition of "thread tapping"

(D10) and (D10') originating from the same publication of document (D1) and consisting of page 29 (D(10)) and of an enlargement of Figure 14 of the same page 29 (D(10')).

In the following these three documents will be cited together as (D1-D10-D10').

IV. Following a request of both parties, oral proceedings were held on 6 July 1999.

At the end of the oral proceedings the requests of the

parties were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 263 274 be revoked.

The respondent (patentee) requested that the appeal be dismissed and the patent maintained on the basis of the amended version submitted during the oral proceedings.

V. The wording of claim 1 as submitted on 6 July 1999 is as follows:

"An implant portion of an oral implant designed for supporting an artificial tooth structure (30) comprising an implant body (10) having a cylindrical shape with self-tapping threads (13) on its exterior surface over a middle region of the implant body, being adapted to be threaded into an opening in a bone (11) of a patient in the vicinity of the occlusal plane, and also having at least one vent (16, 16a, 16b) extending at least part way into the implant body (10), further comprising an upper section which is adapted to be directed away from a base portion of the opening in the bone (11) when installed, including connecting means (19, 19', 21, 24, 35; 42, 44-46, 48, 52, 59; 52, 60, 62, 64) for connecting an abutment (20) for supporting an artificial tooth structure (30) to the implant portion (10), and also comprising at least one channel extending through said threads (13) on the implant body (10),
characterized by
the at least one channel (18, 18a, 18b) being terminated below the uppermost threads (13) and

directing bone chips toward said base portion of the opening in the bone (11) during insertion of the implant body (10) into said opening in the bone (11), one edge (18') of the threads (13) at one side of the channel (18, 18a, 18b) being substantially at a right angle to the circumferential direction of the threads (13), so that to form a cutting edge (18') being adapted, when in engagement with the surrounding bone (11)

(i) to promote self-tapping of the threads (13) in the surrounding bone (11), and

(ii) to shave off pieces of said bone (11) during threading of the implant body (10) into the opening in the bone (11), and

(iii) to direct the pieces of bone (11) into the channel (18, 18a, 18b) such that the channel may direct pieces toward the base portion of the opening."

VI. The appellant argued as follows.

Clarity

Following phrases of claim 1 are not clear:

- "(self-tapping threads) extending over a middle region (of the implant body)",
- "one channel extending through said threads", and
- "(the channel being terminated) below the uppermost threads"

Novelty

Document (D2), page 404, Figure 8, discloses all the features of claim 1. The self-tapping threads are very close to the middle region even if not extending through it. Document (D1-D10-D10'), which shows at page 31 the same embodiment of document (D2), does not necessarily limit the self-tapping to the apical portion. The tapping in fact depends on the form of the hole and not only on the form of the implant. See document (D1-D10-D10'), page 31, Figure 16f. See also description of the patent specification, column 5, from line 33 where it is said that, if necessary, a bone tap can be used to create grooves in the hard upper cortical bone prior to insertion of the implant portion.

Document (D7), right embodiment of Figure 1-1B, page 2, shows an implant according to the claimed invention. At page 157 it is further stated that the chips produced by self-tapping end up inside the vent. This passage, even if not directly related to Figure 1-1B, describes a common feature in the field. The cited figure discloses also that the cutting edge is at right angle as can be evidenced by comparing the right and left embodiment of Figure 1-1B with the middle one. The only feature not contained therein is that the channel terminates under the uppermost threads.

Inventive step

Starting from document (D2), the subject-matter of claim 1 is distinguished therefrom only by the feature that the self-tapping threads are present in the cylindrical part. The invention is, therefore, based on the problem to improve the anchoring of the implant in

the bone.

Document (D1-D10-D10') gives several examples of implants having self-tapping threads of different length on the cylindrical part which can be selected according to the required anchoring strength. That means that extending them to the middle region cannot be inventive. According to the description of the patent in suit, the edge of the channel does not need to be formed in a particular way to perform the cutting function. It is sufficient that it is cut at 90°. The figure in document (D1-D10-D10'), page 29, second embodiment from the bottom right, shows self-tapping threads.

Alternatively, the subject-matter of claim 1 is rendered obvious by the combination of features disclosed in documents (D7) and (D1-D10-D10').

The subject-matter of claim 1 differs from the disclosure of document (D7) in that the channel terminates before the uppermost thread. The affidavit of Mr Linkow submitted during the opposition proceedings which states that the device of document (D7) is not self-tapping in the sense of the invention is not reliable because Mr Linkow is closely linked to the respondent being the inventor of the patent. The statement is also not consistent with Figure 1-1B of document (D7). Document (D1-D10-D10') contains the distinguishing feature.

The claimed function of the channel is to create a cutting edge and to force the chips down towards the base. However, it is not possible to force the chips

towards the base because the chips produced are too few to fill the interstices over the entire length of the threaded portion of the implant body.

During the insertion of the implant and when the channel is half-inserted in the bone, the channel remains open and the bone chips cannot be transported towards the base.

VII. The respondent argued as follows.

Clarity

- The phrase that the self-tapping threads extend over a middle region means that they do not necessarily extend towards the ends;
- the phrase that the channel extends through said threads means that the channel must go through the middle portion but it does not need to be limited to that portion;
- the phrase that the channel extends below the uppermost threads means that the channel does not go through at least the 2 uppermost threads.

Novelty

Document (D2), Figure 8, page 404, does not show a cylindrical shape of the body. The self-tapping, conical apical part is designed to cut the bottom of the hole. In the cylindrical part there is no channel. Document (D1-D10-D10'), which discloses the same embodiment at page 31, Figure 16f, shows that the

installation steps comprise a pre-threading of the cylindrical part of the hole, whereby the bottom is left unthreaded. That means that in the cylindrical portion of the implant there is no self-tapping.

Document (D7) does not disclose self-tapping threads nor a channel closed upwards.

Inventive step

The presence of a channel does not necessarily imply a self-tapping effect.

Document (D1-D10-D10'), Figure 15g at page 29, shows an instrument for the installation of the implant which is designed to tap the bone. The channel has to be specifically designed in order to be self-tapping. The channel of the implant according to (D1-D10-D10') has the only function of giving way to the blood. Document (D1-D10-D10') has been published on 1977. The self-tapping threads have been introduced later. Document (D2), which was published on 1983 does not give any hint for extending the self-tapping effect to the cylindrical part. It does not contain any indication to direct the bone chips towards the base portion of the opening.

Document (D7), page 9, discloses that - being the spiral portion of the implant solid and containing a sluiceway - it is sturdy enough for self-tapping. Page 157 does not refer to Figure 1-1B. Mr Linkow in the affidavit submitted during the opposition proceedings declared that the device disclosed in document (D7) is not self-tapping in the sense of the

invention.

The invention has the purpose to transport the bone chips toward the bottom and that the implant also functions as a tool. The closure of the channel at the top provides that the bone chips migrate towards the base portion during screwing of the implant.

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments*

The feature that the self-tapping threads extend over a middle region of the implant body is disclosed in column 4, lines 52 to 54 and column 5, lines 44 to 47 of the patent specification and represents a limitation of the protection given by the feature: "self-tapping threads over at least part of its exterior surface" contained in claim 1 of the patent specification.

The feature that the channel extends through said threads is derived from claim 1 as originally filed as well as from claim 1 as granted by deletion of the word: "at least".

The feature that the channel is terminated below the uppermost threads is disclosed at column 2, line 27 and in the figures of the patent application and it represents a restriction of the protection given by the functional feature: "for directing bone chips towards said base portion" contained in claim 1 in the granted

version.

There are therefore no manifest grounds for challenging the amendments made after grant to the patent in suit for lack of support in the original disclosure or for extension of the protection sought. The appellant did not raise any objection against the present version of the claims in this respect.

3. *Clarity*

Claim 1 has been amended during the opposition proceedings.

According to Article 102(3) EPC, a patent amended during the opposition proceedings should meet the requirements of the EPC, in particular also the clarity requirements of Article 84 EPC.

Clarity is not however one of the grounds for opposition exhaustively listed in Article 100 EPC. Article 100 EPC is a particular norm specific to the opposition proceedings and it prevails over the general reference to the requirements of the Convention contained in Article 102(3) EPC.

That means that an objection of clarity is admissible in opposition proceedings only for those features whose meaning is directly affected by the amendments performed after grant (see decision T 301/87, OJ 1990, 35).

In this case the features objected to on the basis of Article 84 EPC derive from amendments introduced after

grant. Accordingly the objection on the basis of Article 84 is admissible.

The objected features are however clear.

The wording: "middle region" means that such region does not comprise the ends of the implant body. The wording: "channel extending through said threads" means that the channel has an extent which at least covers part of the threads. The wording: "being terminated below the uppermost threads" means that the channel does not cut at least the two uppermost threads.

4. *Novelty*

Document (D2), see Figure 8 at page 404, discloses an implant portion of an oral implant designed for supporting an artificial tooth structure comprising an implant body having a cylindrical shape with threads on its exterior surface and a conical apical part with self-tapping threads, the implant body being adapted to be threaded into an opening in a bone of a patient in the vicinity of the occlusal plane, and also having at least one vent extending at least part way into the implant body, an upper section which is adapted to be directed away from a base portion of the opening in the bone when installed, including connecting means for connecting an abutment for supporting an artificial tooth structure to the implant portion, and comprising at least one channel extending through the threads in the apical part, being terminated below the uppermost threads and directing bone chips toward said base portion of the opening in the bone during insertion of the implant body, one edge of the threads at one side

of the channel being substantially at a right angle to the circumferential direction of the threads so that to form a cutting edge, said one edge being adapted

- (i) to promote self-tapping of the threads,
- (ii) to shave off pieces of bone during threading of the implant portion into the opening in the bone, and
- (iii) to direct the pieces of bone into the channel such that the channel may direct pieces towards said base portion of the opening."

The implant according to claim 1 differs from the one disclosed in document (D2) in that self-tapping threads are provided over a middle region of the implant and in that the channel extends through said threads.

Even if it were admissible to interpret the disclosure of document (D2) in the light of document (D1-D10-D10'), the conclusion would be the same, because also the implant displayed in Figure 16k of this document comprises self-tapping threads only in its apical part.

Document (D7) (see in particular Figure 1-1B on page 2, right embodiment) discloses an implant containing a spiral portion, the spiral portion being self-tapping (see page 9, right column, second paragraph) and being adapted to be threaded into an opening in a bone of a patient in the vicinity of the occlusal plane, and also having at least one vent (see page 9, the chapter entitled "Vent-plant implants") extending at least part way into the implant body, and a coronal portion

consisting of a solid square shaft including connecting means for connecting an abutment for supporting an artificial tooth structure and being adapted to be directed away from the base portion of an opening in the bone when installed. The implant also comprises at least one channel (sluiceway) extending through said threads on the implant body.

This document is however silent on whether a side of the channel is at a right angle to the circumferential direction of the threads. Figure 1-1B, right-hand embodiment, is too blurred to allow an assessment of such angle. Document (D7) is also silent on whether the one edge is suitable to be a cutting edge, adapted to promote self-tapping of the threads, to shave off pieces of bone during threading of the implant body into the bone and to direct the pieces of bone into the channel. On the other hand, the statement on page 9, right column, second paragraph, that the spiral portion is "sturdy enough for self-tapping" leads rather to the conclusion that the self-tapping of the known spiral portion is the result of a crushing action and not of a cutting action as required by claim 1 of the patent in suit.

Consequently, the subject-matter of claim 1 differs from the implant disclosed in document (D7) in that the at least one channel is terminated below the uppermost threads and directs bone chips towards the base portion of the opening in the bone during insertion of the implant body into said opening in the bone, and in that one edge of the threads at one side of the channel is substantially at a right angle to the circumferential direction of the threads to form a cutting edge being

adapted, when in engagement with the surrounding bone to exert the functions (i), (ii) and (iii) specified in claim 1.

4.2 Inventive step

The distinguishing features of claim 1 against document (D2) (which, in a first approach, has been considered by the appellant as representing the nearest prior art), namely self-tapping threads in the middle region of the implant and a channel extending through said threads, solve the problem of facilitating insertion and of improving anchorage of the implant in the bone, cf. patent specification, column 2, second paragraph.

The threads being self-tapping, the insertion of the implant is facilitated because the implant is screwed in a hole in the bone without the need to first pre-cut grooves in the inner surface of the hole to accommodate the threads of the implant. Since the self-tapping threads are positioned in the middle region, the anchorage forces are more evenly distributed along the length of the implant and not concentrated in the apical portion. Extending the channel in the middle region has finally the effect that more chips created during the self-tapping are deposited toward the base of the hole promoting faster bone growth.

Document (D1-D10-D10') (which the appellant considers to take away the inventive step of claim 1 in combination with document (D2)), on its pages 30 to 33, describes the preparation of the bone fixture site and the subsequent implantation of an oral implant which comprises self-tapping threads exclusively on its

apical end (see in particular Figure 16 and page 30 first paragraph) and, therefore, corresponds to the implant disclosed in document D2. As is quite clear from Figure 16f, the main part of the hole into which the implant is to be inserted is tapped before the insertion of the implant leaving only the downmost part of the hole untapped and ready to be tapped by the apical part of the implant.

The implant of Figure 16 has found its way into practical use and even been standardized (see page 29, text under Figure 14).

By contrast, the same Figure 14 on page 29 shows a collection of "various types and sizes of titanium fixtures and cover screws which were used during the development of the project". These sample fixtures are not described in detail and have apparently never been used in practice. The appellant has pointed to the penultimate fixture in this collection asserting that this sample fixture comprised a channel and self-tapping threads according to the features in the characterising part of claim 1.

The Board, however, cannot share this view. There is nothing in the figure which could lead necessarily to the conclusion that the threads in the middle section are self-tapping and at a right angle to the circumferential direction of the threads so as to form a cutting edge being adapted to exert the functions (i) to (iii) indicated in claim 1. The magnified view according to document (D10') does not permit any other conclusion. It could well be that the implant is inserted into a hole with a pre-tapped interior surface

and that the channel is aimed at housing pieces of bone originating from the pretapping step.

In consequence, the teaching of document (D1-D10-D10') when added to the disclosure of document (D2) cannot lead to the subject-matter of claim 1 in an obvious manner.

Turning to the second approach of the appellant, which considers document (D7) as representing the nearest prior art, the purpose of the invention is again to facilitate insertion of the implant by having self-tapping threads, so that the implant can function like a tool and to facilitate growth of the bone by having a channel which directs chips toward the base portion of the hole in the bone.

Neither document (D7) nor document (D1-D10-D10') recognise the purpose of the invention. Both documents fail also to disclose self-tapping threads in the middle region and a channel terminating before the uppermost threads.

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 as follows:

- claims 1 to 25 and description as submitted during the oral proceedings on 6 July 1999, Figures 1 to 13 as granted

The Registrar:

The Chairman:

S. Fabiani

W. D. Weiß