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D E C I S I O N
of 5 December 2002

Case Number: T 0217/01 - 3.2.2

Application Number: 93924257.4

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IPC: A61C 8/00

Language of the proceedings: EN

Title of invention:
Fixture in a dental implant system

Patentee:
AstraZeneca AB

Opponent:
Friadent GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56, 84

Keyword:
"Clarity (yes)"
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-



Case Number: T 0217/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 5 December 2002

Appellant: AstraZeneca AB
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 21 December 2000
revoking European patent No. 0 668 751 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
U. J. Tronser

Summary of Facts and Submissions

- I. The appellant (patent proprietor) filed an appeal against the decision of the Opposition Division to revoke the patent for lack of inventive step.
- II. Following documents are relevant for the decision:
- D1: EP-A-388 576
- D4: US-A-4 826 434
- D9: Hansson, S.: "The implant neck: smooth or provided with retention elements", Clin. Oral Impl. Res., 1999: 10: 394 to 405
- D10: Palmer et al.: "A five year prospective study of Astra single tooth implants", Clin. Oral Impl. Res. 2000: 11: 179 to 182.
- D14: DE-A-4 130 891, filed by the respondent with letter of 4 December 2002.
- III. Oral proceedings have been held on 5 December 2002. At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 5 and description, columns 1 to 2, as submitted at the oral proceedings, rest of the description and figures as granted. He further requested a reimbursement of the appeal fees.
- The respondent (opponent) requested that the appeal be dismissed.

IV. Claim 1 as submitted during the oral proceedings reads as follows:

"Fixture (1, 10) of a dental implant system for implantation in bone tissue having a generally cylindrical main body provided with threads allowing the fixture to function as a screw and an outer end provided with a conically flaring portion (10) which is intended to at least partly abut the bone tissue when the fixture is implanted, characterized in that the outer side of the conically flaring portion is provided with a circumferentially oriented, defined micro-roughness (9) having a height in the range of 0.05 - 0.15 mm."

V. The appellant presented the following arguments:

Claim 1 was clear. The feature that the flaring portion abutted the bone tissue "when the fixture is implanted" was effective in positioning the flaring portion of the fixture with respect to its stem.

Document D1 was not specifically directed to dental implants, it was not concerned with the long-term problem of bone resorption, but with the problem of prompt adhesion of the bone to the fixture. When, in its description of the prior art document D1 reported that a surface roughness of 0.02 mm or more had been provided by titanium coating, shot blasting or by cutting threads on the surface of the implant, this statement had to be understood as true for at least one of the methods but not equally true for each of them. Such roughness was not designed to be located at the upper portion of a dental fixture. At the priority date of D1 (1989), when the roughness had been provided by

threads, these threads had had a size sensibly larger than 20 mm, see document D4. Threads having such a small dimension as that claimed by the invention had not been known at that time. The lower values for the roughness cited in document D1 referred to a porous titan coating. In any case, the invention was at least based on the selection of a very narrow range of values from the undefined broad range disclosed by document D1.

Document D4 disclosed a roughness on the upper part of the fixture which was produced by etching. There was no incentive to substitute this known roughness by threads according to the invention.

The function of the circular grooves on the collar of the fixture according to document D14 was to provide for an initial fixation of the implant, because the coating (2) of the lower part of the fixture needed several weeks to acquire the necessary adhesion with the bone. The range of values disclosed in the state of the art for the height of the grooves was very broad (some micrometers to some hundred micrometers) when compared with the range claimed by the invention (50 to 150 micrometer).

There was no reason why the skilled person in the field of the invention would combine the teaching of documents D4 and D14 in the way of the invention. Both documents D4 and D14 were not concerned with bone resorption, but with the problem to improve growth of the bone immediately after insertion of the implant. The hint in column 5, line 42, of document D14 to the fact that in the long run bone substance grows in the recesses of a rough surface, had no relation to bone

resorption. Bone resorption was caused by an unfavorable stress distribution in the transition area from the cancellous bone to the soft tissue, see column 3 of the patent in suit, from line 8. There was no evident motivation for modifying the teaching of document D4 by adding a circumferentially oriented micro-roughness in the neck portion.

Document D9, whose Figure 7 was identical to the particular embodiment described in the patent in suit, demonstrated in its comparative Table 6, on page 402, the advantages of a threaded neck portion against a smooth neck surface.

The request for reimbursement of the appeal fee was justified because the Opposition Division did not admit into the procedure the relevant documents D9 and D10, which proved that the claimed implant fixture successfully prevented bone resorption, see letter of 19 October 2000 in opposition proceedings.

VI. The respondent argued as follows:

Claim 1 lacked clarity because the formulation "when the fixture is implanted", did not provide any limitation to the claimed fixture.

The patent in suit did not merely deal with bone resorption in connection with microthreads, but specifically with the regeneration of bone tissue, see column 2, last line. According to column 3, from line 8 onwards, the rapid growth of tissue warranted the axial loads on the implant to be transmitted to the bone tissue in a biomechanically correct way and therefore avoided bone resorption.

Since document D1 only generally disclosed that it was advantageous to use some kind of roughness and that threads could be used to provide roughness to the surface, there was no basis in document D1 for stating that threads could deliver a range of values for the roughness narrower than that positively disclosed by the document itself. It was also obvious that a microroughness could definitely have a positive effect in avoiding bone resorption.

In any case, the subject-matter of claim 1 did not involve an inventive step having regard to documents D4 and D14, column 8, embodiment No. 4, and Figure 3. It was correct, that the primary function of the grooves was to provide for an initial fixation of the implant to the bone. However, the above cited passage disclosed also that such grooves guaranteed a long-time fixation. Replacing the roughness of the upper surface of the fixture of document D4 with threads, as demonstrated by document D14, was a mere workshop modification without any inventive step being involved. It was not proved - for example by laboratory tests - that the claimed range of values for the roughness had a special, surprising effect.

Reasons for the Decision

1. The newly submitted documents

The not prepublished documents D9 and D10, submitted by the appellant during the opposition procedure, have been considered in the procedure as background evidence. Document D14, submitted by the respondent with letter of 4 December 2002, has been considered as

prior art.

2. *Formal matters*

The new version of the patent complies with Article 123 EPC. The respondent did not raise any objection in this respect.

The new claim 1 is clear. The objected feature concerning the fact that the flaring portion abuts the bone tissue when the fixture is implanted contributes to define the form of the fixture. Being the length of the part inserted in the jaw bone defined by anatomical constraints, the feature amounts to positioning the flaring portion with respect to the distal end of the implant. In any case, the above feature was contained in the granted version of the claim and it is not affected by the amendments introduced later. Consequently, it is not open to the objection of clarity.

3. *Novelty*

Lack of novelty was not an objection raised against the present claim 1.

4. *Inventive step*

According to the decision under appeal, D4 is considered the closest state of the art because it shows most of the features of the invention and because the original disclosure starts from a similar state of the art but without surface roughness on the respective flaring conical portion.

Document D4 discloses a fixture of a dental implant system for implantation in bone tissue having an outer end provided with a conical flaring portion (32) which is intended to at least partly abut the bone tissue when the fixture is implanted (see Figures 1 and 2), whereby the outer side of the conically flaring portion is provided with a micro roughness (column 3, lines 50 to 64).

The subject-matter of claim 1 differs therefrom in that said micro roughness is circumferentially oriented and has a height in the range of 0.05 to 0.15 mm.

The technical problem to be solved by the invention consists therefrom in preventing the implant from losing firm fixation in the bone due to pockets formed in the cortical bone around the implant, see column 1, lines 16 to 27. The formation of such pockets can at least be promoted by an unfavorable distribution of loads around the conical neck portion of the implant at the attachment with the bone, see column 3, lines 8 to 15.

Document D4 is equally aimed at the avoidance of pockets, see column 2, lines 56 to 61. There is stated that the aim of the invention is to minimize the chances of soft tissue invasion of the jaw bone as the implant is used. When the superficial soft tissue invades the jaw bone, the cortical bone will inevitably withdraw, leaving pockets and resulting in the implant losing its fixation. As a counter measure, document D4 suggests to provide the conical flaring portion with an etched rough surface. However, document D4 is silent about the influence of an unfavorable distribution of loads on the formation of pockets. Although, the patent

in suit itself recognizes that the mechanism behind the formation of pockets is not quite clear (column 1, lines 22 to 23 of the description), it convincingly describes the unfavorable distribution of loads as a plausible concurrent cause. Furthermore, the patent in suit clearly distinguishes a generic, non oriented roughness, as disclosed by the prior art, from the oriented roughness of the invention. Both can be applied contemporarily, the non oriented roughness being superimposed to the oriented one, see column 2, from line 50 of the patent in suit.

Document D14 is concerned with the stability, immediately after insertion, of an implant having a coating which is designed to form a chemical binding with the bone substance (column 1, from line 45). The problem with such coatings is that the implant has to be immobilized for 8 to 16 weeks to allow the chemical reaction to unfold completely (column 2, line 37). To provide an initial, short-time fixation, Example 4 in column 8 and Figure 3 disclose a series of circumferentially oriented grooves, some millimeters to some hundred millimeters deep, on the neck portion of the implant.

The skilled person in the field would not combine the teaching of documents D4 and D14 in the form of claim 1 because these document do not know the problem of the invention of providing for a long-term, well-balanced distribution of loads.

Even if he would consider document D14 for providing the fixture of document D4 with threads in the upper part, there are no reasons why he would choose threads with depth in the short claimed range (50 to 150 mm)

among the broad range (some mm to some hundred mm) disclosed by document D14. The Board is convinced that he would rather choose a depth of the threads in the upper region of the range disclosed by document D14, outside the claimed range, because such depth is comparable with the depth used in document D4 for the shaft of the implant, and which is known to be optimal for an immediate anchoring of the implant to the bone.

Document D1 does not disclose further elements beyond those contained in document D4 and D14 which can seriously challenge the inventive step of claim 1.

Accordingly the subject-matter of claim 1 contains an inventive step.

This conclusion is confirmed by the not prepublished documents D9 and D10 which demonstrated the success of the claimed subject-matter.

5. *Reimbursement of the appeal fees*

The appeal fee is not to be reimbursed, because documents D9 and D10 only provide secondary indications for an inventive step which could not have been counter balanced the primary arguments against it. Therefore, the fact that they were not considered by the Opposition Division could not have an effect on the *ratio decidendi* of the appealed decision.

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 in amended form on the basis of claims 1 to 5 and description, columns 1 and 2 as submitted at the oral proceedings, rest of the description and Figures as granted.
3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß