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Datasheet for the decision of 5 December 2013

Case Number: T 1169/12 - 3.2.08

02760948.6 Application Number:

Publication Number: 1416872

IPC: A61C8/00

Language of the proceedings: ΕN

Title of invention:

BONEIMPLANT

Patent Proprietor:

Dentsply IH AB

Opponent:

Nobel Biocare AB

Headword:

Relevant legal provisions:

EPC Art. 84, 123(2), 100(c), 100(a), 54, 56

Keyword:

Claims - clarity (yes) Amendments - allowable (yes) Grounds for opposition - added subject-matter (no) Novelty - (yes) Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern **Boards of Appeal** Chambres de recours

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Case Number: T 1169/12 - 3.2.08

DECISION of Technical Board of Appeal 3.2.08 of 5 December 2013

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on

15 March 2012 concerning maintenance of the European Patent No. 1416872 in amended form.

Composition of the Board:

T. Kriner Chairman: Members: C. Herberhold

D. T. Keeling

M. Alvazzi Delfrate

C. Schmidt

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Summary of Facts and Submissions

- I. By decision posted on 15 March 2012 the opposition division decided that European patent EP-B-1 416 872 in amended form according to the second auxiliary request then on file and the invention to which it related met the requirements of the EPC.
- II. Both parties to the proceedings lodged an appeal:

Appellant I (patent proprietor) filed a notice of appeal on 22 May 2012, paying the appeal fee on the same day. The statement of grounds was received on 24 July 2012.

Appellant II (opponent) filed a notice of appeal on 15 May 2012, paying the appeal fee on the same day. The statement of grounds was received on 11 July 2012.

III. Oral proceedings before the Board of Appeal took place on 5 December 2013. At the oral proceedings appellant I filed a new main request. The independent claims of said new main request are identical to the independent claims of the seventh auxiliary request as filed with the grounds of appeal.

At the end of the oral proceedings the requests of the parties were as follows:

Appellant I requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request submitted during oral proceedings.

Appellant II requested that the decision under appeal be set aside and that the patent be revoked.

IV. Independent claims 1 and 2 of the sole present request read as follows:

Claim 1:

"A screw implant (1) for insertion into a bore hole (50) arranged in bone tissue, said implant having a cancellous portion (3) presenting an outer surface, and a cortical portion (2) arranged above said cancellous portion (3), and having an axial length of equal to 3 mm or less than 3 mm, such that, when installed in the bore hole (50), the engagement of said cortical portion (2) with the bone tissue will generally be confined to the cortical bone tissue layer (52), said cortical portion (2) presenting a conical outer surface being threaded for accomplishing said engagement and which has a conical taper such that said conical outer surface forms a non-zero angle (α) of less than 5° in relation to the outer surface of the cancellous portion (3), wherein the implant (1) is provided with at least a first threading (11) extending uninterrupted over the cortical portion (2) and at least part of the cancellous portion (3)."

Claim 2:

"A screw implant (1) for insertion into a bore hole (50) arranged in bone tissue, comprising a cancellous portion (3) having a lower cylindrical cancellous portion (3') and an upper conical cancellous portion (3") presenting a conical outer surface, wherein said implant (1) is provided with a cortical portion (2) arranged above said cancellous portion (3), and having an axial length of equal to 3 mm or less than 3 mm, such that, when installed in the bore hole (50), the engagement of said cortical portion (2) with the bone tissue will generally be confined to the cortical bone

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tissue layer (52), said cortical portion (2) presenting a conical outer surface being threaded for accomplishing said engagement and which has a conical taper such that said conical outer surface forms a non-zero angle (α) of less than 5° in relation to the outer surface of the upper, conical cancellous portion (3"), wherein the implant (1) is provided with at least a first threading (11) extending uninterrupted over both the cortical portion (2) and the conical cancellous portion (3")."

V. The following documents played a role for the present decision:

Dl: WO-A-94/09717;

D5: EP-A-0 424 734;

D7: Steri-Oss Implant;

- D7.1: Excerpts from Steri-Oss Manual:
 Introduction, Table of Contents, pages 2.3,
 2.4 and 2.5,
- D7.2: List of publications relating to Steri-Oss implants;
- D7.3.1: Implants ostéo-intégrés: considérations générales, locales et applications cliniques, 1re partie, by André P. Saadoun in "Clinic/Odontologia" No. 5/1989;
- D7.3.2: Implants ostéo-intégrés: considerations générales, locales et applications cliniques, 2e partie, by André P. Saadoun in "Clinic/Odontologia" No. 1/1990;
- D7.4: US-A-4,826,434;
- D7.5: Production drawing no.DP01-2003- (redacted);
- D7.6: Minutes of the hearing of the witness Mr Steve Hurson;

D8: DE-A-41 30 891; and

D10: WO-A-93/00518.

VI. The essential arguments of appellant II can be summarised as follows:

Admissibility of the new main request
Referring to the written procedure, concerns were
raised that the new main request, which at that time
was still referred to as the seventh auxiliary
request, had been filed too late and should thus be
disregarded. In particular, the relative arrangement
of the cortical and cancellous implant portions and
the details of the threading had already been
discussed at length at the opposition stage such that
there was no plausible reason why the request could
not have been filed during opposition proceedings.

Article 100(c) and Article 123(2) EPC Claims 1 and 2 of the main request extended over the disclosure of the application as originally filed for the following reasons: The wording "such that" in line 4 of claim 1 and in line 5 of claim 2 introduced a causal link between the confinement of the cortical implant portion to the cortical bone tissue layer and the particular axial length of said cortical implant portion, which -if at all- had only been disclosed for a cylindrical cancellous portion and in the context of the further functional feature "so that the cortical portion does not compress more tissue than necessary for having the desired increase in screwing torque" on page 10, lines 33, 34. However, the independent claims of the present main request were not restricted accordingly , comprising even a back tapered cortical portion, which showed no increase in torque upon insertion into the bone. Thus the causal link "so that" could not be generalized from the disclosure on page 10, lines 33, 34, without a functional

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restriction to the increase in screwing torque or a structural limitation to implants with a flaring out cortical portion.

Furthermore there was no literal basis for the cortical portion to be arranged "above" the cancellous portion, such a wording even including a cortical portion overlaying the cancellous portion. With respect to the drawings, only an arrangement "immediately above" could be considered disclosed. Also the passage on page 14, second paragraph cited by appellant I in support related only to a cortical portion increasing in diameter, a feature which had however not been included into the independent claims.

Additionally, the now defined "uninterrupted extension of a first threading over the cortical portion and at least part of the cancellous portion" had only been disclosed on page 12, lines 2, 3, in combination with a threaded surface of the cancellous portion or on page 16, line 23-25 and on page 21, line 9, 10, in the context of the particular embodiments shown in Figures 2, 3, or 8 respectively. However, neither the cancellous thread, nor the specific features shown in Figures 2, 3 or 8 had been included into the claims. Consequently, both amendments amounted to an intermediate generalization.

Moreover, the use of the undetermined article "a" in the wording "provided with <u>a</u> first threading" suggested the existence of a further thread, in addition to the thread of the threaded conical outer surface, for which there was no disclosure whatsoever.

Consequently all these amendments were in violation of Article 123(2) EPC.

Article 84

In the context of the claimed odontology implant, which may be implanted into the mandibular as well as into the maxillar bone, the term "above" could not be considered clear: what was "up" or "above" in one application of the implant was "down" or "below" in the other.

Furthermore there were contradictions between the claims and the disclosure in the specification: Whereas the claims defined a thread "extending uninterrupted over the cortical portion and at least part of the cancellous portion", Figure 7A and the corresponding paragraph [0080] of the description showed a thread interrupted by a cutting recess No. 13'. Moreover, the claim language differentiated between an extension over a portion and an extension over at least a part of a portion. From this difference it had to be concluded that the thread extended along the full axial length of the outer surface of the cortical portion because otherwise the wording "over at least a part of the cortical portion" would have to be expected. Consequently, the claims were in contradiction with paragraph [0045] of the description, which disclosed the extension of the first threading along the full axial length of the threaded outer surface of the cortical portion as facultative, although said feature was required by the claim language.

The alleged public prior use:

Document D7.5 was to be considered as prior art under Article 54(2) EPC. It had been admitted into the proceedings by the opposition division, and the witness' testimony (see D7.6) provided a clear link between the drawing of the screw implant and its public use. Although the pencil drawing covered

several versions of the implant (reductions A-D), the last revision had been on 15 August 1988, long before the priority date of the present application. All of these versions had been sold, and -in addition to the witness testimony-several practitioners had been named which had used the implants. The lack of sales documentation was to be explained by the long time interval between the marketing of the prior use implant and the present proceedings. However, in particular the D revision had stuck in the witness' mind, because of the provision of a functionally unnecessary "marketing hole" in the implant tip for non-technical, sales related reasons, which explained why the witness could still recall even minor details.

Inventive step, Article 56 EPC

Starting from D7.5 as closest prior art, the only difference was that the conical cortical portion was provided with a thread extending uninterrupted to at least a part of the cancellous portion. The axial length of the cortical portion was inevitably below or equal to 3 mm as the cortical bone in odontology applications had a maximum height of 3 mm such that the functional portion in contact with said bone layer could also not be longer. Having regard to the above defined difference, the patent disclosed in paragraph [0014] firstly the effect of an improved primary fixation. It was however well known from document D8, column 3, second sentence and column 5, first paragraph, that surface irregularities, in particular a thread on the cortical portion of the implant, as disclosed in column 6, line 41-48, had exactly this effect. The person skilled in the art would thus apply such a thread to the cortical part of the D7.5 implant which is in contact with the cortical bone portion upon implantation. It was simply an alternative, which

even facilitated the tapping of the thread "in one go", to extend such a thread uninterrupted down to the cancellous part of the implant. As could be seen from D1, Figures 1, 2 and Figure 3 of the patent, such a thread could be manufactured without thinning the socket of the screw. Documents D5 and D10 gave further evidence that the provision of a thread extending uninterrupted from a cortical to a cancellous portion was customary in the art and did not pose any technical difficulties. In fact, the "waist portion" referred to as a technical hindrance by appellant I was nothing more than a milled clearance ("Freistich") required to allow the tapping of the single cancellous thread of the D7.5 implant. Said clearance would simply be omitted by the skilled man when an uninterrupted thread was to be made. In this respect, also arguments based on a particular bore protocol required and particular implant properties derived thereof were irrelevant, because the claims were not restricted to a particular bore hole configuration, but referred to a "bore hole arranged in bone tissue" in general.

Furthermore, the patent disclosed in paragraph [0014] as a second technical effect the provision of a thread on the cortical portion to result in a reduction of bone resorption. Both, D1, on page 1, lines 21-32, and D10, on page 2, last paragraph to page 3, suggested the provision of a threaded cortical portion in order to reach said effect. The provision of a threaded cortical portion was thus also obvious in view of the disclosure of these documents. In particular, D10 showed in Figure 6, which depicted a subgingival dental implant, a thread extending uninterrupted from the cortical to the cancellous portion.

Consequently, claim 1 of the main request was not inventive.

VII. The essential arguments of appellant I can be summarised as follows:

Admissibility of the new main request The view that the term cortical portion defined in claim 1 could also be read on the tip part No. 24 of the screw implant shown in D5, Figure 1 had been brought up by the opponent only during the oral proceedings before the opposition division. The opposition division had even expressed a different opinion in this respect in the summons and changed its view for the first time during the proceedings. Moreover, the feature of "the first threading extending uninterrupted over the cortical portion and at least part of the cancellous portion" had already been present in auxiliary request 4 filed on 8 November 2011 and admitted into the proceedings by the opposition division during oral proceedings. Thus a request admitted into the opposition proceedings had been amended in response to events during the oral proceedings. Already at these proceedings an amendment had been proposed clarifying the relative location of the respective portions of the screw implant, which had however not been admitted due to a clarity objection. With more time available, an alternative wording aiming to overcome the very same issue had been filed at an early stage in the appeal proceedings and consequently the request should be admitted into the proceedings.

Article 100(c) and Article 123(2) EPC

The description as originally filed, page 10, last paragraph, disclosed the preferred axial length of the cortical portion to be "less than or equal to 3 mm".

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The first sentence of said paragraph comprised the wording "so that" and thus a causal link between the axial length of the cortical portion and the engagement of said portion being confined to the cortical bone tissue layer, just as did the claims as originally filed.

Moreover, the description explained on page 8, third paragraph how directional terms like up, down, top, bottom, below, etc. were to be understood throughout the description and the claims, thus implicitly disclosing the term "above".

A first threading extending uninterrupted over the cortical portion and at least part of the cancellous portion was disclosed on page 12, lines 2, 3, page 16, lines 23 to 25, page 21, lines 9, 10 as well as in all the figures apart from Figure 5.

The term "provided with \underline{a} first threading" merely clarified that the thread extending uninterrupted over both the cortical portion and at least part of the cancellous portion was nothing more than the thread provided on the threaded cortical portion.

Article 84

As mentioned above, paragraph [0028] provided the person skilled in the art with clear information how the directional terms "up" and "down" etc. were to be interpreted. If necessary, further guidance was to be found in paragraph [0076], which disclosed "above" to be on the gingival side of the implant, and in paragraph [0056], which disclosed a faster rise in torque once the cortical bore reaches the bore hole.

Regarding the alleged contradiction between the claims and the specification, even if one regarded the cutting recess Figure 7a, No. 13' as an interruption of the thread, there was still a part of the thread present on the cancellous portion between plane P1 and recess No. 13' in Figure 7a as required by the claim. Paragraph [0045] cited by appellant II only supported dependent claim 10 as presently on file, such that there was also no contradiction in this respect.

The alleged public prior use:

As to the prior use invoked, the jurisprudence of the EPO required it to be proven "up to the hilt". However, there was only a single drawing available, showing four different implants, without any indication whether and if which of these were sold. In particular, there was no evidence of the sales, i.e. no orders, no delivery notes, no invoices available. Even if it could be accepted that implants under the name Steri-Oss had been marketed, it was not clear what dimensions those implants had and if they at all corresponded to the implant shown in the drawing D7.5. While the witness, who was an employee of appellant II, provided evidence of such a sale, it had to be kept in mind that considerable time had passed, such that the witness memory might well be unreliable. To conclude, it was not proven with the required standard of proof that an implant as depicted in the drawing had in fact been made publicly available. Consequently, the alleged prior use should not be accepted as prior art under Article 54(2) EPC.

Inventive step, Article 56 EPC

The subject matter of claim 1 differed from the implant of D7.5 not only in the threaded cortical portion, with the thread extending uninterrupted to at least part of

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the cancellous portion, but also in that the cortical portion had an axial length of equal to 3 mm or less than 3 mm. The term "cortical portion" referred to a structurally identifiable portion of the implant and could not be seen as a dynamically and functionally defined area of contact with the cortical bone layer, varying with the particular implant position.

In order to fall within the scope of the claim, the conical part of the D7.5 implant would need to be shortened and provided with a thread. This would thin out the walls of the socket, and either shorten its depth, or require a hole in the cancellous portion shaft. None of these measures would be taken into account by the skilled person because all of them were detrimental to the mechanical stability required for fixation of the abutment.

Moreover, D7.5 disclosed a plug-type implant to be used with a pre-drilled counter-sink hole. In use, further insertion of the implant was stopped by abutment of the cortical head in the couter-sink hole, the smooth outer surface of the conical portion being required in order to seal the implant in the bone and to minimize soft tissue invasion. The provision of threads would ruin the sealing effect, would be incompatible with the bore regimen foreseen and thus would not be performed by the person skilled in the art.

Furthermore the D7.5 implant comprised a considerable waist portion, such that it was not possible to extend the thread uninterrupted to the cancellous portion. To smoothen out the transition between the cortical and the cancellous portion would lead to an even longer conical part contrary to the axial length restriction defined in the claim. D1 and D10 showed a thread

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covering the entire cortical portion. If the entire cortical portion of the D7.5 implant was covered with the thread, the resulting threaded cortical portion would be longer than the upper limit of 3mm defined in the claim. Furthermore, D1 did not show any extension of the cortical thread onto the cancellous portion at all.

In fact, the correct technical problem to consider was to provide a smooth progression of the implant into the bore thanks to the uninterrupted extension of the thread from the cortical to at least part of the cancellous portion. None of the cited documents related to said problem.

Consequently, neither a combination of D7.5 with D8, D1 or D10, even in view of the general knowledge or of further documents D5 and D10, would lead the person skilled in the art to a screw implant as claimed. Claims 1 and 2 of the main request were thus inventive.

Reasons for the Decision

1. Admissibility

The appeals are admissible.

2. Admissibility of the new main request

As detailed in item 2.2 of the impugned decision, the opposition division had considered auxiliary requests 1-15 filed on 8 November 2011 admissible. The amendments in auxiliary requests 4 of said submission correspond to the amendments made at the end of

claims 1 and 2 of the present main request (which corresponds to the seventh auxiliary request filed with the statement of grounds of appeal). The further amendments in the independent claims of the present main request clarify that the cortical portion is arranged "above" the cancellous portion. An amendment aiming to clarify said issue had been presented during oral proceedings before the opposition division, but failed due to lack of clarity. The further amendments in the present main request are thus in reaction to the conclusion reached by the opposition division in the light of the discussion at the oral proceedings, that claim 1 included configurations where the cortical portion was located at the lower part of the implant (see item 2.3.2.3 of the impugned decision).

In view of the short time available during oral proceedings, it appears equitable to allow a reformulation of the amendment put forward in opposition proceedings, in particular because the substantive issue it aims to address remains unchanged. Consequently, the present main request is seen as an appropriate reaction to the course of the opposition proceedings, performed at an early stage of the appeal proceedings. Therefore, the Board admitted the new main request in accordance with Articles 12(1), (2) and (4) RPBA.

- 3. Article 100(c) and Article 123(2) EPC:
- 3.1 Firstly, the Board observes that independent claims 2 and 4 as originally filed (on which present independent claims 1 and 2 are based) already comprise a causal link between the axial length of the cortical portion and the confinement of said cortical portion to the cortical bone tissue layer (item 2.3.1 of the impugned

decision, see the term "such that" in claim 2 as originally filed, line 17-20 and in claim 4 as originally filed, lines 4 to 6). This causal link is also present in the first and second sentence of the disclosure on page 10, last paragraph. Furthermore, claims 11 and 12 as originally filed define that the length of the cortical portion is equal to 3 mm or less than 3 mm and are thus in agreement with the last sentence in page 10, last paragraph. As the causal link was disclosed for a cortical portion in general, it is also disclosed for the preferred sub-range. In particular in view of the claims as originally filed, the Board sees no reason to restrict the subject-matter to a cylindrical cancellous portion. Nor is it necessary to include a further functional limitation which the claims as filed did not have. Even if the restriction to a "flaring out cortical portion" was required for the technical effect of torque increase to take place, this appears to relate to a lack of clarity ("lack of essential feature") which was already present in the claims as granted and which is thus not objectionable in opposition appeal proceedings because Article 84 EPC is not a ground for opposition.

3.2 Secondly, while it is true that the word "above" is not literally disclosed on page 8, third paragraph, first sentence, still said passage discloses that "throughout the description and the claims, any reference to directional terms as "up" and "down" and related terms such as top, bottom, below etc. referring to the implant should be interpreted as "up" meaning towards the head end or trailing end, i.e. the coronal end of implant and "down" meaning towards the insertion end, i.e. the apical end of the implant." Whereas "up" and "top" are mentioned together with their respective opposite ("down" and "bottom"), the opposite of "below"

is not explicitly listed. Nevertheless, since the opposite of "below" is "above", the person skilled in the art clearly and unambiguously obtains the information that a particular portion located towards the trailing end of the implant in relation to a second portion can equivalently be defined as "above" said second portion. This spatial relationship between the cortical and the cancellous portion(s) is present in all embodiments. The current claims define the spatial relationship with respect to all the portions of the implant defined in the claims. A further restriction to "immediately above" is thus unnecessary. There is also no functional relationship between the relative spatial location of the respective portions and the increase in torque upon insertion of the implant. It may be true that an inward taper will not result in an increase in torque upon insertion. However, this is independent of the fact whether such an inwardly tapered portion is located more to the upper or to the lower end of the implant. Consequently, the amendment defining that the cortical portion is arranged "above" also does not warrant a restriction of the conical portion to conical portions with an increase in diameter towards the upper end. Finally, there is no indication, either in the disclosure of the application, or in the prior art to interpret the term "above" in the sense of an overlay structure provided on the implant.

Thirdly, a threading "extending uninterrupted over both the threaded surface of the cortical portion and at least part of the threaded surface of the cancellous portion" is disclosed on page 12, first paragraph as well as on page 16, lines 23 to 25 and page 21, lines 9, 10. Appellant II has objected that in the claims the term "threaded surface of the cancellous portion" (used in page 12, first paragraph) had been replaced by

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"cancellous portion" alone, which amounted to intermediate generalisation, in particular because also the two other passages (page 16, line 23-25 and page 21, lines 9,10) referred to embodiments having a cancellous portion with a second thread. However, the first threading is defined as "extending uninterrupted over at least a portion of the cancellous portion", such that the cancellous portion is inevitably threaded. A second thread on the cancellous portion may (see e.g. Figure 1, 2 of the application as filed) or may not be present (see e.g. Figure 6A, 6B of the application as filed).

- 3.4 Furthermore appellant II was of the opinion that the use of the undetermined article "a" in the term "provided with at least a first threading" implied that a further threading (in addition to the thread on the threaded cortical portion) needed to be present. If the same thread was meant, this should have been referred to by the determined article "the". However, strictly speaking the term "threading" does not have an antecedent even if a "conical outer surface being threaded" has been introduced. It is thus semantically correct to use the undetermined article. Furthermore, it would be illogical to refer to an additional threading by using the wording "a first threading". Indeed, the term "a first threading" simply refers to the very threading all embodiments have on the "outer surface being threaded". As discussed above such a threading is considered disclosed.
- 3.5 Consequently, the requirements of Article 123(2) EPC are fulfilled.
- 4. Article 84

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For the screw implant of the present invention, the term "above" is considered clear per se. In fact, the trailing end of a screw is commonly referred to as the "head" of the screw, a head being on the top or upper end of an entity. Paragraph [0028] of the description only confirms this interpretation. The person skilled in the art would not read the claim contrary to the common sense interpretation of the term "above" and against the explicit teaching in the description.

Moreover, the Board is of the opinion that the provision of the cutting recess does not qualify as an "interruption" of the thread. In accordance with paragraph [0044] of the description, a threading is to be understood as a "helical structure allowing the surface to function as a screw" including "a series of discontinuous protrusions", "subsequently following ribs" or a "conventional thread". Even with the cutting recess present, the thread shown in figure 7A functions as a screw, and thus qualifies as extending uninterrupted down to the plane P2.

Finally, as pointed out by appellant I, the objected passage in paragraph [0045] of the description is in support of dependent claim 10, i.e. in support of a facultative feature, so that no contradiction can be identified.

Consequently, the requirements of Article 84 EPC are fulfilled.

5. The alleged public prior use:

The Board shares the judgement of the opposition division that the witness testimony (see D7.6) provides convincing evidence for all of the screw implants

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depicted in D7.5 (reductions A-D) having been sold to several dental practitioners. There is no inconsistency in the testimony which would cast doubt on the accuracy of the witness memory. In fact, the different reductions A-D performed on the pencil drawing put the evidence credibly in a historical setting where CAD drawings were not yet readily available. The long time interval between the marketing of the product and the present proceedings, in combination with the business transfer between different legal entities, convincingly explains the lack of sales documentation.

As the claimed parameters can be readily determined on the implant itself, they are considered to have been made available to the public once the implant was sold.

Consequently the public prior use and in particular the implant shown in D7.5 is considered to belong to the state of the art in accordance with Article 54(2) EPC.

- 6. Inventive step, Article 56 EPC:
- 6.1 Closest prior art:

It is undisputed that D7.5 represents the closest prior art. The drawing shows:

A screw implant for insertion into a bore hole arranged in bone tissue, said implant having a cancellous portion (D7.5, drawing -A-, the threaded part) presenting an outer surface, and a cortical portion (the head of the screw) arranged above said cancellous portion, said cortical portion presenting a conical outer surface which has a conical taper ("2° REF.") such that said conical outer surface forms a non-zero angle (α) of less than 5° ("2° REF.") in relation to the outer surface of the cancellous portion.

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6.2 Distinguishing features:

- D7.5 does not clearly and unambiguously disclose the following distinguishing features:
- a) said conical outer surface being threaded for accomplishing engagement with the cortical bone tissue layer;
- b) the implant being provided with at least a first threading extending uninterrupted over the cortical portion and at least part of the cancellous portion; and
- c) the cortical portion having an axial length of equal to 3 mm or less than 3 mm, such that, when installed in the bore hole, the engagement of said cortical portion with the bone tissue will generally be confined to the cortical bone tissue layer.

Appellant II was of the opinion that feature c) was implicit for an odontology screw implant, because the thickness of the cortical bone tissue layer in odontology applications was around 0.5 to 1 mm to 3 mm (see paragraph [0026] of the patent specification), thus resulting in a cortical portion, i.e. in the portion actually engaging the cortical bone, of less or equal to 3 mm.

However, in the view of the Board, a "portion" of the implant cannot be understood as functionally defined by reference to the particular implantation performed. This would result in a different "cortical portion" not only for different implant positions (depending on the particular cortical bone height at the chosen

implantation site) but also for different implant insertion depths (with the "cortical portion" being more to the trailing end of the screw implant the deeper the implant is inserted into the bone). Instead, a "portion" of the screw implant needs to be characterized by structural features provided on the implant and thus identifiable on the implant itself. Such structural features could for example be a particular conical taper or a particular thread. Consequently, the term "cortical portion" is understood to relate to the head portion of the screw implant shown in D7.5, which is differentiated from the cancellous portion by its uniform 2° conicity and its unthreaded surface, and which is disclosed to have an axial length of 0.177 inches (4.5 mm). Feature c) is thus not clearly and unambiguously disclosed in D7.5.

6.3 Technical effect(s) and objective problem(s) to be solved:

With respect to feature a) above, appellant II submitted that the thread on the outer surface had the technical effect of engaging the cortical bone tissue, thus solving the problem to "provide stable primary fixation" (see paragraph [0014] of the patent, referred to as problem 1 in the following).

Additionally, with respect to items a) and b) above, the thread enabled proper load distribution to the surrounding bone tissue, thus solving the problem to "stimulate bone growth and inhibit marginal bone resorption" (see paragraphs [0014], [0025] and [0050] of the patent, referred to as problem 2 in the following).

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Appellant I on the other hand submitted that the uninterrupted extension of the thread had the technical effect of a smooth progression of the implant when entering the bone, thus solving the problem of facilitating implant insertion (see paragraph [0041], last sentence, referred to as problem 3 in the following).

With respect to item c), the axial length limitation for the cortical portion (in combination with the small conicity angle) had the technical effect of not compressing more tissue than necessary for having the desired increase in torque, thus solving the problem to keep compression of the cortical bone tissue within acceptable levels (referred to as problem 4 in the following, see paragraphs [0038] and [0039] of the description).

6.4 Would the claimed invention, starting from the closest prior art D7.5 have been obvious in view of any of the problems 1-4 identified above?

6.4.1 D7.5 + D8:

Document D8 addresses the problem of improving primary fixation (problem 1) in column 2, lines 45 to 47, and suggests as a solution to provide surface irregularities, in particular spiral grooves ("Schraubennuten") in the cortical bone contact part (column 3, lines 6-12; column 5, line 1-13, column 6, line 36-40; Figure 1). In view of the broad definition of the term "thread" in paragraph [0044] of the patent, an outer surface with such a spiral groove qualifies as "outer surface being threaded for accomplishing engagement with the cortical bone tissue layer". The person skilled in the art would thus be incited to

provide the D7.5 implant with such a surface irregularity on the cortical portion of the screw implant, i.e. on the portion which comes into contact with the cortical bone tissue layer. In view of the fact that the cortical bone in odontology applications has a height of only 0.5 to 1 to 3 mm (patent paragraph [0026]), that D8 explicitly suggest a contact portion height of 3 mm (D8, column 6, line 41-44), and having in mind that the head of the implanted D7.5 implant is only partially in contact with the cortical bone (see D7.4, Figures 1 and 2), the person skilled in the art would provide only that portion of the head of implant D7.5 with a thread, which - upon implantation - comes into contact with the cortical bone layer. This would result in the provision of a threaded cortical portion of 3 mm or less on the middle part of the head of implant D7.5. Said thread would form a structural feature, identifiable on the screw implant itself, defining a threaded (sub-)portion on the screw implant head. Said threaded (sub-portion) would qualify as "cortical portion having an axial length of equal to or less than 3 mm" as claimed in claim 1.

Due to the typical dimensions of threads used for engagement with the cortical bone ("microthreads", see e.g. D1, Figure 1, No. 9), the Board can see no technical difficulty in providing such a thread. In particular it would not require a considerable thinning of the walls of the screw socket. Also the provision of cutting recesses - should those be required - appears well within the capabilities of the person skilled in the art. At least the remaining upper and lower unthreaded parts of the cortical portion would still show the required sealing effect and prevent tissue invasion.

Consequently, a combination of the teachings of D7.5 and D8 would lead the skilled person to an implant having features a) and c). However, feature b) would still be missing, as the cortical thread would be restricted to the middle of the cortical portion and not extend uninterrupted over at least a part of the cancellous portion.

6.4.2 D7.5 + D8 + general knowledge

In the view of appellant II, it was merely an alternative to provide a single thread extending uninterrupted from the cortical portion to the cancellous portion, which the person skilled in the art would perform as a routine adaptation. In fact, it was simpler for producing the threaded implant, to craft the cancellous and the cortical thread "in one go", which would result in a thread extending uninterrupted from the cortical to the cancellous portion.

However, because the person skilled in the art would provide the thread only in the cortical bone contacting sub-portion of the implant, i.e. in the middle of the conical head as shown in D7.4, Figures 1 and 2, there would be no thread directly adjacent to the cancellous portion and thus no benefit in manufacturing the threads in a "single go". Furthermore, there is a considerable step in diameter ("waist portion") present between the cortical and the cancellous portion of the D7.5 implant. This step poses a hindrance to the provision of a thread extending uninterrupted. Even if - for the sake of the argument - it was accepted that the waist portion was nothing more than a milled clearance ("Freistich") required for tapping the cancellous thread, there is no reason to omit said

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clearance if the adjacent part of the cortical portion is not threaded.

On the other hand, if the person skilled in the art would extend the thread over the complete cortical portion of the D7.5 implant ("to be on the safe side", as put forward by appellant I), there might be a reason to omit such a milled clearance. However in said situation, the axial length of the threaded cortical portion identifiable by structural features on the implant itself would increase to more than 3 mm, contrary to the definition in the claim. To overcome this difference, the solution of a further, additional problem (problem 4) would be required, neither the problem nor its solution being obvious from the common general knowledge.

Consequently, the subject matter of claim 1 is not obvious over the combination of D7.5 and D8 and the general knowledge.

6.4.3 D7.5 + D8 + D10 or D7.5 + D8 + D5

It is true that documents D10 and D5 show a single thread extending uninterrupted from a cortical portion to a cancellous portion (D10, Figure 6; D5, Figure 1, portions 22 and 24).

However - as discussed in item 6.4.2 above- even if the teaching of documents D7.5 and D8 is combined, there is no reason to prolong the cortical thread down to the cancellous portion and to join the threads.

Even if one assumed that the person skilled in the art would look for a way to facilitate implant insertion (i.e. to solve problem 3) and would realize that D5 or

D10 provided a solution for said problem by providing a threading extending uninterrupted over the cortical portion and at least part of the cancellous portion resulting in a smooth progression of the implant, this would amount to the solution of a further partial problem (problem 3 as defined above), which only presents itself after the first problem (problem 1) has been solved. It thus cannot be seen as an independent partial problem, but would constitute a further consecutive development step, which requires the consultation of a further document, and which thus cannot be seen as obvious.

As already discussed above, a prolongation of the cortical thread down to the cancellous portion would again create a cortical portion longer than the 3 mm upper limit defined in the claims.

Moreover, D10 does not show a pronounced step in core diameter such that there is no guidance in said document how to proceed in case of the D7.5 implant, where such a step is present.

In D5, the transition between the cortical and the cancellous thread to which appellant II referred is in the distal part of the implant which again only shows a small change in core diameter. In the part analogous to the step in D7.5 (D5, No. 20 in Figure 1 or Figure 8), there is either no thread at all on the cortical portion (Figure 1), or the thread on at least part of the cancellous portion and the cortical thread do not extend uninterrupted into each other over the step in diameter (Figure 8).

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Consequently, even if the person skilled in the art consulted documents D5 and D10, their teaching would not make the subject matter of claim 1 obvious.

6.4.4 D7.5 + D1

Having regard to problem 2 as defined above, document D1 teaches that the provision of microthreads can solve the problem of bone resorption (D1, page 4, last paragraph). However, as disclosed in D1, page 3, last paragraph and in Figures 1, 2, said microthreads are provided on the entire conically flaring portion, but also limited to said portion. Consequently, even if the person skilled in the art would apply the teaching of document D1, this would not result in a thread extending uninterrupted from the conical cortical portion to the cancellous portion. Joining the cortical and the cancellous thread would meet the same obstacles as discussed above with respect to D8. Again, the cortical portion of D7.5 provided with the microthreads would have an axial length of more than 3 mm.

Thus, the subject matter of claim 1 is not obvious in view of a combination of documents D7.5 and D1, either.

6.4.5 D7.5 + D10

Also document D10 addresses problem 2 on page 2, second paragraph and page 3, second paragraph. It teaches that a thread having a continuously reducing lead will increase local intraosseous pressure which will stimulate bone ingrowth in accordance with Wolff's law. Figure 6 of D10 shows a subgingival odontology implant having such a thread extending uninterrupted from a conical portion to a cylindrical portion. However, providing said thread on the D7.5 implant faces again

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the same difficulties as discussed above with respect to D8. There is no guidance how the thread extending uninterrupted disclosed in D10 can be manufactured when a pronounced step in diameter is present between the cancellous and the cortical portion. Even if that specific obstacle was overcome, Figure 6 teaches to extend the thread up to the trailing end of the conical portion, such that an axial length of the conical portion of more than 3 mm would result.

Consequently, the subject matter of claim 1 is also not obvious in view of the combination of document D7.5 with document D10.

- 6.4.6 With regard to problem 4 defined above, none of the prior art documents relates to this problem and none shows the claimed solution, i.e. a combination of a small angle conicity with an axial length of the cortical portion of 3 mm or less. Thus the subjectmatter of claim 1 is equally non-obvious over prior art D7.5 in view of problem 4.
- 6.4.7 Independent claim 2 has not been challenged by appellant II. It is further restricted with respect to independent claim 1 by the provision of an upper conical cancellous portion located between a cylindrical cancellous portion and the conical cortical portion. In view of the argumentation with respect to claim 1 above, its subject-matter thus equally involves an inventive step.
- 7. To conclude, the Board is of the opinion that, taking into consideration the amendments made by appellant I during the proceedings, the patent and the invention to which it relates meet the requirements of the Convention.

The patent can thus be maintained as amended, provided that the conditions laid down in the implementing regulations are fulfilled.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the department of first instance with the order to maintain the patent as amended in the following version:
 - <u>Description:</u> columns 1 to 19 received during oral proceedings of 5 December 2013;
 - <u>Claims:</u> 1 to 28 received during oral proceedings of 5 December 2013;
 - <u>Drawings:</u> Figures 1A to 10 of the patent specification as granted.

The Registrar:

The Chairman:



V. Commare

T. Kriner

Decision electronically authenticated