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**Datasheet for the decision
of 13 November 2015**

Case Number: T 1826/11 - 3.2.02

Application Number: 04076440.9

Publication Number: 1459689

IPC: A61B17/70, A61B17/88

Language of the proceedings: EN

Title of invention:

System for introducing a material into a bone

Patent Proprietor:

Orthophoenix, LLC

Opponents:

Joline GmbH & Co. KG
Zwicker, Jörk

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 123(2), 123(3)
RPBA Art. 13

Keyword:

late-filed requests - admitted (yes)
Novelty (yes) - after amendment (auxiliary request 7)
inventive step (yes) - after amendment (auxiliary request 7)

Decisions cited:

Catchword:



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Chambres de recours**

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Case Number: T 1826/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 November 2015

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
14 June 2011 concerning maintenance of the
European Patent No. 1459689 in amended form.**

Composition of the Board:

Chairman M. Stern
Members: P. L. P. Weber
 L. Bühler

Summary of Facts and Submissions

- I. The appeals of the patentee and opponent 1 are against the decision of the opposition division, posted on 14 June 2011, finding that the patent as amended according to auxiliary request 5 then on file fulfilled the requirements of the EPC.

The notice of appeal of the patentee was filed on 24 August 2011 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 21 October 2011.

The notice of appeal of opponent 1 was filed on 19 August 2011 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 24 October 2011.

- II. Oral proceedings were held on 13 November 2015.

The appellant-patentee requested that the decision under appeal be set aside and the patent be maintained on the basis of:

- the main request filed during the oral proceedings of 13 November 2015, or
- the auxiliary request 1 filed on 13 October 2015, or, alternatively, that the appellant-opponent 1's appeal be dismissed (auxiliary request 2), or, alternatively, that the patent be maintained on the basis of:
 - the auxiliary requests 4 or 5 filed on 13 October 2015, or
 - the auxiliary request 6 filed during the oral proceedings of 13 November 2015, or,
 - the auxiliary request 7 filed on 13 October 2015.

The appellant-opponent 1 requested that the appellant-patentee's appeal be dismissed, the decision under appeal be set aside, and the European patent No. 1 459 689 be revoked.

The appellant-opponent 1 additionally requested that auxiliary requests 4 to 7 not be admitted into the proceedings.

Auxiliary requests 3 and 6 as filed with letter of 13 October 2015 were withdrawn during the oral proceedings.

As announced with letter of 20 October 2015, opponent 2 was not present at the oral proceedings. The Chairman noted that opponent 2 had been duly summoned to the oral proceedings, which were then continued in its absence in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

III. The following documents are cited in the present decision:

D2: US-A-5419765
D5: US-A-4576152
D11: WO-A-98/56301
D12: WO-A-96/39970

IV. The different versions of claim 1 read as follows.

Claim 1 according to the main request and according to auxiliary request 1 reads as follows:

"A system (10) for treating a human vertebral body comprising:

a cannula (30) whose interior provides a subcutaneous access path into the vertebral body;

a cavity forming instrument (76) sized and configured to be introduced through the cannula and to compress cancellous bone to form a cavity in the vertebral body;
and

an assembly for introducing a material (170) that sets to a hardened condition into the vertebral body comprising the cannula (30), characterized in that the assembly for introducing the material further comprises a tamping instrument (108) for advancement through the cannula, said tamping instrument comprising a body having a length and a terminus which, during advancement through the cannula, is operable to urge material residing in the cannula into the cavity formed in the vertebral body."

Claim 1 according to auxiliary request 2 reads as follows (amendments compared with claim 1 of the main request highlighted by the Board):

"A system (10) for treating a human vertebral body comprising:

a cannula (30) whose interior provides a subcutaneous access path into the vertebral body;

a cavity forming instrument (76) sized and configured to be introduced through the cannula and to compress cancellous bone to form a cavity in the vertebral body;
and

an assembly for introducing a material (170) that sets to a hardened condition into the vertebral body comprising the cannula (30), characterized in that the assembly for introducing the material further comprises a tamping instrument (108) for advancement through the cannula, said tamping instrument comprising a body made of a rigid material having a length and a terminus which, during advancement through the cannula, is operable to urge material residing in the cannula into the cavity formed in the vertebral body."

Claim 1 according to auxiliary request 4 reads as follows (amendments compared with claim 1 of the main request highlighted by the Board):

"A system (10) for treating a human vertebral body comprising:

a cannula (30) whose interior provides a subcutaneous access path into the vertebral body;

a cavity forming instrument (76) sized and configured to be introduced through the cannula and to compress cancellous bone to form a cavity in the vertebral body, wherein the cavity forming instrument (76) comprises an expandable structure (86); and

an assembly for introducing ~~a material (170) that sets to a hardened condition~~ bone cement into the vertebral body comprising the cannula (30), characterized in that the assembly for introducing ~~the material~~ bone cement further comprises a tamping instrument (108) for advancement through the cannula, said tamping instrument comprising a body made of a rigid material having a length and a terminus which, during advancement through the cannula, is operable to urge

~~material~~ bone cement residing in the cannula into the cavity formed in the vertebral body."

Claim 1 according to auxiliary request 5 reads as follows (amendments compared with claim 1 of the main request highlighted by the Board):

"A system (10) for treating a human vertebral body comprising:

a cannula (30) whose interior provides a subcutaneous access path into the vertebral body;

a cavity forming instrument (76) sized and configured to be introduced through the cannula and to compress cancellous bone to form a cavity in the vertebral body, wherein the cavity forming instrument (76) comprises an expandable structure (86); and

an assembly for introducing ~~a material (170) that sets to a hardened condition~~ bone cement into the vertebral body comprising the cannula (30), characterized in that the assembly for introducing ~~the material~~ bone cement further comprises a tamping instrument (108) for advancement through the cannula, said tamping instrument being made of a rigid inert metal material and comprising a body having a length and a terminus which, during advancement through the cannula, is operable to urge ~~material~~ bone cement residing in the cannula into the cavity formed in the vertebral body."

Claim 1 according to auxiliary request 6 reads as follows (amendments compared with claim 1 of the main request highlighted by the Board):

"A system (10) for treating a human vertebral body comprising:

a cannula (30) having a length, whose interior provides a subcutaneous access path into the vertebral body;

a cavity forming instrument (76) sized and configured to be introduced through the cannula and to compress cancellous bone to form a cavity in the vertebral body wherein the cavity forming instrument (76) comprises an expandable structure (86); and

an assembly for introducing ~~a material (170) that sets to a hardened condition~~ bone cement into the vertebral body comprising the cannula (30), characterized in that the assembly for introducing ~~the material~~ bone cement further comprises a tamping instrument (108) for advancement through the cannula, said tamping instrument being made of a rigid inert metal material and comprising a body having a length and a terminus which, during advancement through the cannula, is operable to urge material bone cement residing in the cannula into the cavity formed in the vertebral body, wherein the length of the tamping instrument exceeds the length of the cannula, thereby allowing the distal end of the tamping instrument when advanced through the cannula to extend beyond the distal end of the cannula."

Claim 1 according to auxiliary request 7 reads as follows (amendments compared with claim 1 of the main request highlighted by the Board):

"A system (10) for treating a human vertebral body comprising:

a cannula (30) having a length, whose interior provides a subcutaneous access path into the vertebral body;

a cavity forming instrument (76) sized and configured to be introduced through the cannula and to compress cancellous bone to form a cavity in the vertebral body wherein the cavity forming instrument (76) comprises an expandable structure (86); and

an assembly for introducing ~~a material (170) that sets to a hardened condition~~ bone cement into the vertebral body comprising the cannula (30), characterized in that the assembly for introducing ~~the material~~ bone cement further comprises a tamping instrument (108) for advancement through the cannula, said tamping instrument being made of a rigid inert metal material and comprising a body having a length and a terminus which, during advancement through the cannula, is operable to urge material bone cement residing in the cannula into the cavity formed in the vertebral body, wherein the length of the tamping instrument exceeds the length of the cannula and wherein the body includes a set point marking spaced from the terminus at a distance equal to the length of the cannula."

- V. The arguments of the appellant-opponent 1 relevant for the decision are summarised as follows:

Admissibility of the main request and auxiliary requests 4, 5 and 7

Since the start of the opposition proceedings, the appellant-patentee had had sufficient opportunity to file auxiliary requests, and had already done so several times, so these requests should not be

admitted. Such repeated filing of amended requests had to be considered as close to an abuse of procedure.

Main request, auxiliary request 1

Novelty over D11

The subject-matter of claim 1 was not novel over D11 since the tamping action mentioned in this document necessarily implied the use of a tamping instrument having a length and a terminus. The nature of the material to be pushed was not relevant since the material was not claimed.

Auxiliary requests 2 and 4

Novelty over D11

Any instrument suitable for tamping necessarily had a given rigidity. Nothing more was claimed. The disclosure of an expandable structure, in particular in Figures 5J and 5K of D11, was not in doubt. On page 25 it was explicitly mentioned that bone cement was introduced into the formed cavity.

For these reasons the subject-matter of claim 1 of auxiliary requests 2 and 4 also lacked novelty over D11.

Auxiliary request 5

The use of an inert material, in particular an inert metal, was well-known for medical instruments coming into contact with a patient's body. This was moreover confirmed in D12 in relation to the state of the art described on page 1. Therefore it appeared to be

obvious to use an inert metal for the pin described on page 40, last paragraph of D12. The subject-matter of claim 1 was therefore not inventive.

Auxiliary request 6

Admissibility

For the same reasons as already mentioned for the other requests, and since this request had been filed at the very late stage of the oral proceedings, it should not to be admitted.

Inventive step

The feature relating to an inert metal was not inventive for the same reasons as indicated for claim 1 of auxiliary request 5. The tamping instrument (long pin) mentioned in D12 had also to be longer than the cannula, if only for the surgeon to be able to hold it. Even if the Board considered that it was the active part of the tamping instrument which had to be longer than the cannula, it was to be noted that the claim did not specify how much longer, so that even a very small extension beyond the distal end of the cannula, for instance to make sure that all the material in the cannula could be pushed out of it, would fall under the wording of the claim. For that latter reason, such a small extension would also be obvious. In any case, D5 suggested the use of a longer piston in a cement injection device.

Therefore, the subject-matter of claim 1 was not inventive.

Auxiliary request 7

There was no combinatory effect of using a set point marking and a tamping instrument which was longer than the cannula. The reason why the longer tamping instrument was not inventive had already been explained in relation to auxiliary request 6, and the use of markings to indicate how far an inner part was introduced into an outer part was a straightforward matter, and suggested in any case by document D2 which showed a plunger having markings to indicate how far it had been introduced into a sheath.

Thus, the subject-matter of claim 1 was not inventive.

VI. The arguments of the appellant-patentee relevant for the decision are summarised as follows:

Admissibility of the main request and auxiliary requests 4, 5 and 7

In the main request only dependent claims had been deleted. The auxiliary requests had been filed with the statement setting out the grounds of appeal and corresponded to those filed during the opposition proceedings. Hence, these requests had to be admitted.

Main request, auxiliary request 1

Novelty over D11

In the two relevant passages of D11 cited by the appellant-opponent 1, no tamping instrument according to the definition of claim 1 was directly and unambiguously disclosed. Such a tamping action was possible using something other than a tamping instrument having a length and a terminus as according

to claim 1, e.g. a balloon, or air pressure. The passage on page 82 specifically dealt with materials which did not flow, whereas the claim, by mentioning that the assembly was for introducing material which set to a hardened condition, did clearly require a tamping instrument suitable for pushing bone cement.

Therefore the subject-matter of claim 1 was novel.

Auxiliary requests 2 and 4

Novelty over D11

Nothing was said in this document either about the rigidity of a possible instrument to be used for tamping, or that the long pin was in any way suitable for use with bone cement, so the subject-matter of claim 1 of auxiliary requests 2 and 4 was novel.

Auxiliary request 5

It was neither necessary nor obvious to use an inert metal for the pin described on page 40 of D12. Inert plastics would be the more obvious material to be used, e.g. as a disposable pin. The subject-matter of claim 1 according to auxiliary request 5 was therefore inventive.

Auxiliary request 6

Admissibility

Claim 1 merely clarified the wording of claim 1 according to auxiliary request 6 filed on 13 October 2015 (which had been admitted into the proceedings together with auxiliary requests 4, 5 and 7 before it

had been withdrawn). It made it clear that the tamping instrument could extend beyond the distal end of the cannula. This corresponded to the interpretation of the last feature of claim 1 discussed in the last written submission of the appellant-patentee.

Therefore this request should be admitted into the proceedings.

Inventive step

The additional wording in claim 1 indicated that the tamping instrument was longer than the cannula and could therefore extend into the formed cavity. Such a possible extension of the tamping instrument into the cavity made no sense in relation to solid non-flowing materials as mentioned in relation to the use of the long pin on page 40 of D12.

D5 was not relevant in the context of the treatment of a vertebra because it concerned different orthopaedic operations requiring larger quantities of bone cement.

Therefore, the subject-matter of claim 1 according to auxiliary request 6 was inventive.

Auxiliary request 7

There was in fact a combinatory effect between the feature of the set point marking and the feature of the tamping instrument being longer than the length of the cannula, namely that once the tamping instrument extended beyond the distal end of the cannula, the emptying phase of the cannula ended and the compacting phase began. This set point marking was necessary

because the intention was to go further into the cavity after passing the set point marking.

Since a compaction of the non-flowing material had no technical meaning, there was no realistic objective problem starting from D12 which would lead the person skilled in the art to the subject-matter of claim 1.

D2 was not relevant in this context because it was about delivering a medical substance to an injured tissue to be treated, and not about delivering bone cement to a vertebra. Moreover, there was no marking defining the length of the cannula on the plunger, since the end of the movement of the plunger was defined by the thumb rest at the distal end of the plunger.

Reasons for the Decision

1. The appeals are admissible.
2. The invention is about a set of instruments, claimed as a "system" for treating cancellous bone in a vertebra. The instruments allow subcutaneous access to the vertebra to be treated, creating a cavity in the cancellous bone of the vertebra and injecting a material into the formed cavity which hardens there to replace lost bone tissue. The set of instruments includes a tamping instrument allowing the tamping of the bone cement inside the formed cavity.
3. Admissibility of the main request and of auxiliary requests 4, 5 and 7

The appellant-opponent 1 considered that these requests should not be admitted into the proceedings because

since the start of the opposition proceedings the appellant-patentee had had sufficient opportunity to file auxiliary requests, and had already done so several times. Such repeated filing of amended requests came close to an abuse of procedure.

Claim 1 of the main request, which was filed at the beginning of the oral proceedings, is identical to that of the former main request. In the present main request only some dependent claims were deleted. Auxiliary requests 4, 5 and 7, filed with letter of 13 October 2015, all correspond to auxiliary requests already filed in the first-instance proceedings, and with the statement setting out the grounds of appeal, as fall-back positions. The Board therefore does not see a valid reason for not admitting them, let alone for considering their filing to be an abuse. A patent-proprietor must have some latitude to adapt its requests to the state of the file, and in the present case, the appellant-opponent 1 cannot be surprised by any new feature not present in the former requests.

Therefore, the Board decided to admit these requests into the proceedings pursuant to Article 13(1) and (3) RPBA.

4. Main request

Novelty over D11

It is not disputed that the priority of the patent in suit is valid, so that D11 is a document according to Article 54(3) EPC.

It is also accepted among the parties that D11 discloses a similar set of instruments as that claimed

in claim 1, with the only disputed aspect being whether it discloses or not a tamping instrument as required by claim 1. It is further accepted that there is no explicit disclosure of such an instrument.

Two passages of D11 are cited by the appellant-opponent 1.

Page 26, lines 22 to 29: *"Upon removing the injector tube 92 from the outer guide sheath 72, the physician may, if necessary, tamp residual filling material 96 from the distal end 74 of the outer guide sheath 72 into the cavity 84."*

Page 82, lines 30 to 35: *"Biomaterials which do not flow into the formed cavity, like hydroxyapatite granules or bone mineral matrix, can be pushed down a tube with a long pin whose diameter is slightly more narrow than the inner-diameter of the outer guide sheath, using the minimally-invasive procedure."*

The appellant-patentee considered that no tamping instrument according to the definition of claim 1 was directly and unambiguously disclosed by the two passages cited above. Such a tamping action could be done with something other than a tamping instrument having a length and a terminus according to claim 1, e.g. a balloon, or air pressure. In addition, the passage on page 82 specifically dealt with materials which did not flow, whereas the claim, by mentioning that the assembly was for introducing material which set to a hardened condition, clearly required a tamping instrument suitable for pushing bone. In this context it was important to note that a pin used for dry material was not automatically suitable for use with

bone cement, in view of the possible chemical incompatibilities.

The Board does not agree. As mentioned in the first passage cited above, a guide sheath 72 is disclosed through which a cement injection nozzle is guided (see page 25, lines 20 to 29), and it is indicated that the physician may tamp residual filling material 96 from the distal end 74 of the outer guide sheath 72 into the cavity 84. The Board consequently considers that it is implicit that this tamping function can only be carried out by a body having a length and a terminus, and being long enough to reach the distal end of the guide sheath on the one side and to be held by the surgeon on the other side. It is also self-evident that this body must be compatible with bone cement. Nothing more is defined in claim 1.

It follows that the subject-matter of claim 1 according to the main request is not novel over D11, so the requirements of Article 54 EPC are not fulfilled.

5. Auxiliary request 1

Novelty over D11

The wording of claim 1 according to auxiliary request 1 is identical to that of claim 1 of the main request, so its subject-matter is not novel over D11 for the same reasons.

6. Auxiliary request 2

Novelty over D11

According to claim 1 of auxiliary request 2, the body of the tamping instrument should be made of a rigid material.

In the Board's view, the meaning of this feature is that the body of the tamping instrument should be rigid enough to allow tamping. No other meaning is apparent in the context of the patent in suit. It follows that this feature is also anticipated by D11. Indeed, the cited passage specifically states that the "*physician may ... tamp residual filling material...*" (underlining added). In the Board's opinion this means nothing more than that the body of the tamping instrument must have the necessary rigidity to be able to fulfil the desired tamping function.

Therefore the subject-matter of claim 1 according to auxiliary request 2 also lacks novelty over D11, so the requirements of Article 54 EPC are not fulfilled.

7. Auxiliary request 4

Novelty over D11

According to claim 1 of auxiliary request 4, the cavity-forming instrument comprises an expandable structure, and the material introduced into the cavity should be bone cement instead of more generally any material which sets to a hardened condition. The latter feature means that the tamping instrument must be specifically suitable to be used with bone cement.

As already mentioned above, D11 discloses on page 25, lines 23 to 26, bone cement (methylemethacrylate cement) as a material to be introduced into the cavity. Hence, the tamping instrument (implicitly) disclosed on

page 26, lines 22 to 29 must also be suitable for use with bone cement. The feature of the expandable structure is also anticipated by D11, as can be seen in Figures 5J and 5K, and as is explained on page 24, lines 9 to 11: "*Expansion of the wall 58 enlarges the body 56 and compacts cancellous bone 32 within the interior volume 30.*"

It follows that the subject-matter of claim 1 according to auxiliary request 4 is also anticipated by D11, so the requirements of Article 54 EPC are not fulfilled.

8. Auxiliary request 5

Claim 1 according to auxiliary request 5 additionally requires the tamping instrument to be made of an inert metal material.

8.1 Novelty over D11 and D12

No material for the tamping instrument is mentioned in D11, so the subject-matter of claim 1 according to auxiliary request 5 is novel over D11.

The same holds true for D12. In the paragraph at the end of page 40 (which resembles the second passage of D11 quoted above, i.e. last paragraph of page 82), it is indicated that a long pin is used. It is however not said to be made of an inert metal. Moreover, the passage on page 1, lines 29 to 32 of D12, which mentions that standard tools are usually made of metal, is a statement relating to the tools of the prior art, not to the pin of page 40.

Therefore, the requirements of Article 54 EPC are fulfilled.

8.2 Inventive step

D11 being prior art under Article 54(3) EPC, it is not to be considered for inventive-step examination.

Starting from D12, it is considered that the subject-matter of claim 1 according to auxiliary request 5 is not inventive.

It is well known in the medical field that instruments coming into contact with the patient's body have to be sterile and inert in the sense that they should not provoke undesirable chemical or allergical reactions, or lead to infections. Inert metals belong to the most commonly used materials in this context, as is confirmed on page 1, lines 29 to 32, where it is indicated that standard tools are usually made of metal. It follows that it is obvious to use a pin made of an inert metal for pushing the materials mentioned on page 40, last paragraph, down the tube.

The argument of the patentee that it would be obvious to use an inert plastic material but not an inert metal is not convincing because both types of materials are generally employed for the desired purpose, as indicated in D12, page 1, lines 29 to 32.

Since the last paragraph of page 40 of D12 specifically indicates that the diameter of the long pin is slightly narrower than the inner diameter of the outer guide sheath in which it is meant to be used, the Board considers that the disclosed pin is also suitable for pushing bone cement out of the guide sheath, and not just the non-flowing materials mentioned in that paragraph.

It follows that the subject-matter of claim 1 according to auxiliary request 5 is not inventive, so the requirements of Article 56 EPC are not fulfilled.

9. Auxiliary request 6

9.1 Admissibility

Auxiliary request 6 is based on auxiliary request 6 as filed with letter of 13 October 2015, to which the following expression has been added: "*...thereby allowing the distal end of the tamping instrument when advanced through the cannula to extend beyond the distal end of the cannula.*" In the oral proceedings, auxiliary request 6 as filed with letter of 13 October 2015 was considered admissible for the reasons given above for auxiliary requests 4, 5 and 7 filed with the same letter. During the discussion in the oral proceedings the appellant-patentee explained that the wording "*wherein the length of the tamping instrument exceeds the length of the cannula*" did not quite reflect what the it had intended to express, namely that the distal end of the tamping instrument was able to extend beyond the distal end of the cannula into the cavity. This interpretation of this feature was already addressed in the submission of the appellant-patentee of 13 October 2015.

For this reason, even though the appellant-opponent 1 considered that this request should not be admitted into the proceedings, the Board saw no reason not to admit it. It merely provides a written clarification of the claim in order to bring it into line with the reading of the feature the appellant-patentee had already expressed in its earlier written submissions.

It follows that neither the other party nor the Board was surprised by any new concept or feature.

Auxiliary request 6 is therefore admitted into the proceedings pursuant to Article 13(1) and (3) RPBA.

9.2 Novelty over D11 and D12

Insofar as claim 1 also comprises the feature that the material of the tamping instrument is an inert metal, the same reasoning as for claim 1 of auxiliary request 5 applies, so the subject-matter of claim 1 according to auxiliary request 6 is novel at least for the same reason.

Hence, the requirements of Article 54 EPC are fulfilled.

9.3 Inventive step

The Board considers, however, that the subject-matter of claim 1 according to auxiliary request 6 is not inventive starting from D12.

In the Board's judgement, there is no synergistic effect between the use of an inert metal for the tamping instrument and its length allowing extension beyond the distal end of the cannula. The Board regards the use of an inert metal for the instrument as not inventive for the same reason as for claim 1 according to auxiliary request 5.

According to the appellant-patentee, the second differentiating feature defined the tamping instrument as being long enough to extend from the distal end of the cannula into the cavity made in the vertebra in

order to be able to tamp the bone cement inside that cavity.

In the Board's opinion, however, the wording of the claim does not define (even implicitly) how far beyond the distal end of the cannula the tamping instrument is able to extend. It follows that also a rather small extension beyond the distal end of the cannula would fall under the wording of the claim.

The Board considers that also when using the long pin mentioned in D12 to push non-flowing material into the formed cavity, the physician would be interested in making sure that all the material in the cannula has left it (and hence has been introduced into the cavity). One obvious way to achieve this is to devise the tamping instrument so that it extends slightly beyond the cannula.

For this reason the Board considers that the subject-matter of claim 1 is not inventive when starting from D12.

Therefore, the requirements of Article 56 EPC are not fulfilled.

10. Auxiliary request 7

In comparison to claim 1 according to auxiliary request 5, claim 1 according to auxiliary request 7 additionally comprises the features that the length of the tamping instrument exceeds the length of the cannula and that the body of the tamping instrument includes a set point marking spaced from the terminus at a distance equal to the length of the cannula.

- 10.1 Support for this feature is found on page 23, line 20 to page 24, line 7 and Figure 5 of the application as filed, so the requirements of Article 123(2) EPC are fulfilled.
- 10.2 Compared with claim 1 of the patent as granted, these are additional features which limit the scope of protection. Therefore, the requirements of Article 123(3) EPC are also fulfilled.
- 10.3 Insofar as the subject-matter of claim 1 according to this request at least comprises the feature that the material of the tamping instrument is an inert metal, it is novel over D11 and D12, so the requirements of Article 54 EPC are fulfilled.

The patent as whole discloses the concept of having a tamping instrument which can be introduced into the formed cavity, as is for instance visible in Figure 31 and explained in paragraphs [0065], [0066] and [0109], whereby markings on the tamping instrument (see Figure 5) help in positioning it. It appears therefore that the patent as a whole teaches to use a tamping instrument which is longer than the cannula so as to be able to introduce this tamping instrument into the formed cavity in order to uniformly distribute and compact the bone cement (see e.g. paragraph [0109]) without the application of undue pressure, and whereby the set point marking on the tamping instrument helps the surgeon to know when it reaches the distal end of the cannula or, in other words, when the emptying phase of the cannula ends and the tamping phase may begin (e.g. in paragraph [0065]: *"Like the nozzle 106, the markings 122 on the tamping instrument 108 includes a set point 178, which indicates when the distal end of the tamping instrument 108 aligns with the distal end*

36 of the cannula instrument 30.”), or how far beyond the distal end of the cannula the instrument extends (see e.g. in paragraph [0065]: “The physician is thereby able to tell at a glance the location of the end of the tamping instrument 108, in terms of how far beyond or short of the distal end 36 of the cannula instrument 30 it is.”).

In the Board’s opinion, taking account of the teaching of the patent mentioned above, this capability of the tamping instrument to extend beyond the distal end of the cannula into the formed bone cavity is expressed in claim 1 by the combination of the feature that the tamping instrument should be longer than the cannula with the feature of the set point marking (e.g. instead of a stop) in order to indicate when the distal end of the cannula has been reached.

No such combination of features is disclosed in D12.

- 10.4 The ability of the tamping instrument to advance into the formed cavity has the advantage of allowing the physician to tamp the bone cement within the cavity in order to obtain a more uniform distribution or compaction of the bone cement (see in paragraph [0057]: “The group 18 includes instruments 104,106, and 108 which serve to convey and compact a selected material inside the cavity formed by the structure 86.”; in paragraph [0066]: “The tamping instrument 108 also compacts the material uniformly within the cavity, again without undue pressure.”; in paragraph [0109]: “As Figs. 30 and 31 show, advancement of the tamping instrument 108 displaces progressively more of the residual material 170 from the cannula instrument 30, forcing it into the cavity 168. The flow of material 170 into the cavity 168, propelled by the advancement

of the tamping instrument 108 in the cannula instrument 30, serves to uniformly distribute and compact the material 170 inside the cavity 168, without the application of undue pressure.").

- 10.5 Starting from the embodiment comprising a long pin as described in D12 on page 40, last paragraph, the Board does not see any obvious reason why the person skilled in the art would wish to compress the dry filling material used in D12. Consequently, there is no realistic objective problem that would lead the person skilled in the art to devise a longer pin with a set point marking as claimed in order to reach the interior of the formed bone cavity.

The appellant-opponent 1 considered that a marking on the tamping instrument was an obvious measure for the person skilled in the art to know when the distal end of the tamping instrument was aligned with the distal end of the cannula. It cited D2 as an example of a medicine injection device with markings on its injection plunger (page 6, lines 22 to 27 and 58 to 64).

In the Board's view, D2 is not relevant as it does not concern the injection of bone cement into either a human vertebral body to be repaired or into any other human bone, and consequently does not teach the person skilled in the art any advantage of using a longer pin when repairing a human vertebral body. Moreover, that document gives no apparent reason why the person skilled in the art would wish to push the plunger beyond the distal end of the sheath. On the contrary, the presence of a thumb rest which serves as an abutment rather teaches the opposite. The Board accepts that, in general, markings are often used to indicate

an instrument insertion distance useful for the physician. However, as indicated above, the feature of the set point marking is not to be read in isolation but in combination with the other features of the claim, specifically the feature that the tamping instrument is longer than the cannula. As explained above, when so read the claim requires the tamping instrument to be able to extend beyond the distal end of the cannula (i.e. into the formed cavity), whereby the mark helps the physician to know where the distal end of the tamping instrument is positioned and, hence, when the tamping may begin. The feature of the set point marking also has the additional advantage of possibly reducing X-ray imaging for visualising the position of the distal end of the tamping instrument.

Therefore, the Board considers that the requirements of Article 56 EPC 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 with the following claims and a description to be adapted thereto:

Claims 1 to 7 filed as auxiliary request 7 with letter dated 13 October 2015.

The Registrar:

The Chairman:



D. Hampe

M. Stern

Decision electronically authenticated