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Datasheet for the decision of 2 March 2017

Case Number: T 1424/12 - 3.2.02

Application Number: 07397017.0

Publication Number: 1864616

IPC: A61B17/04, A61B17/68

Language of the proceedings: EN

Title of invention:
A bone fixation device

Patent Proprietor:
BIORETEC OY

Opponent:
Merete Medical GmbH

Headword:

Relevant legal provisions:
EPC Art. 56, 84, 123(2)

Keyword:
Inventive step - (yes) - selection of closest prior art
Claims - clarity (yes)
Amendments - added subject-matter (no)

Decisions cited:

Catchword:

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Case Number: T 1424/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 2 March 2017

Appellant: (Opponent)	Merete Medical GmbH Alt-Lankwitz 102 12247 Berlin (DE)
Representative:	Lusuardi, Werther Dr. Lusuardi AG Kreuzbühlstrasse 8 8008 Zürich (CH)
Respondent: (Patent Proprietor)	BIORETEC OY Hermiankatu 22 33720 Tampere (FI)
Representative:	Berggren Oy, Tampere Visiokatu 1 33720 Tampere (FI)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 11 May 2012 concerning the maintenance of European patent No. 1864616 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	P. L. P. Weber

Summary of Facts and Submissions

I. The opponent has appealed the Opposition Division's decision, dispatched on 11 May 2012, that European patent No. 1 864 616 as amended in accordance with the main request could be maintained.

II. The notice of appeal was received on 21 June 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 16 August 2012.

III. The respondent replied to the statement of grounds by letter dated 2 January 2013.

IV. The appellant filed further submissions with letter dated 2 April 2013.

V. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 6 December 2016.

VI. The appellant and the respondent filed further submissions with letters dated 25 January 2017 and 1 February 2017 respectively.

VII. In particular, the appellant argued that the request found allowable by the Opposition Division in the impugned decision should not have been admitted into the proceedings under Rules 116 and 137(5) EPC, since it had been filed late and related to unsearched subject-matter. Additionally, the subject-matter of claim 1 of that request did not comply with Article 123(2) EPC, since the application as originally filed provided no basis for "deformable ridges", a "preform having a longitudinal axis" and a step of "cutting and

forming the billet". Moreover, the subject-matter of claim 1 contravened Article 84 EPC, lacked novelty and was not inventive.

VIII. Oral proceedings took place on 2 March 2017.

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

The respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the first to fourth auxiliary requests, all filed with letter dated 1 February 2017.

IX. The following documents are mentioned in the present decision:

D5: DE-A-39 19 900;
D7: US-B-6,551,343;
D11: EP-A-0 321 176.

X. Claim 1 of the request found allowable by the Opposition Division reads as follows:

"A method for producing a bioabsorbable osteosynthesis fixation device for the fixation of bone fractures or osteotomies, the fixation device comprising a tip (2), a shaft (4) and a head (3), the shaft (4) having a longitudinal axis (L), a nominal diameter (Dnom) and a maximum diameter (Dmax), the periphery of the shaft (4) comprising deformable ridges (6) capable of deforming to contract the diameter of the fixation device and said ridges extending in a longitudinal direction forming an angle with the longitudinal axis of the shaft, the angle being between -45° and 45°, and the

maximum diameter (Dmax) of the shaft (4) exceeding the nominal diameter (Dnom) of the shaft (4), and wherein the deformable ridges are able to deform for contracting a diameter of the fixation device at locations of the deformable ridges, the method comprising:
melting and cooling a bioabsorbable polymer raw material so as to form an amorphous or partially crystalline preform having a longitudinal axis;
molecularily orienting the preform through a drawing die at a temperature which is above the glass transition temperature and below the melting temperature of the bioabsorbable polymer raw material of the preform wherein the inner surface of the die comprises grooves and ridges so as to form a billet comprising longitudinal ridges and grooves on the surface;
cooling the billet under stress to the room temperature; and
cutting and forming the billet for providing a device comprising the tip, the head and the shaft."

Claims 2 and 3 are dependent claims.

XI. The appellant's arguments may be summarised as follows:

During the oral proceedings the appellant declared that it did not wish to maintain its objections to the admittance into the proceedings of the request found allowable by the Opposition Division. Moreover, it withdrew all objections of lack of novelty against the subject-matter of claim 1 of that request.

(a) *Extension of subject-matter - Article 123(2) EPC*

However, the subject-matter of claim 1 of the request found allowable by the Opposition Division did not comply with Article 123(2) EPC. In the oral proceedings, the appellant declared that its objections under that Article were limited to the features of the "deformable ridges" and the step of "cutting and forming the billet".

More particularly, it had to be considered that claim 1 defined a manufacturing method. Paragraphs [0011] and [0048] of the original application as published, which hinted at a certain deformability of an osteosynthesis fixation device, did not concern any manufacturing method. Only paragraphs [0020] to [0031] of the original application disclosed a manufacturing method. Those paragraphs did not disclose the production of deformable ridges. Moreover, paragraph [0048] disclosed a deformability of the ridges of the fixation device dependent on specific conditions possibly encountered in the performance of a surgical procedure. Extracting merely the general feature of "deformable ridges" constituted a non-allowable generalisation.

As regards the method step of "cutting and forming" the billet, paragraph [0031] of the original application presented "cutting" and "forming" of a billet as alternatives. The reference in that paragraph to "combinations" of further processing methods of the billet had to be interpreted in the context of patent drafting techniques. Such combinations were actually not disclosed to the person skilled in the art. It followed that there

was no disclosure for a manufacturing method including both cutting and forming of the billet as claimed.

(b) *Clarity and support in the description - Article 84 EPC*

Claim 1 contravened Article 84 EPC too. The non-compliance concerned the expressions "deformable ridges", "contracting a diameter of the fixation device", "melting and cooling", "amorphous or partially crystalline preform" and "bioabsorbable polymer raw material".

It was unclear how and when a ridge was "deformable", since the deformability of an element depended on several parameters. Even a steel ball could deform if a sufficiently high force was applied to it. In paragraph [0049] the patent as granted presented two different conditions of use of a fixation device. When the fixation device was inserted in a "substantially hard and inflexible" bone the ridges were deformable, while when the fixation device was inserted in a "substantially soft and brittle" bone they were not. Moreover, the claimed method for manufacturing the fixation device did not comprise any specific step aimed at obtaining the deformability of the ridges. In particular, molecularly orienting the preform could not lead to the desired deformability, since it was known that a molecular orientation increased the rigidity of a structure. The skilled person, even with the help of the description, could therefore not arrive at a clear interpretation of the expression "deformable ridges".

It was also unclear what was meant by the expression "contracting a diameter of the fixation device". In the part preceding it, the claim defined a "nominal diameter" and a "maximum diameter". Paragraph [0050] and figure 16 of the patent as granted further referred to a "minimum diameter". The skilled person would therefore not know whether "contracting a diameter of the fixation device" referred to the nominal diameter, the maximum diameter, the minimum diameter or even a further diameter of the fixation device.

The method step of "melting and cooling" the polymer to obtain a preform was contradictory. It was not understandable how a polymer could be melted and cooled at the same time. Paragraph [0026] of the patent as granted, referred to by the respondent for an interpretation of that step, was not relevant in that respect, since it described a specific continuous process with several features not present in claim 1. Moreover, the claim defined a further cooling step, so that it was not clear how, when and at which temperature the respective cooling steps took place.

It was not understandable how, with the same manufacturing method, both an "amorphous" and a "partially crystalline" preform could be obtained. The result of the manufacturing method was unpredictable. The respondent itself had conceded that the manufacturing method depended on several parameters, to be adjusted considering the properties of the particular polymer employed. However, due to the large variety of polymers encompassed in the claim and to their different chemical properties, the skilled person would not

know to which manufacturing method the claim was limited.

Claim 1 was directed to a manufacturing method employing a generally defined "bioabsorbable polymer raw material". It was known from the prior art that this definition included a large number of different materials possibly having very different chemical properties. However, the patent as granted disclosed the use of only one of such materials in paragraph [0057], concerning the single example described. It followed that the subject-matter of claim 1 was not supported by the description over its whole scope.

(c) Inventive step - Article 56 EPC

For assessing whether the subject-matter of claim 1 involved an inventive step according to the problem-solution approach, any of D5, D7 and D11 could be regarded as the closest prior art.

D5 concerned a bone implant identical to the fixing device manufactured by the method claimed. Although it did not disclose any method for manufacturing such an implant, it constituted a promising starting point towards the invention in the light of the technical problem of providing a suitable method for manufacturing the bone implant.

Both D7 and D11 disclosed a method for manufacturing an implant. D11 disclosed some of the claimed features in more detail, whereas D7 focused on other important aspects. D7 and D11 could therefore be considered as equally promising starting points.

Starting from D11 as the closest prior art, the method steps of the manufacturing method defined in claim 1 were all known from this document. Even assuming that some were not, the skilled person would arrive at them on the basis of D7, which, in particular, showed ridges of a surgical implant in figures 4 and 5. It was obvious for the skilled person to use the manufacturing method disclosed in D11 to obtain the particular fixation device mentioned in claim 1, since that device was known as such. Based on the fact that in the application as originally filed no manufacturing method was claimed, one could conclude that the respondent itself was aware that manufacturing the fixation device according to claim 1 could not amount to an invention. Even paragraph [0025] of the patent as granted disclosed the claimed manufacturing method as a typical method for obtaining the fixation device. For all these reasons it was not even possible to formulate a technical problem starting from the disclosure of D11. Employing the manufacturing method known from D11 to obtain a known product did not bring about anything special and was simply obvious.

XII. The respondent's arguments may be summarised as follows:

(a) *Extension of subject-matter - Article 123(2) EPC*

The subject-matter of claim 1 of the request found allowable by the Opposition Division was derived in particular from paragraphs [0024] to [0031] of the application as originally filed, which disclosed all the steps of the manufacturing method as

claimed. In particular, paragraph [0024] disclosed that the method disclosed in the following paragraphs was employed to manufacture the "fixation devices of the present invention". This implied that all the structural features of the devices of the specific embodiments could be obtained by the manufacturing method disclosed in those paragraphs.

Paragraphs [0011] and [0048] disclosed deformable ridges. Paragraph [0031] disclosed that, after cooling to room temperature, the billet could be further processed by cutting and other mechanical or thermal processing methods. The step of "cutting and forming the billet" was therefore disclosed in the application as originally filed.

(b) *Clarity and support in the description - Article 84 EPC*

The subject-matter of claim 1 was clear and supported by the description.

More particularly, the claim defined that "deformable ridges [were] capable of deforming to contract the diameter of the fixation device". Something deformable would not always deform. It would do so under certain stress conditions. In the case of the patent in suit, these conditions were the ones encountered in the intended use of the fixation device, explained, for example, in paragraph [0049] of the patent. Moreover, from the wording of the claim it was derivable that the deformable ridges were obtained by molecularly orienting and then cooling the preform with which the fixation device was ultimately manufactured.

The skilled person would also have no difficulty in understanding which diameter of the fixation device contracted when the ridges deformed. It would be the diameter at the locations where the deformable ridges of the fixation device, in use, entered a hole into which the fixation device was to be inserted.

The expression "melting and cooling" in the claim did not mean that the polymer had to be melted and cooled at the same time. The cooling step could follow the melting step, as also explained in paragraph [0026] of the patent.

The skilled person knew that several operation parameters could be selected in a process that involved the melting and cooling of a polymer. Depending on the particular selection, the result of the process could be an "amorphous" or a "partially crystalline" preform. The claim encompassed all the combinations of parameters which could give either of those alternatives.

Similarly, the skilled person knew which requirements a "bioabsorbable" polymer raw material had to fulfill and knew a large number of those materials. Moreover, the description of the patent mentioned many examples of such materials, in particular in paragraph [0021].

(c) *Inventive step* - Article 56 EPC

D5 could not be regarded as the closest prior art, since it did not disclose any manufacturing method. Moreover, D5 specifically concerned intramedullary

splints. Such devices had to be fixed with screws inside bones. In contrast, the fixation devices obtained by the claimed invention were used themselves for fixing bone fragments together. Hence D5 concerned devices with a different working principle from the devices obtained by the invention.

Both D7 and D11 disclosed methods for forming surgical fasteners. However, D11 was closer, since it disclosed the manufacture of some kinds of rods.

Starting from D11 as the closest prior art, the skilled person would have no motivation for applying the manufacturing process disclosed in that document to obtain the specific fixation devices as defined in claim 1. More particularly, there was no hint towards obtaining a billet with deformable longitudinal ridges by molecularly orienting the preform through a drawing die in order for the ridges to have the advantageous properties conferred by the presence of long molecular chains in the longitudinal direction. D7 did not teach to apply such a process for obtaining longitudinal ridges with those advantageous properties either. Hence an inventive step should be acknowledged.

Reasons for the Decision

1. The appeal is admissible.

2. *The invention*

2.1 The invention as defined in claim 1 of the request found allowable by the Opposition Division in the impugned decision relates to a method for manufacturing a bioabsorbable osteosynthesis fixation device for the fixation of bone fractures or osteotomies. The device is typically in the form of a pin to be inserted in a hole drilled through two bone fragments to be held together, in order to promote the healing process. The device obtained by the claimed method comprises a shaft with deformable ridges at its periphery, so that the diameter of the fixation device can be contracted. The claimed method involves a die drawing process, according to which a preformed billet, such as a rod, is drawn through a heated die, the inner surface of which comprises grooves and ridges to form the ridges of the fixation device (paragraph [0030] of the patent). Such a forming process causes an orientation of the molecule chains of the billet material mainly along the draw direction, which results in an increase in strength and toughness of the material along that direction. It follows that in the radial direction the material of the fixation device is more easily deformable.

2.2 According to the patent, the deformable "grooved and ridged surface structure" of the fixation device is important in order for it to be possible to push the device into a drilled hole with a diameter smaller than the external diameter of the fixation device (paragraph [0012]).

3. *Extension of subject-matter - Article 123(2) EPC*

3.1 The subject-matter of claim 1 is generally based on claim 1 and paragraphs [0024] to [0031] of the application as originally filed, as also held by the Opposition Division in the impugned decision.

More particularly, those paragraphs disclose the method steps of the manufacturing method, whereas claim 1 comprises the structural features of the bioabsorbable osteosynthesis fixation device.

3.2 As regards the disputed feature of the "deformable ridges" defined in claim 1, the Board considers that especially paragraph [0048] of the application as originally filed provides an adequate basis.

The last three sentences of that paragraph read:

> "The fixation device has a capability of deforming in two ways. When a bone in which a hole is drilled is substantially soft and brittle, the ridges of the fixation device penetrate in the wall of the hole. When a bone in which a hole is drilled is substantially hard and inflexible, the ridges are able to deform so that the diameter of the fixation device contracts, and it can be inserted in the hole".

The fact that paragraph [0048] does not concern a manufacturing method, but rather a condition of use of the finished fixation device, is not decisive. As pointed out by the respondent, the method disclosed in paragraphs [0024] to [0031] concerns the manufacture of "fixation devices of the present invention", i.e. in particular also of a device having the features

necessary for it to be suitable for the use disclosed in paragraph [0048]. As regards the appellant's argument that extracting merely the general feature of "deformable ridges" from the specific disclosure of paragraph [0048] constituted a non-allowable generalisation, the Board notes that the general teaching of that paragraph is that the ridges of the fixation device deform under certain typical conditions encountered during a surgical procedure. The expression "deformable ridges" in claim 1 does not present the skilled person with any fresh information extending beyond that teaching.

3.3 As far as the method step of "cutting and forming" the billet in claim 1 is concerned, paragraph [0031] of the original application explicitly discloses that the billet, once cooled to room temperature, can be further processed by suitable processing methods. According to this paragraph, these methods include cutting as well as "other mechanical processing methods" and "thermal processing" or "combinations of mechanical processing and thermal processing". From a technical point of view, such a teaching is totally reasonable, since the device may have to be further adapted to its intended use. Hence, it cannot be altered in view of possible considerations based on the knowledge of particular patent drafting techniques. Since, for the skilled person, in that context, the term "processing" is technically equivalent to "forming", it is concluded that the application as originally filed comprises the unambiguous teaching that "cutting" can be a specific processing step performed in addition to other "forming" steps.

3.4 For these reasons it is concluded that the claim 1 complies with Article 123(2) EPC.

4. *Clarity and support in the description - Article 84 EPC*

4.1 The appellant argued that some expressions in claim 1 did not fulfil the requirements of Article 84 EPC.

4.2 In particular, it argued that the expression "deformable ridges" was unclear as it could not be established from the wording of claim 1 under which conditions a deformation would take place.

The Board notes that, according to the established jurisprudence, the claims should be read trying to make technical sense out of them, bearing in mind the technical context, presented in the whole patent specification, to which the invention pertains.

In the present case, the invention relates to the manufacture of bioabsorbable osteosynthesis fixation devices, to be used for the fixation of bone fractures or osteotomies. The concept of the deformability of the ridges of such a fixation device is to be interpreted in the light of its intended use. For this reason alone the appellant's argument concerning the possible deformability of a steel ball is totally beside the point. Moreover, in claim 1 the deformable ridges are additionally defined as being able to deform "for contracting a diameter of the fixation device". This wording adds specificity to the concept of the deformability of the ridges. In view of these considerations, the skilled person clearly understands that the ridges of the fixation device obtained by the process defined in claim 1 are able to deform in the radial direction under the known load conditions

typically encountered in the surgical procedures for which the device is intended. This is specified in paragraph [0049] of the patent, which describes on the one hand that the ridges are able to deform when the fixation device is introduced in a "substantially hard and inflexible" bone and, on the other, penetrate in soft and brittle bone. The skilled person knows which parameters have to be satisfied.

4.3 As regards the appellant's objection to the expression "contracting a diameter of the fixation device", the Board notes that claim 1 specifies that the diameter meant is "at locations of the deformable ridges". For the skilled person it is clear that the diameter which contracts is a diameter of the fixation device where the load conditions responsible for the deformation are present. The nominal, maximum and minimum diameters mentioned in claim 1 and the description are fixed measures of the device in a condition of no stress.

4.4 The wording "melting and cooling" in claim 1, when interpreted with a mind trying to make technical sense of the claim, can only refer to two distinct steps taking place one after the other. Paragraph [0026] of the patent specification, which clearly describes a melting step followed by a cooling step, fully supports this interpretation. Whether the specific process described in that paragraph includes further non-claimed steps such as an additional cooling step is not relevant for the interpretation of the claimed steps.

4.5 As far as the formation of an "amorphous or partially crystalline preform" is concerned, this depends on the selection of appropriate parameters of the forming process. The claimed manufacturing method simply

encompasses setting those parameters in order to obtain an amorphous preform as well as setting them differently, in order to obtain a partially crystalline preform. The Board shares the appellant's view that these parameters vary in dependence on the material employed in the manufacturing method. However, the skilled person can specifically set them for each known material on the basis of its known properties.

4.6 Finally, the reference to a generic "bioabsorbable polymer raw material" in claim 1 finds adequate support in the description, since the latter discloses in detail tests carried out with one specific such material, mentioned in paragraph [0057], and explains that a large number of such materials may be employed in the claimed manufacturing method (paragraph [0021]).

4.7 It follows that the appellant's objections under Article 84 EPC do not succeed.

5. *Inventive step - Article 56 EPC*

5.1 When assessing whether the subject-matter of claim 1 involves an inventive step, the problem-solution approach is to be followed in accordance with the established jurisprudence of the boards of appeal.

In accordance with this approach, followed in the oral proceedings, the closest prior art, i.e. the most promising starting point towards the claimed invention, was identified first.

The appellant argued that any of D5, D7 and D11 could be regarded as the closest prior art.

However, as the appellant conceded, while claim 1

defines a manufacturing method, D5 does not disclose any such method. Moreover, as the respondent submitted, D5 specifically concerns intramedullary splints. Such devices are for insertion into the medullary cavity of bones and are typically fixed there by means of screws. In contrast, osteosynthesis fixation devices of the kind obtained by the claimed invention are used themselves as fixing means for holding together fractured bone fragments, for example. It follows that the devices disclosed in D5 are of a different type and involve technical considerations which are different from those pertaining to the claimed invention.

Both D7 and D11 disclose methods for manufacturing surgical fasteners. However, while D11 contemplates the manufacture of osteosynthesis fixation devices of the kind obtained by the claimed invention (page 2, lines 21 to 24 and page 3, lines 33 to 35 and 42 to 43), D7 is specifically concerned with bioabsorbable fasteners for insertion in soft or tough tissue (column 3, lines 40 to 42). Such fasteners also involve technical considerations which are different from those pertaining to the claimed invention.

For these reasons the Board concludes that D11 is the closest prior art.

5.2 It is not disputed by the parties that D11 discloses a method for manufacturing a fixation device, for example in the form of a rod, involving melting and cooling a bioabsorbable polymer raw material so as to form an amorphous or partially crystalline preform having a longitudinal axis, molecularily orienting the preform at a temperature which is above the glass transition temperature and below the melting temperature of the bioabsorbable polymer raw material of the preform so as

to form a billet, cooling the billet under stress to the room temperature, and cutting and forming the billet for providing the fixation device.

D11 does not disclose, in particular, that the fixation device is provided with deformable ridges capable of deforming to contract the diameter of the fixation device, said ridges extending in a longitudinal direction forming an angle with the longitudinal axis of a shaft of the fixation device, the angle being between -45° and 45°.

5.3 The manufacture of such longitudinal ridges by molecularly orienting the preform through a drawing die, the inner surface of which comprises grooves and ridges, has the technical effect of providing long molecular chains in the longitudinal direction of the ridges of the fixation device. This, in turn, renders the ridges stiff in the longitudinal direction while allowing for a certain deformability in the radial direction.

Hence, the above-mentioned distinguishing features of the subject-matter of claim 1 over D11 address the objective technical problem of manufacturing a fixing device for which its insertion into holes of a diameter smaller than the maximum diameter of the part of the fixation device intended to be inserted is facilitated.

5.4 The available prior art does not hint at the solution to this problem. Hence, in the light of the objective technical problem, there is no reason to believe that the skilled person would manufacture a device with longitudinal ridges as defined in claim 1 starting from the method steps disclosed in D11 without exercising an inventive step, the parameters of the manufacturing

process having specifically to be adjusted in order to obtain the deformability as defined in the claim (point 4.2 above).

The appellant's argument that employing a known production method to obtain a known product was obvious as such is not convincing. In general, the skilled person, faced with a technical problem, would need a motivation in the prior art for selecting a specific manufacturing method for the production of a specific article in an obvious way.

5.5 The Board therefore concludes that, starting from the closest prior art, the subject-matter of claim 1 is not obvious. A fortiori, that subject-matter is not obvious either, when a different and less promising starting point amongst the available prior art is selected.

Hence, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

6. If follows that none of the appellant's objections prejudice the maintenance of the patent on the basis of the request found allowable by the Opposition Division in the impugned decision.

The Board sees no other non-compliances either. In particular, since the method defined in claim 1 is specifically directed to the production of a device comprising all the features defined in claim 1 of the patent as granted, Article 123(3) EPC is also complied with.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated