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Datasheet for the decision of 11 January 2023

Case Number: T 0172/19 - 3.2.02

Application Number: 13713282.5

Publication Number: 2830512

IPC: A61B17/16, A61B17/82

Language of the proceedings: EN

Title of invention:
BONE FIXATION MEMBER SYSTEMS

Patent Proprietor:
Synthes GmbH

Opponent:
Keilitz, Wolfgang

Relevant legal provisions:
EPC Art. 54(2)

Keyword:
Novelty - (no)

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Case Number: T 0172/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 January 2023

Appellant: (Opponent)	Keilitz, Wolfgang Keilitz Haines & Partner Patentanwälte PartGmbB Nigerstrasse 4 81675 München (DE)
Representative:	Keilitz, Wolfgang Keilitz Haines & Partner Patentanwälte PartGmbB Nigerstraße 4 81675 München (DE)
Respondent: (Patent Proprietor)	Synthes GmbH Eimattstrasse 3 4436 Oberdorf (CH)
Representative:	Klunker IP Patentanwälte PartG mbB Destouchesstraße 68 80796 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 November 2018 rejecting the opposition filed against European patent No. 2830512 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	N. Obrovski

Summary of Facts and Submissions

I. The appeal is directed against the decision of the opposition division to reject the opposition against European patent No. 2830512.

II. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

III. The respondent (proprietor) requested that the appeal be dismissed.

IV. In preparation for oral proceedings, the board sent a communication setting out its preliminary opinion. The board indicated, among other points, that the subject-matter of claim 1 of the patent as granted was not novel over D3.

V. With a submission dated 9 November 2022, the respondent withdrew its request for oral proceedings. The board then cancelled the oral proceedings and took the present decision in written proceedings.

VI. Claim 1 of the patent as granted reads as follows:

"A bone fixation kit comprising at least one bone fixation member (14) that is configured to compress first and second bone segments in an approximated position, the at least one bone fixation member (14) comprising:

an elongate strap (22) made of at least a first material and having a plurality of teeth (42);

a locking head (26) that extends from the strap (22) along a first direction, the locking head (26) having a housing (70), a strap receiving slot (74) that extends through the housing (70), and a toothed locking member (78) that extends into the strap receiving slot (74) such that when the strap (22) is inserted through the strap receiving slot (74) along an insertion direction, the toothed locking member (78) engages at least one of the teeth (42) to prevent the strap (22) from translating through the strap receiving slot (74) along a direction that is opposite the insertion direction;
a leader portion (30) that extends from the strap (22) along a second direction opposite the first direction; and
a needle (34) that extends from the leader portion (30) such that the leader portion (30) is connected between the strap (22) and the needle (34),
characterized in that the leader portion (30) is made of at least a second material that is different than the first material, such that the leader portion (30) is more flexible than the strap (22)."

VII. Document **D3** (EP 0238 219 A1) is relevant to this decision.

VIII. The appellant's arguments, where relevant to the decision, can be summarised as follows.

Novelty over D3

D3 disclosed all of the features of claim 1, and therefore the subject-matter of claim 1 was not novel.

Novelty over D3 - feature "the leader portion (30) is made of at least a second material that is different than the first material"

D3 disclosed a bone fixation member including a leader portion (part of the spine portion 14 without coating) and a strap (part of the spine portion 14 coated with a polymer and with serrations 22). The leader portion was made of metal and the strap was made of a combination of metal and polymer, as was also apparent from Figures 1-2 of D3, and therefore D3 disclosed this feature.

Novelty over D3 - feature "such that the leader portion (30) is more flexible than the strap (22)"

The flexibility of the spine was not altered when the serrations were stamped (column 4, lines 1-5, in D3).

The polymers mentioned in D3 had melting points well below 200°C. Applying the coating at such temperatures did not affect the flexibility of the stamped spine made of stainless steel, which would require heating to above 500°C for a long period of time for a process similar to tempering to affect its flexibility. The coated spine was stiffer than the spine without a coating because more material had to be bent, and therefore D3 also disclosed this feature.

IX. The respondent's arguments, where relevant to the decision, can be summarised as follows.

Novelty over D3

The subject-matter of claim 1 was novel over D3 because D3 did not disclose the features of the characterising portion.

Novelty over D3 - feature "the leader portion (30) is made of at least a second material that is different than the first material"

D3 disclosed in column 3, lines 40-45, that the device 10 was made of biocompatible metal, most preferably stainless steel, and was coated with a biocompatible polymer. D3 made no differentiation between different portions of the device 10, and therefore all of the elements were formed of the same material.

Figure 2 could not be interpreted such that portions 14 and 14+22 were composed of different materials.

Novelty over D3 - feature "such that the leader portion (30) is more flexible than the strap (22)"

There was no literal disclosure in D3 that the leader portion was more flexible than the strap.

Even if the material of the spine portion 14 including the serrations 22 were to be interpreted as a metal covered with a biocompatible polymer applied by shrinking, fluidized bath or injection moulding, the coating process could still have an influence on the flexibility of the spine portion 14. Hence, the feature was not clearly and unambiguously derivable from the disclosure of D3.

Reasons for the Decision

1. The invention

In order to provide access to certain internal parts of the anatomy, such as the heart during an open heart procedure, midline sternotomies are typically performed. The sternum is cut along the midline, thereby dividing the ribcage into two halves. Upon completion of the surgery, it is desirable to approximate and compress the sternum. The two sternal halves must be maintained in their approximated position so that they are prevented from moving with respect to each other to promote bone fusion in the weeks following the surgical procedure.

The invention deals with a bone fixation kit with at least one bone fixation member that is configured to compress first and second bone segments (for example the two sternal halves) in an approximated position.

The bone fixation member (14) comprises an elongate strap (22), a locking head (26), a leader portion (30) and a needle (34). The strap has a plurality of teeth and the locking head has a toothed locking member which, upon insertion of the strap, prevents the strap from translating along a direction that is opposite the insertion direction. The Figures below show an embodiment of a single bone fixation member (Figure 1) and a plurality of bone fixation members tightened about a target bone (Figure 2).

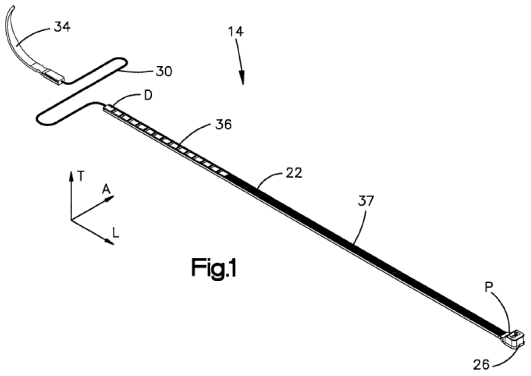

Fig.1

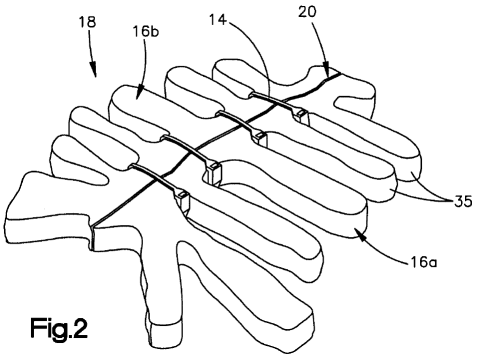

Fig.2

The last feature of claim 1 specifies that the strap is made of at least a first material and the leader portion is made of at least a second, different material, such that the leader portion is more flexible than the strap. This provides for greater flexibility and mobility while the bone fixation member is being placed about the bone segments, thereby permitting easier implementation (see paragraph [0009] of the patent specification).

2. Novelty over D3

2.1 D3 relates to a sternum closure device depicted with reference sign 10 in Figures 1 and 2 of D3, which are reproduced below. The device comprises:
- an elongate strap: the part of the spine portion 14 provided with serrations 22;
- a locking head: the head portion 12, see also column 1, line 53 to column 2, line 5 and column 3, lines 14-23;
- a leader portion: the part of the spine portion 14 without a coating/serrations, located where the reference sign 14 is shown on Figures 1 and 2; and
- a needle: the tail portion 16.

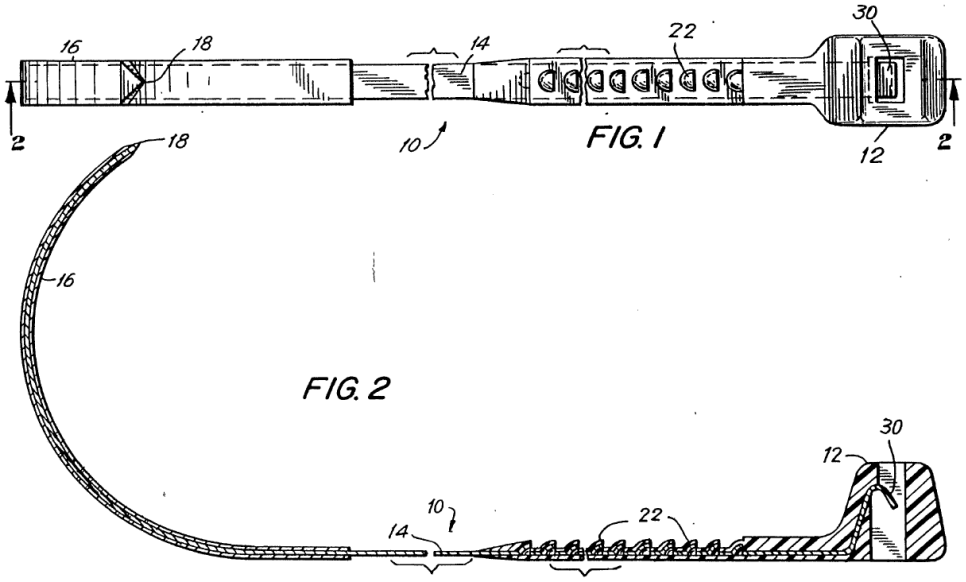

FIG. 1

FIG. 2

It is disputed whether D3 discloses the features of the characterising portion of claim 1, which are separately addressed in the two subsections below.

2.2 Feature "the leader portion (30) is made of at least a second material that is different than the first material"

D3 discloses in column 3, lines 40-45, that the device 10 is made of biocompatible metal, preferably stainless steel, and is coated with a biocompatible polymer. The respondent derives therefrom that all of the components of the device are made of the same material. The person skilled in the art taking into account the entire disclosure of D3 would reach a different conclusion. While the spine portion 14 may be made of stainless steel (see claim 4 of D3), it is not possible for all of the parts of the device 10 to be made of stainless steel alone. This is clear with respect to the head portion 12, which is described in column 4, lines 22-25, as being "formed by locating the spine portion 14 and tang 30 in a mold or form and preferably coating, dipping, or injection molding

around it". These manufacturing techniques would not be suitable to form the head portion 12 out of a material such as stainless steel around the spine portion 14 and tang 30 also made of stainless steel.

Moreover, it is clear to see from the cross-sectional view shown in Figure 2 that the head portion 12 and the material surrounding the part of the spine portion 14 with serrations are integrally formed: the same line pattern is used and there is no division between them. That is to say, the spine portion 14 and the material/ coating surrounding the part of the spine portion 14 with serrations are made of different materials. Hence, the feature is anticipated by the disclosure of D3.

2.3 Feature "such that the leader portion (30) is more flexible than the strap (22)"

The appealed decision identified this feature as distinguishing the subject-matter of claim 1 from D3. The board has come to a different conclusion, for the reasons indicated below.

The coating applied to the spine results in the part with serrations being wider and thicker than the part without serrations (see the tapering in Figures 1 and 2 of D3). If the properties of the spine portion 14 are similar in both parts, the coated part will offer increased resistance to bending and thus be less flexible.

D3 discloses that forming the serrations by stamping "retains the spines original strength and flexibility" (column 4, lines 2-5). However, it is disputed whether the application of the coating would

affect the properties of the part of the spine with stamped serrations and cause increased flexibility.

According to D3, the spine is preferably made of stainless steel. The melting point of the preferred coating polymers disclosed in column 3, lines 42-43, of D3 is well below 200°C. A brief exposure to temperatures well below 200°C would not significantly affect the properties of stainless steel, which has a melting point of about 1400°C-1500°C (depending on the grade) and would thus need a long exposure to much higher temperatures than below 200°C to suffer any relevant change in its properties. Thus, the flexibility of the spine would not be affected by the application of the coating.

Hence, the thin part of the device of D3 (the part defining the leader portion) will be more flexible than the thicker, coated part of the device with stamped serrations (the part defining the elongate strap), and therefore the disputed feature is disclosed by D3.

2.4 It follows that D3 discloses all of the features of claim 1.

3. The ground for opposition under Article 100(a) EPC prejudices the maintenance of the patent as granted because the subject-matter of claim 1 is not novel over D3. Since there are no auxiliary claim requests, the patent must be revoked in accordance with Article 101(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated