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**Datasheet for the decision
of 10 September 2019**

Case Number: T 2249/14 - 3.2.02

Application Number: 10251881.8

Publication Number: 2332470

IPC: A61B17/04

Language of the proceedings: EN

Title of invention:

Partial thickness rotator cuff repair system

Applicant:

DePuy Mitek, Inc.

Headword:

Relevant legal provisions:

EPC Art. 83, 111(1), 123(2)

Keyword:

Sufficiency of disclosure - (yes)

Amendments - added subject-matter (no)

Remittal to the department of first instance - (yes)

Decisions cited:

Catchword:



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Case Number: T 2249/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 September 2019

Appellant: DePuy Mitek, Inc.
(Applicant) 325 Paramount Drive
Raynham, MA 02767 (US)

Representative: Tunstall, Christopher Stephen
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 26 June 2014
refusing European patent application No.
10251881.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: P. L. P. Weber
S. Böttcher

Summary of Facts and Submissions

- I. The appeal of the applicant is against the decision of the Examining Division dated 26 June 2014 to refuse the application because it did not comply with Articles 123(2) and 83 EPC.

The Examining Division considered, in particular, that:

- The feature that the driver had a hexagonal cross-section and terminated at its distal end with threads had no support in the application as filed.
- It was not sufficiently described how the awl and anchor had to be built to accommodate a single driver with both the hexagonal shaft and the threaded end features.

- II. Notice of appeal was filed on 5 September 2014 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 6 November 2014.

The appellant's main request is for the Board to set aside the Examining Division's decision to refuse this application under Articles 123(2), 83 and 84 EPC, and to remit the enclosed claims of the main request back to the Examining Division for further consideration of novelty and inventive step.

- III. Claim 1 of the main request reads as follows:

"A suture anchor kit comprising:

a suture anchor (20) having at least one suture limb (62) extending therefrom, the suture anchor (20) comprising a distal end (54) for entering bone, an opposite proximal end (56), a threaded outer surface

(58), and a side between the distal end (54) and proximal end (56);

a suture anchor passing tool (64) adapted to grasp the suture anchor side;

and characterised in that:

the suture anchor (20) has a hexagonal opening (60) at its proximal end (56);

and further comprising:

a driver having an elongated shaft, a hexagonal cross section (50) near a distal end of the driver for mating with the hexagonal opening (60) of said suture anchor (20), and terminating at the distal end of the driver with threads (34) and a sharp point; and

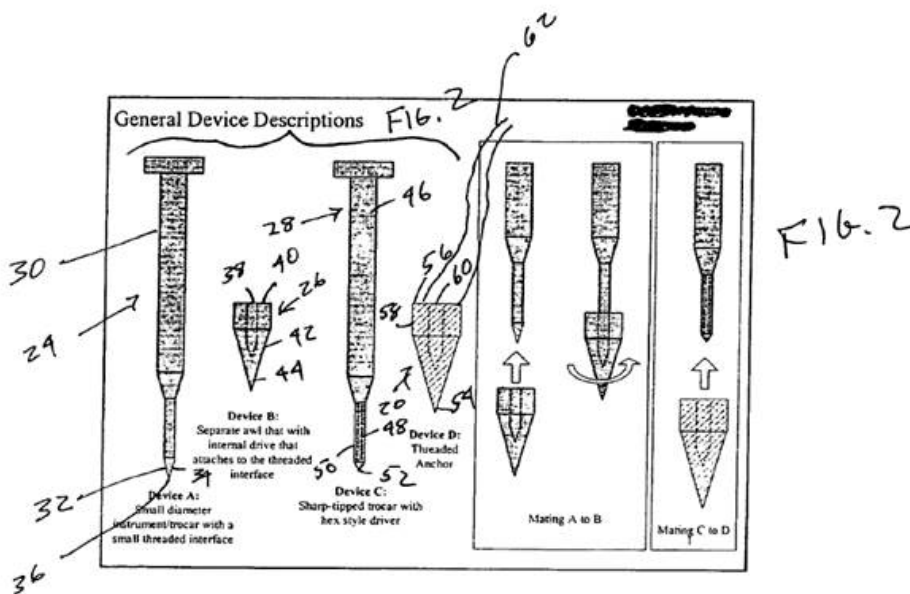
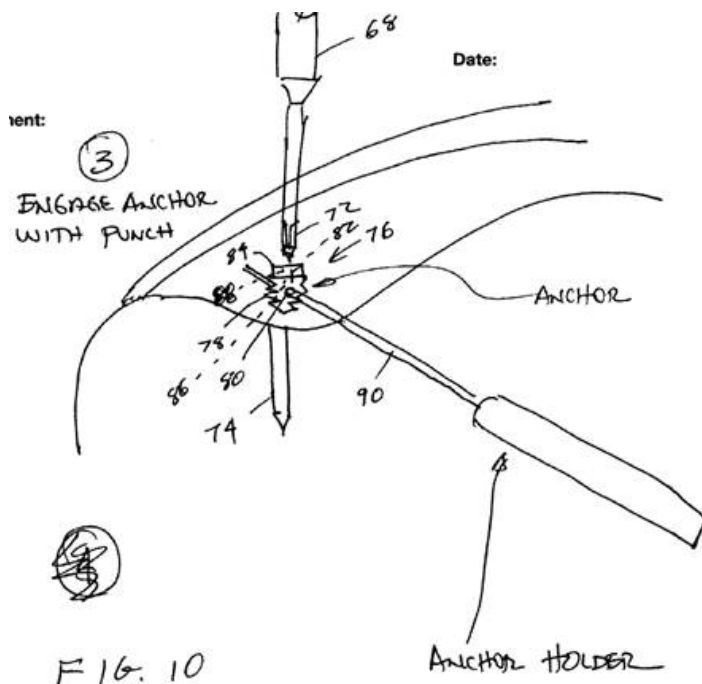
an awl head (26) having a threaded opening (38) at a proximal end (40) thereof for mating with the threads (34) of the driver, and a conical section (42) at a distal end (44) thereof."

IV. The arguments of the appellant are mainly those underlying the reasons for the decision below.

Reasons for the Decision

1. The appeal is admissible.
2. Subject-matter of the application

The subject-matter of claim 1 is a kit of parts for anchoring a partly detached rotator cuff tendon on the humeral head.



According to claim 1, the first driver (24) and the second driver (28) are combined into a single driver.

3. The claims of the main request are the same as the claims discussed at the oral proceedings held during

the examination proceedings, except that reference signs in parentheses have been added to the claims.

4. The appellant's main request is for the Board to set aside the Examining Division's decision to refuse this application under Articles 123(2), 83 and **84** EPC (emphasis added). However, the impugned refusal decision was not based on Article 84 EPC, so the Board will only concentrate on the objections pursuant to Articles 123(2) and 83 EPC.
5. Extension beyond the content of the application as filed

The relevant passages of paragraphs [0042] and [0045] of the application as filed read as follows:

[0042]: *"FIG. 2 depicts and [sic] a suture anchor 20 and instruments 22 for placement of the suture anchor 20 into the humeral head 12 beneath the detached portion 18 of the tendon footprint 16. The instruments 22 include a first driver 24, an awl head 26 and a second driver 28. The first driver 24 has an elongated shaft 30 and terminates at its distal end 32 with threads 34 and a sharp point 36. The awl head 26 has a threaded opening 38 at its proximal end 40 and a conical section 42 at its distal end 44. The threads 34 of the first driver 24 mate with the threaded opening 38 of the awl head 26. The second driver 28 comprises an elongated shaft 46 and near its distal end 48 has a hexagonal cross section 50 and terminates in a sharp point 52. The suture anchor 20 has a distal end 54, proximal end 56, a threaded outer surface 58 and a hexagonal opening 60 at its proximal end 56 which mates with the hexagonal portion 50 of the second driver 28.*

A pair of sutures 62 extend from the suture anchor 20." (emphasis added)

[0045]: *"...In an alternate embodiment not shown, the features (namely the threads 34 and hexagonal cross section 50) of the first and second drivers 24 and 28 are combined into a single driver so only one pass need be made through the tendon 14...."*

In paragraph [0042] the first embodiment described in the application is presented. A first driver serves to mark the bone surface. This first driver is then used together with an awl head to create a hole in the bone. As can be seen in the underlined passage, the first driver terminates with threads at its distal end and with a sharp point. The sharp point and the conical part can also be recognised on Figure 2 of the application as filed. The threads on the driver and the threads in the opening of the awl are meant to cooperate. After that, the first driver and the awl head are taken out of the hole and tendon respectively, and a second driver (with hexagonal cross-section) is used to place the definitive suture anchor into the hole made in the bone. The suture anchor is provided with a hexagonal hole mating the hexagonal shape of the second driver.

In paragraph [0045] it is mentioned that the two drivers could be formed as a single driver with both a hexagonal cross-section near the distal end and a thread at the distal end.

Hence, the feature considered critical by the Examining Division is disclosed verbatim by the combination of these paragraphs. The argument of the Examining Division that on Figure 2 of the application as filed

it was not unambiguously disclosed that the threads were on a conical part of the driver, because the drawings were not precise enough, has, in the present case, no importance for the question of support, since the same wording as in claim 1 appears to be present in paragraph [0042]. Moreover, whether in the end the threads may be present precisely on the conical part, or are only present proximal to the conical part, or are present proximal to the conical part and on the conical part does not play a role for the question of extension beyond the content of the application, since all these options are covered in any case by "*terminates at its distal end*". Additionally, since paragraph [0045] specifies that the feature of the threads and the feature of the hexagonal cross-section would be combined on a single driver, the very combination claimed is also clearly disclosed in the application as filed.

Therefore, claim 1 of the main request fulfils the requirements of Article 123(2) EPC.

6. Sufficiency of description

According to the Examining Division, it was not possible for the person skilled in the art to carry out a driver, awl and suture anchor combination satisfying the requirements of claim 1 without undue burden. It required inventive skill to provide such modification, while still maintaining an awl that could be impacted and an anchor that could be rotated by the same driver.

The Board does not share this opinion. The driver according to claim 1 is required to have a hexagonal cross-section near the distal end mating with the hexagonal opening of the suture anchor, a threading at

the distal end mating with the threads in the threaded opening present in the awl, and eventually a sharp point at its distal end. In other words, the threads must be usable with the awl, and the hexagonal cross-sectional part of the shaft must be usable with the suture anchor. Several options are self-evident in order to satisfy these conditions. First, the external diameter of the threads present on the shaft must be equal or smaller than the largest diameter circle fitting inside the hexagon defining the hexagonal cross-section, so that the threads do not hinder the fitting of the hexagonal part inside the hexagonal hole. Concerning the hole in the awl, it can, for instance, be so as to only accept the threaded part of the driver, or if it should accept a part of the shaft, it must have a diameter greater than the hexagon's external diameter. The hexagonal hole in the suture anchor must be deeper than the length of the threaded part of the driver so that the hexagonal shaft and the hexagonal hole can mate. For the sharp distal end, no special explanation is needed. These are self-evident options the person skilled in the art of simple mechanics would envisage without undue burden.

Therefore, the requirements of Article 83 EPC are fulfilled.

7. Since the objections upon which the impugned decision is based have been considered as not well founded and the other requirements for grant have not yet been decided upon by the Examining Division, remittal of the case to the department of first instance for further prosecution pursuant to Article 111(1) EPC, as requested by the appellant, is justified.

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 for further prosecution.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated