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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MATTEO MANTOVANI and
ENRICO RASIA DANI

Appeal 2018-002128
Application 13/879,764
Technology Center 3700

Before MICHAEL L. HOELTER, MICHAEL J. FITZPATRICK, and JILL D. HILL, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION ON APPEAL

Matteo Mantovani and Enrico Rasia Dani ("Appellants")[1] appeal under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 1 and 3–11. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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[1] The real party in interest is identified as NCS Labs S.R.L. Appeal Br. 1.

STATEMENT OF THE CASE

The Specification

The claimed invention "relates to a fixing device for suture threads to be inserted into a bone tissue." Spec. 1:1–2. More specifically, it relates to "surgical operations, aimed at treating lesions which require re-setting and fixing tendons to the respective portions of bone in order to restore the original footprint or for repairing tendon damage." *Id.* at 1:4–6.

Figure 1 is reproduced below.

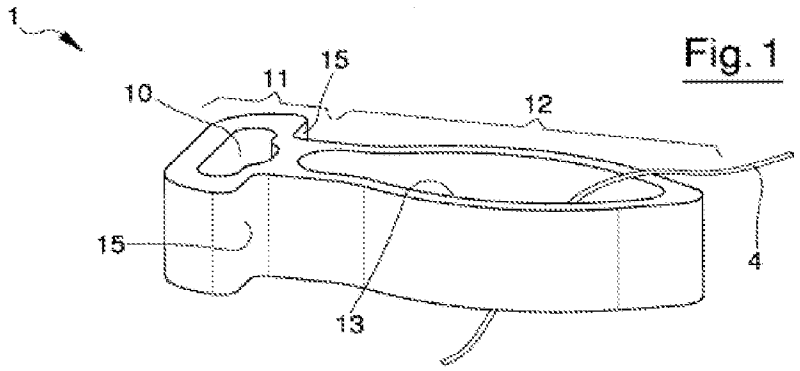

Fig. 1

Figure 1, reproduced above, shows fixing device 1 before deployment in a bone. The fixing device includes first portion 11 with eyelet 10 therethrough and second portion 12 also with eyelet 13 therethrough.

The first portion (11) has a wider maximum width than the second portion, providing a "mushroom shape" and surfaces 15. *Id.* at 4:13–17, 6:16–19.

The second portion (12) is "elongate[d]," has a "convex external configuration," and has "elastic deformability," which features allow it to couple within the interior walls of a channel within which it inserted, as shown in Figure 2. *Id.* at 2:26–27, 3:5–10.

Figure 2 is reproduced below.

Fig. 2

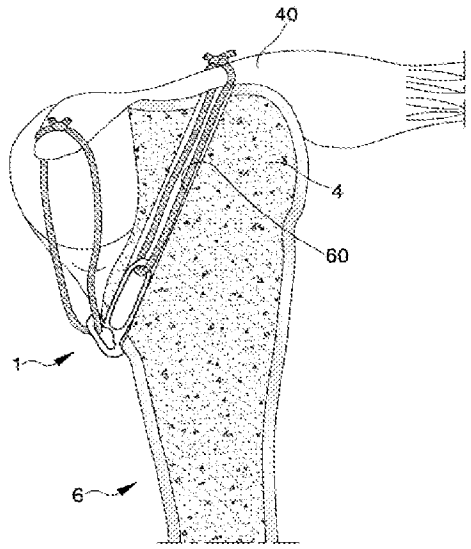

Figure 2, reproduced above, shows the fixing device deployed within channel 60 that has been drilled or otherwise formed through bone 6. *Id.* at 3:24–4:1. The second portion is fully advanced into the channel such that surfaces 15 of the mushroom-shaped first portion abut the exterior surface of the bone. The fixing device is anchored in place by virtue of the elastic return of the second portion against the interior walls of the channel as well as the fact that surfaces 15 of the mushroom shape of the first portion rest against the external surface of the bone. *Id.* at 3:10–23. The fixing device fixes the tendon 40 indirectly and at two separate positions via sutures extending from both eyelets 10 and 13. Spec. 4:2–8.

The Rejected Claims

All pending claims, namely claims 1 and 3–11, stand rejected. Final Act. 1. Independent claim 1 is representative and reproduced below.

> 1. A fixing device for suture threads to be inserted into a bone structure, comprising
>
> a first portion (11, 21) and a second portion (12, 22), the device having an undeployed state, a deployed state, and a

longitudinal dimension, said deployed state being a state when the device is deployed in a bone structure,

the first portion (11, 21) being provided with a first eyelet (10, 20) or eye effectively sized to receive a first suture thread (4) therethrough, the first eyelet or eye defining an opening through which the first suture thread passes through in a direction perpendicular to the longitudinal dimension,

the second portion (12, 22) exhibiting a second eyelet or eye effectively sized to receive a second suture thread (4) therethrough,

the second portion (12, 22) comprising an engagement portion which is effectively sized and shaped such that it can effectively contact and engage an interior surface of a transosseus seating or hole (5) afforded in the bone structure to thereby stably couple the device with the bone structure,

the second portion (12, 22) having a neck portion located between the engagement portion and the first portion, the engagement portion being spaced apart from the first portion, the engagement portion having a medial portion and a distal portion, the medial portion being located between the neck portion and the distal portion,

the fixing device being configured so that, in use, the engagement portion is inserted, distal portion first, into the transosseus seating or hole (5),

the neck portion having a first width transverse to the longitudinal dimension, the first portion comprising a mushroom-shaped portion having a second width transverse to the longitudinal dimension, the second width being larger than said first width in both the undeployed state and the deployed state, the second width being larger than said first width when the first eyelet or eye defines said opening through which the first suture thread passes through in a direction perpendicular to the longitudinal dimension,

the mushroom-shaped portion being integral with the neck portion, the neck portion being integral with the engagement portion,

> the mushroom-shaped portion extending beyond the neck portion in a first direction transverse to the longitudinal dimension in both the undeployed state and the deployed state, the mushroom-shaped portion extending beyond the neck portion in a second direction transverse to the longitudinal dimension in both the undeployed state and the deployed state, the second direction being opposite to the first direction, and
>
> wherein at least the second portion (12, 22) is elastically deformable in order to enable effective coupling to the transosseus seating or hole (5).

Appeal Br. 11 (paragraphing added).

The Appealed Rejections

The following rejections are before us for review:

1. claims 1 and 3–11 under 35 U.S.C. § 112 as failing to comply with the written description requirement (Final Act. 2); and

2. claims 1 and 3–11 under 35 U.S.C. § 103 over Bojarski,[2] Iannarone,[3] and West[4] (Final Act. 5).

DISCUSSION

Rejection 1

The Examiner rejected all pending claims, namely claims 1 and 3–11, under 35 U.S.C. § 112 as failing to comply with the written description requirement. Final Act. 2. More specifically, the Examiner rejected the claims because the limitation of claim 1 reciting "the first eyelet or eye defining an opening through which the first suture thread passes through in a

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[2] US 6,086,591, issued July 11, 2000 ("Bojarski").
[3] US 2008/0275554 A1, published Nov. 6, 2008 ("Iannarone").
[4] US 5,964,764, issued Oct. 12, 1999 ("West").

direction perpendicular to the longitudinal dimension" is allegedly not supported by the application as filed. *Id.* at 2–3.

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. *See id.*

The Examiner states: "The only support for [the perpendicular] limitation can be found in the drawings and the drawings do not clearly illustrate the suture passing in a direction perpendicular to the longitudinal dimension." *Id.* at 3. It is true that there is no *in haec verba* or explicit description, in the application as filed, of a suture passing through an eyelet in "a direction perpendicular to the longitudinal dimension," as recited in claim 1. Yet it is also true that the drawings illustrate the eyelet itself being oriented perpendicular to the longitudinal dimension, as argued by Appellants and agreed to by Examiner. Spec., Fig. 1 (ref. 10); Appeal Br. 3; Ans. 17 ("Appellant is illustrating that the first eyelet has a depth that is in a direction perpendicular to the longitudinal dimension.").

Still, the Examiner asserts that the rejection is justified because, even though the eyelet is perpendicular, a suture can extend through it at myriad angles to the longitudinal direction, with only one of those angle being 90 degrees. *See, e.g.*, Ans. 17 ("The eyelet can have a depth direction perpendicular to the longitudinal axis, but not have the suture passing through that eyelet in a direction perpendicular to the longitudinal dimension."). We agree with the Examiner that, given the size of the eyelet

and suture depicted in Figure 2, for example, a suture could pass through the eyelet in a non-perpendicular direction.

However, a suture is not a requirement of claim 1, which is directed to the fixing device alone. We construe the limitation "the first eyelet or eye defining an opening through which the first suture thread passes through in a direction perpendicular to the longitudinal dimension" as meaning the first eyelet/eye is configured to receive a suture thread pass through it in a direction perpendicular to the longitudinal dimension.

The original drawings clearly illustrate the eyelet having its axis perpendicular to the longitudinal direction. Spec., Fig. 1. And the application as filed describes the eyelet as configured to receive a suture. Spec. 2:16–18. We find that the most apparent direction for a suture to pass through a hole would be along its axis. In light of this disclosure, we find that the application as filed conveys to the person of ordinary skill in the art with reasonable clarity an eyelet that is configured to receive a suture thread in a direction perpendicular to the longitudinal direction and therefore, as recited in claim 1, "the first eyelet or eye defining an opening through which the first suture thread passes through in a direction perpendicular to the longitudinal dimension."

For the foregoing reasons, the Examiner's rejection of claims 1 and 3–11 under 35 U.S.C. § 112 is reversed.

Rejection 2

The Examiner rejected claims 1 and 3–11 under 35 U.S.C. § 103 over Bojarski, Iannarone, and West. Final Act. 5. The Examiner's rejection is based on combining features from three prior art devices, all having to do

with fixing injured tendons or other soft tissue to bones. *Id.* at 5–11. That is where the similarly with the claimed invention ends.

All three prior art devices differ from the claimed invention in that they directly attach to the tendon (or other soft tissue) that they hold in place. Bojarski, Fig. 7 (ref. 12); Iannarone, Fig. 4 (ref. 199); West, Fig. 4 (ref. 35). The prior art devices are advanced into their final anchored positions in one direction until movement in the opposite direction is restricted. In Bojarski and West, the devices are advanced all the way through a channel until a transverse structure at the end emerges to deflect transversely with respect to the channel's axis thereby preventing backward movement. Bojarski, 4:54–55; West, Fig. 6 (ref. 72). In Iannarone, the device is advanced through a channel to a desired position therein, at which point the device is pulled back slightly to deploy spring-loaded claw-like "fixation devices" that grip the inside of the channel, preventing further rearward movement. Iannarone, Fig. 3 (ref. 60a and 60b).

In contrast, the claimed invention is not configured to attach directly to a tendon (or soft tissue). It is attached rather to sutures that, in turn, are attached to a tendon. *See* Spec. Fig. 2. Thus, the claimed invention does not work like the prior art to advance a device into a channel with the device pulling a tendon (or soft tissue) behind it.

Only an elongated "second portion" of the claimed fixing device is advanced into a channel in a bone. The mushroom-shaped "first portion" remains outside, acting as physical stop preventing any further insertion of the device. Additionally, per claim 1, the second portion comprises "an engagement portion which is effectively sized and shaped such that it can effectively contact and engage an interior surface of a transosseus seating or

hole (5) afforded in the bone structure to thereby stably couple the device with the bone structure." Thus, the claimed fixing device, is configured to resist movement in either direction within a channel once it is deployed therein.

The Examiner's rejection starts with the embodiment of Figure 6 of Bojarski, which is reproduced below. *Id.* at 5.

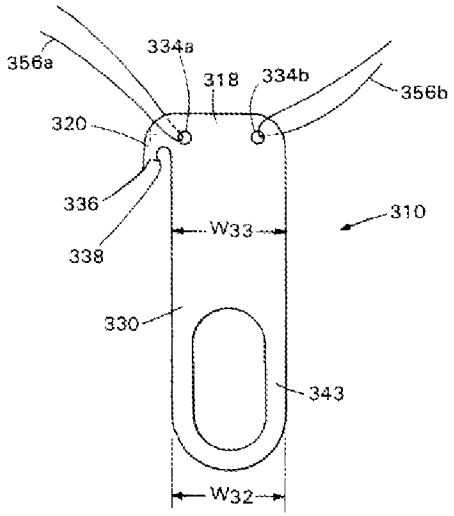

FIG. 6

Figure 6 of Bojarski, reproduced above, shows "anchor" 310 having hook 320 and loop 343. Bojarski 4:53–56. The loop 343 is for connecting a tendon, not a suture, as can be seen in a different embodiment. *Id.* at Fig. 1. Sutures 334a and 334b are attached via holes 334 and 334 to pull the anchor and an attached tendon (not pictured) in the upward direction through a channel drilled in a bone. *Id.* at 4:57–63. The hook is flexible and small enough to allow the anchor to be pulled through a channel (in the upward direction on this page) of substantially the same width as the body of the anchor. *Id.* at 1:60–61, 3:35–37. After the anchor is in place, the hook prevents the anchor from being drawn back through the channel (in the

downward direction on this page), thus facilitating anchoring the tendon with tension. *Id.* at Fig. 7c.

In brief, the Examiner asserts that it would have been obvious to incorporate into Bojarski, a second tooth opposite the disclosed one and form a mushroom shape per West and also to make the asserted second portion of Bojarski (i.e., the portion of it opposite the end that the hook) expandable as taught by Iannarone. *Id.* at 8–11.

In Bojarski, rearward (downward) movement of the device is restricted by hook 320 that provides a physical stop for the device. Bojarski, Fig. 6 (ref. 320); *see also id.* at Fig. 7c (ref. 420). The Examiner states that it would have been obvious to incorporate Iannarone's spring-loaded claws 60a and 60b "to improve the fixation of the device to bone by being able to deform and engage surrounding bone tissue." Final Act. 9. We find the reasoning offered for incorporating the teachings of Iannarone into Bojarski insufficient in the absence of any explanation for how the Bojarski device otherwise would fail to resist backward movement (i.e., Bojarski's single hook 320 already precludes backward movement).

The reasoning is even more dubious in relation to a device "configured so that, in use, the engagement portion is inserted, distal portion first, into the transosseus seating or hole," as required by claim 1. This is so because incorporating Iannarone's claws 60a and 60b into Bojarski would prevent the resulting device from being inserted into a bone channel without destroying or displacing bone tissue in the process.

For the foregoing reasons, the Examiner's rejection of claims 1 and 3–11 under 35 U.S.C. § 103 is reversed.

CONCLUSION

For the reasons discussed, we reverse the Examiner's rejections.

REVERSED