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Datasheet for the decision of 19 February 2020

Case Number: T 2350/15 - 3.2.02

Application Number: 02761831.3

Publication Number: 1437959

IPC: A61B17/04, A61B17/062

Language of the proceedings: EN

Title of invention:
SUTURING APPARATUS

Patent Proprietor:
DePuy Mitek, Inc.

Opponent:
STRAWMAN LIMITED

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c), 104(1)
RPBA 2020 Art. 16(1)(e), 16(2)

Keyword:
Grounds for opposition - added subject-matter (no) - insufficiency of disclosure (no) - lack of novelty (no) - lack of inventive step (no)
Apportionment of costs - (yes)

Decisions cited:
T 0190/99, T 0556/02, T 1018/02, T 0431/03, T 1395/07, T 0197/10, T 1592/14

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2350/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 19 February 2020

Appellant: (Patent Proprietor)	DePuy Mitek, Inc. One Johnson & Johnson Plaza New Brunswick NJ 08933 (US)
Representative:	Viering, Jentschura & Partner mbB Patent- und Rechtsanwälte Grillparzerstraße 14 81675 München (DE)
Appellant: (Opponent)	STRAWMAN LIMITED Orchard Lea Horns Lane Combe Witney, Oxfordshire OX29 8NH (GB)
Representative:	J A Kemp LLP 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 October 2015 concerning maintenance of the European Patent No. 1437959 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	P. L. P. Weber
	C. Schmidt

Summary of Facts and Submissions

I. The appeals of the patent proprietor and the opponent are directed against the interlocutory decision of the Opposition Division dated 7 October 2015 that, account being taken of the amendments according to the auxiliary request 1 then on file, the patent and the invention to which it relates meet the requirements of the EPC.

II. Notice of appeal was filed by the opponent on 17 December 2015 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 17 February 2016. The opponent requested oral proceedings before any decision, other than to revoke the patent in its entirety, was taken.

Notice of appeal was filed by the patent proprietor on 17 December 2015 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 17 February 2016.

III. By letter dated 4 December 2019, the Board summoned the parties to oral proceedings.

IV. By letter dated 10 December 2019, the appellant/ opponent informed the Board that it would not be attending the oral proceedings, but that this didn’t mean that it was withdrawing its appeal or its request for oral proceedings.

V. The oral proceedings were held on 19 February 2020.

The appellant/patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted.

The appellant/opponent had requested in writing that the decision under appeal be set aside and that the patent be revoked.

VI. Claim 1 as granted reads as follows (feature numbering as proposed by the appellant/opponent):

"[1A] A suturing apparatus (10), comprising:

[1B] a first jaw (27) and a second jaw (25) movable with respect to each other;
[1C] and a bendable needle carried by the first jaw and adapted to carry a suture,

characterized in that

[1D] the bendable needle having a generally flat, narrow and elongate configuration and a tip, and
[1E] being movable between a first position wherein the needle is substantially housed within the first jaw and
[1F] a second position wherein a distal portion of the needle protrudes from the first jaw,
[1G] the second jaw comprising a suture receiver (41) spaced apart from the first jaw and
[1H] configured to disengage the suture carried by the bendable needle, when the needle is moved from the first position to the second position;
and
[1I] a mechanism (123) for securing the suture in place within the first jaw prior to being carried by the bendable needle, and

[1L] permitting the release of the suture when carried by the bendable needle."

VII. The arguments of the appellant/opponent relevant for the decision can be summarised as follows:

Article 100(c) EPC

Feature [1H] contained added subject-matter in that it required the disengagement of the suture from the bendable needle to take place when the needle was moved from the first position to the second position, which was exactly the opposite movement of the needle to the one presented in the description of the application as filed. There was no reason to take into account the description and drawings of the patent in suit to interpret the features of the claim since the wording of the latter was not ambiguous, but made technical sense, as was made clear in several decisions of the boards. There was also no reason to give the expression "*when the needle is moved...*" any other meaning than relating to the time during which the described movement occurred.

In addition, the combination of features [1H] and [1I] added subject-matter because the mechanism for securing the suture within the first jaw was only disclosed in relation to the embodiment of Figures 13-20 and not in relation to that of Figures 1-8 and 25-27.

Article 100(b) EPC

The person skilled in the art could not carry out the invention over the whole scope of claim 1. In particular, neither the claim nor the description defined the concept of "flat" needle, and, in any case,

even if one admitted that this term designated a needle having one cross-sectional dimension larger than the other, the claim also covered the option of the flatness of the needle being at 90° to that shown in the figures, for which no embodiment was presented in the patent.

Article 100(a) EPC – lack of novelty

In view of P1

P1 was novelty-destroying for feature [1D] in particular because any needle was bendable. Moreover, "generally flat" in claim 1 could mean lying in a plane, which was the case for the needle disclosed in P1.

In view of P8

Figure 5 showed a front view of the upper jaw in which it could be seen that the width of the needle was 25% greater than the depth of the needle shown in Figures 4 and 6, so that feature [1D] was anticipated.

Article 100(a) EPC – lack of inventive step

The subject-matter of claim 1 was not inventive in view of P1 combined with P3, P4 or P5. The differentiating features did not provide any technical effect and, even if they were considered to simplify the clamp of P1, they were suggested by P3, P4 or P5.

VIII. The arguments of the appellant/patent proprietor relevant for the decision are essentially those endorsed by the Board and underlying the reasons for this decision set out below. In particular, in respect

of Article 100(c) EPC, the appellant/patent proprietor argued that it was clear for the person skilled in the art that feature [H] had to be understood to define a movement where the terms "first" and "second" were inverted, i.e. the same movement disclosed in the description and the drawings.

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

P1: US-A-3901244
P3: US-A-6113610
P4: T.Duerig et al., "An overview of nitinol medical applications", Materials Science and Engineering A273-275, 1999, pages 149-160.
P5: US-A-2738790
P8: US-A-3842840

Reasons for the Decision

1. The appeals are admissible.

2. The invention

The invention is about a (manually operated) suturing apparatus in which a bendable needle transports the suture from one jaw to the other. One of the jaws is provided with a suture-securing means holding the suture before it is transported through the tissue, and the other jaw is provided with a suture receiver to retain the suture once it has been passed through the tissue and the needle has been withdrawn. Details of a preferred embodiment are shown in Figures 1 and 13 reproduced below.

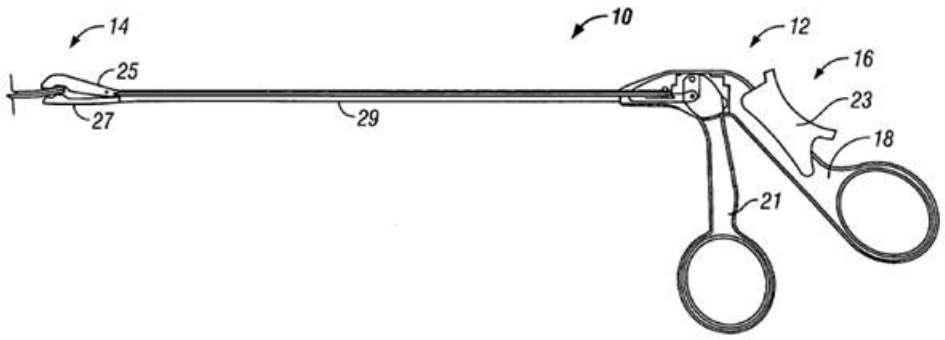


FIG. 1

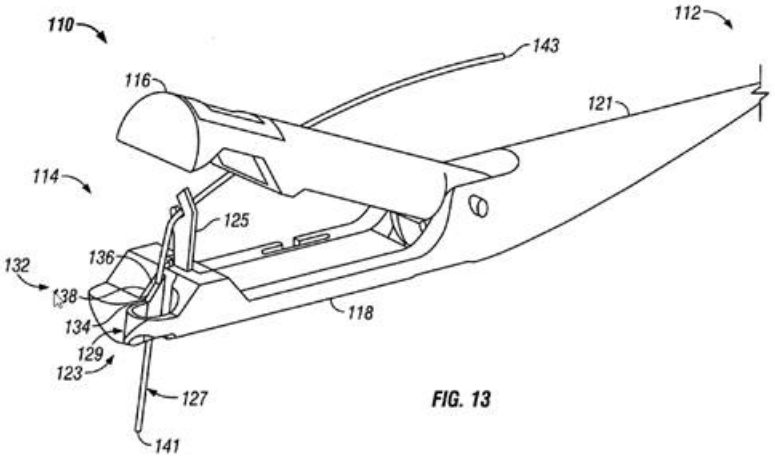


FIG. 13

3. Objection pursuant to Article 100(c) EPC

3.1 The appellant/opponent considered that feature [1H] contained added subject-matter in that it required the disengagement of the suture from the bendable needle to take place when the needle was moved from the first position (in which the needle was substantially housed in the first jaw) to the second position (in which a distal portion of the needle protruded from the first jaw), which was exactly the opposite movement to the one presented in the description of the application as filed. According to that description, it was the needle's movement from the second to the first position of the needle which generated the disengagement of the suture from the needle. Moreover, there was no reason to take into account the description and drawings of

the patent in suit to interpret the features of the claim since the wording of the latter was not ambiguous, but made technical sense. There was also no reason to give the expression "when the needle is moved..." any other meaning than relating to the time during which the described movement occurred. Hence, feature [1H] added subject-matter because it defined the opposite motion to that described in the description of the application as filed.

3.1.1 Interpretation of claim 1

In the Board's opinion, it is established case law that claims should not be read alone but in the context of the patent as a whole with a mind willing to understand (e.g. T 0190/99, point 2.4 of the Reasons; T 0556/02, point 5.3 of the Reasons). This means that a word or expression in a claim must always be given the same meaning as the one the author of the patent wished to give it. This line of thought is confirmed in T 1592/14 (point 5 of the Reasons), which was cited by the appellant/patent proprietor.

In the present case, for a person skilled in the art having read the patent as a whole, it is clear that a mistake was made in claim 1, namely "first" and "second" were inverted in this litigious feature. This is evident not only from a whole-content-disclosure point of view but also from a technical point of view.

Indeed, the object of the patent is a suturing apparatus, and it is only once the suture has passed through the tissue that it should be released from the needle. Or, said differently, it makes no technical sense to release the suture during the movement which brings the suture through the tissue, namely the

movement from the first to the second position. Hence, even if the person skilled in the art had read the claim alone, contrary to the opinion of the appellant/ opponent, they would have immediately understood that in the claim wording the two words "first" and "second" had been inverted.

This also means that the decisions T 0431/03 (point 2.2.2 of the Reasons), T 1018/02 (point 3.8 of the Reasons), T 1395/07 (point 4 of the Reasons) and T 0197/10 (point 2.3 of the Reasons) cited by the appellant/opponent in any case do not apply because they start with the assumption that the claim wording is clear and makes technical sense in itself for the person skilled in the art, which as explained above is not so in the present case.

The technically sensible interpretation of claim 1 is supported by the rest of the specification since, indisputably throughout the description and figures, it is when the needle goes back from the second to the first jaw, or more precisely once the suture is retained, that the suture is released from the needle.

Paragraph [0023] of the patent: *"…The opposing jaw 25 may include an optional receiver which is adapted to remove the suture from the needle 32 as the needle 32 is withdrawn back into the lower jaw 27. At this point, the suture extends through the tissue and into the upper jaw… A suture receiver is optional since the tissue may frequently serve as a receiver for the suture once the needle is retracted."* (emphasis added by the Board)

Paragraph [0025] and Figures 7A and 7B: *"In the upper jaw 25, a suture receiver 41 is provided to remove the*

suture 34 from the needle 32. A metal or elastomeric flap, or paddle, 43 is provided to engage the needle 32 and threaded suture 34 as illustrated in Figure 7A. This flap 43 forces the suture 34 from the needle slot 40 as the needle 32 is withdrawn as illustrated in Figure 7B." (emphasis added by the Board)

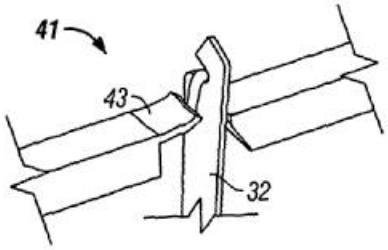


FIG. 7A

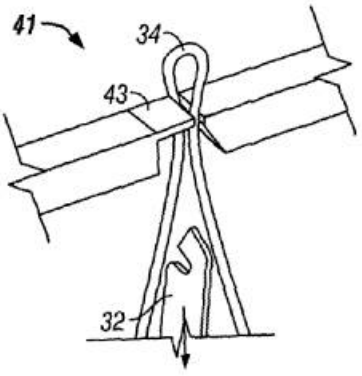


FIG. 7B

Paragraph [0026] and Figures 8A and 8B: *"In a similar embodiment, the needle 32 and threaded suture 34 is forced through an elastomeric pad 45 which similar engages the suture 34 and removes it from the needle slot 40 as the needle 32 is withdrawn as illustrated n Figure 8B."* (emphasis added by the Board)

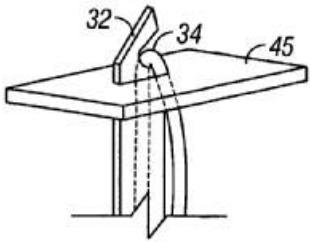


FIG. 8A

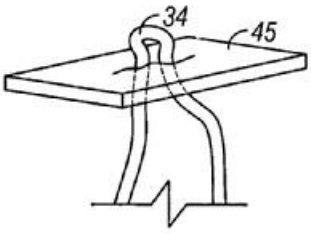


FIG. 8B

This is also explained in relation to a further embodiment, in paragraphs [0045] and [0046] and Figures 28 to 30:

"*The opening to the notch 235 is directed distally such that the suture is forced into the needle during deployment through the tissue and so that the suture releases easily as the needle is retracted.*" (emphasis added by the Board)

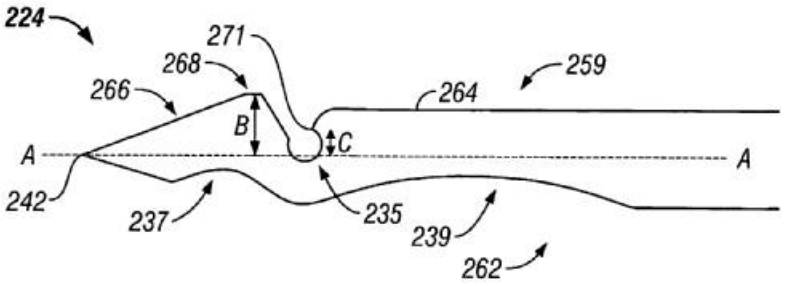


FIG. 28

"*The paddles 282 are preferably configured to abut one another at a pinch point 286, as shown in Figure 30, to permit a needle to travel therebetween while retaining a carried suture when the needle is retracted.*" (emphasis added by the Board)

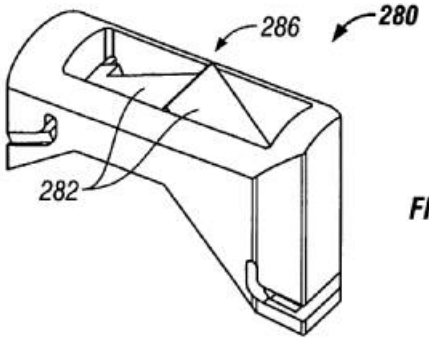


FIG. 30

From the above, it is clear that a person skilled in the art, having read the patent as a whole, will understand that the suture is released when the needle is moved from the second to the first position. In

other words, the person skilled in the art will immediately recognise that a "typo" has been made in claim 1, in that "first" and "second" have been inverted in feature [1H]. In such a case the person skilled in the art will read the claim wording including the correction. It is also clear from the above that the "when" has to be understood in its most current meaning, namely during the movement from the second to the first position. The appellant/patent proprietor confirmed this interpretation.

3.1.2 Therefore, feature [1H] does not add any subject-matter.

3.2 The appellant/opponent further considered that the combination of features [1H] and [1I] added subject-matter because the mechanism for securing the suture within the first jaw was only disclosed in relation to the embodiment of Figures 13-20 and not in relation to that of Figures 1-8 and 25-27.

In the Board's opinion, there is a general basis for the combination on page 4, last paragraph, of the application as filed, where it is mentioned that "[a] *retaining mechanism holds a suture in place to be engaged by the needle*". This is thus applicable to any of the embodiments disclosed in the application as filed. Moreover, in any case the mechanism for securing the suture in the first jaw is functionally not linked to any other mechanism within the jaws, so that it is clear for the person skilled in the art that it can be used wherever necessary. Hence, the appellant/ opponent's objection is not convincing.

3.3 For the reasons above, the ground for opposition pursuant to Article 100(c) EPC does not prejudice the maintenance of the patent as granted.

4. Objection pursuant to Article 100(b) EPC

The appellant/opponent considered that the ground for opposition pursuant to Article 100(b) EPC prejudiced the maintenance of the patent because the person skilled in the art could not carry out the invention over the whole scope of claim 1. In particular, neither the claim nor the description defined the concept of "flat" needle, and, in any case, even if one admitted that this term designated a needle having one cross sectional dimension larger than the other, the claim also covered the option of the flatness of the needle being at 90° to that shown in the figures, for which no embodiment was presented in the patent.

The Board does not share this opinion. A claim and even a patent cannot define all the details necessary for carrying out the invention described and claimed. It is the person skilled in the art with common knowledge who has to be able to carry out the invention. In the present case, it is clear from the patent in suit, in particular the figures, that flatness within the meaning of the patent in suit means that one cross sectional dimension is larger than the other cross sectional dimension. Moreover, it is technically self-evident that the smaller dimension must be so as to allow the bending of the needle in the first jaw. A needle turned by 90° around its axis (contrary to what is shown in the embodiments) would not allow such bending, and moreover would not allow the fetching of the suture. This does not have to be written in the patent in suit; it is technically self-evident. The

person skilled in the art will chose the different technical parameters so as to obtain a working embodiment on the basis of that described in the patent, and will eliminate theoretical non-working embodiments. The appellant/opponent did not demonstrate that, by adopting the basic structural concept of the suturing apparatus described in the patent in suit, the person skilled in the art would not be able to carry out the invention.

Therefore, the ground for opposition pursuant to Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

5. Objection of lack of novelty pursuant to Article 100(a) EPC

5.1 In view of P1

The appellant/opponent considered that P1 was novelty-destroying in particular because any needle was bendable (in view of its normal flexibility), and "generally flat" in claim 1 could mean lying in a plane, which was the case for the needle disclosed in P1 (see Figures 2 and 4 below).

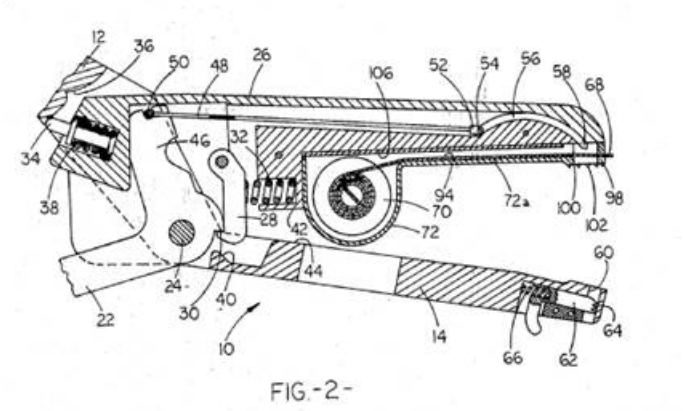


FIG.-2-

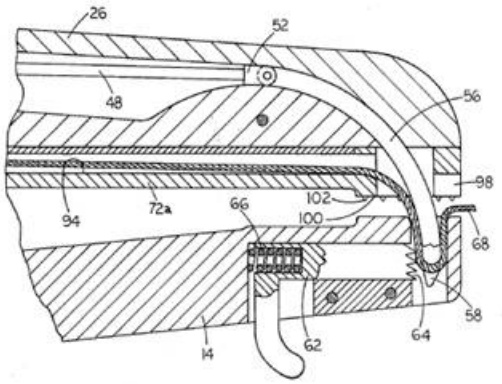


FIG.-4-

In the Board's opinion, the needle disclosed in P1 cannot be qualified as "bendable". As can be seen in the figures above, the suturing apparatus disclosed in P1 uses a curved needle (56) which travels in a correspondingly curved path. Hence, the needle is not bent in use. In the context of the invention of the patent in suit the meaning of "bendable" is different since - as can be seen in the drawings (e.g. Figure 5B), for instance - when the needle is pushed distally it has to bend to follow the angled path in the first jaw. This cannot be considered to be the normal flexibility present in a needle as disclosed in P1.

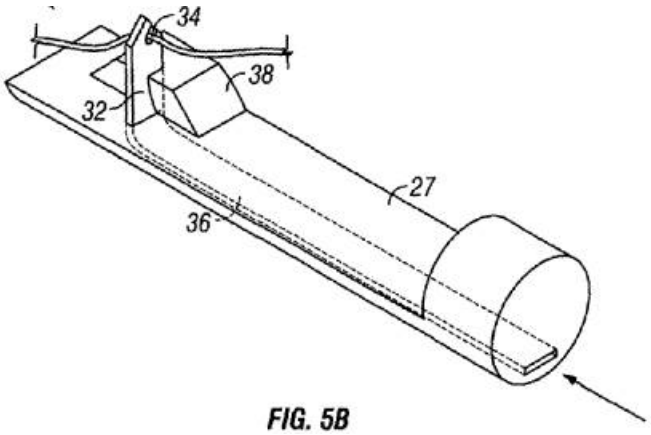


FIG. 5B

In the same way, the needle disclosed in P1 appears to have the shape and cross-section of a normal curved needle classically used for suturing, i.e. with a circular diameter. Nothing in the document indicates something else. Hence, such a needle is not flat within the meaning of the patent in suit. Nor does the fact that it lies flat on a planar surface make it a "flat needle" within the meaning of the patent in suit, as explained under point 4 above.

5.2 In view of P8

The appellant/opponent considered that Figure 5 (see below) showed a front view of the upper jaw in which it could be seen that the width of the needle (62) was 25% greater than the depth of the needle shown in Figures 4 or 6 (the latter also shown below).

P8 discloses the same technology and is from the same inventor as P1, so that there is no great difference of disclosure. Nothing in P8 points to such a difference of cross-sectional dimensions. On the contrary, the same Figure 5 shows a rounded upper end of the needle, which instead confirms that the needle is round. Thus, P8 does not disclose a flat needle.

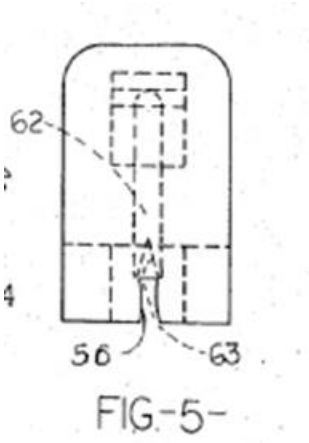


FIG-5-

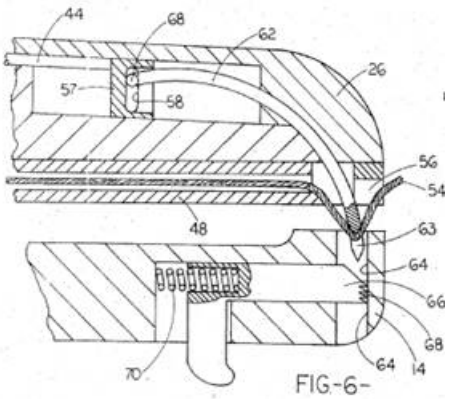


FIG-6-

In any case, the needle is of the same kind as that disclosed in P1, i.e. not bendable, as required by claim 1.

5.3 For the reasons above, the ground for opposition of lack of novelty pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

6. Objection of lack of inventive step pursuant to Article 100(a) EPC

6.1 All inventive-step objections by the appellant/ opponent start from P1. This document is combined with P3, P4 or P5.
According to the appellant/opponent the possible differentiating features did not provide any technical effect and, even if they might provide the effect of simplifying the clamp of P1, they were suggested by any of P3, P4 or P5. P3 was from the same technical field as P1. It uses a needle for passing sutures and provided a simpler alternative mechanism to a pivoting mechanism for deploying a needle in a suturing device. P4 confirmed that nitinol was particularly interesting for medical devices due to its high flexibility, and the person skilled in the art would recognise this property and advantageously replace the needle mechanism of P1. P5 was a suturing device with a flat

needle operated between two jaws in a similar way to that of P1, so that the person skilled in the art would have used the flat needle to arrive at the subject-matter of claim 1 in an obvious way.

6.2 P1 discloses a suturing clamp comprising a cartridge carrying a suture bobbin. Once the flesh is clamped between the jaws of the clamp, a needle 56 carrying the suture is pushed out of the first jaw 26 through the flesh into the second jaw 14 including a suture receiver 64, 66 (see column 3, lines 15 to 27, Figure 1 below and also Figures 2 and 4 reproduced above under point 5.1).

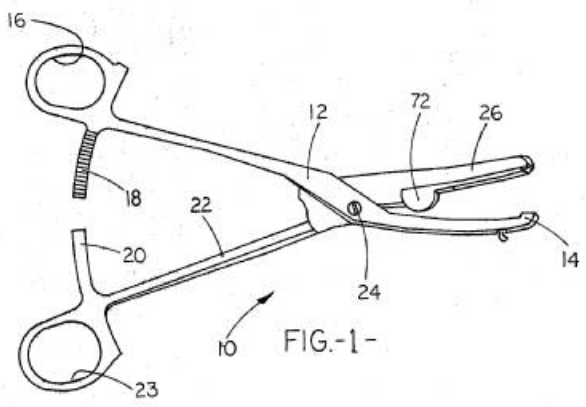


FIG.-1-

6.3 Starting from P1, the differentiating features are (as explained above):

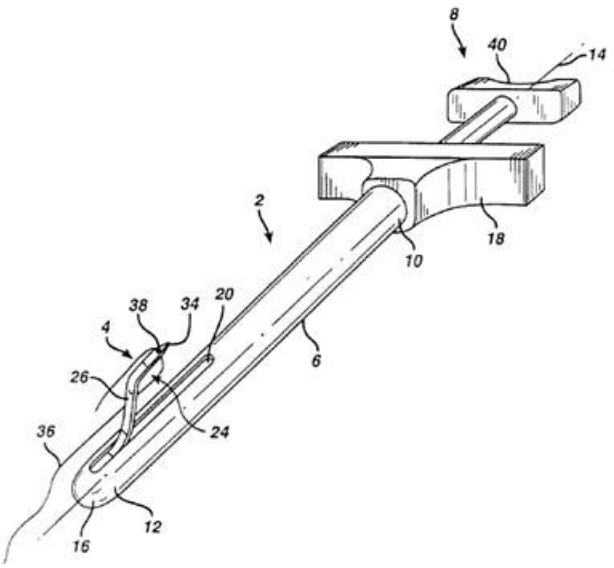
i) a bendable needle carried by the first jaw (part of feature [1C])
ii) the bendable needle having a generally flat configuration (part of [1D])

The Board considers that, contrary to the appellant/ opponent's opinion, these features can improve the compactness of the jaws (as found by the Opposition Division) and simplify the needle-actuating mechanism (paragraphs [0003] and [0004] of the patent). A flat

needle (instead of the curved needle of P1) results in a compact structure, while its bendability represents a simple possibility of converting the force along the axis of the instrument into a force perpendicular to it.

6.4 P3 discloses a suturing device for closing trocar incision sites (column 1, lines 44 and 45: "*The present invention is a simple instrument for closing trocar incision sites and delivering sutures.*").

FIG. 1



This device essentially consists of a tubular element 6 at the interior distal end of which a resilient needle 4 is fixed. With the aid of a rod-like element 28 moving longitudinally the needle 4 carrying the suture 36 is allowed or not to come out of the tubular element 6 through a slot present in the latter (see Figure 1 here above and Figures 3A, 3B and 3C below). The needle can be considered to be flat.

FIG. 3A

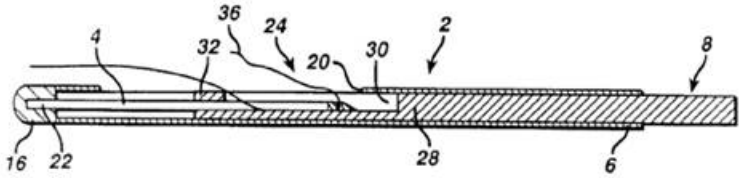


FIG. 3B

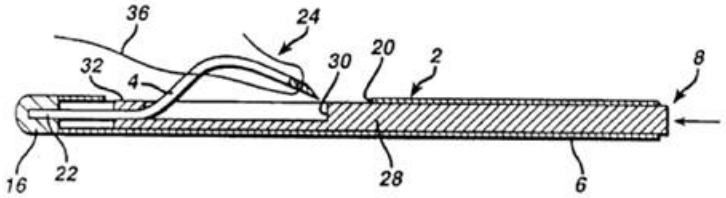
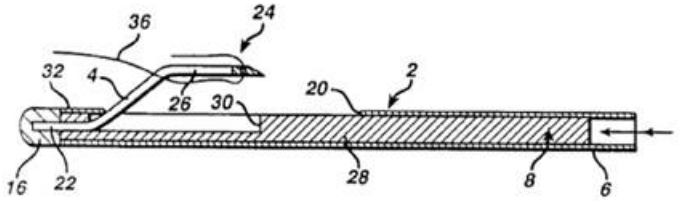


FIG. 3C



As mentioned, the suturing device of P1 is a so-called "suturing clamp", so it is already questionable whether a person skilled in the art wishing to simplify the drive mechanism of the needle would seek any solution in a document such as P3, which discloses a suturing device not even having jaws that works in a completely different way and, according to P3, is intended specifically for closing trocar puncture wounds.

Moreover, even if they looked at it, they would not arrive at the subject-matter of claim 1. In order to suture a wound, the device according to P3 is brought beneath the tissue to be sutured, the needle is freed

and then the whole device is pulled to pull or push the needle through the tissue (column 4, lines 4 to 22). There is no action on the needle alone to push it through the tissue while the tissue is held between jaws as in the device of P1.

Therefore, the Board sees no reason as to why the person skilled in the art would see any promising effect of the use of a needle according to P3 in relation to the completely different needle-pushing mechanism of P1, and to the compactness or simplicity of the suture clamp of P1.

6.5 The same applies for a combination with P5. Even if this document shows a flat needle 38 with a hook 40 for fetching the suture when it is pulled back (see column 2, line 69 and following), the suturing instrument according to this document has no jaws for holding the tissues to be sutured, and it is specifically intended for the stitching of the mitral valve to the heart wall (see for instance column 1, lines 15 to 30). Even if the person skilled in the art envisaged transferring the technology presented in this document to the suture clamp of P1, it would not lead them in an obvious way to the claimed subject-matter, since the suture would be in the second jaw right from the start and not in the first as required by the claim, so that there appears to be no need for a suture receiver in the opposite jaw contrary to what the claim requires. It is even questionable whether the person skilled in the art would retain the movable jaws present in the device according to P1, since the device according to P5 appears not to need any.

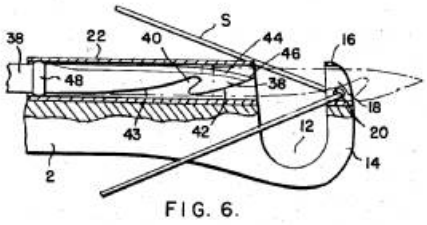


FIG. 6.

Therefore, the combination of P1 with P5 does not lead to the subject-matter of claim 1 in an obvious manner either.

6.6 P4 is an article about the use of nitinol in medical applications. The appellant/opponent explained that this article confirmed that nitinol was particularly interesting due to its high flexibility (see page 151, first full paragraph). The person skilled in the art would recognise this property and therefore advantageously replace the needle mechanism of P1 with such material.

The Board does not share the appellant/opponent's view. P4 is a very general article on the applications of nitinol in medical devices. Such different devices as stents, graspers, atrial septal occlusion devices, hip implants, etc, are mentioned in the article. It is therefore highly questionable whether a person skilled in the art wishing to improve the suture clamp according to P1 would ever think of finding a promising solution in such an article. Moreover, even if they looked at it, suture clamps are not mentioned in it. So it would anyway require an inventive step to recognise that the use of nitinol may be advantageous in a suture clamp. And this would still not mean that it would specifically be advantageous to replace the needle mechanism, and to replace it with a flat needle. In the

opinion of the Board, this is a typical reasoning with hindsight.

Therefore, the combination of P1 with P4 does not render the subject-matter of claim 1 obvious either.

6.7 For the reasons above, the ground for opposition of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

7. Costs

In its statement setting out the grounds of appeal, the appellant/opponent requested oral proceedings before any decision, other than to revoke the patent in its entirety, was taken.

Consequently, the Board summoned the parties to oral proceedings. By letter dated 10 December 2019, the appellant/opponent informed the Board that it would not be attending the oral proceedings, but that this did not mean that it was withdrawing its appeal or its request for oral proceedings. Hence, the Board went ahead with the scheduled oral proceedings.

However, since the Board intended to maintain the patent according to the main request of the appellant/ patent proprietor (the patent as granted), the oral proceedings (in the absence of the appellant/opponent) served no purpose and could have been cancelled, had it not been for the request of the appellant/opponent. Indeed, the appellant/patent proprietor is not adversely affected by the decision to maintain the patent on the basis of its main request, and would thus

not have needed any oral proceedings to defend its case.

By maintaining its request for oral proceedings, the appellant/opponent thus not only obliged the Board to hold the oral proceedings but also obliged the appellant/patent proprietor to come to the oral proceedings and to prepare for them.

Under these circumstances, pursuant to Article 104(1) EPC and Article 16(1)(e) and 16(2) RPBA 2020, the Board finds it equitable that the appellant/opponent bears the costs (for preparation, travel and presence) incurred by the appellant/patent proprietor for the oral proceedings before the Board.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

3. The appellant/opponent shall bear the costs of the oral proceedings before the Board of appeal.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated