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Datasheet for the decision of 23 April 2018

Case Number: T 1064/15 - 3.2.02

Application Number: 10011872.8

Publication Number: 2338421

IPC: A61B17/04, A61B17/06, B26D3/08

Language of the proceedings: EN

Title of invention:
Barbed suture

Patent Proprietor:
Quill Medical, Inc.

Opponent:
ITV Denkendorf Produktservice GmbH

Headword:

Relevant legal provisions:
EPC Art. 56, 100(a), 100(b)

Keyword:
Main request - sufficiency of disclosure - (no)
Auxiliary request - inventive step (yes)

Decisions cited:
T 0014/83, T 0815/07, T 1034/12

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 1064/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 23 April 2018

Appellant: (Opponent)	ITV Denkendorf Produktservice GmbH Körschtalstrasse 26 73770 Denkendorf (DE)
Representative:	Patentanwälte Ruff, Wilhelm, Beier, Dauster & Partner mbB Kronenstraße 30 70174 Stuttgart (DE)
Respondent: (Patent Proprietor)	Quill Medical, Inc. 1633 Westlake Avenue N., Suite 400 Seattle WA 98109 (US)
Representative:	Small, Gary James Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 11 March 2015 concerning maintenance of European patent No. 2338421 in amended form**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	M. Stern

Summary of Facts and Submissions

I. The appeal of the opponent is directed against the interlocutory decision of the Opposition Division posted on 11 March 2015 that, account being taken of the amendments according to the main request made by the proprietor during the opposition proceedings, the patent and the invention to which it relates meet the requirements of the EPC.

II. Notice of appeal was filed on 19 May 2015, and the appeal fee was paid on the same day. The statement of grounds of appeal was filed on 21 July 2015.

III. Oral proceedings were held on 23 April 2018.

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

The respondent-patent proprietor 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 auxiliary request 1 filed with a letter dated 23 March 2018.

IV. The following documents are cited in the decision:

E1: GB-A-1091282
E2: US-A-5306288

V. The arguments of the appellant-opponent and of the respondent patent-proprietor where relevant for the decision are summarised in more detail in the corresponding parts of the reasons for the decision.

Concerning sufficiency of disclosure in relation to the main request, the respondent-patent proprietor essentially considered that paragraph [0024] of the patent gave a definition of the diameter of non-circular cross-sections, that it was easy to measure the defined dimension with a micrometre and that, since the claim covered circular and non-circular cross-sections, the requirements for sufficiency were satisfied anyway because it was possible to carry out the invention for circular cross-sections, as this was the case for needles the cross-section of which was not specified.

Concerning inventive step in relation to the auxiliary request, the appellant-opponent essentially considered that the suture of E1 was circular in shape since it was twisted during manufacturing and that the use of common sense alone along with commercially available needles (illustrated by E2) when carrying out the invention of E1 led to the subject-matter of claim 1 in an obvious way.

VI. Claim 1 as considered allowable by the opposition division and corresponding to the version according to the patent as granted reads as follows:

"A barbed suture (S1...S4) for connecting human or animal tissue in combination with a surgical needle (N1...N4), said combination comprising a barbed suture attached to a surgical needle,

wherein the suture comprises a plurality of barbs projecting from an elongated body having a first end and a second end and a diameter (SD1...SD4) of a circular or non-circular cross section in the range of from about 0.001 mm to about 1 mm, each barb facing in

a direction and being adapted for resisting movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces,

and wherein the surgical needle has a diameter (D1...D4) with a ratio of the surgical needle diameter to the elongated body diameter of up to 3:1,

characterised in that

the ratio of the surgical needle diameter to the elongated body diameter is not lower than 1.47:1."

VII. Claim 1 according to auxiliary request 1 reads as follows:

"A barbed suture (S1...S4) for connecting human or animal tissue in combination with a surgical needle (N1...N4), said combination comprising a barbed suture attached to a surgical needle,

wherein the suture comprises a plurality of barbs projecting from an elongated body having a first end and a second end and a diameter (SD1 ...SD4) of a circular cross section in the range of from about 0.001 mm to about 1 mm, each barb facing in a direction and being adapted for resisting movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces,

and wherein the surgical needle has a diameter (D1...D4) with a ratio of the surgical needle diameter to the elongated body diameter of up to 3:1,

characterised in that

the ratio of the surgical needle diameter to the elongated body diameter is not lower than 1.47:1."

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention relates to a barbed suture-needle combination useful for connecting body tissue in various surgical contexts, and more particularly to optimisation of the wound closure strength (paragraph [0010]), for which purpose the ratio of the surgical needle diameter to the diameter of the elongated body of barbed suture has to fall within a predetermined range.

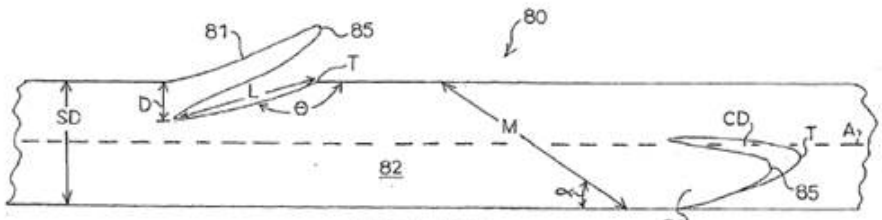

FIG. 7A

3. Main request – sufficiency of disclosure

3.1 In order for this ground for opposition to prejudice the maintenance of the patent in suit it must be established that the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The person skilled in the art must be able to carry out the invention on the basis of the patent

as a whole (T 14/83) without undue burden, possibly using his common general knowledge.

3.2 Claim 1 requires the diameter (SD) of the elongated body to be within a first specified range of values and requires the ratio of the surgical needle diameter (D) to the elongated body diameter (SD) to be within a second specified range of values, whereby the elongated body can have a circular or non-circular cross section.

While these requirements can be implemented for circular cross-sections, when trying to carry out the claimed invention using elongated bodies with non-circular cross-sections the question arises of which dimension of a non-circular cross-section must be considered to be its diameter.

3.3 In the present case, the wording of claim 1 requires the diameter of the elongated body to be taken into account, but does not specify how it should be defined; so it is not possible to deduce any definition of the diameter of a non-circular cross-section from the claim wording itself.

It follows that it must be examined whether any information relating to the definition of the diameter for non-circular cross-sections can be found in or inferred from the description and figures of the patent in suit.

3.4 In the description of the patent only paragraphs [0023] and [0024] deal with non-circular cross-sections.

In paragraph [0023] of the patent it is explained that:

"*Although the sutures are described below in a preferred embodiment with a circular cross section, the sutures according to the present invention have a non-circular cross sectional shape that increases the surface area and facilitate the formation of the barbs. Cross sectional shapes may include, but are not limited to, oval, triangle, square, parallelogram, trapezoid, rhomboid, pentagon, hexagon, cruciform, and the like. Typically, barbs are cut into a polymeric filament that has been formed by extrusion using a die with a circular cross section, and thus, the cross section of the filament will be circular, as that is what results during such extrusion. However, extrusion dies can be custom made with any desired cross-sectional shape*."

While this paragraph explains that non-circular cross-sections are used instead of the circular ones presented in the preferred embodiments, and that these shapes may be manufactured with suitable extrusion dies, there is no indication as to which dimension of the non-circular cross-section is important or not.

Of the two paragraphs, only [0024] deals with the definition of the term "diameter", reading as follows:

"*Hence, the term "diameter" as used here is intended to mean the transverse length of the cross section, regardless of whether the cross section is circular or some other shape*." (emphasis added)

The word "hence" normally introduces a logical consequence of what was set out before, which would mean that the logical consequence of using circular and non-circular cross-sections would be that the "transverse length of the cross section" should be considered as the diameter. However, in the present

case this logical conclusion does not help, since there is no indication in this sentence as to which "length" should be considered or how and/or in relation to what that length should be "transverse"; and that definition is not a generally accepted one for which no further explanation would be necessary.

Even when considering the examples of non-circular cross-sections given in paragraph [0023], namely oval, triangle, square, parallelogram, trapezoid, rhomboid, pentagon, hexagon, cruciform, it does not become clearer what the "transverse length of the cross section" could be in all these cases. A multitude of "transverse" segments, each having a length, can be defined for any of the shapes above. It is, however, far from clear which one should be used for the ratio defined in the claim. For instance, in the case of a parallelogram the transverse length could be the "width", the "length", the "diagonal" or any other segment length.

Hence, in the Board's view, paragraph [0024] is not in itself sufficient to define unequivocally what this transverse length of the cross-section should be.

3.5 Moreover, none of the embodiments presented in the detailed description and/or shown in the figures exhibits a non-circular cross-section of the elongated body; so the person skilled in the art cannot find any teaching in these elements which would help him to understand the meaning of the definition in paragraph [0024].

3.6 The respondent-patent proprietor considered that in the English language the word "length" designated the greater of two or the greatest of three dimensions of a

body and therefore this word in paragraph [0024] had that same meaning, and would indeed have to be understood as the greatest dimension of the cross-section.

The Board does not share this view. Even if this definition is true, in itself it does not define how it should be applied in particular in relation to a diameter and/or in specific cases, as for example with a cruciform shape or a hexagon to name only two of the shapes mentioned in paragraph [0023].

Moreover, the definition in paragraph [0024] does not refer to the "length" of the cross-section, but to the "transverse length" of the cross-section. What the word "transverse" is supposed to mean in this context is not defined in any way with reference to the general definition of the word "length" in English language. Should "transverse" mean any line joining one point of a boundary to any other point of the boundary, or should it mean only the lines starting perpendicularly to any tangent to a boundary point and joining the other side of the boundary, or something else again? This remains undefined.

3.7 The respondent-patent proprietor further considered that the person skilled in the art could take a micrometre and measure all the dimensions of the cross-section, and if all fell within the specified range the suture would fulfil the requirements of the claim, which meant that he was able to carry out embodiments with a suture having an elongated body with a non-circular cross-section falling under the wording of claim 1.

The Board does not share this view. An invention is a way to solve a particular problem. In the present case, as indicated above, the invention of the patent in suit aims at achieving a closure strength better than in the state of the art by using a specific barbed suture, with a particular ratio of needle diameter to diameter of the elongated body. Corresponding tests with circular cross-section elongated bodies are presented in paragraphs [0159] to [0176].

However, as already explained, in the suture-needle combination claimed in the patent in suit the suture can also have any non-circular cross-section; so in such a case the person skilled in the art is faced with the undefined parameter "diameter (SD)" in the definition of the ratio to be respected and consequently does not know how to choose the cross-section in order to obtain the desired technical effect. For the conditions of sufficiency of disclosure to be fulfilled it is not enough to be able to manufacture an object falling under the wording of a claim. That object must also exhibit the alleged or desired technical effect obtained with that invention (T 815/07). In the present case the person skilled in the art is left alone with that undefined parameter for an essential part of the scope of the claim, since there is no single non-circular shape for which he knows which dimension the "transverse length" should be. In other words, he is left with the question not only of how to measure the "diameter (SD)" but also, more fundamentally, of what to measure in order to obtain the desired technical effect.

3.8 The respondent-patent proprietor further considered that since the wording of the claim required circular and non-circular cross-sections of the elongated body

of the suture, this was equivalent to mentioning no specific shape for the cross-section. In such a case it was obvious that the requirements of sufficiency of disclosure were fulfilled because needle-suture combinations having an elongated body of circular cross-section and fulfilling the teaching of the patent could easily be carried out. The application of the teaching of the patent to non-circular cross-sections was in that case only a question of an ambiguity being present in the specification. The situation was similar to that of the needle; the dimension representing the diameter of the needle was not questioned, although in that case only the general word "diameter" was used.

The Board does not share this opinion either. The respondent-patent proprietor voluntarily specified in the description of the patent (paragraphs [0023] and [0024]) and in claim 1 that the cross-section of the elongated body forming the suture could be circular or non-circular. In other words, the respondent-patent proprietor himself intended the teaching of the patent to be applicable to both circular and non-circular cross-sections and specifically sought protection for both types of embodiment. Moreover, it should be noted that the field of non-circular cross-sections is far wider than that of circular ones, since it encompasses an enormous variety of shapes (some of them being cited in paragraph [0023]). This makes it even more important to know how the key parameter of such shapes, namely the diameter, is determined. In such a context, it would be insufficient and disproportionate if the sole disclosed possibility of carrying out the invention with circular cross-section elongated bodies were enough to satisfy the requirements of sufficiency of disclosure. Such an approach cannot have been intended by the legislator, because in the Board’s view this

would go against the general principle that the protection obtained with the patent has to be commensurate with the disclosed teaching. As explained above, when it comes to non-circular cross-sections, this is not the case for the patent in suit.

The fact that for the diameter of the needle, also mentioned in the claim, the word "diameter" is used without any more precise wording does not change the above finding. On the contrary, on a fair reading of the claim, this simply means that the diameter of the needle was not intended to fall under the definition of the diameter used for the elongated body and, hence, falls within the normal definition of a diameter, namely the length of a line passing through the centre of a circle and joining two opposite points of it. Or, in other words, since nothing more precise is mentioned, neither in the claim nor in the description, the cross-section of the needle is usual, i.e. circular.

3.9 Hence, the ground for opposition under Article 100(b) EPC prejudices the maintenance of the patent as granted, because on the basis of the patent disclosure as a whole, taking common general knowledge into account, the person skilled in the art is not able to determine which dimension is meant by the diameter (SD) for an essential part of the claim, or in other words, with a needle having a given diameter, he does not know how to select the cross-section dimension of a non-circular suture in order to improve the closure strength, which was supposed to be an essential part of the teaching of the patent in suit. This is in line with decision T 1034/12 of this Board concerning non-circular sutures.

4. Auxiliary request 1 – inventive step

4.1 The appellant-opponent considered that the subject-matter of claim 1 was not inventive starting from E1 in view of E2.
E1 disclosed a needle-suture combination according to the first part of claim 1. In particular, although Figure 12 showed a cruciform cross-section, since according to page 4, lines 7 to 9, the suture was twisted to produce a long spiral the final cross-section had to be considered circular in shape, which was also confirmed by the general wording of claim 1 of E1. Moreover, this document recommended the use of fine needles in combination with the barbed suture disclosed there (page 3, lines 109 to 111; page 4, lines 37 to 39). The subject-matter of claim 1 was not inventive in view of the general technical considerations to be applied when manufacturing a barbed suture-needle combination. The needle had to be thick enough to allow the barbed suture to be drawn through the channel created in the tissue by the needle, and this channel had not to be too large so as not to cause more damage than necessary to the patient's tissue and also so as to permit the anchoring of the barbs in the tissue. Between these self-evident limits the person skilled in the art had to choose the adapted needle from among the limited number of commercially available ones. These commercially available ones were for instance listed in E2. There could be no inventive step in choosing fine needles among such a limited number of available ones. As could be seen from tables 13A and 13B, the respondent-patent proprietor also chose precisely the same needles as mentioned in table I in E2.

4.2 The first part of claim 1 stipulates that "the suture comprises a plurality of barbs projecting from an

elongated body having a first end and a second end and a diameter (SD1 ...SD4) of a circular cross section". In the Board's opinion this means that the elongated body forming the suture core element has to have a circular cross-section and that the barbs have to project from this body of circular cross-section. This wording does not cover a suture having part of it of circular cross-section without barbs and part of it of a different cross-section but with the barbs projecting from it. However, the latter is precisely the case with the suture-needle combination disclosed in E1. Indeed, as explained starting on page 3, line 128: "*The suture is made from drawn monofilament nylon of circular cross section 23 (shown in a dashed line in Figure 12) which is rolled to produce a monofilament of cruciform cross section as shown in Figure 12.*

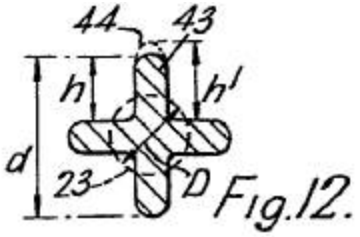

Fig.12.

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The ribs 43 of the cross are so cut by either a simple angled cut or a 'V' shaped cut 42 to produce a series of barbs 44, which are distorted or bent outwards to make the slender barbs 44 more prominent. The suture is finally twisted in its longitudinal axis to produce a long spiral."

Even if the suture is twisted at the end of the manufacturing process, the shape of the section of the portion with the barbs will remain the same, namely a cruciform cross-section. The circular cross-section of the elongated body of the claim mentioned above is therefore not disclosed in E1. The more general wording

of claim 1 of E1 cannot change this finding, since such a general disclosure does not disclose the specific circular shape.

4.3 Therefore the subject-matter of claim 1 differs from the suture-needle combination according to E1 in that (i) the barbs are formed on an elongated body having a circular cross-section and (ii) the ratio of the surgical needle diameter to the elongated body diameter is chosen to fall between 1.47:1 and 3:1.

4.4 (i) The appellant-opponent did not explain why in its opinion the person skilled in the art would abandon the cruciform cross-section of the elongated body and choose a circular cross-section. The Board does not see any reason for this either. In particular, since, as explained in the paragraph reproduced above, the ribs of the cross are used to produce the barbs 44, it would seem contrary to the teaching of this document to abandon this shape favourable for manufacturing.

For that reason alone, the subject-matter of claim 1 is inventive.

4.5 (ii) Moreover, while E1 mentions the use of fine needles, it not only does not define what kind of needles are considered to be fine, but also and more importantly it does not hint at the importance of the ratio of the surgical needle diameter to the elongated body diameter in relation to the wound closure strength, which is the main teaching of the patent in suit. Therefore, the person skilled in the art starting from the suture of E1 with a given diameter would not be prompted to choose a needle diameter which satisfies the mentioned condition of the claim.

Document E2 does not change this finding, since not only is it about sutures without barbs, such that it is already questionable whether the person skilled in the art would consult it, but more importantly it cannot suggest what it does not disclose, namely that the ratio of the surgical needle diameter to the elongated body diameter is of relevance to the closure strength and should be chosen to fall within the range of claim 1.

4.6 Therefore, the subject-matter of claim 1 is inventive pursuant to Article 56 EPC in view of the cited documents, and so the ground for opposition pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent on the basis of auxiliary request 1.

5. The Board is satisfied that the description has been adapted to the claims according to auxiliary request 1.

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 with the order to maintain the patent on the basis of:

claims 1 to 11 of auxiliary request 1 as filed with the letter dated 23 March 2018;

description:
. pages 1 to 3 and 5 to 24 of the patent as granted and;
. page 4 as filed during the oral proceedings; and
. figures according to pages 28 to 35 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated