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Datasheet for the decision of 8 November 2017

Case Number: T 1034/12 - 3.2.02

Application Number: 07015906.6

Publication Number: 1858243

IPC: H04N1/04, A61B17/06

Language of the proceedings: EN

Title of invention:
Barbed suture in combination with surgical needle

Patent Proprietor:
Quill Medical, Inc.

Opponent:
ITV Denkendorf Produktservice GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(b)
EPC R. 115(2)
RPBA Art. 15(3)

Keyword:
Sufficiency of disclosure - (no)
Oral proceedings - held in absence of the respondent

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

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1034/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 8 November 2017

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:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 22 February 2012 rejecting the opposition filed against European patent No. 1858243 pursuant to Article 101(2) EPC.**

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 against the decision of the Opposition Division, posted on 22 February 2012, to reject the opposition.

The notice of appeal was filed on 27 April 2012 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 3 July 2012

II. Oral proceedings were held on 8 November 2017.

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

The respondent/patent proprietor requested in writing that the appeal be dismissed.

Although duly summoned by communication dated 16 August 2017, the respondent/patent proprietor did not attend the oral proceedings, as announced by letter dated 17 October 2017. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party.

III. The following documents are cited in the decision:

E1: GB-A-1091282;

GK1: Excerpt Oxford Dictionaries Online, "Diameter", one page, Copyright © 2011 Oxford University Press;

GK2: Excerpt Wolfram MathWorld (online), "Generalized Diameter", one page, Copyright © 1999-2011 Wolfram Research.Inc.;

GK3: Excerpt Wolfram MathWorld (online), "Polygon Diameter", one page, Copyright © 1999-2011 Wolfram Research.Inc.;

GK4: Excerpt Wikipedia, the free encyclopedia, "Diameter", two pages, last modified 18 March 2011;

GK5: The Concise Oxford Dictionary of Current English, ninth edition, edited by Della Thompson, Copyright © Oxford University Press 1964, 1976, 1982, 1990, 1995, page 779 "length".

IV. Claim 1 of 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 (S1...S4) attached to a surgical needle (N1...N4),

wherein the suture (S1...S4) comprises a plurality of barbs (7, 9, 17, 18, 19, 20, 35, 37, 39, 47, 48, 49, 50, 67, 77, 78, 81, 97, 107, 115, 125, 127, 129, 135) projecting from an elongated body (2, 12, 32, 42, 62, 72, 82, 92, 102, 112, 122, 132) having a first end (4, 14, 34, 44, 64, 74, 94, 124) and a second end (16, 46, 76, 96) and a diameter (SD),

each barb (7, 9, 17, 18, 19, 20, 35, 37, 39, 47, 48, 49, 50, 67, 77, 78, 81, 97, 107, 115, 125, 127, 129, 135) facing in a direction and being adapted for resisting movement of the suture (S1...S4) when in tissue, in an opposite direction from the direction in which the barb (7, 9, 17, 18, 19, 20, 35, 37, 39, 47,

48, 49, 50, 67, 77, 78, 81, 97, 107, 115, 125, 127, 129, 135) faces,

the elongate body (2, 12, 32, 42, 62, 72, 82, 92, 102, 112, 122, 132) has a non-circular cross sectional shape

charaterised in that

the surgical needle (N1...N4) has a diameter (D1...D4) with a ratio of the surgical needle diameter (D1...D4) to the elongated body diameter (SD) of between about 3:1 and 1.47:1."

V. The arguments of the respondent/patent proprietor can be summarised as follows:

The person skilled in the art found in paragraph [0031] a clear definition of the dimension to be taken as the diameter of a non-circular cross-section. The person skilled in the art would understand that it was the greatest dimension of that cross-section which had to be considered. This definition was confirmed by several documents reflecting common general knowledge which had been filed. They confirmed in particular that the word "length" used in the paragraph mentioned had to be understood as the greatest dimension across the cross-section. Also E1 confirmed that definition of the diameter for a suture having the shape of a cross in its Figure 12. For the specific shape of an equilateral triangle addressed by the appellant/opponent, according to the more general definition of a diameter, the side length of the triangle was the dimension to consider as it was the longest line segment.

Therefore, the person skilled in the art could carry out the invention without undue burden.

VI. The arguments of the appellant/opponent are essentially those underlying the decision.

Reasons for the Decision

1. The invention

The invention relates to a barbed suture useful for connecting body tissue in various surgical contexts, and more particularly to the optimisation of the disposition and/or configuration of the barbs on such sutures. In order to optimise the wound closure strength (paragraph [0010]), the ratio of the surgical needle diameter to the diameter of the elongated body of barbed suture has to fall within a predetermined range.

2. Ground for opposition pursuant to Article 100(b) EPC

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 0014/83) without undue burden, possibly using his common general knowledge.

2.1 The ratio defined in the feature of the characterising part of claim 1 needs the diameter (SD) of the elongated body to be known. However, the last pre-characterising feature defines that the elongated body has a non-circular cross-sectional shape. The person

skilled in the art is therefore confronted with the question of which dimension of a non-circular cross-section has to be considered as its diameter.

2.2 According to the respondent/patent proprietor, paragraph [0031] of the patent gave a definition which was clear enough and meant that the dimension to be taken into account was the greatest dimension of the cross-section. The respondent/patent proprietor further submitted that this was confirmed by common general knowledge definitions of the diameter as according to documents GK1 to GK5. There was therefore no doubt as to how the ratio defined in the claim had to be determined and the person skilled in the art did not have any difficulty carrying out the invention.

According to the appellant/opponent, the patent in suit did not define which dimension of such a non-circular shape was the diameter. The wording of paragraph [0031] not only was not clear in itself, but it also did not become clearer when considering the common general knowledge definitions proposed by the respondent/patent proprietor.

2.3 In the present case, the wording of claim 1 simply defines that the diameter of the elongate body has to be taken into account but does not specify how it should be defined, so that 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 related 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.

2.4 In the description of the patent only paragraphs [0030] and [0031] deal with non-circular cross-sections. In paragraph [0030] 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.

Out of the two, only paragraph [0031] deals with the definition of the term diameter and reads 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 what "length" should be considered, 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 explanations would be necessary.

Even when considering the examples of non-circular cross-sections given in paragraph [0030], namely oval, triangle, square, parallelogram, trapezoid, rhomboid, pentagon, hexagon, cruciform, it does not become clearer what could be the "transverse length of the cross-section" 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, according to the Board, paragraph [0031] is not in itself sufficient to define unequivocally what this transverse length of the cross-section should be.

2.5 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 that 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 [0031].

2.6 The respondent/patent proprietor filed several documents of common general knowledge which according to him would support its view that the "transverse length of the cross-section" had the normal meaning of "greatest length".

Since paragraph [0031] is an autonomous definition of the word "diameter" in the patent in suit, it seems questionable whether the general knowledge definitions as filed by the respondent/patent proprietor should have any relevance for the determination of the said meaning. However, for the sake of completeness the Board will analyse these filings.

The general definitions filed by the respondent/patent proprietor are not identical and even partly contradictory. For example, the Oxford Dictionaries Online GK1 definition is: "*a straight line passing from side to side through the centre of a body or figure, especially a circle or a sphere*", but the definition of the generalised diameter in GK2 (Wolfram Mathworld) is "*the greatest distance between any two points on the boundary of a closed figure*". These two definitions are obviously not always compatible, because the greatest distance between any two points does not necessarily pass through the centre of a given figure, such as the triangle mentioned in the list in paragraph [0030]. The respondent/patent proprietor submitted that the relevant dimension in an equilateral triangle is the length of a side. The side, however, obviously does not go through the centre of the triangle, so that the common-general-knowledge definition of GK1 is contradicted.

The same is true for the definition given in GK3 ("*The diameter of a polygon is the largest distance between any pair of vertices*") and that given in GK4 ("*For a convex shape in the plane, the diameter is defined to be the largest distance that can be formed between two opposite parallel lines tangent to its boundary*"). A segment according to any of these definitions does not necessarily cross the centre of the figure.

The respondent/patent proprietor additionally filed GK5, an excerpt of the Concise Oxford Dictionary presenting the definition of the word "length", and submitted that the definition given there ("*the greater of two ... dimensions of a body*") demonstrated that the word "length" in paragraph [0031] should have that same meaning, and therefore would indeed have to be understood as the greatest dimension of the cross-section.

The Board does not share this view. GK5 gives a very general definition without indicating how that definition 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 [0030].

Moreover, the definition in paragraph [0031] does not refer to the "length" of the cross-section, but to the "transverse length" of the cross-section. What the word "transverse" should mean in this context is not defined in any way by referring to the general definition of the word "length" in a general dictionary. Should "transverse" mean to define any line joining one point of a boundary to any other point of the boundary, or should it only mean the lines starting perpendicularly

to any tangent to a boundary point and joining the other side of the boundary, or even something else? This remains undefined.

The person skilled in the art is therefore faced with several definitions from which he does not know which one to choose or which one might have been meant, and which in any case do not clarify what the transverse length addressed in the patent in suit could be.

2.7 The respondent/patent proprietor argued that Figure 12 of E1 confirmed the definition for the shape of a cross.

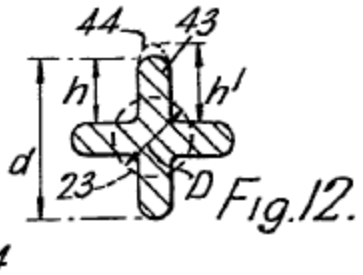

Fig.12.

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In relation to this figure it is stated in the description on page 4, lines 16 to 20:

"*Circular monofilament Nylon. Diameter (i.e. distance D in Figure 12) 0.018-0.025 inches.*

Cruciform monofilament Nylon as shown in Figure 12. Diameter (i.e. distance d in Figure 12) 0:020-0.030 inches."

This seems to indicate that the author of E1 used the word "diameter" to refer both to the distance "d" of the cross shape and to the diameter "D" of the circular monofilament.

In the opinion of the Board, this is, however, only evidence that at the beginning of the years 1960 (the filing date of E1 is 7 July 1964) the author of E1 gave the name diameter to that dimension of the cross shape shown in Figure 12. This does not constitute evidence either for this being a general definition or a definition generally admitted in the field, or for that definition being equivalent to the "transverse length" defined in the patent in suit.

2.8 The Board considers that also the problem to be solved to improve the closure strength, and the corresponding tests presented in the description of the patent, do not help the person skilled in the art to find out the necessary definition either, because the tests were made with a circular section elongated body suture of Figure 6A having a particular arrangement of the barbs, so that nothing concerning a non-circular cross-section of the elongated body can be deduced from this teaching.

2.9 The Board wishes to add that, contrary to the respondent/patent proprietor, it disagrees with the position taken by the Opposition Division in this case, according to which it would be possible to manufacture a needle-suture combination falling under the wording of claim 1 when taking any one of the possible definitions given by the respondent/patent proprietor, so that it would be possible to carry out the invention.

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 better closure strength than in the state of the art by using a specific barbed sutures, with a particular ratio of

needle diameter to diameter of the elongated body. Corresponding tests with circular cross-section elongated bodies are presented from paragraph [0166] to [0183].

However, as already explained, in the suture-needle combination claimed in the patent in suit the suture has a non-circular cross-section, so that 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 0815/07). In the present case the person skilled in the art is left alone with that undefined parameter, since there is not a 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.

2.10 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 into account common general knowledge, the person skilled in the art is not able to determine which dimension is meant by the diameter (SD) in 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 the main teaching of the patent in suit.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated