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Datasheet for the decision of 26 October 2021

Case Number: T 1738/17 - 3.2.02

Application Number: 10184766.3

Publication Number: 2335889

IPC: A61B17/04, A61B17/06

Language of the proceedings: EN

Title of invention:
Barbed sutures

Patent Proprietor:
Ethicon LLC

Opponent:
Covidien LP

Relevant legal provisions:
RPBA 2020 Art. 13(2)
EPC Art. 76(1), 123(2), 83, 100(c), 56

Keyword:
Amendment to appeal case - exceptional circumstances (no) - taken into account (no)
Added subject-matter
Sufficiency of disclosure
Inventive step

Decisions cited:
T 1064/15, T 1852/13

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Case Number: T 1738/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 26 October 2021

Appellant: (Opponent)	Covidien LP 15 Hampshire Street Mansfield, MA 02048 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Respondent: (Patent Proprietor)	Ethicon LLC 475 Street C, Suite 401 Los Frailes Industrial Park 00969 Guaynabo (PR)
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 8 June 2017 rejecting the opposition filed against European patent No. 2335889 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. The appeal was filed by the opponent against the opposition division's decision to reject its opposition to the contested patent, which had been granted on the basis of a third-generation divisional application of an earlier European patent application published under WO 2004/030520 A2 ("the root application").

II. In this decision, the opposition division held *inter alia* that the patent disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and that the subject-matter of claim 1 of the patent as granted did not contain added subject-matter in respect of the root application and that it involved an inventive step, especially in view of the following documents:

D1: *Medical Textiles: Application of an Absorbable Barbed Bi-directional Surgical Suture*,
Philip P. Dattilo, Jr. *et al.*, Journal of Textile and Apparel, Technology and Management, vol. 2(2), Spring 2002, pages 1-5
D2: EP 1 075 843 A1
D3: WO 98/52473 A

III. On 25 October 2021, the day before the oral proceedings before the board, the appellant filed further written submissions, asserting that the main request lacked sufficiency of disclosure and inventive step. These submissions referred to decision T 1064/15 and included an annotated photograph, presented as a higher-quality version of Figure 3 on page 3 of D1.

IV. At the end of the oral proceedings before the board on 26 October 2021, the parties' requests were as follows.

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

The respondent/patent proprietor ("the respondent") requested that the appeal be dismissed as a main request or, if the decision under appeal were set aside, that the patent be maintained in amended form on the basis of the claims of auxiliary request 1, which had been filed with the respondent's reply to the statement of grounds of appeal on 21 February 2018, and an adapted description comprising an amended paragraph [0122] filed during the oral proceedings before the board.

V. Claim 1 of the **main request** (claim 1 as granted) reads as follows:

"A barbed suture (30, 40) for connecting human or animal tissue, said suture comprising (a) an elongated body (32, 42) formed from a suture filament and having a first end (34, 44), a second end (46) and a diameter (SD) and (b) a plurality of barbs (35, 37, 39, 47, 49, 51) projecting from the body, each barb created by a blade cutting into the suture filament to create a barb cut having a barb cut length (L), such that said barb is 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, wherein

(I) the barbs have a disposition on the body comprising a staggered disposition, wherein the staggered disposition includes a first set (35, 47)

of the barbs being radially spaced about 120 degrees from a second set (37, 49) of the barbs and the second set of the barbs being radially spaced about 120 degrees from a third set (39, 51) of the barbs; and
(II) the barbs have a configuration comprising (i) a barb cut depth (D) with a ratio of the barb cut depth (D) to the elongated body diameter (SD) ranging from about 0.05 to about 0.6, (ii) the barb cut length (L) with a ratio of the barb cut length (L) to the elongated body diameter (SD) ranging from about 0.2 to about 2, and (iii) a barb cut distance (P) with a ratio of the barb cut distance (P) to the elongated body diameter (SD) ranging from about 0.1 to about 6."

VI. Compared to claim 1 as granted, claim 1 of **auxiliary request 1** further includes the following feature added to the end of the claim:

"and (iv) a barb cut angle θ ranging from about 140° to about 175°."

VII. The **appellant's arguments**, as far as relevant for the present decision, can be summarised as follows.

Main request - admittance of the appellant's submissions filed on 25 October 2021

Decision T 1064/15 concerned an earlier patent of the respondent, the content of which was very close, and indeed identical in some parts of the description, to that of the patent in suit. In particular, in both cases, claim 1 referred to the diameter of the barbed suture and encompassed sutures having a non-circular cross-section. Therefore, the conclusion in T 1064/15

that the invention was not sufficiently disclosed also applied similarly to the present case.

The respondent had been involved in this earlier case and so could not be surprised by the appellant's submission. In addition, decision T 1064/15 had been published only after the statement of grounds of appeal had been filed, and had been found by the appellant's recently appointed representatives when preparing for the oral proceedings. Moreover, merely citing case law did not represent an amendment of the appellant's case.

The photograph filed with the submissions of 25 October 2021 was identical to Figure 3 of D1, which was already on file: indeed, it could be downloaded with the document. It was simply of better quality. The annotations represented geometric parameters of the barbs, measured on the photograph using similar image analysis techniques to those mentioned in both D1 (the paragraph above Figure 5) and in the contested patent itself (paragraph [0110]). These measurements could also have been made using Figure 3 of D1. Thus, no new matter had been introduced by the appellant.

Furthermore, no new inventive step objection was raised on the basis of this photograph. The latter had been filed merely to supplement the previously raised inventive step objection starting from D1, and to show that D1 contained pointers to the claimed ranges, contrary to the board's statement in the preliminary opinion (point 5.3).

D1 was very short, and Figure 3 appeared on the same page as the passages of D1 mentioned in the statement of grounds of appeal. It could therefore be expected that the respondent had considered this figure as well.

Moreover, the suture represented in Figure 3 was a suture produced by the patent's original applicant, Quill Medical, Inc., and was thus already known by the respondent.

For these reasons, these new submissions should be admitted into the proceedings. Adjourning the oral proceedings on this ground would not be justified.

Main request - added subject-matter

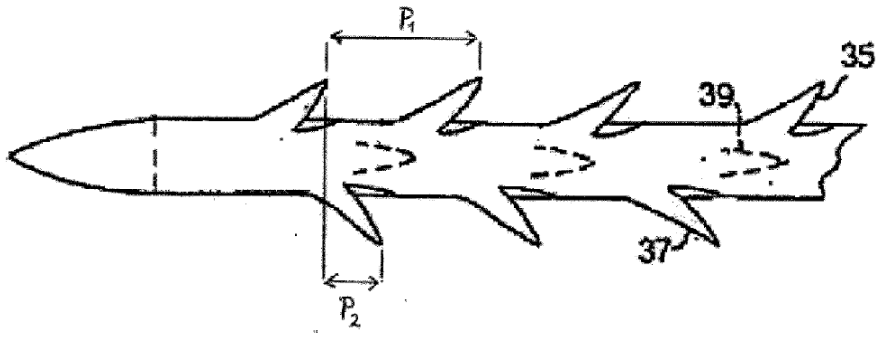
The description of the root application as filed disclosed a list of four different optional parameter ranges for the parameters D, L, P and θ respectively (pages 3-4 and 34-35). The selection of a particular combination of three of these ranges without any limitation on the fourth parameter, as in claim 1 as granted, which referred only to D, L and P, resulted in a new combination which was not directly and unambiguously disclosed in the root application as filed, contrary to the requirements of Article 76(1) EPC.

Claim 21 of the root application could not provide an appropriate basis for granted claim 1 either. While claim 21 comprised the barb parameter ranges defined in claim 1, claim 21 further required that θ should be in a specific range. Since claim 1 did not comprise this limitation on θ, it was based on an unallowable intermediate generalisation of this earlier disclosure, also in breach of Article 76(1) EPC.

Auxiliary request 1 - sufficiency of disclosure

First, the patent included a definition of the barb cut distance P only for twist cut sutures (paragraph

[0114]) but not for the staggered sutures claimed. For the latter, as shown in annotated Figure 3A of the patent below, P could be understood either as the longitudinal distance P1 between two barbs *of the same set*, or as the longitudinal distance between adjacent barbs *of different sets*, in particular the distance P2 by which the second set of barbs was offset with respect to the first:



On the one hand, the only distance mentioned with respect to the staggered sutures was the "longitudinal distance between two of barbs 35" (paragraphs [0054]-[0055]), which was P1. On the other hand, applying the definition of paragraph [0114] to staggered sutures implied that the barb cut distance was to be measured on the staggered suture after a twist to align the barbs, which amounted to measuring P2.

Moreover, no clear relationship between P1 and P2 could be derived from the patent. Indeed, the description of the manufacture of the staggered sutures in paragraphs [0054]-[0055] was clearly erroneous because, if the blades were offset by twice "half of" the longitudinal distance P1, the third set of barbs would not be staggered in relation to the first set. However, the intended offset could not be deduced unambiguously. Hence, while P2 was one third of P1 in the particular configuration of three sets of barbs uniformly staggered along the suture, P2 could in fact have any

value less than P1, since in Figure 3A the different sets of barbs were not uniformly spaced.

The claimed range for P was thus broader, in an arbitrary manner, if P=P2 than if P=P1. The result was that the person skilled in the art was left in the dark when trying to carry out the invention as claimed.

Secondly, several combinations of parameters D, L, P and θ that fell within the ranges defined in claim 1 were mutually incompatible. For example, paragraph [0142] of the patent taught that the barb cut distance P had to be greater than the barb cut length L for staggered sutures, as otherwise the barbs would overlap. Therefore, at least the claimed configurations for which P was between 0.1 and 0.2 did not work. Thus, the invention could not be carried out over the whole range claimed.

For these reasons, the requirements of Article 83 EPC were not met.

Auxiliary request 1 - inventive step

D1 disclosed (Figure 4) a staggered barbed suture from which the subject-matter of claim 1 differed only in that the barb parameters D, L, θ and P fell within the particular ranges claimed.

The respondent, who as the proprietor bore the burden of proof, had provided no evidence that these particular ranges provided any technical advantage for the staggered sutures claimed. The experimental data compiled in the various tables in the description of the patent (paragraphs [0115]-[0118]) in fact concerned a different type of suture, namely twist cut barbed

sutures. The statement in paragraph [0119] that the desirable ranges established for this particular type of suture "should be the same" for staggered sutures was merely an unproven allegation. In fact, these ranges were so broad that they applied to all the different types of suture disclosed in the patent. There was no comparative data to support the idea that the selected ranges provided an advantage over barb geometries outside of the scope of the claim. Paragraph [0105] disclosed that the twist cut sutures were in fact superior to the staggered sutures in terms of wound holding capability.

Furthermore, no technical effect could be achieved, at least for the incompatible combinations of parameters claimed.

Thus, the technical problem to be solved could not be to "optimize the performance of a barbed suture", as stated in paragraph [0011] of the patent, but merely to select particular values for the different parameters within the admissible ranges. Almost any selection would thus represent a solution to this problem. In particular, the ranges claimed were so broad that they *prima facie* encompassed substantially all the barb configurations that would have been seriously contemplated by the person skilled in the art. At least for these reasons, the subject-matter of claim 1 could not involve an inventive step.

Moreover, even if it were assumed that the claimed ranges allowed for optimised performance of the suture, a different conclusion could not be reached. Figure 5 of D1 and the paragraph above it in fact disclosed the same parameters for specifying the barb configuration. Figure 5 itself, though schematic, would suggest to the

person skilled in the art a possible barb geometry close to or even within the claimed ranges. Moreover, D2 (paragraph [0017]) and D3 (page 14, lines 28-35) both disclosed barb cut depths D and barb cut distances P falling within the claimed ranges. Barb cut lengths L falling within the claimed range could also be deduced from Figure 2 of D2 and Figures 14 and 16 of D3.

Thus, starting from D1, considered alone or in combination with D2 or D3, the subject-matter of claim 1 would have been obvious to the person skilled in the art. The subject-matter of claim 1 did not therefore involve an inventive step.

VIII. The **respondent's arguments**, as far as relevant for the present decision, can be summarised as follows.

Main request - admittance of the appellant's submissions filed on 25 October 2021

The diameter or cross-section of the suture had never been a subject of discussion in the earlier proceedings, let alone in connection with the question of sufficiency of disclosure. The objection raised in this respect had never been presented before. Decision T 1064/15, cited in support of this objection, concerned a different case and had no bearing on the present one.

Similarly, the appellant had never relied upon Figure 3 of D1 in its earlier submissions. In fact, the newly submitted photograph, presented as a high-quality version of the figure in D1 and downloadable separately from D1, itself constituted a new piece of evidence, not least because it had been annotated with various measurements of length. The inventive step reasoning

based on this new figure thus also constituted a new objection.

Therefore, these new objections and new evidence constituted amendments to the appellant's case. They could well have been filed much earlier. Indeed, T 1064/15 had been published in 2018 and the new photograph could have been filed together with D1, yet they were filed only on the very last afternoon before the oral proceedings. The appellant had not put forward any exceptional circumstances, justified by cogent reasons, which would justify such a very late filing. Hence, pursuant to Article 13(2) RPBA 2020 these new submissions should not be admitted.

If these submissions were admitted into the proceedings, they would raise a host of new issues. In view of their extremely late filing, the proceedings should therefore be adjourned to give sufficient time to the respondent to analyse these issues and prepare its counter-arguments.

Main request - added subject-matter

Claim 1 as granted was first supported by original claim 21 of the root application as filed. This claim comprised the parameter ranges defined in granted claim 1, with the inclusion of an additional parameter range for the barb cut angle. The removal of the latter met the conditions of the established three-point test, as held in the decision under appeal (point 2.5), and did therefore not violate Article 76(1) EPC.

Moreover, the same conclusion was reached if granted claim 1 was regarded as derived from original claims 1 and 5 with the addition of the preferred ranges for the

parameters D, L and P taken from the description (for example, from pages 34 and 35). This addition did not amount to a selection of multiple options from a list, but was simply a further refinement of the barb configuration already defined in claims 1 and 5. Hence, claim 1 as granted did not contain added subject-matter.

Auxiliary request 1 - sufficiency of disclosure

First, the definition of the barb cut distance P was clear to the person skilled in the art from reading the patent specification. In particular, in the light of the measurement disclosed in paragraph [0114] for twist cut sutures, the person skilled in the art would have understood that the barb cut distance P was the longitudinal distance between two cuts on the same longitudinal line of the suture in the state in which it was cut, i.e. the distance P1 in the appellant's denomination.

Secondly, potential incompatibilities between the parameter ranges defined in claim 1 were restricted to the outer limits of those ranges in claim 1 and would not prevent the person skilled in the art from carrying out the invention.

The requirements of Article 83 EPC were therefore met.

Auxiliary request 1 - inventive step

The burden of proof when alleging that the technical problem described in the patent had been solved was not with the proprietor but with the opponent, i.e. the appellant. In the present case, the appellant had not submitted any convincing evidence supporting its

allegations: quite on the contrary, the patent clearly explained that the ranges determined for the twist cut sutures were also applicable to the staggered sutures (paragraph [0119]). The influence of the different parameters on the suture properties was discussed at length throughout the description, and there was no reason to think that the established ranges did not lead to improved holding properties in the case of the staggered sutures. In this respect, the fact that twist cut sutures might have a better wound holding capability than staggered sutures, as disclosed in paragraph [0105], did not mean that the staggered sutures claimed did not themselves have a technical effect and thus solve the technical problem mentioned in paragraph [0011].

Claim 1 defined the optimised barb configuration in relation to no fewer than four interrelated parameters, each in a specific numerical range. Without knowledge of the invention, the person skilled in the art starting from D1 would not have arrived at the claimed invention in an obvious manner, even in the light of D2 or D3. The "interval" and "barb spacings" disclosed in these documents were not comparable to the barb cut distance of claim 1. Figure 5 of D1 and the figures of D2 and D3 were schematic drawings from which no measurements could be derived. Moreover, D2 and D3 did not even mention a barb cut angle. The subject-matter of claim 1 thus involved an inventive step.

Reasons for the Decision

1. The subject-matter of the contested patent

1.1 The patent relates to a barbed suture for closing or binding together wounds in human or animal tissue, an

example of which is shown in Figures 3A-3B, reproduced below. Compared to a conventional suture, a barbed suture (30) includes one or more spaced barbs (35, 37, 39) which project from the surface of the elongated body (32) of the suture. The barbs are arranged to allow passage of the barbed suture through tissue in one direction but to resist movement of the barbed suture in the opposite direction. Hence, barbed sutures do not have to be knotted, like conventional sutures (paragraphs [0002], [0004]).

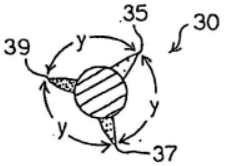


FIG. 3B

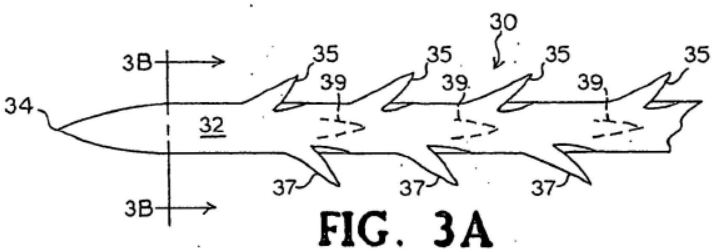


FIG. 3A

The barbs can conveniently be made by cutting, for example by means of a cutting machine including a plurality of blades configured for escarpment of barbs onto a suture filament, usually one set of axially spaced barbs at a time (paragraphs [0030]-[0032]).

1.2 More particularly, the patent aims to provide an improved barbed suture which has not only an increased tensile strength, but also an enhanced ability in holding and maintaining wound edges together (paragraph [0011]).

In accordance with the patent, these improved properties result from the combination of a specific spatial arrangement of the barbs on the suture body along with an optimised geometry of the individual barbs:

(a) as shown in Figures 3A-3B above, the barbs are disposed on the suture body in a 120-degree staggered disposition including three sets of barbs (35, 37, 39), each comprising a plurality of aligned barbs axially spaced along the longitudinal axis of the suture. The sets are staggered with respect to each other (paragraph [0021], Figure 3A) as well as radially spaced about 120 degrees from each other (paragraph [0049]; Figure 3B). Such a disposition maximises the retention force of the suture (paragraph [0069]);

(b) the barbs are cut into the filament so as to maximise the barb density along the suture filament, which increases the ability of the barbed suture to anchor tissues, without compromising the filament integrity (paragraph [0124]). The optimal barb density is defined by the fact that a first parameter, barb cut distance P, is in a particular range (claim 1). P is illustrated in Figure 7B, albeit for a different type of suture (namely twist cut sutures; see point 5.1 below):

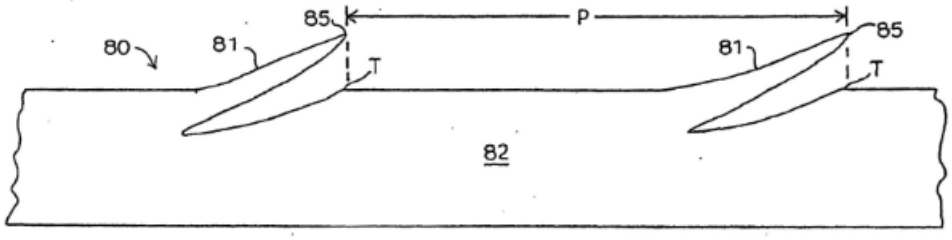


FIG. 7B

(c) the barbs have an individual geometry defined by three further geometric parameters: barb cut depth D, barb cut length L and barb cut angle θ, as shown in Figure 7A:

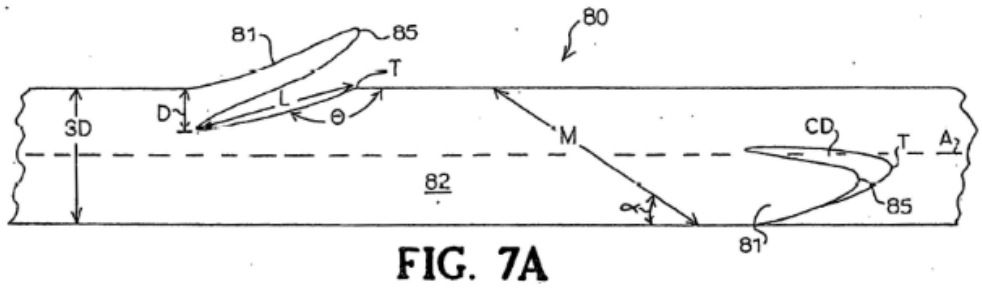


FIG. 7A

D, L and θ are not independent but linked by the following equation (paragraph [0111]):

$$\sin(180°-\theta)=\sin(\theta)=D/L$$

The patent discloses optimal ranges for the parameters D, L and θ (granted claims 1, 2; paragraphs [0120]-[0122]).

2. Admittance of the appellant's submissions filed on 25 October 2021

2.1 In its statement of grounds of appeal, the appellant did not raise any objection or reasoning relying on the diameter or the shape of the cross-section of the sutures, or on Figure 3 of D1. It was only on 25 October 2021 (the day before the oral proceedings), i.e. after notification of the summons to oral proceedings, that the appellant made such submissions. These submissions, and *a fortiori* the new, annotated, higher-quality Figure 3 accompanying them, therefore constitute amendments to the appellant's case.

2.2 According to Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

2.3 Contrary to the appellant's view, there are no such exceptional circumstances in the present case that would justify the filing of these submissions only at such a late stage in the proceedings.

2.3.1 Decision T 1064/15, on which the appellant based its reasoning on insufficiency of disclosure, was published in 2018, i.e. it was available to the appellant more than two years before the summons in the present case was issued in February 2021. It is immaterial whether the appellant only came across this decision late, because such circumstances cannot outweigh the need for procedural economy and the principle of fairness to the other party.

2.3.2 The appellant also explained that the higher-quality Figure 3 was available for downloading together with D1. This figure could thus already have been filed with the appellant's statement of grounds of appeal to support the inventive step objection raised therein in view of D1.

In this respect, the board is not convinced by the appellant's argument that filing the new figure had been triggered by new matter raised in the board's preliminary opinion. Indeed, the board's statement in point 5.3 that "D1 itself does not contain any pointer towards any numerical ranges for the barb geometry parameters" did not introduce any new matter into the proceedings but merely concurred with the respondent's view, presented in the latter's reply to the statement of grounds of appeal (point 5.5.1: "D1 is completely silent with regard to specific barb geometries (...) D1 provides no guidance whatsoever to lead him in that direction"). Moreover, deriving barb parameters from the figures of D1 was already an argument presented by

the appellant in the first-instance proceedings and addressed in the appealed decision (point 4.6.1). Thus, the new Figure 3 and the reasoning based on it could and should have been filed earlier.

2.3.3 A change of representative by the appellant, even shortly before the oral proceedings, cannot justify such a late filing either.

2.3.4 Furthermore, contrary to the appellant's argument, it is irrelevant whether the respondent was already aware of decision T 1064/15 or of the suture depicted in Figure 3, or even that Figure 3 appeared on the same page as other figures of D1 already under discussion. The respondent cannot be expected to speculate on potential evidence or lines of argument that the appellant has not presented.

2.4 For these reasons, pursuant to Article 13(2) RPBA 2020 the board decided not to take the appellant's submissions filed on 25 October 2021 into account.

3. Main request - added subject-matter

3.1 The parties dispute whether the particular combination of numerical ranges for barb cut depth D, barb cut length L and barb cut distance P defined in claim 1 as granted can be directly and unambiguously derived from the root application as originally filed.

3.2 The claimed ranges for barb cut depth D, barb cut length L and barb cut distance P are disclosed in the root application together with a number of other geometric features of the barbs, also presented as advantageous, such as a barb cut angle θ in a specific range, a corrugated underside, an arcuate base, and

varying barb sizes (page 3, line 30 - page 4, line 3; page 34, lines 2-4, and the discussion of parameters L, D, θ and P on pages 34-35).

While the description of the root application does indeed mention that these features may be present in *any combination* (page 4, line 3: "or combinations thereof"; page 34, line 3: "and/or"), there is no suggestion in the root application of the *particular selection* defined in claim 1 as granted. Although conceptually encompassed by the original disclosure of the root application, this selection does not emerge clearly and unambiguously from the original disclosure as a whole and therefore constitutes new technical information extending beyond the content of the root application as filed, contrary to the respondent's view.

3.3 The respondent has also referred to original claim 21, which explicitly discloses the combination of the parameter ranges for D, L and P, but with an additional parameter range for barb cut angle θ.

The argument that removal of the latter (thereby leading to the combination defined in claim 1 as granted) does not introduce added subject-matter, in particular as the "three-point test" would show, does not convince the board.

Indeed, by defining particular ranges for D, L, P and θ, original claim 21 defined a particular set of barb geometries, with barbs of specific thickness, length and cut orientation that were disposed along the suture filament in a particular density. The parameters D, L and θ cannot be varied independently of each other, but are geometrically linked by the formula indicated in

point 1.2(c) above. Hence, by removing the limitation on θ, a different, broader set of barb geometries is defined in claim 1 as granted: however, this set does not correspond to the set defined by original claim 21, nor is it derivable from the description, as discussed in point 3.2 above. This results in presenting the person skilled in the art with new technical information. There is therefore no basis for omitting the angle θ from the combination originally disclosed in claim 21.

In this respect, it is emphasised that the "three-point test" is only meant to provide an aid to determining the allowability of an amendment, and cannot take the place of the assessment made above (see for instance T 1852/13).

3.4 It follows that, contrary to the respondent's argument and to the opposition division's finding (point 2 of the appealed decision), the subject-matter of claim 1 of the main request does not meet the requirements of Article 76(1) EPC.

4. Auxiliary request 1 - added subject-matter

4.1 Compared to claim 1 as granted, claim 1 of auxiliary request 1 further includes the limitation that the barb cut angle θ ranges from about 140° to about 175°, i.e. it contains the same limitation on θ as originally disclosed in claim 21 of the root application.

It follows that claim 1 of auxiliary request 1 includes the same four parameter ranges for D, L, P and θ as defined in original claim 21 (see point 3.3 above).

The board is therefore satisfied that the subject-matter of claim 1 of auxiliary request 1 meets the requirements of Article 76(1) EPC. The appellant had no objection in this respect.

4.2 The description of the application on the basis of which the contested patent was granted contains the description of the root application *verbatim*, plus the claims of the latter redrafted as aspects of the invention. It follows that the requirements of Article 123(2) EPC are also met. The appellant did not contest this point either.

5. Auxiliary request 1 - sufficiency of disclosure

5.1 It is true, as put forward by the appellant, that the patent specification only includes an explicit definition of the barb cut distance P for twist cut sutures (paragraph [0114]), which are different from the staggered sutures claimed.

However, the person skilled in the art would understand from paragraph [0114] that, for a twist cut suture, the barb cut distance P is measured as the longitudinal distance between two adjacent barbs after the barbs have been aligned longitudinally by twisting the suture back into the state in which it was cut: in other words, the barb cut distance P corresponds to the longitudinal distance between the respective terminus of the cuts of the two adjacent barbs when the aligned set of barbs was cut (see Figure 7B).

Since the staggered suture is cut in an untwisted state as described in paragraphs [0064]-[0066], no twisting is necessary to return the suture to the state in which it was cut. Therefore, contrary to the appellant's

view, the person skilled in the art would infer by analogy that the barb cut distance P for a staggered suture is the longitudinal distance between two adjacent barbs *of the same set of aligned barbs*, i.e. the distance called P1 by the appellant.

The appellant submitted that a person skilled in the art applying the measurement methodology described in paragraph [0114] to staggered sutures would instead apply a twist to align the two nearest barbs 35, 37 of different sets, and would thus measure the distance P2 instead of P1. The board disagrees. Due to the staggered disposition, applying such a twist would in fact align only the two nearest barbs under investigation with the longitudinal axis of the suture, and not the remaining barbs. Hence, in contrast to the situation described in paragraph [0114] for twist cut sutures, where the whole set of barbs is aligned longitudinally, no "longitudinal cut distance P between two adjacent barbs" could be measured unambiguously; in particular, it would not be possible to calculate the average for several pairs of adjacent barbs, as described in paragraph [0114]. The person skilled in the art would therefore recognise that applying a twist to staggered sutures to measure barb cut distance P does not make any technical sense.

The interpretation of P as P1 that has been adopted above is also consistent with the fact that, as the appellant itself noted, the only distance mentioned with respect to staggered sutures is "the longitudinal distance between two of barbs 35" referred to in paragraphs [0054]-[0055]. The fact that these paragraphs obviously contain an error is irrelevant, since this error merely concerns the offset between the sets of barbs, i.e. the distance P2 and not P1.

Hence, contrary to the appellant's view, the person skilled in the art would derive from the patent specification a clear and unambiguous definition of the barb cut distance P for the staggered sutures as well.

5.2 The appellant further argued that the invention as claimed could not be carried out for some combinations of the parameters D, L, P and θ that did not work, although they were within the ranges defined in claim 1.

In particular, the appellant referred to the requirement that the barbs of the staggered suture should not overlap, which resulted in the criterion P>L (paragraph [0142]). Given the range claimed for L, according to the appellant this prevented the person skilled in the art from producing the staggered sutures claimed for all values of P between about 0.1 and about 0.2 (in units of the elongated body diameter).

Irrespective of whether the appellant's assertion that the barbs of a staggered suture as claimed should not overlap is correct, the board notes that the allegedly problematic values of P remain close to the lower limit claimed and that the extent of the corresponding range (about 0.1 to about 0.2) remains very small compared to the overall extent of the range claimed (about 0.1 to about 6). In fact, when taking the inclination of the barbs into account, it can be inferred that the lowest permitted value P_{min} of P at which the barbs are still prevented from overlapping is obtained when L=0.2 and θ=140° (see point 1.2(c) above):

$$P_{min} = L|\cos\theta| = 0.2x|\cos 140°| \approx 0.15$$

which is even closer to the lower limit of the claimed range for P of about 0.1, if not even identified with

it in practice due to the uncertainty arising from the term "about".

Therefore, if the range claimed for P encompasses values incompatible with staggered sutures, as alleged by the opponent, these incompatibilities are in any case restricted to only the very limits of the ranges defined in claim 1, hence to the edges of the claim. Specific combinations of the geometric parameters that do not work would be immediately ruled out by the person skilled in the art as being outside the scope of practical application of the claimed subject-matter, so their existence does not justify an objection of insufficiency of disclosure.

5.3 For these reasons, the board concludes that, contrary to the appellant's argument, the invention as defined in auxiliary request 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

6. Auxiliary request 1 - inventive step

6.1 The appellant raised an inventive step objection in relation to claim 1 of auxiliary request 1, taking the barbed suture disclosed in Figure 4 of D1, reproduced below, as the starting point. It is common ground that D1 discloses the same geometric parameters D, L, P and θ to characterise the barb configuration of the suture as those in the contested patent (see Figure 5 reproduced below, and the paragraph above the figure in D1). However, D1 does not disclose any particular numerical ranges for these parameters.

Figure 4. Bi-directional barbed suture showing midpoint (Courtesy of Quill Medical, Inc.)

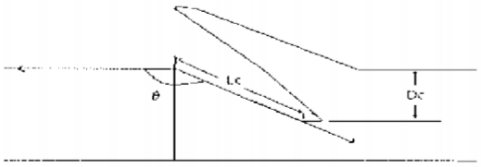


Figure 5. Geometry of individual barb (Source: Dattilo, P. Absorbable Bi-directional Barbed Suture. MS Thesis. North Carolina State University. 2002.)

The point disputed by the parties is whether the particular combination of ranges for the parameters D, L, P and θ defined in claim 1 of auxiliary request 1 is inventive over D1.

6.2 The appellant first argued that there was no convincing evidence demonstrating that these particular ranges actually led to an improvement in staggered sutures and thus solved the technical problem mentioned in paragraph [0011] of the patent, namely optimising the performance of a barbed suture.

It is true that the experimental data presented in the description, especially in the various tables, concerns twist cut sutures and not the claimed staggered sutures. However, the description discusses in general terms in paragraphs [0120]-[0125] how the various geometric parameters involved are functionally interrelated and directly or indirectly influence both the tensile strength and the retention force of the barbed suture. In view of these explanations, and despite the absence of comparative data, the board sees no reason to question the explicit statement in paragraph [0119] that similar considerations also apply to staggered sutures. The board considers it credible that the particular ranges defined in claim 1 have a technical effect and solve the technical problem stated in the patent.

Contrary to the appellant's view, under these circumstances the burden is on the opponent to prove the opposite. In the present case, the appellant (as the opponent) has not submitted any proof or evidence convincingly casting doubt on the assertion that the problem has been solved by the patent. In particular, the fact that the same considerations may additionally apply to further types of barbed suture (as mentioned in paragraph [0119]), or the fact that twist cut sutures might in fact have better wound holding capabilities than staggered sutures (as disclosed in paragraph [0105]), does not mean that the determined ranges do not lead to improved performance in staggered sutures.

The fact that some combinations of the parameters claimed may be incompatible (point 5.2 above) does not contradict the conclusion above, either, since the person skilled in the art would regard these incompatible combinations as not covered by the claim.

6.3 The barbed suture of claim 1 is distinguished from that shown in Figure 4 of D1 by no fewer than four interrelated parameters, each in a specific range. Contrary to the appellant's argument, a mere routine optimisation starting from D1 would not lead the person skilled in the art to the set of barb configurations claimed.

6.3.1 While D1 does indeed suggest optimising the barb geometry in order to improve the performance of the suture (page 5, section "Future Trends", lines 12-16), D1 itself does not contain any pointer towards numerical ranges for the barb geometry parameters, and does not provide any guidance or direction which would

suggest the barb configuration specified in claim 1 to the person skilled in the art.

In this respect, Figure 5 of D1 is a schematic drawing merely illustrating relevant parameters to characterise the barb configuration. Contrary to the appellant's argument, the person skilled in the art would not be able to infer any angle or dimensional ratio from this purely schematic drawing.

6.3.2 The appellant further argued that the person skilled in the art would find suggestions of the combination of ranges claimed in D2 or D3, which both disclose barbed sutures. The board disagrees on this point as well.

Indeed, while a barb cut depth D falling within the claimed range is disclosed in D2 (paragraph [0017]) and D3 (page 14, lines 28-35), neither of these documents directly and unambiguously anticipates the ranges for L, P and θ that are also claimed, let alone a combination of these ranges. A barb cut angle θ is not even mentioned in either of the documents. The "interval" 7 referred to in D2 (paragraph [0017]) does not correspond to the barb cut distance P used in the contested patent (see point 5.1 above), but rather to the length of barbless filament between two adjacent barbs, as illustrated in Figure 1. However, this is not directly comparable to the barb cut distance P. Similarly, the definition of the "barb spacings" mentioned in D3 (page 14, lines 31-32) does not unambiguously correspond to the barb cut distance P. Furthermore, the figures of D2 and D3 are also merely schematic drawings (and moreover, they are of low quality or even hand sketched) from which the person skilled in the art would not be able to infer an angle or dimensional ratio.

6.3.3 The appellant's further argument, that the ranges specified in claim 1 are so broad so that they *prima facie* encompass substantially all the barb configurations that would be seriously contemplated by the person skilled in the art, does not convince the board either. The appellant itself submitted, in the written procedure, that D3 (page 14, lines 23-35) disclosed a barb cut spacing P of 10, i.e. one much larger than the claimed maximum of 6.

6.3.4 The board thus concludes that, contrary to the appellant's argument, the person skilled in the art starting from D1 would not have arrived at the claimed invention in an obvious manner. The subject-matter of claim 1 of auxiliary request 1 therefore involves an inventive step (Article 56 EPC).

7. **Auxiliary request 1 - further objections**

The appellant had no further objections to the claims of auxiliary request 1, or to the description being adapted by incorporating the amendments to paragraph [0122] that were filed by the respondent during the oral proceedings before the board on 26 October 2021. The board had no objections either.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Claims: claims 1-14 of auxiliary request 1 filed on 21 February 2018

Description: paragraphs [0001]-[0121] and [0123]-[0173] of the patent specification, and paragraph [0122] filed during the oral proceedings before the board on 26 October 2021

Drawings: Figures 1A-13D of the patent specification.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated