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Datasheet for the decision of 31 August 2017

Case Number: T 0645/14 - 3.3.10

Application Number: 03747449.1

Publication Number: 1501559

IPC: A61L17/04, A61L17/06, A61L17/12

Language of the proceedings: EN

Title of invention:

SURGICAL THREAD AND SURGICAL IMPLANT WITH THE SAME

Patent Proprietor:

Ethicon GmbH

Opponent:

Aesculap AG

Headword:

Relevant legal provisions:

EPC Art. 100(a), 54(2), 56

Keyword:

Grounds for opposition - lack of patentability (no)

Dec			

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 0645/14 - 3.3.10

D E C I S I O N

of Technical Board of Appeal 3.3.10

of 31 August 2017

Appellant: Ethicon GmbH

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 5 February 2014 concerning maintenance of the European Patent No. 1501559 in amended form.

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón

C. Schmidt

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Summary of Facts and Submissions

I. The appeal lies from the interlocutory decision of the opposition division which maintained European patent No. 1 501 559 in the form of auxiliary request 10 then pending. Both the patent proprietor (appellant 1) and the opponent (appellant 2) appealed this decision.

- II. Notice of opposition had been filed on the ground of lack of novelty and inventive step (Article 100(a) EPC).
- III. The documents cited in the opposition proceedings included the following:

D2: DE 100 46 119 A1

D6: US 3,316,557

IV. The opposition division concluded that the surgical threads of claim 1 as granted were not novel over those disclosed in document D6, and that those of claim 4 as granted were already disclosed in document D2.

In the context of auxiliary request 10 then pending, the opposition division concluded that document D2 was the closest prior art, the problem underlying the claimed invention was providing further surgical threads, said problem was solved by the claimed threads, and the solution was inventive as the skilled person would not consider combining D2 with the teaching of documents in the field of textile technology.

V. Claims directed to a surgical thread 1 to 5 of the patent as granted, which is the main request of

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appellant 1, read as follows:

- "1. A surgical thread comprising a core (12, 22, 82) that is made from at least one resorbable material and a covering (10, 20, 80) that is made from at least one non-resorbable material and/or slowly resorbable material which is more slowly resorbable than the resorbable material of the core, the covering comprising threads and characterised in that the threads of the covering are arranged in the surgical thread as a single covered twist or a spinning covering twist and wherein before the resorption of the core, the threads of the covering are dimensionally stabilized against tensile forces by the core, and wherein after resorption of the core, the dimensional stabilisation is missing so that when subjected to a tensile force, the covering can move from its nonlinear arrangement into a thereabouts linear arrangement.
- 2. A surgical thread comprising holding threads (42, 43) made from at least one resorbable material and a loop (44) made from at least one non-resorbable and/or slowly resorbable material, in a plied loop twist (40), characterised in that, before resorption of the holding threads, the loop is dimensionally stabilised against tensile forces by the holding threads, and wherein after resorption of the holding threads, the dimensional stabilisation is missing so that when subjected to a tensile force, the loop can move from its non-linear arrangement into a thereabouts linear arrangement.
- 3. A surgical thread that is designed as a plied or cabled yarn, comprising at least two yarns that are twisted about an axis, each of the two yarns comprising

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at least one resorbable thread (33, 35) and at least one non-resorbable and/or slowly resorbable thread (32, 34), characterised in that, before resorption of the at least one resorbable thread, the at least one non-resorbable and/or slowly resorbable thread is dimensionally stabilised against tensile forces by the at least one resorbable thread, and wherein after resorption of the at least one resorbable thread, the dimensional stabilisation is missing so that when subjected to a tensile force, the at least one non-resorbable and/or slowly resorbable thread can move from its non-linear arrangement into a thereabouts linear arrangement.

- 4. A braided surgical thread comprising at least one resorbable thread (52, 53, 54) and at least two non-resorbable and/or slowly resorbable threads (51), characterised in that before resorption of the at least one resorbable thread, the at least two non-resorbable and/or slowly resorbable threads is dimensionally stabilised against tensile forces by the at least one resorbable thread, and wherein after resorption of the at least one resorbable thread, the dimensional stabilisation is missing so that when subjected to a tensile force, the at least two non-resorbable and/or slowly resorbable threads can move from its non-linear arrangement into a thereabouts linear arrangement.
- 5. A surgical thread that is made using a crochet galloon technique, comprising at least one warp thread (72, 73) made from at least one resorbable material and a weft thread (71) made from at least one non-resorbable and/or slowly resorbable material, characterised in that, before resorption of the warp thread, the weft thread is dimensionally stabilised against tensile forces by the warp thread, and wherein

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after resorption of the warp thread, the dimensional stabilisation is missing so that when subjected to a tensile force, the weft thread can move from its non-linear arrangement to a thereabouts linear arrangement."

- VI. During the oral proceedings before the board of appeal, which took place on 31 August 2017, appellant 1 filed auxiliary request 1 and withdrew the other auxiliary requests then pending.
- VII. The arguments of appellant 1 relevant for the present decision were the following:

Neither document D6 nor D2 disclosed a surgical thread which, after resorption of a component thereof, contained components which could move into a thereabouts linear arrangement. For this reason alone, the claimed surgical threads were novel.

Document D2 was the closest prior art. The claimed threads represented an improvement over those of D2 but even if, nevertheless, the problem underlying the claimed invention were to be considered merely to provide further surgical threads containing resorbable and non-resorbable or slowly resorbable components, the claimed solution, characterised in that the non-resorbable or slow-resorbable components could move from a non-linear arrangement into a thereabouts linear arrangement after the former were resorbed, was not hinted at in the prior art. For this reason, the claimed surgical threads were inventive.

VIII. The arguments of appellant 2 relevant for the present decision were the following:

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Figure 3 of document D6 disclosed a vascular implant comprising a core strand of absorbable collagen and a spirally wrapped non-absorbable synthetic garn. Once the collagen was absorbed, the remaining synthetic garn was no longer constrained and could move into a thereabouts linear disposition. For this reason, claim 1 of the patent as granted was not novel.

Example 3 of D2 disclosed a braided surgical thread comprising fast-degrading threads and slow-degrading threads braided over them. Once the former were degraded, the latter could move to a thereabouts linear arrangement, and thus document D2 rendered the threads of claim 4 of the patent as granted not novel.

For those parts of the claimed subject-matter which were novel, document D2 was the closest prior art. In view of the lack of fair comparative data, the problem underlying the claimed invention was only to provide a further surgical thread containing absorbable and non-absorbable or slow-absorbable components. The solution to this problem, which was characterised in that its non-absorbable or slow-absorbable components were able to move from a dimensionally stabilised disposition into a thereabouts linear arrangement after resorption of the more absorbable components, was a straightforward choice for a person skilled in the art already hinted at in document D2. The claimed threads were thus not inventive.

- IX. The final requests of the parties were the following:
 - Appellant 1 requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or in the form of auxiliary request 1, filed during the oral

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proceedings before the board.

- Appellant 2 requested that the decision under appeal be set aside and that European patent No. 1 501 559 be revoked.
- X. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Novelty

- 2. Document D6
- 2.1 Document D6 relates to vascular implants (column 1, line 17) which could form a stable residual fabric with sufficient strength to contain blood pressure pulses (column 3, lines 53-57). The embodiment of Figure 3 (column 7, line 65 to column 8, line 4) relates to a composite having a core strand of degradable collagen (14) and, spirally wrapped over it, a non-absorbable synthetic garn (15) made from polypropylene (column 6, line 72).
- 2.2 Appellant 2 argued that, due to the construction of the composite, once the collagen core (14) was absorbed by the body, garn (15) could move to a thereabouts linear arrangement. For this reason, document D6 disclosed all the features of claim 1 of the patent in suit.
- 2.3 However, it is not the unavoidable consequence of the absorption of core (14) that garn (15) could move to a thereabouts linear arrangement, as it cannot be ruled

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out, for example, that garn (15) would break if attempted to be brought into a thereabouts linear arrangement. For this reason, it is concluded that document D6 does not disclose a thread whose covering, after resorption of the core, can move from its non-linear arrangement into a thereabouts linear arrangement when subjected to a tensile force, as required by claim 1 of the patent in suit, which is thus novel over D6.

3. Document D2

- 3.1 Document D2 relates to medical implants [0002] which contain fast-resorbable and slow-resorbable polymers [0017]. Example 3 discloses a braided surgical thread comprising a braided core made of fast-degrading LGA 1090 surrounded by a 10-bobbin braid made of two types of slow-degrading polymers, LGA 9010 and P-L-LA.
- 3.2 Appellant 2 argued that, once the fast-degrading core was no longer part of the thread, the remaining slow-degrading threads could move into a thereabouts linear arrangement. In this context, it was relevant that document D2 disclosed that these threads elongated easier after absorption of the fast-resorbable polymer [0042], [0023]. For this reason, D2 disclosed all the features of claim 4 of the patent as granted.
- 3.3 However, document D2 merely discloses surgical threads which are easier to stretch or elongate after absorption of a fast-resorbable polymer component. It does not disclose that the structure formed by the remaining threads could became longer than the original implant, let alone that any thread forming part of it could move to a thereabouts linear arrangement. In fact, document D2 discloses that, after absorption of

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one of the polymeric constituents, the breaking extension is maintained [0038], lines 29-30, i.e. the surgical thread does not became longer. Thus, the braided surgical threads of claim 4 of the patent in suit are novel.

4. No further novelty objections have been raised by appellant 2, or are apparent from the available prior art. It is thus concluded that the claimed surgical threads and surgical implants containing them are novel, as required by Article 54(2) EPC.

Inventive step

5. Closest prior art

The opposition division and the parties considered that document D2 was the closest prior art. The board sees no reason to differ.

Document D2 discloses surgical threads intended to fix, support or replace diseased or injured body parts [0004] such as cruciate ligament [0039], or for the surgery of inguinal hernias [0028] [0043], comprising a faster resorbable and a slowly resorbable polymer [0017], which can form a braided thread (example 3), and whose stiffness decreases once the first of the polymers is resorbed (example 3, [0023]). Paragraph [0023] of document D2 discloses that the extensibility of the material increases once the resorbable polymer is no longer present in the construction.

The slowly resorbable component of D2 is not inevitably capable of moving from a non-linear arrangement into a thereabouts linear arrangement, after resorption of the

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fast resorbable part.

6. Technical problem underlying the invention

In the following, it will be examined whether the claimed subject-matter is inventive under the assumption that the technical problem underlying the claimed invention is merely that of providing a further surgical thread which allows, as that of the prior art, the reduction of tissue damage at later stages of implantation by becoming more extensible.

Since the solution to this problem is not obvious, it is not necessary to examine whether a more ambitious problem had also been solved.

7. Solution

The solution to this technical problem are the surgical threads of claims 1 to 5, characterised at least in that, after resorption of a resorbable component, their non-resorbable or slowly resorbable component can move from a non-linear arrangement into a thereabouts linear arrangement when subjected to a tensile force.

8. Success

By having a non-resorbable or slowly resorbable component which can move from an initial non-linear arrangement, stabilised by the absorbable part, into a thereabouts linear arrangement once said stabilisation is missing due to resorption, the claimed surgical thread would be less stiff at later stages of implantation, and thus reduce the risk of tissue damage.

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Appellant 2 argued in the written proceedings that it had not been made credible that the claimed threads could show any effect with respect to adaptation to the tissue in order to decrease damage, as the examples of the patent in suit were limited to a specific resorbable and a specific non-resorbable materials. However, the effect of reducing tissue damage does not derive from the chemical composition of the material used but from their relative disposition, and would be achieved independently from the nature of the resorbable and of the non-resorbable or slow-resorbable threads used.

- 9. It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious in view of the state of the art.
- The skilled person, trying to obtain a further surgical thread which avoids tissue damage at later stages after implantation, does not find in D2 an indication towards constructions which contain less resorbable threads whose tridimensional, non-linear disposition is stabilised by resorbable parts and which, once said resorbable part is no longer present, can move to a thereabouts linear arrangement, which implies in fact that the claimed surgical thread becomes longer than it originally was. For this reason, it is concluded that the surgical threads of claims 1 to 5, all of them requiring this principle, are not obvious over the teaching of D2.
- 9.2 Appellant 2 argued that paragraph [0023] of document D2 hinted at the claimed solution, by disclosing a construction which became more stretchable (höheres Dehnungsvermögen).

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However, the claimed invention does not relate merely to a more stretchable material, but provides a specific type of construction which may become longer. Paragraph [0024] of D2 discloses that the maximum elongation of the threads should be adapted to the natural stretching of the tissue to which they are applied, i.e. that it should not became longer at later stages of healing. Furthermore, document D2 relies on mechanical properties of the polymers, not on any specific tridimensional arrangement thereof.

9.3 Appellant 2 further argued that paragraph [0038] of D2 disclosed that the fibres forming the thread had angles of 5° to 60°, and that that made it obvious that the surgical threads could move to a linear disposition after absorption of the more absorbable component.

However, paragraph [0038] discloses that the maximum extension of the surgical thread before braking is maintained after resorption of one of the materials (lines 29-30), which could not have been the case if the remaining threads could move to a thereabouts linear disposition. Thus, this argument of appellant 2 does not succeed.

For these reasons, it is concluded that document D2 does not provide a hint towards the claimed solution.

10. As the surgical threads of claims 1 to 5 and the surgical implant comprising them of claim 9 are novel and inventive, as required by Articles 54(2) and 56 EPC, the ground of opposition under Article 100(a) EPC does not preclude the maintenance of the patent as granted.

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Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The patent is maintained as granted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated