BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal ~~Yes~~ / No

File Number: T 897/90 - 3.3.2

Application No.: 85 109 148.8

Publication No.: 0 170 966

Title of invention: Dry coating of surgical filaments

Classification: A61L 17/00

D E C I S I O N
of 7 May 1991

Applicant: ETHICON INC.

Headword:

EPC Article 56

Keyword: "Inventive step (yes) - improvement not foreshadowed by prior art"

Headnote

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 897/90 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 7 May 1991

Appellant : ETHICON INC.
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Decision under appeal : Decision of Examining Division of the European Patent Office dated 11 July 1990 refusing European patent application No. 85 109 148.8 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : Lançon P.A.M.
Members : Nuss A.J.
Schulte R.L.J.

Summary of Facts and Submissions

I. European patent application No. 85 109 148.8 was filed on 22 July 1985 and published under No. 0 170 966.

II. The Examining Division refused this application under Article 97(1) EPC on the ground that the claims on file did not meet the requirements of Article 56 EPC. The decision was based on the originally filed Claims 1 to 20.

Independent Claims 1 and 5 read as follows:

1. A synthetic surgical filament having improved and substantially equal dry and wet tiedown properties, said surgical filament having been coated with from about 0.02 to 0.25 percent by weight of a composition consisting essentially of a dry, powdered, substantially water-insoluble, absorbable salt of a C_6 or higher fatty acid.

15. A method for imparting improved and substantially equal dry and wet tiedown properties to a surgical filament which comprises applying to the surface of said surgical filament in the form of a dry powder a water-insoluble, absorbable salt of a C_6 or higher fatty acid, and thereafter removing from the surface of said surgical filament excess said powder by rubbing said surface in intimate contact with a relatively powder free, non-abrasive surface until no powder is visible to the naked eye on said surgical filament surface.

III. In its decision, the Examining Division took the view that the claimed suture differed from that described in

document (I) **GB-A-2 011 977** by the amount of calcium stearate applied and the powder form of the coating, the known suture being indeed coated with a gel of calcium stearate in a volatile organic solvent in order to provide tie-down properties. It was, however, known that in view of surface swelling due to organic solvents, a multi-component coating was less convenient to use than a single component composition and that it was only important to well cover the outer surfaces of the sutures in order to reduce frictional forces during tie-down. It would, therefore, be obvious for a skilled man to use calcium stearate free of solvents in order to avoid the problems stated in document (I). Since this lubricant is moreover known to be available as an onctuous powder, he would thus realise that it could be applied directly as a powder like sodium carbonate, another known lubricant for surgical filaments referred to in the present application, without having to cope, however, with the disadvantage of the latter to be dissolved prematurely.

IV. The Appellant lodged an appeal against the decision of the Examining Division.

V. In their written submissions and at oral proceedings before the Board, which took place on 7 May 1991, the Appellant argued essentially as follows:

(i) The surgical filament of the present application was clearly novel in that it differed from that of document (I) by two distinct features, namely:

- the coating consisted of powder particles of a higher fatty acid salt which were applied to the filament without shearing forces being involved, in contrast to the known coherent coating with a gel of higher fatty acid salts, prepared in a

separate step by refluxing a dispersion of the salt in a volatile organic solvent;

- the very low amount of higher fatty acid salt applied to the filament (0.02 to 0.25 percent by weight) instead of the much higher amounts used in document (I) (1 to 5 percent by weight).

(ii) Because of the nature of surgical procedures, sutures such as those described in document (I) were generally passed one or more times through moist body tissue with the drawback that part of the lubricant material of the coherent coating could be kept back in the tissue and cause adverse bodily reaction several days after surgery. In addition, tissue reactions might also occur as a consequence of traces of solvent entrapped in the coating material. Moreover, the preparation of a coating gel by refluxing a dispersion of the fatty acid salt in the organic solvent was considered to be troublesome although necessary, because sutures coated with a dispersion of ungelled fatty acid salt in an organic solvent had the additional drawback to dust or flake significantly during tie-down. Document (I) did not contain any hint about how to avoid said difficulties, nor did document US-A-4 201 216 (V), mentioned in the present application, according to which a film forming polymer was necessary in order to obtain a continuous adhering film of higher fatty acid salt on the substrate. Although in the latter document the coating was normally applied to the suture as a solution or dispersion of the polymer and fatty acid salt in a volatile organic solvent, the coating composition could alternatively be applied as a solid by passing the coating composition over

or between solid blocks of the coating material, which implied melting of the coating material due to heat developed by friction. Furthermore, in this document, solvent coating was used despite the knowledge that organic solvents might cause surface dissolution and/or swelling or softening of the suture material to be coated. Consequently, none of these documents contained an incentive to replace the known coherent coating by a non-coherent one composed only of a small quantity of solvent free powder of higher fatty acid salt.

As to document US-A-4 143 423 (referred to below as document (VI)), this document mentioned coatings of sodium bicarbonate powder to prevent self-adhesion during storage or to ease installation of surgical appliances with sticky surfaces such as gloves, condoms, drains, catheters and tubings. Surgical sutures were not mentioned. In view of the solubility in water of such coatings, they would, however, easily disappear after the first drag through the moist body tissue. Such coatings would be improper to improve the tie-down properties of sutures because of their failure to be kept on the suture surface during several drags, a prerequisite for easy knot forming of the surgical filament.

VI. At the end of the hearing, the Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of Claims 1 and 15 filed at oral proceedings and dependent Claims 2 to 14 and 16 to 20 as originally filed, and a description to be adapted to the new claims.

VII. Claims 1 and 15 on file read as follows:

1. A synthetic surgical filament having substantially equal dry and wet tie-down properties, said surgical filament having been coated with a substantially water insoluble, absorbable salt of a C_6 or higher fatty acid, except calcium oleate,

characterized in that the coating consists of 0.02 to 0.25 percent by weight of the salt in form of a dry powder.

15. A method for imparting substantially equal dry and wet tie-down properties to a surgical filament by coating the surface of the surgical filament with a water insoluble, absorbable salt of a C_6 or higher fatty acid, except calcium oleate,

characterized in that the water insoluble absorbable salt is applied to the surface in the form of a dry powder, the excess powder being removed from the surface of the surgical filament by rubbing the surface in intimate contact with a relatively powder-free, non-abrasive surface until no powder is visible to the naked eye on said surgical filament surface.

Reasons for the Decision

1. The appeal is admissible.

2. Present Claims 1 and 15 do not refer any longer to a synthetic surgical filament having "improved" tie-down properties. This amendment takes account of the fact that in the present two-part form of these claims the preamble of these claims reflects a state of the art which is different from that on which the original claims were

based, namely document (I) instead of document (V). A comparison of the wet and dry tie-down ratings achieved on the claimed sutures (see table I of the application) with those mentioned in document (I) (see column 8, line 19) shows indeed that these ratings are substantially identical in both cases. Consequently, the amendment of both Claims 1 and 15 satisfies not only the requirements of Article 123(2) EPC but also those of Rule 29(1)(a) EPC which prescribes that where a two-part form of claim is used, the prior art which is nearest to the invention will have to figure in the preamble of the claim, stating such features of it as are necessary for the definition of the claimed subject-matter and which are, in combination, already part of this prior art (cf. decision T 13/84, OJ EPO 1986, 253).

Both independent claims further contain in the preamble a disclaimer which excludes calcium oleate from the protection sought by these claims. In the opinion of the Board, this amendment is allowable under Articles 123(2) and 84 EPC because it concerns a coating substance mentioned and exemplified in the application as filed which manifestly does not lead to a surgical filament with the claimed "substantially equal dry and wet tie-down properties" (see table I of the present application) and because the subject-matter remaining in the claims cannot be defined more clearly and concisely directly, i.e. by a positive listing of all remaining "substantially water insoluble, absorbable salts of a C_6 or higher fatty acid".

3. The present application concerns dry coated surgical filaments and a method for preparing them.

3.1 Document (I) is considered to be the closest state of the art. It relates to a surgical filament (suture) coated with a lubricating composition comprising a gel of a

polyvalent metal ion salt of a C_6 or higher fatty acid in a volatile organic solvent. The gel is applied directly to the suture and the solvent removed by drying to provide a final coating add-on of from about 1 to 5 percent residual fatty acid salt by weight of the dry suture. The fatty acid salt is preferably a calcium salt of a C_6 to C_{22} fatty acid (e.g. calcium stearate). The sutures thus obtained have excellent wet and dry tie-down ratings of 9 to 10 respectively.

The gel is prepared by refluxing a dispersion or slurry of the selected fatty acid salt(s) in an organic solvent under atmospheric pressure and for the time necessary to allow for complete gelation of the mixture. The gelled composition is conveniently applied to the suture by passing the filament through a container of the gel and wiping excess gel from the suture as it exits the container. Eventually, the gel structure breaks down to a dispersion of small gel particles in excess solvent. It has been found that sutures coated with a dispersion of ungelled fatty acid salt in an organic solvent have a definite whitish appearance and dust or flake significantly during tie-down, and are consequently considered to be unsatisfactory by many surgeons. The gelled fatty acid salts are accordingly much preferred over the ungelled ones as a suture coating composition; it is only important that the outer surface be well covered in order to reduce frictional forces during suture tie-down (see Claims 1 to 6; page 1, lines 5 to 7 and lines 101 to 126; page 2, lines 45 to 50; lines 60 to 62; lines 66 to 69 and lines 86 to 104 and example I).

3.2 However, in view of the detailed explanations provided by the Appellant at the oral proceedings, it is plain that these known coated sutures are not quite satisfactory when

used for wound repair involving sewing moist body tissue (see point V (ii) above).

4. In relation to the above prior art, the technical problem to be solved by the present application is thus to find coated sutures having not only equally good tie-down properties as the known ones, but being at the same time also safer insofar as they do not present, when used in surgery, the disadvantages as mentioned above.

This problem is solved by coating a synthetic surgical filament with an amount of 0.02 to 0.25 percent by weight of a substantially water insoluble, absorbable salt of a C_6 or higher fatty acid salt (except calcium oleate) in form of a dry powder according to present Claim 1.

It is plausible to the Board that the application of a minimal amount of a dry powder of lubricant material to the surgical filament will lead to reduce adverse tissue reactions as a consequence of the absence of organic solvent residues in the coating and less quantities of foreign (coating) material kept back in the sewn body tissues. In view of this, the Board is satisfied that the technical problem mentioned above has been credibly solved by the claimed coated surgical filament (see page 1, lines 16 to 28; page 5, lines 9 to 11 and lines 17 to 22 in combination with table I of the present application).

5. Since none of the documents mentioned in the decision of the Examining Division discloses a coated synthetic surgical filament as claimed or a process for preparing such a filament, the claimed subject-matter is novel.

6. It remains to be examined whether the requirement for inventive step is met by the present claims.

6.1 Document (I) is concerned with the preparation of an improved surgical filament, i.e. one having excellent wet and dry tie-down ratings of 9 to 10 respectively. However, in order to achieve this, it is necessary to coat the suture with a minimum amount of about 1% fatty acid salt by weight of the dry suture, whereby it is imperative to use the coating material in form of a gel in an organic solvent, ungelled dispersions being considered to be unsuitable (whitish appearance, dusting or flaking during tie-down). In view of this teaching, the man skilled in the art would have considered as essential for obtaining a well-performing suture not only the minimum amount of 1% of lubricant material applied but also its gel form, the latter being manifestly of prime importance for obtaining a well adhering lubricating coating on the filament. Therefore, when trying to find a safer but still well-performing coated suture, the man skilled in the art would certaintly not have considered to suppress the organic solvent from the known coating composition. Consequently, in the absence of any incentive in document (I) to make solvent free coatings of higher fatty acid salts, the claimed solution must be regarded as non-obvious vis-à-vis the closest state of the art. This conclusion is in no way impaired by the fact that the preferred coating material (calcium stearate) is available as a powder.

The experimental results shown in table I of the present application are clear evidence that except for calcium oleate the claimed sutures still have equally high and wet tie-down ratings in comparison to those mentioned in document (I), although they have now a substantially lower coating weight (0.041% in the case of calcium stearate) than that of the known sutures (2.26% for calcium stearate according to example I of document (I)). In view of what has been said in the preceding paragraph, these results must be considered as quite unexpected.

6.2 Document (V) relates to a quite different type of suture as that claimed always comprising a coating of a **film-forming polymer** in combination with a substantially water soluble salt of a higher fatty acid salt, which is applied to the suture from a solvent solution to provide a final coating add-on from normally about 2 to 10% by weight, the ratio of said fatty acid salt to said polymer being from about 1:4 to 4:1. These known sutures show dry and wet tie-down ratings of merely 7.5 and 8 respectively (see in paragraph example 9).

It is true that in this document it is pointed out that the suture material may be subject to some surface dissolution and/or surface swelling or softening by reason of the action of the film former solvent thereon and that there may also be some weakening of the suture following the application of such coatings. However, since the man skilled in the art knew from document (I) discussed above that a **gel** of higher fatty acid salts in an organic solvent (without the film-forming polymer) would lead to excellent, i.e. higher, dry and wet tie-down ratings, **without affecting the surface** of the suture (no whitish appearance), he would not have had any reason to abandon the use of solvents in suture coating. Moreover, as pointed out by the Appellant, the knowledge that organic solvents may have undesirable effects on the suture has not led in document (V) to coatings free of organic solvent, whether applied as a solution or as melt of the constituents thereof. This clearly supports the non-obviousness of the solution now claimed.

6.3 Document (VI) is of no relevance for the question of inventive step. It concerns the application of a coating of sodium bicarbonate powder to prevent self-adhesion during storage of surgical appliances having sticky

surfaces such as gloves, condoms, drains, catheters and tubings. In view of the completely different use of such coatings and their solubility in water (body fluids), the man skilled in the art would actually not consider document (VI) as proper to give any hint towards a solution to his technical problem.

6.4 It follows from the above that the man skilled in the art had no reason to believe that safer but still well performing sutures could be obtained by coating a surgical filament with an extremely low quantity of higher fatty acid salts in form of a powder which is, moreover, no longer applied as a well-adhering coherent or uniform coating as in the solvent coating technique. In the present application it is indeed sufficient to apply the powder to the surface of the filament and to remove therefrom excess powder by rubbing until no powder is visible to the naked eye. Thus, quite unexpectedly, the troublesome preparation of a coating gel in an organic solvent, as required in document (I), has become entirely superfluous.

All in all, neither the claimed coated suture nor the claimed coating method are foreshadowed by the state of the art.

Consequently, the subject-matter of Claim 1 as well as that of Claim 15, therefore, involves an inventive step.

Since dependent Claims 2 to 14 and 16 to 20 concern particular embodiments of the claimed product and the method for preparing it, they too are allowable.

7. As the patent is to be granted on the basis of amended claims, the description needs to be adapted to the new

claims. The case is, therefore, remitted to the Examining Division.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Examining Division with the order to grant a patent on the basis of: Claims 1 and 15 filed during oral proceedings; Claims 2 to 14 and 16 to 20 as originally filed, and a description to be adapted.

The Registrar: The Chairman:

P. Martorana P.A.M. Lançon