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D E C I S I O N
of 16 April 1997

Case Number: T 0514/92 - 3.2.2

Application Number: 85305391.6

Publication Number: 0170512

IPC: A61B 17/08

Language of the proceedings: EN

Title of invention:
Coated surgical staple

Patentee:
ETHICON INC.

Opponent:
United States Surgical Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - (confirmed)"

Decisions cited:
T 0219/83, T 0037/85

Catchword:
-



Case Number: T 0514/92 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 16 April 1997

Appellant: United States Surgical Corporation
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Representative: Marsh, Roy David
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Respondent: ETHICON INC.
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Representative: Mercer, Christopher Paul
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 2 April 1992
rejecting the opposition filed against European
patent No. 0 170 512 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: M. G. Noel
J. H. Van Moer

Summary of Facts and Submissions

- I. European patent No. 0 170 512 was granted with three claims, on the basis of European patent application No. 85 305 391.6.

Claim 1 reads as follows:

"A sterile surgical staple comprising a pair of legs joined at one end by a crown with substantially the entire surface of said staple coated with a fluorocarbon polymer having a molecular weight of from 2,000 to 50,000."

Claim 3 is made dependent of claim 1 in that a surgical stapling instrument is claimed, comprising a magazine for carrying a plurality of staples according to claim 1.

- II. Following rejection of an opposition filed against the European patent, the Appellant (Opponent) lodged an appeal on 2 June 1992 against the Opposition Division's decision, filed a statement of grounds and paid the appropriate fee in due time.
- III. In a communication dated 4 February 1997 accompanying the summons to oral proceedings the Board informed the parties that the discussion would turn on the issue of inventive step of the claimed subject-matter **vis-à-vis** all cited prior art documents.

IV. Oral proceedings were held on 16 April 1997, during which the following documents were more particularly considered:

(3) US-A-4 275 813

(4) EP-A-0 092 383

(8) US-A-4 012 551

V. The Appellant argued essentially as follows:

From document (4) it was known that surgical staples could be coated on substantially all their surface with polytetrafluoroethylene (PTFE), such as Teflon, irrespective of the molecular weight of the fluorocarbon polymer used. Also document (3) recommended using halogenated polyalkylene such as polytetrafluoroethylene in general.

Since low molecular weight fluorocarbon polymers in the range of from about 2 000 to about 50 000 and associated properties, were well known in the art and sold commercially by the same manufacturer (Du Pont) as Teflon, it was obvious to try other available coatings such as fluorotelomer Vydax, which was a special low molecular weight form of PTFE and was derived from the same molecule, in order to overcome the jamming problem in a multiple fire stapler application.

Moreover, the examples given in the contested patent were restricted to demonstrate the superiority of Vydax over soap or silicone coatings compositions, but not the superiority of Vydax over Teflon. Therefore, the disclosure of the patent was misleading in that it created

an artificial difference between the properties of Vydux and Teflon. In fact, the selection of a low molecular weight polytetrafluoroethylene was obvious for a person skilled in the art and provided no special advantage over high molecular weight polytetrafluoroethylene.

- VI. The Respondent (Proprietor of the patent) replied that it was clear from the patent specification that high molecular weight polytetrafluoroethylene (Teflon) or even silicone, tended to collect at the anvil of a multiple fire stapler whereas staples coated with low molecular weight fluorocarbon polymer such as Vydux were less apt to jam after extended operation. Therefore, the two different molecular weight PTFE materials could not be regarded as equivalent.

In document (4), the relevant prior art referred to the disadvantages of the known coating compositions such as soap or Teflon, i.e. high molecular weight PTFE, and recommended to use a silicone coating instead. Therefore the disclosure of document (4) clearly led away from the use of any sort of PTFE coating. Neither in document (3) was there any mention or suggestion of the use of low molecular weight fluorocarbon polymers. Consequently, neither documents (4) or (3) provided any incentive to a person skilled in the art to try the low molecular weight polytetrafluoroethylene polymers of the present invention.

- VII. The Appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained as granted.

Reasons for the Decision

1. The appeal is admissible.
2. *Closest prior art*

Document (4) represents the prior art which comes closest to the subject-matter of the patent in suit, as was also agreed by both parties. It describes a sterile surgical staple comprising a pair of legs joined at one end by a crown with substantially the entire surface of said staple coated with a silicone elastomeric material. The prior art referred to in this document mentions that coatings previously used to improve the properties of surgical staples had been either soap compositions or polytetrafluoroethylene compositions, i.e. Teflon, to assist in both the placement of the staple and the function of the stapling instrument (cf. page 1, lines 19 to 23 and page 2, lines 11 to 14). However, the molecular weights of the known compositions are not specified.

Document (3) can complete the background mentioned in document (4), since it acknowledges as known staples coated with non-absorbable, surgically acceptable plastic materials, including halogenated polyalkylenes such as polytetrafluoroethylene (cf. column 3, lines 36 to 41). Also here, no mention is made of any molecular weight for the materials used.

Therefore, the subject-matter of claim 1 in suit is distinguished over the closest state of the art by a coating being made of fluorocarbon polymer with a molecular weight of from 2 000 to 50 000.

3. *Inventive step*

3.1 According to the patent (cf. page 2, lines 11 to 13 and 18), a disadvantage of the previous coated staples is that high molecular weight polytetrafluoroethylene (Teflon) tends to collect at the anvil, and in a multiple fire stapler, jamming can occur. The same disadvantage was found with respect to high molecular weight silicone-coated surgical staples, which were not commercialized for this reason (cf. page 4, lines 46 to 47).

The main problem addressed by the present patent was, therefore, to provide sterile surgical staples with a coating which showed a reduced tendency to cause jamming at the anvil in a multiple fire stapling instrument compared with conventionally coated staples.

The solution is given by the feature as claimed of coating surgical staples with a low molecular weight fluorocarbon polymer in the range of 2 000 to 50 000.

Staples coated with such material are less apt to jam after extended operation of the stapler than is the case with surgical staples coated with silicone and high molecular weight polytetrafluoroethylene materials. Even though low molecular weight PTFE may (to some extent) collect at the anvil, this does not interfere with the operation of the instrument (cf. patent, page 2, lines 48 to 52 and page 4, lines 45 to 46).

3.2 Although there is no mention in documents (3) and (4) of any molecular weight for conventional polytetrafluoroethylene materials, such as Teflon, high molecular weight polymers ranging from at least 50 000 to about 10 000 000 according to document (8) (cf. column 2, lines 21 to 31), are necessarily meant, since

the present invention is a development of the solution described in document (4) which belongs to the patent Proprietor, having in mind the additional information contained in documents (3) and (8), both mentioned in the patent in suit.

The Respondent has not denied that low molecular weight fluorocarbon polymers (fluorotelomer) were available to the public under the designation "Vydax" at the priority date of the patent and used in a number of industrial lubricating and release applications as acknowledged in the patent itself (cf. page 2, lines 36 to 41 and page 3, lines 29 to 32). Such materials usually have molecular weights in the range of from about 2 000 to about 50 000, as set out in document (8) already referred to (cf. column 2, lines 30 to 42). However, the low molecular weight telomer was applied there differently, i.e. as a base film layer in combination with an additional upper layer of high molecular weight fluorocarbon polymer, in order to increase the lubricity of razor blades coating edges and to reduce blade pull problems on the hairs.

For the assessment of the presence of any inventive step the question to be asked was, therefore, whether the skilled person could find in the prior art available at the priority date of the present patent, a suggestion to replace high molecular weight by low molecular weight fluorocarbon polymer in staple coating applications. The fact that all the features of the claimed subject-matter are known **per se** (and acknowledged as such in the patent) does not show conclusively the obviousness of the combination (cf. T 37/85, OJ EPO 1988, 86).

- 3.3 Among all documents cited in the proceedings, only documents (3) and (4) refer to the field of coating surgical staples.

In document (4), Teflon is clearly regarded as unsuitable, because it is degraded by gamma radiation sterilization and the lubricity of the coated product tends to vary considerably. Consequently, document (4) would lead a person skilled in the art away from using polytetrafluoroethylene compositions, whatever their molecular weight may be. Instead, silicone is preferred, in particular for achieving improvement in both penetration and extraction forces in the skin to close a wound by using an automatic type stapling instrument. The jamming problem of the stapler is not addressed, however, in this document. On the contrary, silicone is regarded as a suitable material, although it was previously thought that silicone coating materials might stick in automated instruments used to set the staples. Therefore, there cannot be any suggestion in document (4) that Teflon should be replaced by another fluorocarbon polymer material having a lower molecular weight, in order to reduce the jamming problem of the stapling instrument.

In document (3) the problem addressed is that the surgical staples tend to move sideways on one another and bind because the grooves of the stapling instrument are too large when used with staples made from very small diameter wire. To overcome these difficulties, the staples may be coated with non-absorbable, surgically acceptable materials, such as polytetrafluoroethylene, for implantation within the body. However, these materials are less favoured by the medical profession because they may form particles which migrate within the body and the long term result of such migration of a number of particles is unknown. For this reason, absorbable and biologically degradable

plastic materials are preferred. Therefore, not only the staple twisting problem addressed in document (3) is different from the anvil jamming problem set in the patent in suit, but also this document clearly teaches away from using polytetrafluoroethylene in general, i.e. of any molecular weight.

From the foregoing, it results that without an **ex-post facto** analysis, the skilled person could not find in the prior art documents any suggestion to coat surgical staples with a low molecular weight fluorocarbon polymer material in the range of from 2 000 to 50 000 to solve the problem stated above.

- 3.4 It is true that, as submitted by the Appellant, the superiority of Vydax over Teflon is not clearly shown in the patent specification, as the examples given in the description do not compare Vydax with Teflon as far as the jamming problem is concerned. However, the Appellant on whom the onus of proof rests has not shown either convincingly that the anti-jamming effects were not in fact obtained. It is established (T 219/83, OJ EPO 1986, 211, Headnote I) that if an Opponent fails to prove his point because there is controversy which the EPO is unable to resolve, the Patentee should be given the benefit of the doubt. Therefore, the unsupported allegations made by the Appellant are not sufficient to counter the presumption that a known material was used in a new and non-obvious manner to take advantage of a new beneficial effect. Neither is it sufficient to assert that an invention can be carried out on the sole basis of the common general knowledge of a person skilled in the art. Some sort of incentive to try the invention must be found out from a document. In the present case, such a suggestion was not present in any of the prior art documents involved in the proceedings.

3.5 For all these reasons the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC. As a consequence, the other claims dependent therefrom can also stand.

Order

For these reasons it is decided that:

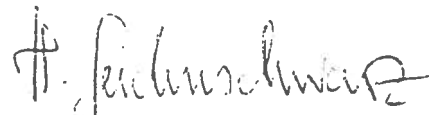
The appeal is dismissed.

The Registrar:



S. Fabiani

The Chairman:



H. Seidenschwarz