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# Datasheet for the decision of 17 February 2009

**Case Number:** T 0403/07 - 3.2.02

**Application Number:** 97250072.2

**Publication Number:** 0797962

**IPC:** A61F 2/00

**Language of the proceedings:** EN

**Title of invention:**
Areal implant

**Patentee:**
Ethicon GmbH

**Opponent:**
Aesculap AG

**Headword:**
-

**Relevant legal provisions:**
-

**Relevant legal provisions (EPC 1973):**
EPC Art. 52(1), 54, 56

**Keyword:**
"Novelty (no, main request)"
"Inventive step (yes, auxiliary request)"

**Decisions cited:**
-

**Catchword:**
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0403/07 - 3.2.02

# D E C I S I O N
**of the Technical Board of Appeal 3.2.02**
**of 17 February 2009**

**Appellant:** (Opponent)
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**Representative:**
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**Respondent:** (Patent Proprietor)
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**Representative:**
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**Decision under appeal:**
**Decision of the Opposition Division of the European Patent Office posted 9 January 2007 rejecting the opposition filed against European patent No. 0797962 pursuant to Article 102(2) EPC 1973.**

**Composition of the Board:**

**Chairman:** M. Noel
**Members:** S. Chowdhury
A. Pignatelli

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division relating to European patent No. 0 797 962, rejecting its opposition to the grant thereof. The decision was dispatched on 9 January 2007.

The appeal was received on 7 March 2007 and the fee for the appeal was paid on the same date. The statement setting out the grounds of appeal was received on 9 May 2007.

II. The opposition was filed against the entire patent and based on Article 100 (a) EPC 1973 (lack of novelty and inventive step). The opposition division decided that the patent met the requirements of Articles 52(1) EPC 1973, and rejected the opposition, accordingly.

III. Oral proceedings were held before the Board on 17 February 2009, at which the following requests were submitted:

The appellant requested that the decision under appeal be set aside and that the European patent No. 0 797 962 be revoked.

The respondent (patentee) requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of the claims of the auxiliary request filed during the oral proceedings before the Board.

IV. Claim 1 of the main request reads as follows: -

"Areal implant, in particular for abdominal wall closure, with a flexible basic structure made from a knitted fabric comprising non-resorbable material or resorbable material, which has a resorption time of at least 60 days and/or an in vivo decrease in strength which leads to a tearing strength remaining after 30 days which is at least 10 % of the initial tearing strength, or a combination of such materials, wherein the knitted fabric of the basic structure is designed to stretch more than the tissue region destined to receive the implant below a critical force and stretch less than this tissue region above the critical force, the critical force being below the highest load allowable for this tissue region, and with a synthetic resorbable material, which stiffens the basic structure, whose resorption time is less than that of the basic structure".

Claim 1 of the auxiliary request is identical to claim 1 of the main request except that the words "in particular" are cancelled and the new claim includes the following additional feature (of claim 2 as granted) added to the end of claim 1 of the main request:

"wherein the knitted fabric of the basic structure is constructed in such a way that a plunger pressing test carried out on an implant 100 $cm^2$ in area with semi-spherical plunger 50 mm in radius produces a plunger force- plunger path length diagram which corresponds to a force-length change diagram, in which the plunger force is at most 15 N up to 10 mm plunger path length, less than 50 N at 20 mm plunger path length, and less than 200 N at 30 mm plunger path length, and in which

the plunger force for plunger path lengths of more than 30 mm increases sharply to a value between 200 N and 1000 N at a plunger path length of 38 mm".

V. The following documents were of particular interest in the appeal procedure:

Dl: A. Pans et al. European Surgence Research EURSURGRES 1992, 24: 54-60
D2: Kunstoffe und Elastomere in der Medizin, Prof. Heinrich Planck, 1993 Kohlhammer Verlag Stuttgart, S. 71-77
D6: G. E. Wantz et aL, (1991), Incisional hernioplasty with Mersilene, Surg. Gynecol Obstat 172: 129-137
D13: Ethicon catalogue, 1 April 1989.

VI. The parties argued as follows:

Appellant

The subject-matter of claim 1 lacked novelty in view of D1 which disclosed a flexible areal implant for abdominal wall closure comprising a basic structure made from a knitted fabric comprising non-resorbable material and synthetic resorbable material knitted according to an interlock method. The resorbable material would inevitably stiffen the basic structure. The feature 1.4 of the claim (see 2.2 below) was unclear and merely a recitation of the problem. In any case this feature was at most a qualitative description of the elastic behaviour of the implant which the D1 fabric would also have, because all knitted structures would show the elastic behaviour as described in D2.

Table 2 of the patent in suit compared the force-extension curves of Mersilene with that of the implants of the patent and D13 showed these curves graphically. The behaviour of Mersilene was the same as that of variants A to E of the patent initially and showed only trivial differences at higher forces. Table 2 also showed that the maximum force of all these meshes was comparable. These slight differences did not justify an inventive step.

Respondent

D1 was concerned with the healing effect of a mesh implant not its elasticity. D1 described a Dacron mesh coated with absorbable polyglactin and page 55 referred to a knitted implant which would have quite different properties, and no structure falling within the terms of claim 1 was described in D1. Mersilene was not a standard product so that it was not clear that the Mersilene referred to in the different documents all had the same elasticity properties. D1 described three different prostheses and it was not clear which one was described being referred to. D13 showed that the elastic properties of the claimed implant was significantly different to that of Mersilene.

The polyglactin used in D1 would not necessarily provide stiffening for the Mersilene. The person skilled in the art would not go to the highest force for a particular tissue but realise that a critical force below but near this force must be selected and the elastic behaviour adjusted accordingly. None of the prior art documents gave the design concept of the claimed implant, which was novel, accordingly.

It was the object of the invention to provide an areal implant for an abdominal wall closure which was light to carry, and relatively firm and easy to handle during an operation but lost its rigidity after a relatively short time in the body tissue. Moreover, it should possess elastic properties which made it more comfortable for the patient to carry.

This combination of objects was achieved by stiffening the basic structure by a synthetic resorbable material whose resorption time was less than that of the basic structure, which made the areal implant relatively firm and easy to handle during the operation but light after a relatively short time in the body tissue. The elastic properties ensured better comfort for the patient.

## Reasons for the decision

1. The appeal is admissible.

Main request

2. Novelty

2.1 Document D1 discloses an areal implant for abdominal wall closure (see last line of the Abstract). Three prostheses are studied (page 55, second complete paragraph), of which one comprises Dacron and polyglactin fibrils put together in fibres and knitted according to an interlock method. Thus, the implant has a flexible basic structure made from a knitted fabric

comprising a non-resorbable material and a synthetic resorbable material.

The synthetic resorbable material by definition has a resorption time which is less than that of the basic non-resorbable structure. Moreover, the resorbable material will inevitably stiffen the basic structure, because two materials when knitted together will inevitably result in a mutual stiffening of the materials, however small. It is noted that the degree of stiffening is not defined in claim 1 and, according to Table 4 of the patent, need only be very small.

2.2 Claim 1 of the patent in suit is, therefore, characterised over D1 by the feature referred to as feature 1.4 during the proceedings, which is that the knitted fabric of the basic structure is designed to stretch more than the tissue region destined to receive the implant below a critical force and stretch less than this tissue region above the critical force, the critical force being below the highest load allowable for this tissue region.

2.3 This part of claim 1 is meant to define the elastic properties of the claimed abdominal wall closure. However, it is very broad in scope because the highest load allowable for the tissue is very wide ranging, given the range of tissues which may be treated when different mammals, different organs, age, sex, etc. are taken into consideration. Indeed the respondent itself stated at the oral proceedings that it was intended to include within the scope of claim 1 wall closures for a wide variety of tissues, not just abdominal wall tissues. A further problem is that claim 1 does not

specify how much below the highest load the allowable critical force should be.

2.4 Thus, this part of the claim describes the elastic behaviour of the wall closure in a qualitatively manner only. It expresses the elongation behaviour depicted in Figure 8 of the patent, according to which the Force vs. Elongation curve is flat below a certain point and rises steeply thereafter, in order to perform the function described in paragraph 37 of the patent.

2.5 The knitted mesh of D1 will necessarily exhibit this elastic behaviour because it is inherent in all knitted structures. This is described in D2 on page 71 where it is stated that the Force-elongation curve of a knitted structure is determined first by the reversible deformation of the mesh, before the force is taken up by the material. This also corresponds to the intuitive expectation that the structure of a knitted material will first take up the forces and extend easily, and then the material will take up the forces and not extend so easily.

3. The qualitative feature 1.4 is, therefore, implicit in the structure of D1. Thus, D1 discloses a knitted structure having all the features of claim 1, whose subject-matter lacks novelty.

Auxiliary request

4. Admissibility

Claim 1 is formed by the combination of features of claims 1 and 2 as granted. The appellant had no formal

objection to the claim, nor has the Board. Moreover, the late request gives rise to no new arguments or documents and is admissible.

5. Novelty

The appellant had no objection in this respect, a view with which the Board concurs.

6. Inventive step

6.1 It is the object of the invention to provide an areal implant for an abdominal wall closure which is light to carry, and relatively firm and easy to handle during an operation (e.g. when cutting to size and inserting) but loses its then undesired rigidity after a relatively short time in the body tissue (paragraph 11 of the patent in suit). Moreover, it should possess elastic properties which make it more comfortable for the patient to carry. The desired elastic properties are expressed by feature 1.4 and described in paragraph 37.

This combination of objects is achieved by stiffening the basic structure by a synthetic resorbable material whose resorption time is less than that of the basic structure. As a result, the areal implant is relatively firm and easy to handle during the operation but loses its then undesired rigidity after a relatively short time in the body tissue, because the stiffening synthetic material is resorbed. Moroever, the elastic properties as defined at the end of the claim ensure better comfort for the patient.

6.2 Neither the above problem nor the solution thereto is discussed in the prior art, for which reason claim 1 involves an inventive step.

6.3 As regards the problem the appellant cited D6, saying that it recommended the use of a prosthesis of Mersilene because it was supple and elastic enough to conform freely to the curvatures of the visceral sac and successful. D6 states, in fact, that there was no problem with prior art Mersilene implants, particularly as regards patient comfort. The present problem was not discussed in D6 or in any other document.

6.4 As regards the solution, it comprises more than simply making the implant even more elastic than Mersilene. It means tailoring the force-extension curve thereof around the highest load allowable for abdominal tissue such that its Force-extension curve is well below the curve for Mersilene, as illustrated in D13. From D13 and Table 2 of the patent it is seen that the force required to obtain the same extension, in the upper regions, is about double for Mersilene, which is not insignificant, contrary to the appellant's statement.

The solution was also not in the prior art, accordingly.

## Order

**For these reasons, it is decided that:**

1. The decision under appeal is set aside.

2. The case is remitted to the department of the first instance with the order to maintain the patent in the following version:

   Claims 1 to 15 filed during the oral proceedings before the Board.

   Description and Figures 1 to 11 as granted.

The Registrar | The Chairman

A. Wolinski | M. Noel