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D E C I S I O N
of 22 July 2003

Case Number: T 0571/98 - 3.3.2

Application Number: 88900458.6

Publication Number: 0299004

IPC: A61L 31/00

Language of the proceedings: EN

Title of invention:

Surgical composite and use of a composite for manufacturing
(part of) a device for use in bone surgery

Patentee:

BIOCON OY

Opponent:

Johnson & Johnson Professional, Inc.

Headword:

Surgical composite/BIOCON OY

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"Main request and auxiliary requests 1 to 4 - added matter -
yes: no linkage between two features in the application as
filed"

Decisions cited:

G 0009/91, G 0010/91

Catchword:

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Case Number: T 0571/98 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 22 July 2003

Appellant: Johnson & Johnson Professional, Inc.
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Respondent: BIOCON OY
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Representative: KEIL & SCHAAFHAUSEN
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
25 March 1998 concerning maintenance of
European patent No. 0299004 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
C. Rennie-Smith

Summary of Facts and Submissions

- I. European patent No. 0 299 004 based on international application No. PCT/FI87/00177 was granted on the basis of 7 claims.

Independent claim 1 as granted reads as follows:

"1. Surgical composite comprising a material selected from a resorbable (co)polymer, said material containing oriented, at least partially fibrillated structural units which have been induced by drawing the material in solid state, characterized in that the composite is a device for use in bone surgery or forms part thereof, wherein at least the surface of the device has a profiled structure which includes said fibrillated structural units."

- II. Notice of opposition was filed against the granted patent by the opponent.

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step and under Article 100(b) for insufficiency of disclosure.

The following documents were *inter alia* cited during the proceedings:

- (1) EP-A-202 090
- (6) Akt. Traumatol., 15, 145-149, 1985
- (12) EP-A-204 931

III. The interlocutory decision of the Opposition Division established that the patent could be maintained in an amended form under Article 106(3) EPC on the basis of the set of claims of the main request filed during the oral proceedings on 9 June 1997.

In its decision, the Opposition Division first established that the main and auxiliary requests submitted during the oral proceedings fulfilled the requirements of Articles 84 and 123(2)(3) EPC and of Rule 57(a) EPC.

As to Article 83, the Opposition Division noted that the only objection maintained by the opponent related to the expression "**at least partially** fibrillated" used in claim 1. It expressed the view that this wording merely implied the obvious technical fact that the fibrillation may never be really complete. It therefore considered that the objection raised under Article 83 was not well-founded.

Concerning novelty, the Opposition Division found that the subject-matter of claim 1 was novel as none of the available prior art documents disclosed a surgical device made of a resorbable (co)polymer having **fibrillated structural units** and a **non-smooth** surface.

As regards inventive step, the Opposition Division was of the opinion that document (12) represented the closest state of the art.

It further defined the problem to be solved over this document as to provide a resorbable bone surgical device having improved strength and fixation properties.

This problem was solved by the presence of fibrillated structural units in the composite constituting the device.

In its view, since the next closest relevant prior art documents (1) and (6) were both silent about the occurrence of fibrillated structural units in the disclosed composites, which were also used for making surgical devices, it considered that the claimed subject-matter involved an inventive step.

- IV. The appellant (opponent) lodged an appeal against the said decision.

- V. In a communication of the Board dated 11 April 2002, the Board expressed *inter alia* its preliminary view that the sentence in claim 1 of the set of claims as maintained by the Opposition Division, ie "the surface of the device has a profiled structure which includes said fibrillated structural units", had no basis in the application as originally filed.

- VI. In reply to this notification the appellant filed on a new independent claim 1 as claim 1 of its main request with its letter dated 20 December 2002.

This claim reads:

"1. Device for use in bone surgery comprising a resorbable (co)polymer, said (co)polymer being drawn in solid state to a composite containing oriented, at least partially fibrillated structural units, wherein the drawn composite is shaped into the device for use in bone surgery, and wherein **the surface** of the device has a profiled structure which **includes said fibrillated units.**" (Emphasis added).

It further filed three auxiliary requests with its letter dated 2 June 2003.

Independent claim 1 of the first auxiliary request reads:

"1. Device like a screw or a rod with a scaly covering for use in bone surgery comprising a resorbable (co)polymer, said (co)polymer being drawn in solid state to a composite containing oriented, at least partially fibrillated structural units, wherein the drawn composite is shaped into the screw or rod with a scaly covering for use in bone surgery, and wherein **the surface** of the screw or rod with a scaly covering **includes said fibrillated units.**" (Emphasis added).

Independent claim 1 of the second auxiliary request reads:

"1. Screw or rod with a scaly covering for use in bone surgery comprising a resorbable (co)polymer, said (co)polymer being drawn in solid state to a composite containing oriented, at least partially fibrillated

structural units, wherein the drawn composite is shaped into the screw or rod with a scaly covering for use in bone surgery, and wherein **the surface** of the screw or rod with a scaly covering **includes said fibrillated units.**" (Emphasis added).

Independent claim 1 of the third auxiliary request reads:

"1. Screw for use in bone surgery comprising a resorbable (co)polymer, said (co)polymer being drawn in solid state to a composite containing oriented, at least partially fibrillated structural units, wherein the drawn composite is shaped into the screw for use in bone surgery, and wherein **the surface** of the screw **includes said fibrillated units.**" (Emphasis added).

VII. Oral proceedings were held before the Board on 22 July 2003. During the oral proceedings, the respondent filed a new set of claims as fourth auxiliary request.

Independent claim 1 of this set of claims reads:

"1. Screw for use in bone surgery comprising a resorbable (co)polymer, said (co)polymer being drawn in solid state to a composite containing oriented, at least partially fibrillated structural units, wherein the drawn composite is shaped into the screw for use in bone surgery, and wherein at least **the surface** of the screw **includes said fibrillated structural units.**" (Emphasis added).

VIII. During the oral proceedings, the Board asked the respondent to show the basis in the application as originally filed for the technical feature of claim 1 requiring that the surface of the device includes the fibrillated structural units obtained by drawing the composite in solid state. In reply, the respondent first argued that, since this feature, which was present in claim 1 of the set of claims of the patent as granted and of the patent as maintained by the Opposition Division, was neither contested by the opponent nor by the Opposition Division, the Board was not allowed to raise any objection under Article 123(2) with respect to this particular feature in the light of the Enlarged Board of Appeal's decisions G 9/91 (OJ 1993, 408) and G 10/91 (OJ 1993, 420).

It further submitted that the basis for this feature could be derived from the teaching of the application as originally filed taken as a whole. In fact, the application as filed disclosed that by drawing a (co)polymer in solid state to a composite at least partially fibrillated structural units were obtained in the material. In its view, it was therefore clear to the skilled person reading example 6, which described the moulding of a screw using such a material, that the cross-section of the screw and consequently the surface of the screw thus obtained must include the fibrillated structural units.

IX. The appellant submitted that the reference to G 9/91 and G 10/91 was misplaced as in the present case objections under Article 123(2) were raised during the opposition proceedings and considered by the Opposition Division.

It moreover argued that no basis could be found in the application as filed for the linkage of "fibrillated structural units" to "the surface".

In its written submissions, it also maintained objections with respect to Articles 84, 123(2), 83, 54 and 56 EPC against the patent as maintained.

- X. The appellant requested that the decision under appeal be set aside and that the European patent No. 0 299 004 be revoked.

The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims maintained by the Opposition Division with the wording of claim 1 as filed with its letter of 20 December 2002 (main request) or on the basis of its first, second or third requests filed with its letter of 2 June 2003 or of its fourth auxiliary request filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request*
 - 2.1 Article 123(2) EPC

Independent claim 1 as originally filed reads:

"1. Surgical materials and devices, which have been manufactured of resorbable polymer, copolymer or polymer mixture and can be used as bone fracture, osteotomy, arthrodesis or joint damage fixation materials or their components and as bone tissue reconstruction- and augmentation materials or their components, characterised in that the mentioned materials and devices or their components contain at least partially fibrillated structural units."

Independent claim 1 of the main request has now been directed to a device for use in bone surgery made of a resorbable (co)polymer composite containing at least partially fibrillated structural units, wherein the surface of the device has a profiled structure which includes the fibrillated units. The product is further defined by two process steps, namely a drawing step of the copolymer to a composite containing at least partially fibrillated units and step of shaping the composite into the device.

As all the requests on file contain the feature requiring that the surface of the device includes the fibrillated units it appears suitable to examine first whether this common feature has been disclosed in the application as originally filed.

- 2.2 As to the first argument of the respondent that, according to decisions G 9/91 and G 10/91, Article 123(2) should not be at issue as far as this feature is concerned because it has never been at issue previously, the Board observes the following:

It is indeed true as mentioned by the respondent that decisions G 9/91 and G 10/91 both state that "in case of amendments of the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirement of the EPC" (section 19).

It is however not correct to deduce from this sentence that the Opposition Division would not be allowed to check whether unamended features in a claim fulfil the requirement of Article 123(2) if no such objection was raised by the opponent.

As is apparent from the Opposition Division's decision this is precisely what the Opposition Division did. In fact, in the Opposition Division's decision on page 4, paragraph 2 it is stated that "The amended claims 1 to 7 of the main request filed during Oral Proceedings and the amended claims 1 to 7 of the auxiliary request and the new pages 4,8,9,11 and 12 of the description filed with the letter of 25/8/97 meet the requirements of Art. 123(2) and Art. 123(3)".

The only conclusion which can be drawn from this statement is that, in the Opposition Division's opinion, **all** the features of the claims of the main and of the auxiliary requests, ie the whole subject-matter, fulfills the requirements of this Article, otherwise the sentence quoted above would make no sense.

Accordingly, as the appellant's request dated 21 May 1998 is that the interlocutory decision be set aside and that the patent be revoked in its entirety, the

Board clearly has jurisdiction to give a decision upon the correctness of this earlier decision taken by the Opposition Division.

It therefore appears that the decisions cited by the respondent do not apply to the present case.

2.3 As regards the structure of the material, the application as originally filed recites: "Such a resorbable material consists among other things of oblong crystalline microfibrils and of tie-molecules connecting microfibrils and of oriented amorphous regions. In a partially fibrillated structure the amorphous regions between microfibrils form a more significant part of the material than in an ultraoriented material where in the extreme case amorphous material exists only as crystal defects around the ends of the polymer molecule chains." (page 7, lines 22 to 30).

In addition, the microscopic structure of the oriented fibrillated units are schematically shown in figures 1 and 3 of the application as originally filed.

The Board notes however that the application as filed is totally silent about the distribution of the fibrillated units within the composite. In fact, the application as filed does not disclose whether the fibrillated structural units are either evenly or unevenly distributed in the composite or whether they are preferably present in a certain particular area of the composite.

The Board observes also that the word "surface" in itself appears only once in the application as filed but in relation to an alveolar ridge (page 14, lines 18 and 19; ...the surface of the alveolar ridge.).

Accordingly, the Board concludes that the feature requiring that the surface of the device includes the fibrillated units was not disclosed in the application as originally filed.

The subject-matter of claim 1 of this request therefore infringes the requirements of Article 123(2) EPC.

- 2.4 Concerning the basis for the contested feature provided by the respondent in the application as originally filed, ie the application as a whole and example 6 in particular, the Board, as it is apparent from point 2.3 above, could not find any direct and unambiguous disclosure of the fact that the surface of the device includes said fibrillated units.

Example 6 merely recites that fibrillated rods are compression moulded in a mould with a screw-like mould cavity at about 160°C. However, this example, like the rest of the application, remains silent about the distribution of the fibrillated units in the material. Moreover, this example does not say anything in relation to the behaviour of the fibrillated units during the moulding process.

Thus the respondent's second argument, that it is clear to the skilled person reading the application as filed that the fibrillated units are in fact evenly distributed everywhere in the material and that they

are not affected by the moulding process, amounts merely to a statement which is not supported by any particular disclosure in the application.

It is moreover contradicted by the amendment introduced into the description as filed in the course of the examination proceedings before the examination division reciting that "**it is advantageous** to provide the surface of the device made of the composite with a profiled structure which includes said fibrillated structural units", which presents this embodiment as a preferred one (page 4, line 10) (Emphasis added).

Under these circumstances, there is no basis to be found in the application as filed for the linkage of "fibrillated structural units" to "the surface".

3. *Auxiliary requests 1 to 3*

As these requests also contain the feature requiring that the surface includes the fibrillated units, the conclusion under 2.2 holds good for these requests as well.

4. *Auxiliary request 4*

4.1 Admissibility of the request

This request was submitted during the oral proceedings.

In that respect, the Board notes that this request is the result of very minor amendments made to the third auxiliary request. In fact, they merely consisted in reintroducing part of the wording of claim 1 as granted

in claim 1 of auxiliary request 3 (ie "**at least** the surface of the device has a profiled structure which includes said fibrillated **structural** units" instead of "the surface of the device has a profiled structure which includes said fibrillated units ").

As these amendments constituted an attempt to overcome the objections under Article 123(2) EPC discussed during the course of the oral proceedings, the Board decided this request is admissible.

4.2 Article 123(2)

The introduction of the term "at least" in this request does in fact not change the situation described above since the claim still encompasses the embodiment wherein the surface includes the fibrillated structural units.

Accordingly, the conclusion under 2.2 holds good for this request as well.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked

The Registrar:

The Chairman:

A. Townend

U. Oswald