

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 10 July 2002

Case Number: T 0196/99 - 3.2.5

Application Number: 88311763.2

Publication Number: 0321176

IPC: B29C 55/00

Language of the proceedings: EN

Title of invention:

Molecularly oriented thermoplastic member and process of forming same

Patentee:

JOHNSON & JOHNSON ORTHOPAEDICS INC.

Opponents:

HOWMEDICA INC.
Biocon Ltd.

Headword:

-

Relevant legal provisions:

EPC Art. 84, 123, 54

Keyword:

"Clarity; main request, auxiliary request (yes)"
"Extension of the protection conferred; main request (yes),
auxiliary request (no)"
"Novelty; auxiliary request (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0196/99 - 3.2.5

D E C I S I O N
of the Technical Board of Appeal 3.2.5
of 10 July 2002

Appellant: JOHNSON & JOHNSON ORTHOPAEDICS INC.
(Proprietor of the patent) 501 George Street
New Brunswick
New Jersey 08903 (US)

Representative: Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

Respondent I: HOWMEDICA INC.
(Opponent 01) 359 Veterans Boulevard
Rutherford, NJ 07070 (US)

Representative: Naismith, Robert Stewart
CRUIKSHANK & FAIRWEATHER
19 Royal Exchange Square
Glasgow G1 3AE
Scotland (GB)

Respondent II: Biocon Ltd.
(Opponent 02) Box 3
FIN-33721 Tampere, Finland (FIN)

Representative: Lenz, Nanno Matthias
Keil & Schaafhausen
Patentanwälte
Cronstettenstrasse 66
D-60322 Frankfurt am Main (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 18 December 1998
revoking European patent No. 0 321 176 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: W. Moser
Members: W. R. Zellhuber
W. Widmeier

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the decision of the Opposition Division revoking the European patent No. 0 321 176.
- II. Oppositions were filed against the patent as a whole and based on Article 100(a) EPC (lack of novelty, Article 54 EPC, and lack of inventive step, Article 56 EPC). The Opposition Division held that the ground for opposition of lack of novelty prejudiced the maintenance of the patent having regard to the prior art as disclosed in document

D11: EP-A 0 202 090.
- III. Oral proceedings were held before the Board of Appeal on 10 July 2002. Respondent I (opponent 01), although duly summoned, was not represented at these proceedings.
- IV. The appellant requested that the decision under appeal be set aside and that the European patent No. 0 321 176 be maintained on the basis of the following documents:
- (a) main request: claims 1 to 15, filed on 8 April 1999; or
 - (b) auxiliary request: claim 1, filed on 8 October 2001, and claims 2 to 15, filed on 8 April 1999.
- Respondent I and respondent II (opponent 02) requested that the appeal be dismissed.
- V. Claim 1 of the main request reads as follows:

"1. A process of forming a self-supporting, high strength, thermoplastic member having a minimum cross-sectional dimension of at least 0.79 mm, comprising the steps of:

providing a thermoplastic polymer capable of being absorbed in an animal body;

melting the thermoplastic polymer and forming the melted polymer into a preformed member by an intermittent process;

cooling the preformed member to a temperature below the glass transition temperature of the thermoplastic polymer to cause nucleation and to cause the preformed member to become self-supporting;

reheating the self-supporting, preformed member to a temperature above the glass transition temperature, but below the melting temperature, of the thermoplastic polymer;

drawing the preformed member under tension during said reheating step;

cooling the drawn member while maintaining the tension applied thereto; and

discontinuing the application of tension after the drawn member has cooled to permit it to relax,

thereby providing said self-supporting, high strength, thermoplastic member."

Claim 1 of the auxiliary request reads as follows:

"1. A process of forming a self-supporting, high strength, thermoplastic member having a minimum cross-sectional dimension of at least 0.79 mm, comprising the steps of:

providing a thermoplastic polymer capable of being absorbed in an animal body;

melting the thermoplastic polymer and forming the melted polymer into a preformed member by an intermittent moulding process;

cooling the preformed member to a temperature below the glass transition temperature of the thermoplastic polymer to cause nucleation and to cause the preformed member to become self-supporting;

reheating the self-supporting preformed member to a temperature above the glass transition temperature, but below the melting temperature, of the thermoplastic polymer;

drawing the reheated self-supporting preformed member under tension during said reheating step;

cooling the drawn reheated self-supporting preformed member while maintaining the tension applied thereto; and

discontinuing the application of tension after the drawn reheated self-supporting preformed member has cooled to permit it to relax,

thereby providing said self-supporting, high strength, thermoplastic member."

VI. In the written procedure and during oral proceedings, the appellant argued essentially as follows:

The subject-matter of claim 1 of the main request was clear and the amendments had been made in accordance with the requirements of Article 123(3) EPC.

The term "intermittent" used in claim 1 of the main request was a clear English term. As pointed out in the respective feature of claim 1, it related to the process of forming the melted polymer into a preformed member and had thus to be construed as meaning that one member was formed after the other.

In these passages of claim 1 of the patent in suit as granted, which describe the process of drawing and cooling the thermoplastic member, the term "self-supporting" was used to identify the member rather than to describe its property. By omitting that term in these passages, the scope of claim 1 of the main request had thus not been extended with respect to the scope of claim 1 of the patent in suit as granted.

The subject-matter of claim 1 of the auxiliary request was novel. Document D11 concerned a continuous extrusion process, and, thus, did not disclose a process of forming melted polymer into a preformed member by an intermittent moulding process.

Furthermore, document D11 did not disclose the feature of cooling of a preformed member under tension. According to page 13, lines 16 to 22 (example 1) of document D11, a second stage of orientation of a filament was carried out by passing it through an oven, with the oven being located between two godets that

were at ambient temperature. However, document D11 did not show any details concerning the apparatus. The step of cooling of the filament was likely to be carried out after the filament passed the godets, which implied that cooling was performed without maintaining the tension.

VII. As regards the subject-matter of claim 1 of the main request, the respondents I and II argued essentially as follows:

Claim 1 according to the main request did not comply with Article 84 EPC and Article 123(3) EPC.

The term "intermittent process" used in claim 1 of the main request was indefinite and not suitable to distinguish the claimed process from an extrusion process.

Furthermore, by deleting the term "self-supporting" previously included in claim 1 as granted, the scope of claim 1 as amended according to the main request had been extended with regard to the scope of claim 1 of the patent in suit as granted. According to the amended wording of claim 1 of the main request, the thermoplastic member needed not to be self-supporting during the reheating, drawing and cooling steps, contrary to claim 1 of the patent in suit as granted.

Thus, claim 1 of the main request did not comply with Article 123(3) EPC.

VIII. With regard to the subject-matter of claim 1 of the auxiliary request, no submissions in writing by the respondents I and II had reached the Board.

During oral proceedings, respondent II argued essentially as follows:

No objections were raised with regard to the formal requirements of Articles 84 and 123 EPC. However, the subject-matter of claim 1 of the auxiliary request was not novel.

Document D11, cf. Figure 7 and Example 1 on pages 12 to 14, disclosed a process of extruding an element having a limited length. Thus, it disclosed a process of forming an element by an intermittent moulding process. Moreover, any extrusion process had once to be ended. The feature of forming a member by an intermittent moulding process did thus not distinguish the process according to claim 1 of the auxiliary request from the process disclosed in document D11.

Furthermore, document D11 also disclosed the feature of cooling the drawn member under tension. According to Example 1 on page 13, lines 16 to 22, and Table 1 on page 15, a filament was oriented and drawn by passing it through a heated oven with the oven located between two godets running at different speeds. The filament, by leaving the oven and coming into contact with the respective godet at ambient temperature was inevitably cooled while maintaining the tension applied by the godets.

Finally, document D11 also concerned a process of forming a self-supporting member. According to page 9, line 17 of document D11, the filaments were quite stiff, and according to page 9, line 35 to page 10, line 3 of document D11, they were so stiff that clamps enclosing the filament wound around a bar could not be

hand tightened. The Young's modulus of $1,3 \times 10^{10}$ N/m² ($1,9 \times 10^6$ psi) of the filament, indicated on page 13, lines 24 and 25 of document D11, corresponded to that of wood.

The subject-matter of claim 1 of the auxiliary request was thus not novel within the meaning of Article 54 EPC.

Reason for the Decision

1. *Main request*

1.1 Clarity (Article 84 EPC)

The term "intermittent" is to be construed as meaning "occurring at irregular intervals, not continuous or steady", cf. "The New Oxford Dictionary of English", Oxford University Press 1998. Thus, the term "intermittent process" used in claim 1 has a clear meaning and, in the present case, is related to the process of forming the melted polymer into a preformed member. That step thus concerns a non-continuous process, wherein one member is formed after the other, thereby emphasizing the difference with respect to a continuously running extrusion process.

The subject-matter of claim 1 is also supported by the description, which has been amended in order to bring it in line with the claims.

The description of the patent in suit as amended refers to an injection moulding process as an example of an intermittent process, cf. page 3, line 30.

References relating to a process of forming the members by a continuous process, eg. extrusion, previously included in the description of the patent as granted, cf. page 3, lines 29 to 32, 40 and 42, page 4, line 45 to page 5, line 16, and Figure 4, have been deleted.

The Examples 1 to 4 on pages 5 and 6 of the description of the patent in suit as amended, which relate to a continuous extrusion process for forming the members, are specified as not being according to the invention, whilst Example 5 on page 6, which describes an injection moulding process, is indicated as representing an embodiment according to the invention.

In the Board's judgement the feature in question is thus clear and supported by the description as amended. Claim 1 therefore meets the requirements of Article 84 EPC.

1.2 Extension (Article 123(3) EPC)

Claim 1 of the patent in suit as granted comprised the following features:

- a) "... reheating the self-supporting member to a temperature above the glass transition temperature of the thermoplastic polymer, but below its melting temperature;"
- b) "applying tension to the self-supporting member during said reheating step;"
- c) "cooling the reheated self-supporting member while maintaining the tension applied thereto; and"

- d) "discontinuing the application of tension after the self-supporting member has cooled to permit the self-supporting member to relax."

In claim 1 of the main request, the features corresponding to the above-mentioned features (b), (c) and (d) of claim 1 as granted, do not refer to a self-supporting member, but to a preformed member. The term "self-supporting", however, describes a distinct property of the member. Its meaning is explicitly defined on page 2, lines 38 to 43 of the patent in suit as granted. Since, according to claim 1 of the main request, the preformed member is no longer defined as being a self-supporting member during the steps of tensioning and cooling, the claim has been amended in such a way as to extend the protection conferred, contrary to the requirements of Article 123(3) EPC.

Admittedly, a thermoplastic member when reheated above the glass transition temperature becomes in general softer. However, there is no support that a member consisting of a thermoplastic polymer capable of being absorbed in an animal body would no longer be self-supporting when heated above glass transition temperature. Consequently, a person skilled in the art would not inevitably understand the wording of claim 1 of the patent in suit as granted in such a way that, as far as the above-mentioned features (b), (c) and (d) are concerned, the term "self-supporting" denotes the member solely linguistically rather than describing a property.

The main request of the appellant is thus not allowable.

2. *Auxiliary request*

2.1 Formal requirements

2.1.1 The term "by an intermittent moulding process" does not render the subject-matter of claim unclear for the reasons already set out above with respect to claim 1 of the main request.

The subject-matter of claim 1 of the auxiliary request thus meets the requirements of Article 84 EPC.

2.1.2 The subject-matter of claim 1 is disclosed in the application as filed in claim 1 in connection with page 3, line 11, and page 3, lines 37 and 52 to 57.

The features of dependent claims 2 to 15 are disclosed in claims 4 to 15 and 19 of the application as filed, respectively.

Claim 1 of the auxiliary request comprises all the features of claim 1 of the patent in suit as granted. Moreover, the introduction of the features of a minimum cross sectional dimension of at least 0.79 mm and of applying an intermittent moulding process results in a restriction of the protection conferred as compared with claim 1 of the patent in suit as granted.

The amendments thus comply with the requirements of Article 123(2) and (3) EPC.

2.2 Novelty

2.2.1 In the course of the appeal procedure, document D11 was cited as destroying the novelty of the subject-matter

of claim 1.

This document discloses a process for manufacturing fastening members of an absorbable, thermoplastic polymer by forming an extruded oriented filament into the configuration of the fastener member.

The process comprises the step of annealing an extruded filament at a temperature between the glass transition temperature and the melting temperature of the polymer. Annealing is carried out with the filament under restraint so as to prevent shrinkage of the filament, and so as to maintain the orientation of the filament, cf. page 8, lines 22 to 31.

In the process according to Example 1, disclosed on page 12, line 34 to page 14, line 6, melted polymer is extruded into a monofilament. The extruded filament is cooled in a water bath and, thereafter, oriented by applying tension in a two-stage orientation process. The second stage of orientation of the extruded filament with a draw ratio of 1.07 is carried out by passing the filament through a heated oven with the latter located between two godets that are at ambient temperature. The two godets run at different speeds, cf. page 15, Table 1.

The thus oriented monofilament having a diameter of 0,76 mm (29,8 mils) and a Young's modulus of $1,3 \times 10^{10}$ N/m² ($1,9 \times 10^6$ psi) is wound on a forming bar, annealed in an oven for 16 hours and, after removing from the oven, cooled to room temperature. Thereafter, the monofilament is cut to produce U-shaped staples, cf. page 14, lines 3 to 6.

2.2.2 Document D11 thus suggests forming a melted polymer into a filament by a continuous extrusion process, drawing and annealing that filament, and, thereafter, forming individual members by cutting the filament into pieces having the desired configuration.

According to claim 1 of the auxiliary request, however, an intermittent moulding process is used for forming a preformed self-supporting member, which implies that one preformed member is moulded after the other.

2.2.3 Furthermore, according to claim 1, a self-supporting preformed member is formed by an intermittent moulding process. A definition of a member of being self-supporting is indicated on page 2, lines 38 to 43 of the patent in suit.

There is no disclosure in document D11 as to whether or not the extruded filament was self-supporting before and during carrying out the orientation process. The mention of an appropriate stiffness and the indication of a Young's modulus concern the extruded filament after having been oriented.

Document D11, therefore, does not disclose a process, wherein a preformed member formed by an intermittent moulding process is cooled to cause the preformed member to become self-supporting, and, wherein that self-supporting member is reheated, drawn and cooled.

2.2.4 Further, document D11 does not disclose a process, wherein a drawn reheated self-supporting member is cooled, while maintaining the tension applied thereto for drawing and orienting the filament.

Document D11 does not mention such a cooling step. Furthermore, the apparatus for carrying out that second stage of orientation, to which respondent II referred, is not shown. Therefore, there is also no indication that there is a space between the oven and the subsequent godet and that the filament is cooled in that space. Consequently, there is no disclosure referring to cooling the drawn reheated filament while maintaining the tension applied thereto for drawing and orienting it.

- 2.2.5 Finally, the filament manufactured according to Example 1 of document D11 has a diameter of 0.76 mm (29.8 mils) thus being outside the range indicated in claim 1, which refers to a minimum cross-sectional dimension of at least 0.79 mm.
- 2.2.6 The subject-matter of claim 1 is therefore novel with regard to the prior art as disclosed in document D11.
- 2.2.7 Furthermore, in the Board's judgement, the subject-matter of claim 1 is also novel with regard to the prior art as disclosed in the remaining documents cited in the course of the opposition procedure.
- 2.2.8 The subject-matter of claim 1, and, consequently, also that of dependent claims 2 to 15 of the auxiliary request is therefore novel within the meaning of Article 54 EPC.
- 3. Since the question of whether or not the subject-matter of the patent in suit involves an inventive step has not yet been considered by the Opposition Division, the Board, based on the discretionary power conferred to it by Article 111(1) EPC, considers it appropriate to

remit the case to the Opposition Division for further prosecution.

Order

For these reasons it is decided:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution.

The Registrar:

The Chairman:

M. Dainese

W. Moser