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Datasheet for the decision of 26 January 2012

Case Number: T 0254/09 - 3.3.09

Application Number: 98949404.2

Publication Number: 941158

IPC: B32B 27/08, A61J 1/00

Language of the proceedings: EN

Title of invention:
Multilayered polymer structure for medical products

Applicant:
Baxter International Inc.

Opponent:
Sealed Air Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty, Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0254/09 **-** 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 26 January 2012

Appellant: (Patent Proprietor)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 18 November 2008 concerning maintenance of European patent No. 941158 in amended form.

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
W. Sekretaruk

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 0 941 158 in respect of European patent application No. 98 949 404.2, filed on 18 September 1998 as international application No. PCT/US1998/019690 in the name of Baxter International Inc., was announced on 24 November 2004 in Bulletin 2004/48.

The patent was granted with 40 claims, claims 1 and 25 reading as follows:

"1. A multiple layer structure for fabricating medical products comprising:

a core layer of an ethylene vinyl alcohol copolymer having an ethylene content of 25-45 mole percent;
an inner layer consisting of a polyolefin suitable for contact with a solution and positioned on a first side of the core layer;
an outer layer positioned on a second side of the core layer opposite the inner layer, the outer layer consisting of a polyamide and
two tie layers, one of each adhered to the first and second sides of the core layer and positioned between the inner layer and the core layer and between the outer layer and the core layer;

wherein the core byer [sic] the inner layer, the outer layer and the tie layer are coextruded to each other."

"25. A method for fabricating a multilayered structure comprising the steps of:

providing a core layer of an ethylene vinyl alcohol copolymer having an ethylene content of 25-45 mole percent;
providing an inner layer consisting of a polyolefin suitable for contact with a solution and positioned on a first side of the core layer;
providing an outer layer positioned on a second side of the core layer opposite the inner layer, the outer layer consisting of a polyamide.
providing a first tie layer between the outer layer and the core layer;
providing a second tie layer between the inner layer and the core layer; and
cast coextruding the outer layer, the core layer, the inner layer and the first and second tie layer to define a multilayered structure."

Claims 2 to 24 and 26 to 40 were dependent claims.

II. An opposition against the patent was filed by

Sealed Air Corporation on 24 August 2005.

The opponent requested revocation of the patent in its entirety on the grounds of Articles 100(a) EPC (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

The opponent cited ***inter alia*** the following document:

D4 US A 4 997 710.

III. With its decision announced orally on 9 October 2008 and issued in writing on 18 November 2008 the

opposition division maintained the patent in amended form on the basis of the claims according to the 2nd auxiliary request filed during the oral proceedings, which the opponent did not attend.

Claims 1 and 19 of the 2nd auxiliary request corresponded essentially to claims 1 and 25 as granted including the following amended definition of the inner layer:

"an inner layer positioned on a first side of the core layer, said inner layer having a thickness of from 127-178 µm (5-7 mils) and consisting of an ethylene homopolymer or a copolymer of ethylene and an alpha olefin".

The main request (claims as granted) and the 1st and 2nd auxiliary requests were found to meet the requirements of Articles 83 and 123(2) EPC. The main request and the 1st auxiliary request, however, were not allowed because of lack of novelty of the claimed subject-matter over D4.

As to the 2nd auxiliary request, the opposition division found that the claimed subject-matter was novel in that the thickness of the inner layer of from 5-7 mils was not disclosed in D4. Concerning inventive step the opposition division argued that the problem to be solved was the increase in the oxygen barrier of the multilayered structure. In view of the multiple possibilities for changing the oxygen-barrier properties of the structure (e.g. using aluminium foils, changing the composition of the core layer) the skilled

person was not prompted by D4 to increase the thickness of the inner layer in order to solve this problem.

IV. Notice of appeal against the decision was filed by the patent proprietor (hereinafter appellant) on 27 January 2009. The prescribed fee was paid on the same day. The grounds of appeal were received on 18 March 2009. With its letter setting out the grounds of appeal the appellant filed sets of claims according to a new main request and seven auxiliary requests.

V. The opponent (hereinafter: respondent) did not respond to the appellant's grounds of appeal and did not provide any arguments during the appeal proceedings.

VI. In a communication dated 13 December 2011 the board made its preliminary observations on essential issues of the case.

As to the opposition ground according to Article 100(b) EPC the board stated that the claims attacked by the opponent under this article in the opposition proceedings were no longer part of the appellant's requests on file.

The board raised an objection under Article 100(c) EPC because the layers in the multilayer structure of claim 1 have to be "coextruded" rather than "cast coextruded", as disclosed in the application as filed.

Concerning novelty the board stated that the claimed invention was new over D4 in that the ethylene content of 25-45 mole percent in the ethylene vinyl alcohol copolymer (EVOH) forming the core layer of the

multilayer structure was below the ethylene content of 68 mole percent in the EVOH core-layer of D4.

In respect of this distinguishing feature the board noted that no inventive step arguments had been provided which were based on this different ethylene content.

VII. In its letter of response dated 4 January 2012 the appellant contested that the omission of the word "cast" violated Article 123(2) EPC.

Concerning the issue of inventive step the appellant saw more than one distinguishing feature between the claimed invention and D4. ***Inter alia*** it was argued that D4 related to a seven-layer structure as set out in claim 1 and examples 1, 2, 3 and 4 of D4, in contrast to the five layers defined for the multilayer structure of the claimed invention. Thus, starting from D4, the skilled person would have to decide to dispense with the first tie layer and to omit the ethylene alpha olefin copolymer layer in order to arrive at the claimed multilayer structure. Because there was no disclosure in D4 which would prompt the skilled person to do so, the claimed subject-matter was also inventive.

VIII. Oral proceedings were held before the board on 26 January 2012. These the respondent did not attend, as announced in its letter dated 10 January 2012.

During the oral proceedings the appellant filed a new main request, namely claims 1 to 28 and description pages 2 to 6. The claims essentially corresponded to the claims of the main request filed on 18 March 2009,

except that in claim 1 "coextruded" was amended to "cast coextruded" in order to overcome the Article 100(c) EPC objection of the board. Claims 1 and 18 of the new main request read as follows:

"1. A multiple layer structure for fabricating medical products comprising:

a core layer of an ethylene vinyl alcohol copolymer having an ethylene content of 25-45 mole percent;
an inner layer consisting of an ethylene homopolymer or a copolymer of ethylene and an alpha-olefin suitable for contact with a solution and positioned on a first side of the core layer;
an outer layer positioned on a second side of the core layer opposite the inner layer, the outer layer consisting of a polyamide and
two tie layers, one of each adhered to the first and second sides of the core layer and positioned between the inner layer and the core layer and between the outer layer and the core layer;

wherein the core layer the inner layer, the outer layer and the tie layers are cast coextruded to each other, and wherein the inner layer is thicker than the outer layer."

"18. A method for fabricating a multilayered structure comprising the steps of:

providing a core layer of an ethylene vinyl alcohol copolymer having an ethylene content of 25-45 mole percent;

providing an inner layer consisting of an ethylene homopolymer or a copolymer of ethylene and an alpha olefin suitable for contact with a solution and positioned on a first side of the core layer;
providing an outer layer positioned on a second side of the core layer opposite the inner layer, the outer layer consisting of a polyamide.
providing a first tie layer between the outer layer and the core layer;
providing a second tie layer between the inner layer and the core layer; and
cast coextruding the outer layer, the core layer, the inner layer and the first and second tie layer to define a multilayered structure wherein the inner layer is thicker than the outer layer."

The appellant reiterated that the subject-matter of claim 1 of the main request differed from the disclosure of D4 not only in the ethylene content of the EVOH copolymer of the core layer but also in the arrangement of the layers in the structure. The term "cast coextruded to each other" meant that the five layers defined in claim 1 had to be next to each other, i.e. that a layer having a different function could not be positioned within the sequence of the coextruded layers.

Furthermore, it was clear from claim 1 that the inner layer was exclusively composed of an ethylene homopolymer or a copolymer of ethylene and an alpha-olefin and the outer layer of a polyamide. This, however, did not exclude the embodiment that the inner layer was divided into sub-layers, in accordance with

Figure 2 and paragraph [0034] of the patent specification.

IX. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of claims 1-28 of the main request (including pages 2-6 of the description), filed on 26 January 2012, or on the basis of one of auxiliary requests 1-7, filed on 18 March 2009.

X. Byh its letter dated 10 January 2012 the respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. In the appeal proceedings, sufficiency of disclosure was not an issue. In fact, after deletion of granted claims 13 to 15, 38 and 39 in the opposition proceedings the respondent did not pursue its objection under Article 100(b) EPC. The board saw no reason to challenge the finding of the opposition division in this respect.

As regards the opponent's initial objection under Article 100(c) EPC concerning the omission of the word "cast" in granted claim 1, this objection was overcome by the claims of the new main request filed during the oral proceedings before the board. As regards the other amendments to claim 1 (nature of the polymer of the inner layer and thickness ratio of the inner/outer layer), these amendments are clearly and unambiguously

derivable from pages 6 and 8 of the application as filed, so that the board is satisfied that claim 1 and the remaining claims of the main request meet the requirements of Article 123(2) EPC.

3. Novelty

3.1 The multilayer structure of claim 1 is characterized by five types of layers, namely the core layer, the inner layer, the outer layer and two tie layers, which are coextruded **to each other**. The board agrees with the appellant that the wording "each other" means that the five layers have to be arranged next to each other in the order specified in the claim.

It should also be noted that claim 1 requires that the inner layer consists of an ethylene homopolymer or an ethylene α-olefin copolymer (EAO copolymer) and the outer layer consists of a polyamide. This means that no other than the above-mentioned polymers can form the inner and the outer layer. This definition does not exclude the possibility that each of these layers can be divided into sub-layers and that the claimed multilayer structure therefore can have more than five layers. An embodiment with more than five layers is realized in the seven-layer structure according to Figure 2, which is explained in paragraph [0034] of the patent specification. In this seven-layer structure the inner solution contact layer is divided into three sub-layers 16a, 16b and 16c, which, in accordance with claim 1, all consist of an ethylene homopolymer or an EAO copolymer.

3.2 The only relevant document in the proceedings is D4. D4 discloses a gas-impermeable thermoplastic packaging film which can be heat-sealed to itself or to another material to form a flexible or semi-flexible package. The film of D4 is particularly directed at packaging food products for pasteurisation or cooking, for example by being submerged in heated water (column 1, lines 6-15). The films of D4 have seven layers. As shown in examples 1 to 4 of D4 they have an outer polyamide layer, a first tie layer, a layer of an EOA copolymer, a second tie layer, a core layer of ethylene vinyl alcohol copolymer (EVOH), a third tie layer and an inner sealant layer of an EOA copolymer.

Firstly, D4 does not disclose an ethylene content of 25-45 mole percent for the EVOH copolymer of the core layer. The only detail concerning the EVOH used in D4 is given in column 4, lines 56 to 58, where it is stated that the vinyl acetate content of the EVOH of the core layer in the examples was about 32 mol percent, i.e. having an ethylene content of about 68 mol percent, which is outside the scope of claim 1. For this reason alone the subject-matter of claim 1 is novel over D4.

Apart from that, the seven-layer structure of D4 does not fall within the definition of present claim 1, because an "extra" EAO layer is arranged between the outer polyamide layer and the core layer. As explained above, the term "coextruded to each other" in claim 1 does not allow the presence of such an "extra" layer.

4. Inventive step

4.1 The patent in suit relates to multilayered structures for fabricating medical-grade products, in particular for producing medical solution containers and medical tubings (patent specification, paragraph [0001]). Such containers for medical products should be functional over a wide range of temperatures and should, on the one hand, withstand radiation sterilization conditions without degrading their physical properties and, on the other hand, should maintain their flexibility and toughness at low temperatures (paragraph [0002]). A further desired property is the provision of a barrier to the passage of oxygen, carbon dioxide and water (paragraph [0007]).

The invention is realized by a multilayer structure according to claim 1 defining five types of layers which are coextruded to each other in a specified sequence and wherein the EVOH copolymer of the core layer has a certain ethylene content. As mentioned above under novelty, one mode of realization is the seven-layer structure of Figure 2, wherein the inner layer is divided into three sub-layers.

As shown in the example, a multilayer structure in accordance with claim 1 has a low oxygen permeability and a low water vapour transmission (paragraphs [0042/43] of the patent specification).

4.2 In agreement with the appellant, D4 may be considered to represent the closest prior art because it also discloses a multilayer film which has to withstand higher temperatures (cook-in film) and protects

enclosed products (food) against the influence of oxygen and vapour (column 1, lines 5 to 15, and lines 44 to 47; column 2, lines 14 to 17).

The multilayer structure of D4 is composed of seven layers which, as distinct from the seven-layer structure according to Figure 2 of the patent, has an extra EAO-layer between the outer and the core layer and has a higher ethylene content in the EVOH copolymer of the core layer.

4.3 The problem underlying the patent in suit in the light of the closest prior art is therefore seen in the provision of an alternative multilayer structure which is suitable for medical applications.

4.4 When looking for alternative structures to D4, there was no indication, either in D4 alone or in combination with other documents, which would induce a skilled person to change the ethylene content in the EVOH copolymer of the core layer of D4 and either to change the order of the layers so that the extra EAO layer of D4 would become part of an inner layer structure with three sub-layers in accordance with the embodiment of Figure 2 of the patent or to omit two of the essential layers in the structure of D4, namely the extra EOA layer and the second tie layer in order to arrive at a five-layer structure of the patent

Consequently, the multiple layer structure claimed in claim 1 and the process for preparing it claimed in claim 18 of the main request are based on an inventive step.

5. For the above reasons, the main request is allowable. There is therefore no need to discuss the other requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:
   - claims 1-28 and
   - description pages 2-6

   both received during the oral proceedings of 26 January 2012,
   - drawing sheet 1/1 of the patent specification.

The Registrar The Chairman

G. Röhn W. Sieber