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**Datasheet for the decision
of 10 May 2007**

Case Number: T 0451/05 - 3.2.06

Application Number: 94300197.4

Publication Number: 0607028

IPC: A61F 5/441

Language of the proceedings: EN

Title of invention:
Ostomy bag with multi-stage filter

Patentee:
E.R. Squibb & Sons, Inc.

Opponent:
Coloplast A/S

Headword:
-

Relevant legal provisions:
EPC Art. 54(2)

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0451/05 - 3.2.06

DECISION
of the Technical Board of Appeal 3.2.06
of 10 May 2007

Appellant: Coloplast A/S
(Opponent) Holtedam 1
DK-3050 Humlebaek (DK)

Representative: Hammond, Andrew David
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Respondent: E.R. Squibb & Sons, Inc.
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Princeton
New Jersey 08543-4000 (US)

Representative: Holmes, Miles Keeton
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 4 February 2005
rejecting the opposition filed against European
patent No. 0607028 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: P. Alting Van Geusau
Members: G. Pricolo
K. Garnett

Summary of Facts and Submissions

- I. The appeal is from the decision of the Opposition Division posted on 4 February 2005 to reject the opposition filed against European patent No. 0 607 028 granted in respect of European patent application No. 94300197.4.
- II. Independent claims 1 and 17 as granted read as follows:
- "1. An ostomy bag for holding body waste that passes through a stoma comprising,
- a) an envelope (12,14) formed of flexible plastic sheet material defining a waste collection chamber (90; 134) for body waste that includes gaseous and semi-liquid waste material, said envelope having interior surface portions and a top end portion,
 - b) a waste inlet opening (28) formed in said envelope proximate said top end portion, said waste inlet opening being of predetermined size and including means for fitting said opening around a stoma,
 - c) gas outlet means (36; 136) formed in said envelope proximate said top end portion and spaced from said waste inlet opening,
 - d) a deodorizing filter (44) joined to said envelope in alignment with said gas outlet means for deodorizing gaseous waste material before said gaseous waste material exits from said bag through said gas outlet means, and
 - e) means in said envelope for protecting said deodorizing filter from contact by semi-liquid waste material, and for permitting the flow of gaseous waste, and for obstructing the flow of semi-liquid waste, said protection means comprising a porous protection film

(60) preceding the deodorizing filter; characterised in that the protection means further comprises open cell foam material (70;146) preceding the porous protection film such that the gaseous waste must pass through said open cell foam material, and through the porous protection film before it passes through said filter".

"17. A method of producing an ostomy bag to prevent contamination of a gas deodorizing filter during use of the ostomy bag, comprising;

- a) forming a waste gas outlet (36) in a wall of the bag,
- b) bonding a waste gas deodorizing filter (44) to the inside of the bag in alignment with the gas outlet,
- c) providing a porous protection film (60) that resists passage of semi-liquid waste but permits passage of gas waste, to precede and cover the inlet of the deodorizing filter, and characterized by:
- d) providing a gas transmissible protection filter of open cell foam material (70) for obstructing semi-liquid waste and locating the protection filter in the bag to precede the porous protection film such that gaseous waste in the bag must pass through the protection filter (70) and the porous protection film (60) before it enters the deodorizing filter."

III. In coming to its decision the Opposition Division held that the claimed subject-matter was novel and inventive over the available prior art including:

D1 : US-A-4 411 659;

D3 : EP-A-475 608;

D5 : GB-A-2 139 501.

- IV. The appellant (opponent) lodged an appeal against this decision, received at the EPO on 11 April 2005, and simultaneously paid the appeal fee.

With its statement setting out the grounds of appeal, which was received at the EPO on 30 May 2005, the appellant raised a fresh ground of opposition under Article 100(c) EPC. Furthermore, in connection with the grounds of opposition under Article 100(a) EPC considered by the Opposition Division, the appellant filed the following new documents:

First declaration of Professor R.J. Young dated 13 May 2005;

accompanied by

Annex 2: pages 71 and 72 of the book "Plastics - Microstructure, properties and Applications" by N.J. Mills, Edward Arnold Publishers, 1986.

- V. By letter dated 15 November 2005 in response to the statement of grounds of appeal, the respondent (patent proprietor) filed further documents, in particular:

E10 : brochure "Gore-Tex® Membrane Products", 1980
W.L. Gore & Associates, Inc.

- VI. On 5 April 2006 the appellant further filed:

Second declaration of Professor R.J. Young dated 3 April 2006.

- VII. In an annex to the summons for oral proceedings pursuant to Article 11(1) Rules of Procedure of the boards of appeal, the Board stated that the crucial issue at stake as regards novelty was whether the porous polyurethane backing of D3 had the technical features of an open cell foam material. As regards inventive step, the Board expressed a preliminary opinion according to which document D1 represented a more appropriate starting point than D6, which was regarded by the Opposition Division as the closest prior art.
- VIII. By letter dated 15 December 2006 the appellant stated that it did not give its approval to introduction of the fresh ground of opposition under Article 100(c) EPC and filed first to fifth auxiliary requests for maintenance of the patent in amended form.
- IX. Oral proceedings, at the end of which the decision of the Board was announced, took place on 10 May 2007.

The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent filed two photographs identified as

"Sample: Sureskin"; and

"Sample: Duoderm"; and

copy of two photographs being Figures 2 and 3 from "Fibres and Textiles in Eastern Europe", January/December 2005, Vol. 13, No. 6(54);

and requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of one of the first to fifth auxiliary requests filed with the letter dated 15 December 2006.

- X. The arguments submitted by the appellant in respect of the patent as granted can be summarized as follows:

It was common ground that D3 disclosed an ostomy bag according to the preamble of claim 1 of the patent in suit, in which a gas-permeable liquid impermeable membrane was provided for protecting the deodorizing filter. According to the teaching of D3, the membrane was created by solution-coating a porous polyethylene film with polyurethane, the coating being such as to create a layer having a thickness in the range of 10 to 15 microns and microporous interlinked pores having a pore size desirably 1 to 10 microns and preferably about 3 to 8 microns. Since the thickness of the material was greater than the diameter of the pores and the pores were interconnected, the polyurethane backing was to be regarded as an open-cell foam. This conclusion was confirmed by the declarations of Prof. Young. Therefore, D3 disclosed also the features defined in the characterizing portion of claim 1 of the patent in suit. The subject-matter of claim 1 thus lacked novelty.

In any event, the subject-matter of claim 1 did not involve an inventive step. D1, which represented the closest prior art, disclosed an ostomy bag in accordance with the preamble of claim 1 of the patent in suit, in which ribs were used to effect spacing between the microporous protection film adjacent to the

deodorizing filter and a fluid impermeable wall of the bag. When looking for a solution to the objective technical problem of providing spacing means more comfortable for the user, the skilled person would be provided with an unambiguous prompting from D5 to employ an open cell foam material instead of the ribs. By substituting the ribs of D1 with a layer of open cell foam as per D5 the skilled person would arrive directly at an ostomy bag as defined in claim 1.

XI. The respondent's replies to these arguments can be summarized as follows:

The microporous polyurethane backing described in D3 was provided with elongated intersecting channels that did not form a cellular structure. A foam having cellular structure could only be created if particular process conditions were observed. For example, assuming that the solvent bubbled up when drying and thus formed cells, these cells could collapse if the polyurethane did not cure quickly. D3 did not specify the process conditions under which the backing was created and therefore it could not be said that a cellular structure was the inevitable result of the steps disclosed therein. Since Prof. Young did not explain why structures other than that of a foam could not be obtained on the basis of the instructions given in D3, his declarations did not constitute proof that the polyurethane backing of D3 was inevitably an open cell foam. Furthermore, Prof. Young confused "pores" and "cells". Pores in a material did not necessarily form cells. In fact, a porous material such as Gore-tex® referred to in E10 would certainly not be classified as

a foam, as admitted by Prof. Young himself in the second declaration.

In D1 the ribs not only performed a spacing function, but also further functions, namely supporting the filter element and providing free drainage of liquid and semi-liquid matter away from the entrance of the filter. Although the use of foam material in place of the ribs might provide the spacing effect, it would not provide any structural support nor would it provide drainage away from the filter entrance. Moreover, since the rib structure of D1 did not extend over the whole surface of the gas discharge port preceding the deodorizing filter, there was no motivation for the skilled person to provide a layer of foam material completely sealing the port, such that the gaseous waste had to pass through it as required by claim 1 of the patent in suit.

Reasons for the Decision

1. The appeal is admissible.
2. *The ground of opposition under Article 100(c) EPC*

The ground for opposition according to Article 100(c) EPC was neither raised or substantiated in the notice of opposition nor introduced into the proceedings by the opposition division. This ground of opposition, first mentioned by the appellant in its statement of grounds of appeal, has therefore to be considered as a fresh ground for opposition. In accordance with the decision G 10/91, such a fresh ground may not be

considered in appeal proceedings without the approval of the patentee.

Since the patentee has stated that it does not give its approval (see point VIII above), the ground of opposition under Article 100(c) EPC is disregarded.

3. *Novelty (patent as granted)*

3.1 The appellant questioned novelty in respect of D3. This document indisputably discloses an ostomy bag according to the preamble of claim 1 of the patent in suit as granted.

The feature of the known ostomy bag corresponding to the means for protecting the deodorizing filter from contact by semi-liquid waste material, and for permitting the flow of gaseous waste, and for obstructing the flow of semi-liquid waste is the gas-permeable liquid-impermeable membrane (see claim 1 of D3). This membrane comprises (see Fig. 1 and col. 1, lines 19 to 26 and 35 to 40) a porous film (10) of polyethylene which corresponds to the porous protection film preceding the deodorizing filter mentioned in claim 1 of the patent in suit.

Further, according to the teaching of D3 and with reference to the wording used in the characterising portion of claim 1 of the patent in suit, the porous protection film (polyethylene film 10) is coated with a porous polyurethane backing (14) which precedes the porous protection film such that the gaseous waste must pass through said backing and through the porous protection film before it passes through the

deodorizing filter (see col. 1, lines 32 to 34). Hence, if the porous polyurethane backing is an open cell foam material, then D3 also discloses the features according to the characterizing portion of claim 1.

Therefore, the issue of novelty over D3 hinges on the question whether the porous polyurethane backing is an open cell foam material or not.

- 3.1.1 D3 discloses (see col. 2, lines 14 to 17) that the porous polyurethane backing is created by solution-coating such as to create microporous interlinked pores. The pores have a pore size of 1 to 10 μm , preferably about 3 to 8 μm (col. 2, lines 7 to 10). The backing has a thickness of 10 to 15 microns (col. 2, lines 26, 27).

The Board in principle agrees with the appellant's argument that the fact that the polyurethane backing of D3 is obtained by solution-coating rather than through the use of blowing agents, as is common in the art (see in particular point 8 of the first declaration of Prof. Young), is irrelevant for deciding whether the porous polyurethane backing is an open cell foam material or not. What is relevant, is whether the polyurethane backing of D3 has the structural characteristics of an open cell foam material.

- 3.1.2 The Board is not aware of a precise and generally accepted definition of an open cell foam material. However, the Board accepts Prof. Young's opinion (see the second declaration, points 6 and 10), according to which a foam contains cells with walls between them. If the cells are interconnected in such a manner that gas can pass from one to another, such as shown in Fig.

3.13(b) of Annex 2 to the first declaration of Prof. Young, the foam is termed open-celled. Therefore, it can be asserted than an open cell foam material consists of cells that are interconnected. Also, in the Board's view, the cells must be distributed throughout the entire mass of the material, as shown in the above-mentioned Annex 2.

3.1.3 The appellant, on the basis of Prof. Young's declarations (see in particular points 6 to 10 of the first declaration and points 10, 11 of the second declaration), asserts that, since the polyurethane backing has interlinked pores and a thickness larger than the diameter of the cells, then it must be classified as an open-cell foam.

This assertion is based on the assumption that the pores of the polyurethane backing are cells.

3.1.4 In his second declaration (point 5), Prof. Young asserts that Gore-Tex® is clearly porous but not a foam. In the same declaration, Prof. Young states that "*a porous film could be an open-celled foam or just a thin film with a series of pin-holes in it*". However, Gore-Tex®, which is not an open-celled foam, is also not a thin film with a series of pin holes in it: in fact, as shown by the Figures at the bottom of the fifth page of E10 (a document which was filed during the oral proceedings before the Opposition Division), the Gore-Tex® structure is essentially formed by nodes interconnected with fibrils. These form interconnected pores. Moreover, the thickness of a Gore-Tex® layer is larger than the pores (see the tables on the fifth page of E10).

Accordingly, a porous material is not necessarily classified as a foam even if it has a structure comprising interconnected pores and a thickness larger than the diameter of the pores.

In the Board's view this is due to the fact that pores are not always cells, such as the pores of the Gore-Tex® structure. In fact, in the pores of the Gore-Tex® structure it is not possible to identify walls of cells (in fact, the outline of the walls, in analogy to an open-cell foam). In contrast thereto, in the foamed structures shown in Annex 2 to the first declaration of Prof. Young the walls of the cells (the walls or the outline of the walls of, respectively, the closed cell foam shown in Fig. 3.13(a) and the open cell shown foam in Fig. 3.13(b)) are clearly identifiable.

- 3.1.5 In Figures 2 and 3 from "Fibres and Textiles in Eastern Europe", filed by the respondent during oral proceedings, the interconnected pores of a microporous polyurethane membrane (magnification x1000 and x5000 respectively) are clearly evident. However, in this structure it is not possible to identify walls of cells or their outline. In the Board's judgment the average skilled person would not characterise such microporous polyurethane membrane as an open cell foam, just as he would not characterise Gore-Tex® as an open cell foam.
- 3.1.6 D3 does not give specific details of the solution-coating process used for obtaining the porous polyurethane backing. Therefore, it cannot be excluded that the porous polyurethane backing obtained in accordance with D3 has a structure analogous to that of

the microporous polyurethane membrane shown in Figures 2 and 3 of "Fibres and Textiles in Eastern Europe". Nor has the appellant submitted evidence that such structure would not be obtained when following the teaching of D3. Accordingly, it cannot be excluded that the porous polyurethane backing of D3 is not an open cell foam material.

- 3.1.7 The lack of a clear and unambiguous disclosure of the porous polyurethane backing of D3 being an open cell foam has the consequence that D3 is not prejudicial to the novelty of the subject-matter of claim 1 of the patent as granted.

The subject-matter of independent method claim 17 is likewise novel over D3 because the claimed method of producing an ostomy bag has as a direct result an ostomy bag having the features defined in the characterizing portion of claim 1.

- 3.2 The appellant has not raised novelty objections on the basis of any of the other documents cited. The board also sees no reason for objecting to the novelty of the claimed ostomy bag and method on the basis of any of these documents.

4. *Inventive step (patent as granted)*

- 4.1 The problem underlying the patent in suit (see par. [0009]) is to provide an ostomy bag with a multi-stage filter system that prevents semi-liquid waste material from contaminating a deodorizing element but does not inhibit evacuation of gaseous waste through the deodorising element.

4.2 The Board has no reason to depart from the undisputed view that document D1 represents the closest state of the art as it is structurally very similar to the claimed ostomy bag and relates to the problem of protecting the deodorizing filter assembly against clogging (see col. 1, lines 46, 47).

D1 discloses an ostomy bag according to the preamble of claim 1 of the patent in suit, namely (see Figs. 1 to 4) an ostomy bag for holding body waste that passes through a stoma comprising,

a) an envelope (10) formed of flexible plastic sheet material defining a waste collection chamber for body waste that includes gaseous and semi-liquid waste material, said envelope having interior surface portions and a top end portion,

b) a waste inlet opening (16) formed in said envelope proximate said top end portion, said waste inlet opening being of predetermined size and including means for fitting said opening around a stoma,

c) gas outlet means (23) formed in said envelope proximate said top end portion and spaced from said waste inlet opening,

d) a deodorizing filter (26) joined to said envelope in alignment with said gas outlet means for deodorizing gaseous waste material before said gaseous waste material exits from said bag through said gas outlet means, and

e) means (layer 46, and two sets of ribs 32, 33, see Figs. 5 and 7) in said envelope for protecting said deodorizing filter from contact by semi-liquid waste material, and for permitting the flow of gaseous waste, and for obstructing the flow of semi-liquid waste, said

protection means comprising a porous protection film (46) preceding the deodorizing filter (see col. 6, lines 45 to 49).

- 4.3 The subject-matter of claim 1 is undisputedly distinguished from the known ostomy bag in that the protection means further comprises open cell foam material preceding the porous protection film such that the gaseous waste must pass through said open cell foam material and through the porous protection film before it passes through said filter.

The Board agrees with the appellant that the provision of this feature in the ostomy bag results in improved comfort for the user, since an open cell foam material is relatively soft. However, it also provides a filtering stage in addition to the deodorizing filter, since claim 1 specifies that the gaseous waste must pass through the open cell foam material.

Therefore, the objective technical problem solved starting from D1 can be seen in improving the user's comfort and the filtering function.

- 4.4 In the ostomy bag according to D1, the protection means comprises the layer 46 made of a gas-permeable but water resistant barrier material and the two sets of ribs 32, 33. Ribs 32 and 33 function as spacers for preventing the wall (intermediate barrier film) 13 of the ostomy bag from engaging the filter element 26 (see col. 4, line 67 to col. 5, line 1). They also function to support the filter element, to prevent obstruction of the gas pathway through the discharge port and filter assembly, and at the same time allow liquid and

semi-solid material to drain downwardly within front chamber 22 away from the gas discharge port and filter element (col. 5, lines 1 to 9). The ribs 32, 33 are (see Figs. 5 to 7) integral with the body section 27 of a filter holder 25 (col. 4, lines 52 to 56). Only the transverse ribs 32 completely bridge the opening 31 in the body section 27 of the filter holder; the other ribs 33 terminate short of the narrow wall defining opening 31 (see col. 5, lines 35 to 43).

The appellant submitted that the skilled person would regard it as obvious to replace the ribs 33 with an open cell foam layer in view of the teaching of D5 (see page 2, lines 98 to 106) that an open cell foam layer also acts as a cushioning pad making the bag more comfortable to wear for the user.

However, irrespective of whether the skilled person would consider replacing only ribs 33 as suggested by the appellant, or both ribs 32 and ribs 33, there is no indication in the prior art suggesting the provision of the layer of open cell material in a manner such that gaseous waste is forced to pass through it, i.e. to provide the layer of open cell material in the ostomy bag of D1 such that it seals the opening 31 in the body section 27 of the filter holder 25.

In fact, neither the ribs 32, 33 of D1 nor the layer of open cell foam material according to D5 provide such a pre-filtering function in addition to the filtering function of the deodorizing filter. According to D5 the function of open cell foam layer is to keep front wall 42 of the bag spaced apart from intervening wall 52 (see page 1, lines 116 ff.). It also provides a

cushioning pad (page 2, lines 98 to 106). However, there is no suggestion that it should be arranged such that the gaseous waste must pass through it before it passes through the filter. In fact, according to D5 the layer of open cell foam material could even be provided loose in the bag (page 2, line 1), whereby most of the gas would flow around it rather than through it. D5 further discloses (page 2, lines 2 to 4) that the bag may have "*all or part of its marginal edge region fixed to one or other or both of the adjacent front wall and intervening wall*". However, this general statement is not a disclosure of fixing the marginal edge region to both walls. In fact, the disclosure of fixing the marginal edge region to both walls would rather be considered by the skilled person in combination with the fixing of part of the marginal edge region, such as not to impede the flow of gas. D5 further discloses on page 2, lines 120 to 123 that the foam layer may have a deodorising capability. However, the next sentence in D5 makes it clear that in the case where the foam material carries or has impregnated in it an effective deodorant material, thus providing in effect a filtering stage, the patch filter 62 may be omitted. Therefore reading into D5 a double stage filtering can only be based on hindsight.

It follows from the above that, although the skilled person might consider the provision of a layer of open cell foam material in the ostomy bag of D1 in order to improve the user's comfort, e.g. by replacing the ribs 33 by an open cell foam pad which terminates short of the narrow wall defining opening 31, there is no indication in D5, or in any of the other available documents (none of which were in fact relied upon by

- the appellant when starting from D1), which would suggest providing, in the ostomy bag of D1, an open cell foam material in the specific manner as defined in the characterizing portion of claim 1 in order to solve the above mentioned technical problem of improving the user's comfort and the filtering function.
- 4.5 The Board notes that in its statement of grounds of appeal the appellant also formulated lines of argument based on D3 and D1, or D3 and other prior art documents. These lines of argument, which were not relied upon during the oral proceedings, must fail because they are all based on the incorrect assumption that D3 discloses a layer of open cell foam material.
- 4.6 Therefore the subject-matter of independent claim 1 involves an inventive step (Article 56 EPC).
- 4.7 The subject-matter of independent method claim 17 likewise involves an inventive step because the claimed method of producing an ostomy bag has as a direct result an ostomy bag having means for protecting the deodorizing filter that correspond to those present in the ostomy bag according to claim 1.
5. It follows that the Opposition Division's decision to reject the opposition must be confirmed. It is therefore unnecessary to consider the auxiliary requests of the respondent.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Patin

P. Alting van Geusau