

Internal distribution code:

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

D E C I S I O N
of 24 January 2002

Case Number: T 0793/99 - 3.2.6

Application Number: 91300615.1

Publication Number: 0443728

IPC: A61F 5/441

Language of the proceedings: EN

Title of invention:
Ostomy bag with filter combination

Patentee:
E.R. SQUIBB & SONS, INC.

Opponent:
Coloplast A/S

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - yes"

Decisions cited:
-

Catchword:
-



Case Number: T 0793/99 - 3.2.6

D E C I S I O N
of the Technical Board of Appeal 3.2.6
of 24 January 2002

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

Representative: Beetz & Partner
Patentanwälte
Steinsdorfstrasse 10
D-80538 München (DE)

Respondent: E.R. SQUIBB & SONS, INC.
(Proprietor of the patent) Lawrenceville-Princeton Road
Princeton
New Jersey 08543-4000 (US)

Representative: Holmes, Miles Keeton
Novapat International S.A.
9, rue du Valais
1202 Genève (SZ)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 7 June 1999
rejecting the opposition filed against European
patent No. 0 443 728 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: P. Alting van Geusau
Members: G. Pricolo
M. J. Vogel

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received at the EPO on 17 August 1999, against the interlocutory decision of the Opposition Division dispatched on 7 June 1999 which maintained the European patent No. 0 443 728 in amended form. The appeal fee was paid on 17 August 1999 and the statement setting out the grounds of appeal was received at the EPO on 18 October 1999.

In its statement of grounds of appeal the appellant referred to two further documents to be considered when deciding on inventive step.

II. The respondent (patentee) filed a notice of appeal, received at the EPO on 5 August 1999, against the above mentioned decision of the Opposition Division, and simultaneously paid the appeal fee. Since no statement of grounds of appeal was filed, a communication pursuant to Article 108 and Rule 65(1) EPC was issued on 11 November 1999. With letter dated 21 December 1999 the respondent confirmed that a statement of grounds of appeal had not been filed and requested that the patent be maintained in the form allowed in the decision of the Opposition Division.

III. The opposition had been filed against the patent as a whole and was based on Article 100(a) in conjunction with Articles 54(2) and 56 EPC.

In its decision the Opposition Division considered that the subject-matter of claim 1 according to the second auxiliary request filed at the oral proceedings held on 28 April 1999 met the requirements of the EPC.

IV. From the documents considered by the Opposition Division, the following documents played a role in the appeal proceedings:

D1: GB-A-2 059 797

D6: Gore-tex membrane products, 1980

V. In an annex to the summons for oral proceedings pursuant to Article 11(2) Rules of Procedure of the Boards of Appeal the Board expressed its preliminary opinion that claim 1 appeared to meet the requirements of Articles 123(2) and 84 EPC, and that the documents filed by the appellant with the statement setting out the grounds of appeal did not appear more relevant than the evidence already on file. However, inventive step would need further discussion during the oral proceedings.

VI. Oral proceedings took place on 24 January 2002.

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

The respondent requested that the appeal be dismissed and the patent be maintained in amended form on the basis of

Claims: 1 as filed during the oral proceedings;
2 to 7 as attached to the decision under appeal;

Description: columns 1 to 8 as attached to the decision under appeal;
insertion page 2 as filed during the

oral proceedings;

Drawings: Figures 1 to 7 as attached to the decision under appeal.

VII. Claim 1 reads as follows:

"A bag for receiving discharge from the human body comprising: front and rear walls (12,14) formed of polymer material, said walls having edges sealed together, said rear wall having a stomal aperture (22); an intervening membrane (40) located between the front and rear walls of the bag disposed between said stomal aperture (22) and a filter and gas venting opening (30), said intervening membrane (40) comprising a gas-permeable, liquid impermeable sheet (44); and a filter (32) attached to one of the walls over said filter and gas venting opening (30) in the wall through which filter and gas venting opening gases exit the bag; wherein the intervening membrane (40) comprises a thermoplastic film (42) sealable to said walls, said film being secured to at least one surface of the liquid impermeable, gas permeable sheet (44) of microporous polytetrafluoroethylene; characterised in that the microporous polytetrafluoroethylene has pore sizes between 0.1 microns and 6 microns, and said intervening membrane (40) has a gas flow rate of at least 100 cubic centimetres per square centimetre per minute at at least 579 Pascals (6 centimetres of water pressure), and wherein the area of the intervening membrane (40) is at least twice the area of the filter (32)".

VIII. The arguments of the appellant can be summarized as follows:

Since there was no concrete disclosure of the feature that the area of the intervening membrane was at least twice the area of the filter in the application as originally filed, its inclusion in claim 1 constituted an infringement of Article 123(2) EPC. Moreover, the "open end" character of this feature rendered claim 1 unclear, contrary to the requirements of Article 84 EPC.

Furthermore, the subject-matter of claim 1 did not involve an inventive step. Starting from the closest prior art, represented by document D1, the problem underlying the claimed bag was to be seen in the provision of a membrane which was liquid impermeable, allowed an adequate flow rate so as to avoid ballooning of the bag, and was resistant against clogging.

The general disclosure in document D1 of a microporous polytetrafluoroethylene Gore-tex membrane would lead the skilled person to consider document D6 as the latter included detailed information about Gore-tex membranes and laminates available on the market.

Since D1 disclosed that the filter should be dimensioned and fabricated so as to provide a gas flow therethrough within a certain range, and that the membrane should present less resistance than the filter to the passage of gas, the skilled person would only take into consideration the membranes of D6 that allowed a gas flow greater than the upper limit disclosed by D1 of the range for the filter, namely the membranes of D6 having a pore size greater than 0.1 microns.

The skilled person, seeking to provide a good air flow

through the membrane by selecting a pore size greater than said minimum value of 0.1 microns but at the same time being aware that the pore size should not be too high so as not to compromise the liquid impermeability of the membrane, would thus have selected one of the membranes of D6 that had pore sizes between 1 micron and 5 microns. As disclosed by D6, such membranes also had a gas flow rate greater than 100 cubic centimetres per square centimetre per minute at at least 579 Pascals (6 centimetres of water pressure).

Another obvious possibility to arrive at the selection of such membranes was by simple routine experiments. Indeed, only seven tests were necessary in order to make a proper selection amongst the available materials disclosed by D6.

Once such selection of the material to be used for the membrane was made, the only remaining parameter that could still be adjusted in order to provide the necessary difference in the gas permeability between the membrane and the filter, and in order to avoid the clogging problem, was the area of the membrane. Because of this one-way street situation the skilled person was immediately led to the provision of an intervening membrane having an area which was at least twice the area of the filter, thereby arriving at the entire combination of claimed features.

Moreover, the latter feature was only an aggregative one the addition of which could not be regarded inventive because there was no functional cooperation with the features relating to the pore size and to the gas flow rate of the intervening membrane.

IX. In support of its request the respondent relied essentially on the following submissions.

The teaching underlying the patent in suit consisted in the provision of a minimum size of the membrane relative to the filter that allowed adequate gas flow even in case the membrane was partly blocked.

Document D1 disclosed that clogging of the membrane could be avoided simply if the latter was made of Gore-tex material because of the hydrophobic properties of this material, but did not appreciate that such a membrane could still become clogged in use, e.g. when the bag was filled and the patient lay in bed or sat in a bent position. In D1 the membrane was not much bigger than the filter; if it were to be significantly bigger than the filter, then the membrane and the filter could not be packaged in a small sub-assembly as illustrated.

Moreover, the materials of document D6 which satisfied the requirement to have a pore size in the range of 0.1-6 microns and a flow rate of at least 100 cubic centimetres per square centimetre per minute at at least 6 centimetres of water pressure were the materials having the pore sizes of 1, 3 and 5 microns. The area required for such materials to pass the physiological flow rate of gas was always smaller than the filter size specified in D1. Therefore, there was no actual need for the membrane to be any larger than the filter.

Consequently, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. The appeal of the opponent is admissible.
2. *Amendments (Article 123 EPC)*
 - 2.1 Basis for the definition of claim 1 can be found in the original application in independent claim 2, dependent claims 4, 6, 7, 16, and on page 7, lines 4 to 7 of the description.

The amendments made by the respondent during oral proceedings remove some inconsistencies in the wording of claim 1 and do not introduce any additional subject-matter.

Dependent claims 2 to 7 are based on original claims 3, 8 to 10, 12, 13.

The description of the patent in suit is adapted to be consistent with the claims as amended.

Hence, the amendments do not introduce subject-matter which extends beyond the content of the application as filed.

- 2.2 With respect to granted claim 1, claim 1 includes the additional limiting feature that the area of the intervening membrane is at least twice the area of the filter.

Therefore, the amendments do not result in an extension of the protection conferred.

- 2.3 The appellant argued that the introduction of the

feature that "the area of the intervening membrane is at least twice the area of the filter" infringes Article 123(2) EPC.

However, the relevant feature is literally disclosed in original claim 16, and therefore its inclusion in claim 1 is not contrary to Article 123(2) EPC.

2.4 It follows that none of the amendments give rise to objections under Article 123 (2) and (3) EPC.

3. *Clarity (Article 84 EPC)*

3.1 Claim 1 clearly defines the matter for which protection is sought and therefore meets the requirements of Article 84 EPC.

3.2 The appellant questioned clarity of claim 1 on the basis of the "open end" character of the feature: "the area of the intervening membrane is at least twice the area of the filter".

The Board has already treated this question in its annex to the summons to oral proceedings. The appellant has not supplied further arguments concerning this point.

The open-end formulation of the mentioned feature is not objectionable under Article 84, since it is clear that there is a limitation for the maximum area of the intervening membrane, namely the area of the bag itself.

4. *Novelty*

Novelty of the subject-matter in accordance with claim 1 follows from the fact that none of the cited documents discloses a bag for receiving discharge from the human body having an intervening membrane comprising a gas-permeable sheet of microporous polytetrafluoroethylene having pore sizes between 0.1 micron and 6 microns.

Novelty was not in fact disputed.

5. *Inventive step*

5.1 D1 undisputedly represents the closest prior art, in accordance with the preamble of claim 1. Using the wording of claim 1, D1 discloses a bag for receiving discharge from the human body comprising: front and rear walls (11,12) formed of polymer material, said walls having edges sealed together, said rear wall having a stomal aperture (14); an intervening membrane (20) located between the front and rear walls of the bag disposed between said stomal aperture (14) and a filter and gas venting opening (17), said intervening membrane (40) comprising a gas-permeable, liquid impermeable sheet (24b); and a filter (21) attached to one of the walls over said filter and gas venting opening (17) in the wall through which filter and gas venting opening gases exit the bag; wherein the intervening membrane comprises a thermoplastic film (24a) sealable to said walls, said film being secured to at least one surface of the liquid impermeable, gas permeable sheet (24b) of microporous polytetrafluoroethylene.

5.2 Starting from the ostomy bag disclosed in D1 the technical problem underlying the patent in suit can be

seen in the improvement of gas venting when using the ostomy bag under less favourable conditions, for example when the bag is filled and the patient is lying in bed or is sitting in a bent position.

5.3 This technical problem is solved by the provision of the features of claim 1 and in particular by the provision of the features defined in the characterizing portion of claim 1, that

- (i) the microporous polytetrafluoroethylene has pore sizes between 0.1 micron and 6 microns,
- (ii) the intervening membrane has a gas flow rate of at least 100 cubic centimetres per square centimetre per minute at at least 579 Pascals (6 centimetres of water pressure), and
- (iii) the area of the intervening membrane is at least twice the area of the filter.

5.4 The Board agrees with the appellant's opinion that in view of the specific reference to a Gore-tex membrane in D1 (page 3, line 126) the skilled person would turn to document D6, relating to Gore-tex membrane products, in order to select a suitable Gore-tex material from those available on the market for the bag construction disclosed in D1. Selecting Gore-tex laminates having a pore size of 1, 3 or 5 microns from the seven pore sizes disclosed in D6 (0.02, 0.2, 0.45, 1, 3, 5 and 10 to 15 microns) would then be obvious because of the suggestion in D1 to use laminates (page 2, line 117) and because the required gas flow should be higher than the maximum gas flow through the filter element, ie higher than ca. 15 to 45 cubic centimetres of air per

square centimetre per minute at 6 centimetres of water pressure (these values have been calculated by the appellant and, as was agreed upon by the respondent, correspond to the values of 100 cc per square inch at 124 mm of water pressure in 10 to 30 seconds disclosed on page 3, lines 58 to 66 of D1).

Since it was not contested by the respondent that Gore-tex laminates having pore size of 1, 3 and 5 microns would provide a gas flow rate of at least 100 cubic centimetres per square centimetre per minute at at least 6 centimetres of water pressure (see lower table on page 5 of D6), and the Board has no reason to doubt the appellant's calculations, it comes to the conclusion that the inclusion of above mentioned features (i) and (ii) in the filter element of the bag of D1 merely follows from the application of teachings found in D1 using the disclosure of D6 for determining the properties of the materials mentioned in D1.

- 5.5 Therefore, the question arises whether the inclusion of above mentioned feature (iii) also follows in an obvious manner from the cited prior art.

D1 deals with the technical problems involved when designing an ostomy pouch (see D1, page 1, lines 34 to 53), and solves it essentially by the provision of a filter assembly having a breathable but water-repellent intervening membrane (rear or inside panel) that protects the porous filter pad from becoming deactivated by liquid within the bag, the non-adherent and water-repellant character of the material from which the intervening membrane is made preventing solid and liquid materials within the bag from blocking the flow of gases through the filter pad (page 1,

lines 90 to 99; page 4, lines 72 to 80; claim 1). Hence, the skilled person would consider that the solution to one of the issues involved, ie the clogging problem, proposed by D1 consists in the selection of a material having a non-adherent character, in particular a Gore-tex material which is resistant to soiling and adherence of particulate matter (page 4, lines 73 to 80), so that during normal use a self-cleaning effect is obtained. The Board therefore agrees with the respondent that D1 is silent about a clogging problem due to the situation in which part of the content of the pouch obstructs the membrane for a longer period of time such as occurs in the conditions referred to under point 5.2 above.

Furthermore, D1 teaches that the resistance to the passage of gas presented by the intervening membrane (rear panel) must be less than the resistance presented by the filter pad itself (page 3, lines 92 to 99; claim 25). The skilled person having selected a Gore-tex laminate having pore size of 1, 3 or 5 microns among those known from D6 (see point 5.4 above) would however know (because disclosed by D6 - see lower table on page 5) that such laminates provide a gas flow rate of more than 100 cubic centimetres per square centimetre per minute at at least 6 centimetres of water pressure. Since D1 specifically discloses that the filter should allow the passage of ca. 15 to 45 cubic centimetres of air per square centimetre per minute at 6 centimetres of water pressure (see point 5.4 above), the skilled person would notice that the Gore-tex laminates selected from D6 already present less resistance than the filter pad in the proposed unit construction of filter pad and protecting laminate.

In view of the above, the skilled person would have no reason to consider the provision of an intervening membrane having an area being substantially larger than the area of the filter.

In this respect, the teaching of D1 to provide a preassembled filter assembly in which the filter pad (21) is sandwiched between the front panel (23) and the intervening membrane (panel 24; see page 4, lines 81 to 107) would rather lead the skilled person towards the provision of an intervening membrane having an area corresponding roughly to the area of the filter pad with some extra area around the filter pad sufficient to form, with the front panel, an envelope enclosing completely the filter pad as shown in figure 7 of D1.

- 5.6 The appellant argued that once the selection of a material to be used for the membrane was made, the only remaining parameter that could still be adjusted in order to provide the necessary difference in the gas permeability between the membrane and the filter, and in order to avoid the clogging problem, was the area of the membrane. This led to a one-way-street situation which automatically led the skilled person to the claimed subject-matter.

However, starting from the prior art assembly of D1, the skilled person would have no reason to carry out any such adjustments as the necessary difference in the gas permeability between the membrane and the filter is already exceeded if Gore-tex laminates having pore size of either 1, 3 or 5 microns are selected from D6, as explained above (point 5.5).

Furthermore, even if the skilled person would notice that the arrangement shown in D1 is still subject to clogging of the membrane when in use, despite the selection of a Gore-tex material in accordance with D6, he would not necessarily come to the conclusion that the only parameter that can still be adjusted is the area of the intervening membrane relative to the area of the filter. Indeed, the skilled person may for instance take into consideration enlarging the area of the whole filter assembly shown in Figure 7 of D1 (thereby increasing both the area of the intervening membrane and that of the filter), or may look for other materials or alternative constructions of the bag.

In this respect it is noted that D1 specifically emphasizes the advantages of a filter assembly in which a liquid barrier layer is secured to one of the faces of the filter pad over substantially the entire extent of such a face (see claim 1 of D1), it being "easier to manufacture and fabricate" (page 1, lines 48 to 53) and adapted to be "secured within any of a variety of collection appliances" (page 4, lines 100 to 103). On the basis of this disclosure, the skilled person would consider that any modifications of the particular construction of the filter assembly disclosed in D1 would probably compromise the mentioned advantages and would therefore be hesitant to adopt a different design.

- 5.7 The appellant also argued that the feature that the area of the intervening membrane is at least twice the area of the filter is merely aggregative and has to be considered as an isolated additional feature without any inventive merit.

The Board cannot follow this view. The larger area of the membrane, pore size and gas flow rate (per unit of area and per unit of time) clearly are functionally interdependent to maintain adequate gas flow under all conditions, ie also if some blockage occurs (see page 7, lines 41 to 45 of the patent) during an extended period of time.

- 5.8 The remaining available prior art is silent about any relationship between the clogging problem and the area of the intervening membrane.
- 5.9 Therefore, the subject-matter of claim 1 is found to involve an inventive step.
- 6. Dependent claims 2 to 7 define preferred embodiments of the bag of claim 1. Thus their subject-matter also is found novel and involving an inventive step.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the first instance with the order to maintain the patent on the basis of the following documents:

Claims: 1 as filed during the oral proceedings;
 2 to 7 as attached to the decision under appeal;

Description: columns 1 to 8 as attached to the
decision under appeal;
insertion page 2 as filed during the
oral proceedings;

Drawings: Figures 1 to 7 as attached to the
decision under appeal.

The Registrar:

The Chairman:

M. Patin

P. Alting van Geusau