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**Datasheet for the decision  
of 27 September 2011**

**Case Number:** T 2005/08 - 3.2.08  
**Application Number:** 03013344.1  
**Publication Number:** 1378219  
**IPC:** A61F 5/443, A61F 5/448  
**Language of the proceedings:** EN

**Title of invention:**  
Ostomy appliance

**Applicant:**  
Bristol-Myers Squibb Company

**Opponents:**  
Hollister Incorporated  
Coloplast A/S

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 54, 83, 100(b), 100(a)

**Relevant legal provisions (EPC 1973):**  
-

**Keyword:**  
"Sufficiency of disclosure (yes)"  
"Novelty (yes)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 2005/08 - 3.2.08

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.08  
of 27 September 2011

**Appellant:** Coloplast A/S  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office, posted  
on 29 July 2008, concerning maintenance of  
European patent No. 1378219 in amended form.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** R. Ries  
E. Dufrasne

## Summary of Facts and Submissions

- I. Oppositions were filed against European patent No. 1 378 219 as a whole by the present appellant (opponent O2) and by opponent O1.

In its interlocutory decision dispatched on 29 July 2008, the opposition division held that the subject matter of the claims according to the main request then on file met the requirements of the EPC and that the patent could be maintained in amended form on the basis of this request.

- II. On 7 October 2008, the appellant lodged an appeal against this decision and paid the appeal fee on the same date. The statement setting out the grounds of appeal was received on 8 December 2008.

- III. For the present decision, the following documents have played a role:

D5: US-A-5 618 276;

D10: GB-A-1 461 358;

Annex A: Comments on D5 by the patent proprietor in a divisional application.

- IV. Oral proceedings were held before the Board on 27 September 2011.

The appellant requested that the decision under appeal be set aside and that patent No. 1 378 219 be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and the patent be maintained on the basis of one of the auxiliary requests 1 to 8 filed with letter dated 26 August 2011.

Although duly summoned, the party as of right (opponent O1) did not attend the oral proceedings, as already announced by letter dated 3 August 2011. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without that party.

V. Independent claim 1 of the main request read as follows:

"An ostomy body fitment for attaching an ostomy appliance to a person's body, the body fitment comprising:

a pliable adhesive pad (44) having a first adhesive surface for contacting the person's skin and a second adhesive surface opposite the first adhesive surface; and

a backing (50) overlying and contacting a portion of the second adhesive surface;

the adhesive pad and the backing defining:

a first zone (60) in which the second adhesive surface of the adhesive pad is substantially exposed at least in use; and

a second zone (58) in which the second adhesive surface of the adhesive pad is contacted by the backing to substantially cover the second adhesive surface in the second zone;

wherein the portions of adhesive in the first and second zones are integral with each other, and the

adhesive is not transferable from the second zone to the first zone characterized in that in the first zone, the adhesive pad is sufficiently flexible to enable the pad to be reshaped manually by folding or rolling back a portion of the adhesive pad in the first zone into adhesive contact with a portion of the exposed second adhesive surface, wherein the adhesive pad comprises a laminate of a first adhesive layer (62) providing said first adhesive surface, a second adhesive layer (64) providing said second surface and a flexible sheet (66) between said first and second layers."

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

Articles 100(b) and 83 EPC; sufficiency of disclosure:

Claim 1 required, as a functional feature, that in the first zone the adhesive pad (44) comprised a flexible sheet (66) sandwiched between the first and second adhesive layers. Sheet (66) had to be sufficiently flexible to enable the pad to be reshaped manually by folding or rolling back a portion of the adhesive pad in the first zone. As set out in the patent specification, paragraph [0037], sheet (66) could be made of flexible plastics, for example polyethylene, which permitted the pad to be substantially folded or rolled from the edge. To meet these criteria, the polyethylene sheet had to be flexible, at least partly resilient, provide structural integrity to the pad and allow rolling the pad. However, the patent specification did not provide adequate information

about a suitable material leading the skilled person necessarily and directly towards success when performing tests of different polyethylene layers.

This lack of guidance was increased by the technical teaching of document D5, which described in column 3, lines 28 to 44 and Figure 2 an ostomy appliance having inter alia a backing layer (18) composed of a resilient foam of polyethylene. Because of the stretchability and the recoverability of the elastomeric backing material, layer (18) in D5 tended to resume its original shape when distorting forces were removed. The patent proprietor himself explained with respect to document D5 (Annex A) that the foam of polyethylene constituting the backing layer (18) was not shapeable to enable the user to customize the stomal aperture according to his needs. In case of any deforming force being applied to the adhesive, the backing layer (18) restored the adhesive layer into its original shape. Based on the teaching of D5 and the patent proprietor's own explanations, a layer of polyethylene did not provide the important properties of flexibility and shapeability which were required for the intermediate sheet (66) featuring in claim 1 of the patent. Polyethylene therefore could not function as a material which was suitable for the claimed ostomy appliance.

Given this situation, the skilled person trying to fulfil the above mentioned criteria was left with an undue burden of trial-and-error experiments to establish the correct resilient layer of polyethylene in order to provide a satisfactory result. No guidance was given anywhere in the patent specification as to which of the plethora of material parameters should be

adjusted to provide a suitable material satisfying the functional language of claim 1.

Hence the patent in suit did not disclose the claimed subject matter sufficiently clearly and completely for it to be carried out by a person skilled in the art.

Articles 100(a), 54 EPC; novelty:

Document D10 disclosed an ostomy appliance comprising all the technical features of the ostomy body fitment set out in claim 1 of the patent. As shown in D10, Figures 2 to 4, the ostomy body fitment comprised a layer (11) having first and second adhesive surfaces. The inside diameter of layer (11) was smaller than that of the gasket ring (12) so that the unsupported part of adhesive layer (11) could be rolled or folded, as depicted in Figure 4, or as described on page 6, lines 21 to 24 and in claim 24. Moreover, the paragraph from D10, page 1, line 68 to page 2, line 9 taught that the adhesive layer could comprise a plurality of layers made of the material referred to in D10 and an intermediate layer or layers of a flexible synthetic foam or material. Nothing in this paragraph suggested that the layer structure of page 1, line 88 to page 2, line 9 related to specific embodiments, even less the embodiment shown in Figure 3. Rather, the entire nature of this paragraph suggested that it related to all embodiments of the invention of D10, including those depicted in Figures 3 and 4. Consequently, the subject matter of claim 1 lacked novelty over the disclosure of document D10.

VII. The arguments of the respondent can be summarized as follows:

Articles 100(b), 83 EPC; sufficiency of disclosure:

The patent specification clearly taught that the laminate adhesive pad (44) sandwiching flexible sheet (66) must be shapeable by folding or rolling back the edges of the adhesive pad around the stomal aperture. To this end, paragraph [0037] of the specification explained that flexible plastics, for example polyethylene, were a suitable choice for the flexible sheet. A person skilled in this field of technology would be able to find without difficulty a polyethylene sheet of appropriate thickness, which was suitable to fulfil the required properties, i.e. that the rim portion of the pad could be folded or rolled around the central opening (52).

Articles 100(a), 54 EPC; novelty:

With respect to the ostomy body fitment described in document D10, the laminate structure shown in Figure 3 of this document was attached to a stiff backing gasket (12). The shapeable first zone was restricted to the area which remained unsupported by the gasket (12). Only a small protrusion of layer (11) existed towards the centre of opening (15). Given that this small protrusion did not comprise a layered structure, the ostomy body fitment set out in claim 1 requiring such a layered structure was novel over the disclosure of document D10.



## Reasons for the Decision

1. The appeal is admissible.
2. Articles 100(b), 83 EPC:

The ostomy body fitment set out in claim 1 of the patent provides, inter alia, a first unsupported zone (60) of the adhesive pad (44) having a three-layer structure. Once the person skilled in the art has been told by claim 1 that the adhesive pad (44) must be sufficiently flexible to enable the pad to be reshaped manually by folding or rolling back a portion of the exposed second adhesive surface and that the pad must comprise a flexible sheet (66) sandwiched between the first and second layers, he would be able to put into practice the ostomy appliance. Contrary to the appellant's position, the "flexibility" of sheet (66) is the only parameter required by claim 1. The patent specification provides the skilled person with additional guidance as to which type of material is a suitable choice for sheet (66). Paragraph [0037] of the specification directs him in particular towards plastics or, more specifically, to polyethylene flexible sheets. By carrying out some routine experiments the person skilled in the art would be able to test whether an adhesive pad sandwiching a sheet of plastic or polyethylene actually was sufficiently "flexible" to enable the pad to be reshaped manually by folding or rolling back a portion of the adhesive pad. In performing such tests, the skilled person would be well aware that the thickness of the sheet could adversely affect its flexibility and consequently, the person skilled in the art would also consider sheets of

different thicknesses. It is noted in this context that the appellant has not provided any substantiating technical evidence to support its allegation that suitable flexible sheets could not be selected in this manner.

Based on these considerations, the Board cannot see a plausible reason as to why the claimed ostomy device could not be put into practice by a person skilled in the art on the basis of the patent specification.

- 2.1 The appellant further argued that the ostomy appliance disclosed in document D5 comprised a backing layer (18) which was composed of a resilient foam of polyethylene and resumed its original shape when distorting forces were removed (D5, Figure 2; column 3, lines 28 to 44). In its view, this went to show that a polyethylene sheet was not a suitable material to meet the adhesive pad flexibility requirements of claim 1 of the patent and that for this reason, the claimed ostomy device could not be put into practice. This finding was supported by the patent proprietor's comments on D5 (Annex A).

The appellant's argument, and in particular its reference to Annex A, which is concerned with the substantive examination of a different patent application, is misleading. The basic idea of the ostomy appliance of D5 is that the adhesive pad (D5, Figure 2, faceplate 11) may flex, expand or contract in order to conform with the body contours and to accommodate changes in such contours (D5, column 3, lines 44 to 46). To satisfy these needs, a backing layer (18) of close-cell polyethylene foam has been

selected because of its stretchability and recoverability (D5, column 3, lines 33 to 44). The ostomy devices disclosed in document D5 do not require that the adhesive pad (faceplate 11) including backing layer (18) must be shapeable so that the aperture can be shaped manually to define a customized opening. Based on the disclosure of document D5, there is no reason to concluded that polyethylene in general represents a material which is totally unsuitable for the flexible sheet (66) of the claimed ostomy device.

The requirements of Article 83 EPC are therefore met and the ground according to Article 100(b) EPC cannot succeed in respect of the patent in suit.

3. Articles 100(a), 54 EPC; novelty

The only prior art on which the appellant based its ground of lack of novelty of the subject matter of claim 1 was represented by document D10.

In fact, document D10 discloses on page 1, line 82 to page 2, line 9 the ring seal of an ostomy appliance, consisting of a layer of the material referred to in D10 and a layer of a foam material, such as polyethylene foam or a textile material, which could be bonded to the ostomy appliance. In another embodiment, the ring seal may comprise a plurality of layers made from the material of D10 and an intermediate layer or layers of a flexible synthetic foam material or a textile material.

Turning to the triple layer ring seal depicted in Figure 3 and described in the corresponding passage on

page 5, lines 115 to 130 of document D10, the sealing ring consists of a polyethylene foam layer (32) sandwiched between two layers (11) and (31) of the composition claimed in this document. D10 further mentions in claim 24 and at page 6, lines 22 to 26 that the outer annular seal (11), which is comparable to the unsupported area (56) in the first zone (60) of the claimed ostomy appliance, is pliable and may easily be folded in around the edge of the opening (15), as also shown in Figure 4 of D10.

However, document D10 does not disclose an unsupported first zone of the triple layer adhesive pad in which the second adhesive surface of the three-layered adhesive pad is exposed at least in use and which is sufficiently flexible to be folded or rolled back. In the embodiment shown in D10, Figure 3, a part of the first adhesive layer (11), i.e. only one single layer, remains unsupported by the gasket and is exposed. In Figure 4 and also in the associated passage in D10, page 6, lines 22 to 26, reference is made only to a single layer outer annular seal which may be folded. Moreover, the passage on page 1, line 82 to page 2, line 9 referred to by the appellant does not disclose clearly and unambiguously that the exposed pliable outer part of annular seal (11) is actually composed of a triple layer laminate. Arguing in that way is possible only on the basis of hindsight, i.e. in the knowledge of the invention. Hence, the ostomy body fitment set out in claim 1 of the patent cannot be derived directly and unambiguously from the disclosure of document D10.

Given this situation, the subject matter of claim 1 is novel over D10.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner