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**Datasheet for the decision  
of 23 February 2010**

**Case Number:** T 1203/07 - 3.2.02

**Application Number:** 98924070.0

**Publication Number:** 0991382

**IPC:** A61F 5/443

**Language of the proceedings:** EN

**Title of invention:**  
An ostomy appliance

**Patentee:**  
Coloplast A/S

**Opponent:**  
Hollister Incorporated

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 56

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

**Keyword:**  
"Inventive step (no)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1203/07 - 3.2.02

**DECISION**  
of the Technical Board of Appeal 3.2.02  
of 23 February 2010

**Appellant:** Hollister Incorporated  
(Opponent) 2000 Hollister Drive  
Libertyville, Illinois 60048-3781 (US)

**Representative:** Elmeros, Claus  
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**Respondent:** Coloplast A/S  
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**Representative:** Schwarze, Holm  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
9 May 2007 concerning maintenance of European  
patent No. 0991382 in amended form.

**Composition of the Board:**

**Chairman:** D. Valle  
**Members:** P. L. P. Weber  
J. Geschwind

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal on 18 July 2007 against the decision of the opposition division posted on 9 Mai 2007 to maintain the patent in amended form. The fee for appeal was paid simultaneously and the statement setting out the grounds of appeal was received on 18 September 2007.

II. The following documents are relevant for the decision:

D1 = US - A - 5 147 340

D3 = EP - A - 0 686 381

D4 = US - A - 5 559 165

D5 = US - A - 4 477 325

D6 = US - A - 4 738 257.

III. Oral proceedings took place on 23 February 2010.

The appellant requested that the decision under appeal be set aside and that the patent be revoked. He further requested that, if the Board of Appeal was not minded to accept the opponent's view regarding Article 84 EPC the following question be referred to the Enlarged Board of Appeal:

"Is a substantial amendment during opposition consisting in the deletion of all drawings and the corresponding description sufficient basis for an objection to patentability based on whether the amended patent complies with Article 84 EPC?"

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

main request or of one of the auxiliary requests 1 to 3 on file or on the basis of the auxiliary request 4 filed during the oral proceedings. He further requested that documents D3 and D4 should not be introduced into the proceedings, and to introduce into the proceedings documents D5 and D6.

IV. Claim 1 of the main request reads as follows:

"An ostomy appliance comprising  
- a body side member having an adhesive wafer for securing said body side member to a user's skin, said body side member having a body side member opening therein for receiving a stoma of said user when said body side member is secured to said user's skin,  
- a collection bag having a bag opening therein and means for detachably securing of said collection bag to said body side member with said bag opening in alignment with said body side member opening so as to receive bodily excretions from said stoma,  
characterized in that said collection bag includes a plastically mouldable adhesive substance at an edge of said bag opening to permit moulding of said plastically mouldable adhesive substance so as to obtain a close fit to said stoma."

Claim 1 of the first auxiliary request is the same as that of the main request.

Claim 1 of the second auxiliary request reads as follows (additions with respect to the main request are underlined):

"An ostomy appliance comprising

- a body side member having an adhesive wafer for securing said body side member to a user's skin, said body side member having a body side member opening therein for receiving a stoma of said user when said body side member is secured to said user's skin,  
- a collection bag having a bag opening therein and means for detachably securing of said collection bag to said body side member with said bag opening in alignment with said body side member opening so as to receive bodily excretions from said stoma,  
characterized in that said collection bag includes a plastically mouldable adhesive substance in the form of hypoallergenic, substantially non-memory putty-like adhesive at an edge of said bag opening to permit moulding of said plastically mouldable adhesive substance so as to obtain a close fit to said stoma."

Claim 1 of the third auxiliary request reads as follows (additions with respect to the main request are underlined):

"An ostomy appliance comprising  
- a body side member having an adhesive wafer for securing said body side member to a user's skin, said body side member having a body side member opening therein for receiving a stoma of said user when said body side member is secured to said user's skin,  
- a collection bag having a bag opening therein and means for detachably securing of said collection bag to said body side member with said bag opening in alignment with said body side member opening so as to receive bodily excretions from said stoma,  
characterized in that said collection bag includes a plastically mouldable adhesive substance in the form of

hypoallergenic, substantially non-memory putty-like adhesive at an edge of said bag opening to permit moulding of said plastically mouldable adhesive substance so as to obtain a close fit to said stoma wherein the hypoallergenic, substantially non-memory putty-like adhesive comprises a) a blockcopolymer having a major content of diblock copolymer, b) a tackifying liquid constituent, and c) a waxy constituent."

Claim 1 of the fourth auxiliary request is made of the granted claims 1 and 5.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Documents

D3 and D4 are introduced into the proceedings since highly relevant.

The respondent argues that D3 was introduced for the first time into the proceedings in opposition, that is at a very late stage to support a completely new line of argumentation and it was not relevant. D4 was not relevant either and late filed.

However, D3 and D4 have been introduced as a reaction to the new filed claims and are considered highly relevant. D3 was already known by the patentee since it was cited in paragraphs 15, 16 and 17 of the patent specification. D4 concerns in particular the chemical

features of the adhesive material introduced in claim 1 of the third auxiliary request.

D5 and D6 are not introduced into the proceedings.

Both documents have been submitted by the respondent during the oral proceedings in order to support his argument regarding the inventive step of claim 1 of the main request. These documents are late filed.

Furthermore the passages of D5 pointed out by the respondent do not appear prima facie relevant.

Regarding D6 the respondent was not able to indicate any specific relevant passage.

### 3. Main request

The subject-matter of claim 1 of the main request is novel. It is undisputed that D1 discloses all the features of claim 1 except that the adhesive substance included in the collection bag is "plastically mouldable".

The appellant maintains that also the above feature was known by D1. The adhesive substance made only sense if it were plastically deformable. D1 itself showed it in the following passages:

- column 3, lines 5 to 7: "Pouch barrier ring ... is readily deformable";
- column 3, line 55 to 57: "compressible ... material";
- column 5, lines 17 to 19: "barrier ring 19 is sized to accommodate the stoma".

Furthermore, according to D1, the adhesive substance could contain a super-absorbent material such as karaya

(see column 3, lines 33 to 36). This material was known as being plastically mouldable.

However, it is not proved beyond any reasonable doubt that D1 discloses a material which is plastically mouldable. The passages cited by the appellant in support of his arguments contain the words "deformable" and "compressible" which can refer to plastically mouldable as well as elastic materials, the plastically mouldable material being permanently deformable, the elastic material - on the contrary - taking its original shape back again when the applied load is withheld. Both materials are also compressible, that is capable of being reduced in size under pressure. The further cited passage saying that the barrier is sized to accommodate the stoma can very well refer to the procedure of cutting out the material and not to permanently deforming it. Finally, the appellant was not able to submit any proof that any mixture including the substance cited in D1 under the name of "karaya" necessarily had the propriety of being plastically mouldable.

However, the subject-matter of claim 1 of the main request does not involve an inventive step. The distinguishing feature of claim 1 with respect of D1 is banal. The skilled person in the field - in order to achieve a close fit around the stoma - will certainly choose a material which is plastically mouldable. The feature is also very well known in the field, see for example D3, page 2, line 37, page 3, line 54, page 4, line 33, page 5, lines 6 and 7 and Figure 4.



The respondent argued that D1 disclosed only elastic material. The material should necessarily be elastic and not plastically mouldable in order not to escape under pressure when held under compressive load as disclosed at column 4, line 36. To this purpose D1 disclosed the use of elastomeric materials, which have elastic properties, see for example column 3, line 10. D3 was not relevant, since the plastically mouldable material was intended to be put on the faceplate and not to be included in the collection bag like the claimed invention. Furthermore the appliance according to D3 comprised a two-layers material, the first layer being adhesive, the second easily deformable, see page 2, lines 24 to 32. D3 did not address the sizing problem which was important for D1, see D1, column 5, lines 18, 19, since the opening was pre-sized, see D3, page 5, line 15. The material of D1 had a low profile, whereas that of D3 was thick, compare D1, column 1, line 22, column 2, lines 2 to 6 and D3, page 5, line 2.

However, contrary to the assertion of the respondent, D1 does not disclose only an elastic material in the form of elastomers. According to D1, the material contains elastomers, but only in part, see D1, column 3, lines 8 to 11 and lines 33 to 36. Its function may be very well to give cohesion to the material and not necessarily elasticity, as the appellant pointed out. The plastically mouldable material would not necessarily escape under pressure, since the deformation depends on the amount of pressure applied and the operator will certainly apply the pressure suitable to the purpose of closely fitting the material to the stoma and not more. D3 is relevant since it belongs to the field of the invention and

discloses the claimed material. The specific way of using the material - whether on the faceplate like in D3 or in the collection bag like in the invention, whether as a component of a two-layers material or alone, whether having a low or a thick profile - is not relevant for the issue of the present case. It is sufficient that D3 discloses a material having the claimed characteristic of being plastically mouldable and that such material is suitable for performing the function of the invention.

4. Auxiliary requests 1 to 3

Claim 1 of the first auxiliary request is the same as the main request.

The additional feature of claim 1 of the second auxiliary request that the adhesive substance is provided in the form of hypoallergenic, substantially non-memory putty-like adhesive is banal. The skilled person will certainly choose a hypoallergenic substance for using it in contact with the skin; see also D3, page 2, line 7, 8. The feature that the substance is adhesive is known from D1, see for example column 3, line 46. The use of a non-memory, putty-like substance is also very well known in the field, see for example paragraph 13 of the patent in suit and D3, where it is said, for example, that the used material is soft, easily deformable and extrudable by finger pressure (page 3, line 54), which is considered to be equivalent to the designation: "non-memory, putty-like".

The respondent argued that the purpose of the putty-like material was to improve shaping and adherence.

However such a general purpose does not contain anything inventive in itself either.

The additional features of claim 1 of the third auxiliary request do not go beyond a normal workshop activity without any inventive activity being involved. The features are known or hinted at in the field. See D4 (which belongs to the field of the invention, see column 1, lines 10 to 16) column 3, lines 17 to 23 and tables 1 and 2 for a blockcopolymer having a major content of diblock copolymer; column 3, line 57 for a tackifying liquid constituent; and column 4, line 60 for a waxy constituent.

The patent in suit does not give any indication which could convince the Board of a surprising technical effect of the claimed combination of features. In the oral proceedings no convincing argument was brought forward either regarding the technical effect of the additional features. Therefore the subject-matter of claim 1 of the third auxiliary request does not involve an inventive activity having regard to the teaching of D1, D3 and D4.

The objection of the respondent that D4 does not indicate that the material described therein can be used for a mouldable ring is irrelevant since this use is already known by D1.

5. Fourth auxiliary request

The fourth auxiliary request comprises a claim 1 made of the granted claims 1 and 5. The request has been filed at a later stage of the oral proceedings and it

appears prima facie unlikely to pass the patentability test. The Board considers therefore appropriate in this case to follow the request of the appellant and make use of the discretion given by the Article 13 of the Rules of procedure of the Boards of Appeal of the European Patent Office by not admitting the auxiliary request four into the proceedings at such a late state.

6. Since neither the main request nor the auxiliary requests 1 to 3 comply with Article 56 EPC and since the fourth auxiliary request has not been introduced into the proceedings, it is not necessary to consider the formal objections raised by the appellant nor to consider the request of the same appellant to refer a question to the Enlarged Board of Appeal.

## **Order**

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

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

D. Sauter

D. Valle