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**Datasheet for the decision
of 19 July 2011**

Case Number: T 0417/08 - 3.2.08

Application Number: 01931455.8

Publication Number: 1280483

IPC: A61F 5/448

Language of the proceedings: EN

Title of invention:

Ostomy carrier device with flexible flange

Patent Proprietor:

Coloplast A/S

Opponent:

Hollister Incorporated

Headword:

-

Relevant legal provisions:

EPC Art. 123(2)

Relevant legal provisions (EPC 1973):

EPC Art. 56

Keyword:

"Allowability of amendments - main request (no)"

"Inventive step - auxiliary request (yes)"

Decisions cited:

-

Catchword:

-

Case Number: T 0417/08 - 3.2.08

DECISION
of the Technical Board of Appeal 3.2.08
of 19 July 2011

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

Representative: Elmeros, Claus
HØIBERG A/S
St. Kongensgade 59A
DK-1264 Copenhagen K (DK)

Respondent: Coloplast A/S
(Patent Proprietor) Holtedam 1
DK-3050 Humlebaek (DK)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 14 December 2007
rejecting the opposition filed against European
patent No. 1280483 pursuant to Article 101(2)
EPC.

Composition of the Board:

Chairman: T. Kriner
Members: P. Acton
U. Tronser

Summary of Facts and Submissions

I. The appellant (opponent) filed a notice of appeal, received at the EPO on 22 February 2008, against the opposition division's decision, posted on 14 December 2007, rejecting the opposition. The appeal fee was paid on 20 February 2008 and the statement of grounds was received on 22 April 2008.

II. Oral proceedings took place before the board of appeal on 19 July 2011.

The appellant requested that the decision under appeal be set aside and that European patent No. 1 280 483 be revoked.

The respondent requested that the patent be maintained on the basis of the following documents:

the claims according to auxiliary request A submitted with letter dated 3 September 2008 (main request)

or

the only claim according to the first auxiliary request submitted during oral proceedings and a description and the drawings to be adapted thereto.

III. Independent claim 1 according to the main request reads:

"An ostomy carrier device comprising:

- a flexible adhesive base plate (21) for securing the carrier device to a user's skin around a stoma, the

base plate having an opening (22) for receiving the stoma,

- a circumferential flange (30) made of a flexible material connected to the base plate, the circumferential flange having a first surface (36) facing towards the base plate, a second opposite surface (37) facing away from the base plate, a circumferential inner portion (33) with an inner edge and a circumferential outer portion (34) with an outer edge,

said flange being attached to the base plate corresponding to an innermost edge portion of the flange (feature A),

the second surface of the flange being adapted for removable and adhesive connection with an ostomy collecting bag,

- wherein the carrier device defines a general plane of reference, a thickness thereof being defined in a direction perpendicular thereto,

- wherein the outer portion of the flange is free to move relative to the base plate,

characterized in that

- only a part of the inner portion of the flange is attached to the base plate, that a portion of the inner portion of the flange is free to move relative to the base plate (feature B) and that

- the outer portion of the flange is more flexible than the portion of the inner portion of the flange that is free to move relative to the base plate (feature C)."

Claim 1 according to the 1st auxiliary request reads:

"An ostomy carrier device comprising:

- a flexible adhesive base plate (21) for securing the carrier device to a user's skin around a stoma, the base plate having an opening (22) for receiving the stoma,

- a circumferential flange (30) made of a flexible material connected to the base plate, the circumferential flange having a first surface (36) facing towards the base plate, a second opposite surface (37) facing away from the base plate, a circumferential inner portion (33) with an inner edge and a circumferential outer portion (34) with an outer edge,

said flange being attached to the base plate corresponding to an innermost edge portion of the flange (feature A),

the second surface of the flange being adapted for removable and adhesive connection with an ostomy collecting bag,

- wherein the carrier device defines a general plane of reference, a thickness thereof being defined in a direction perpendicular thereto,

- wherein the outer portion of the flange is free to move relative to the base plate,
- the outer portion of the flange is more flexible than the inner portion of the flange (feature D),
- the flange comprises a substantially circumferential hinge formed between the outer and inner portions of the flange (feature E),

characterized in that

the hinge has a thickness which is less than the thickness of the inner and outer portions of the flange to which it connects, preferably less than 75% of the thickness of the inner portion of the flange (feature F)."

The designations of features A to F have been added by the Board.

IV. The following documents are relevant for the present decision:

D1: WO-A-96/38 106

D3: WO-A-98/17 212

V. The appellant's arguments can be summarised as follows:

Main request

Feature A, according to which "the flange was attached to the base plate corresponding to an innermost edge portion of the flange", was not disclosed in the

originally filed application and could not be interpreted as meaning that the flange was attached at the base plate at least at its innermost edge. Such an interpretation would be in contradiction with the subject-matter of claim 6 as granted, which required that "the flange is connected to the base plate in the vicinity of the inner edge of the flange".

Feature B, according to which "the outer portion of the flange is more flexible than the portion of the inner portion of the flange that is free to move relative to the base plate", was not disclosed in the application as filed either. The original application specified that the outer portion was more flexible than the inner portion, but did not distinguish between the flexibility of that part of the inner portion of the flange which was free to move and of that which was not.

Therefore, claim 1 according to the main request did not comply with the requirements of Article 123(2) EPC.

1st auxiliary request

D1 and D3 disclosed all the features of claim 1 apart from features D and E. These features did not have any technical effect over the device disclosed in the prior art and did not solve any technical problem. Since a hinge represented a well-known means for influencing the flexibility of a flange, it was obvious for the skilled person to include it in the flange according to D1 or D3.

Therefore, the subject-matter of claim 1 according to the 1st auxiliary request did not involve any inventive step.

VI. The respondent's arguments can be summarised as follows:

Main request

Figures 2a to 2f, disclosing the different embodiments of the invention, showed that the innermost region of the flange was attached at the base plate and that there was no unattached portion of the flange extending inward of the innermost edge of the attachment region. Therefore, feature A could only be interpreted as meaning that the flange was attached at the base plate at least at its innermost edge. Claim 6 as granted did not contradict this interpretation since it meant that further, separate regions of attachment could be foreseen radially outward from the innermost edge, as for example shown in Figure 2c. Therefore, feature A was clearly disclosed in the application as filed.

Feature B was disclosed by claims 1 and 2 as filed in combination with the 2nd paragraph of page 7 of the application as originally filed.

1st auxiliary request

Since none of the available prior art documents either disclosed or suggested the use of a hinge in the flange of an ostomy carrier, it was not obvious for the skilled person to introduce a hinge in the flange according to D1 or D3 for separating the inner and outer parts therefrom.

Hence, the subject-matter of claim 1 according to the 1st auxiliary request involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Allowability of the amendments

2.1 Feature A, which is present in claim 1 according to both requests, can only be interpreted as meaning that the flange is attached at the base plate "at least" at its innermost edge, in the sense that the flange does not extend radially inward of the innermost edge of the attached portion. This interpretation is supported by the fact that all embodiments of the present invention as disclosed in Figures 2a to 2f show this attachment.

Claim 6 as granted does not contradict this interpretation, since it merely specifies that the flange is connected to the base plate not only at the innermost edge but also in its vicinity, i.e. radially outward of the innermost edge, as for example in Figure 2c.

Therefore, feature A of claim 1 according to the main request and to the 1st auxiliary request complies with the requirements of Article 123(2) EPC.

2.2 The last feature of claim 1 according to the main request (feature C) was not disclosed in the application as filed. While the application defines

different flexibilities between an inner and outer portion of the flange, it does not specify any relationship between the flexibility of the outer portion and of that part of the inner portion which is free to move.

The combination of claims 1 and 2 with the 2nd paragraph of page 7 as filed discloses only that a part of the inner portion of the flange is free to move and that the outer portion of the flange is more flexible than the inner portion taken as a whole. Hence this disclosure cannot support feature C.

Therefore, feature C does not comply with the requirements of Article 123(2) EPC, and claim 1 according to the main request is not allowable.

3. Novelty

D1 (see particularly Figure 3) discloses:

An ostomy carrier device comprising:

- a flexible adhesive base plate (6) for securing the carrier device to a user's skin around a stoma, the base plate having an opening (6a) for receiving the stoma,

- a circumferential flange (7) made of a flexible material connected to the base plate, the circumferential flange having a first surface facing towards the base plate, a second opposite surface facing away from the base plate, an inner portion with an inner edge and an outer portion with an outer edge,

said flange being attached to the base plate corresponding to an innermost edge portion of the flange (the adhesive region 8 extends up to the innermost edge portion of the flange, see page 5, lines 10 to 14), the second surface of the flange being adapted for removable and adhesive connection with an ostomy collecting bag (see page 6, lines 18 to 22),

- wherein the carrier device defines a general plane of reference, a thickness thereof being defined in a direction perpendicular thereto,

- wherein the outer portion of the flange is free to move relative to the base plate.

The features above are disclosed by D3 as well (see particularly Figure 1).

Moreover, each of D1 and D3 discloses a flange made of one single material comprising a portion with constant thickness and a rim at the radially inner edge thereof. Therefore, the inner portion of the flange - which comprises the rim, that part of the flange which is attached to the base plate and a portion of the flange which is free to move with respect to the base plate - is as a whole less flexible than the outer portion of the flange. Hence D1 and D3 disclose features B and D as well.

Therefore, even an amended version of claim 1 according to the main request which complied with the requirements of Article 123(2) EPC would not be allowable since its subject-matter would not be novel.

4. Inventive step - auxiliary request

Under consideration of the findings above, the subject-matter of claim 1 according to the auxiliary request differs from the device according to D1 and D3 by features E and F.

Starting from the device according to D1 and D3, these features lead to a more flexible outer part which assures a better bond with the collecting bag, thereby solving the problem of improving the wear comfort of the user.

Since none of the ostomy devices of the cited prior art discloses a flange with a hinge, there is no suggestion to provide an ostomy carrier device as disclosed in D1 or D3 with a hinge, let alone with a hinge according to features E and F. Although hinges are indeed well known per se in the art, there is no suggestion to select such means to increase the flexibility of a flange of an ostomy carrier. This finding is also supported by the fact that all devices known from the prior art disclose flanges with plane surfaces.

Therefore, the subject-matter of claim 1 according to the 1st auxiliary request involves 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 department of first instance with the order to maintain the patent on the basis of the following documents:

the claim according to the first auxiliary request submitted during oral proceedings and a description and drawings to be adapted thereto.

The Registrar:

The Chairman:

V. Commare

T. Kriner