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**Datasheet for the decision
of 19 June 2012**

Case Number: T 0481/10 - 3.2.08

Application Number: 98958640.9

Publication Number: 1033952

IPC: A61F 5/44, A61F 5/448,
A61F 5/443

Language of the proceedings: EN

Title of invention:
Repositionable pouch with floating landing zone

Patent Proprietor:
Bristol-Meyers Squibb Company

Opponents:
Coloplast A/S
Hollister Incorporated

Headword:
-

Relevant legal provisions:
EPC Art. 100(a)(b)

Keyword:
"Main request, first auxiliary request: inventive step (no)"
"Second auxiliary request: added subject-matter (no),
inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0481/10 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 19 June 2012

Appellant I:
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Decision under appeal:
Interlocutory decision of the Opposition
Division of the European Patent Office posted
21 December 2009 concerning maintenance of
European patent No. 1033952 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
A. Pignatelli

Summary of Facts and Submissions

- I. Oppositions were filed against European patent No. 1 033 952 as a whole by opponents 01 and 02.
- II. By its interlocutory decision dispatched on 21 December 2009 the opposition division held that the subject matter of the claims according to the sixth auxiliary 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.
- III. On 25 February 2010, appellant I (opponent 02) lodged an appeal against this decision, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 27 April 2010.

Appellant II (the patent proprietor) also lodged an appeal against this decision on 1 March 2010, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 30 April 2010.

- IV. On appeal, the parties essentially referred to documents

D1: WO-A-96/38106,

D3: EP-A-0 793 951 and

D6: US-A-5 356 399.

- V. Oral proceedings took place before the Board on 19 June 2012.

The following requests were made:

The appellant I and the respondent (opponent I) requested that the decision under appeal be set aside and the patent be revoked.

The appellant II requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims according the main request or on the basis of one of the first or second auxiliary requests (corresponding to the set of claims upheld by the opposition division), all requests filed with letter dated 17 May 2012.

VI. Claim 1 of main request reads as follows:

"An ostomy system (10) comprising:

(a) an ostomy pouch (12, 142) including a pouch envelope (18) formed of flexible plastic material defining a waste collection chamber (46) for body waste that passes through a stoma, a waste inlet opening (30) formed in said envelope (18) for positioning around said stoma to permit passage of waste material from said stoma to said collection chamber (46), flexible annular adhesive pouch coupling means (50) on said envelope at said waste inlet opening (30) for coupling with a body side mounting wafer (14), and

(b) a body-side mounting wafer (14, 144) joinable to a body surface around a stoma (120), said body side mounting wafer (14) having an opening (16) for a stoma (120) and a non-adhesive landing area surface (74, 102) on a front side of the mounting wafer for coupling engagement with the annular adhesive pouch coupling

means (50), said non-adhesive landing area includes a first portion (74) that is immovable with respect to a body surface around a stoma (120) when said mounting wafer (14) is secured to said body surface, and a second portion (102, 150) that is deflectable away from said body surface when said mounting wafer (14) is secured to said body surface and characterized in that the pouch coupling means (50) couples against the first and second portions of the non-adhesive landing area (74, 102) when the pouch (12, 142) and wafer (14, 144) are coupled, and said non-adhesive landing area has an exposed first peripheral edge and said second deflectable portion (76) of said non-adhesive landing area (102, 150) is provided at said exposed first peripheral edge to permit manual gripping of said mounting wafer (14, 144) at the exposed first peripheral edge when said pouch (14) is detached from a coupled position with said mounting wafer (14, 144)."

Claim 1 of the first auxiliary request reads (amendments over claim 1 in bold):

"An ostomy system (10) comprising ... characterized in that... and **in that** said non-adhesive landing area has an exposed first peripheral edge, **having a predetermined periphery and substantively the entire periphery of said non-adhesive landing area at said exposed peripheral edge being deflectable away from said body surface** and said second deflectable portion (76) ... with said mounting wafer (14, 144)."

Claim 1 of the second auxiliary request reads
(amendments over claim 1 of the first auxiliary request
in bold):

"An ostomy system (10) comprising:

(a) an ostomy pouch (12, 142) including a pouch envelope (18) formed of flexible plastic material defining a waste collection chamber (46) for body waste that passes through a stoma, a waste inlet opening (30) formed in said envelope (18) for positioning around said stoma to permit passage of waste material from said stoma to said collection chamber (46), flexible annular adhesive pouch coupling means (50) on said envelope at said waste inlet opening (30) for coupling with a body side mounting wafer (14), and

(b) a body-side mounting wafer (14, 144) joinable to a body surface around a stoma (120), said body side mounting wafer (14) having an opening (16) for a stoma (120) and a non-adhesive landing area surface (74, 102) on a front side of the mounting wafer for coupling engagement with the annular adhesive pouch coupling means (50), said non-adhesive landing area includes a first portion (74) that is immovable with respect to a body surface around a stoma (120) when said mounting wafer (14) is secured to said body surface, and a second portion (102, 150) that is deflectable away from said body surface when said mounting wafer (14) is secured to said body surface and **wherein** the pouch coupling means (50) couples against the first and second portions of the non-adhesive landing area (74, 102) when the pouch (12, 142) and wafer (14, 144) are coupled, and said non-adhesive landing area has an exposed first peripheral edge, having a predetermined periphery and substantively the entire periphery of

said non-adhesive landing area at said exposed first peripheral edge being deflectable away from said body surface, **the periphery being generally rectangular with rounded corners** and the deflectable second portion of said non-adhesive landing area extending inwardly from said exposed first peripheral edge to a generally circular boundary within the confines of said exposed first peripheral edge and said second deflectable portion (**102, 150**) of said non-adhesive landing area (102, 150) is provided at said exposed first peripheral edge to permit manual gripping of said mounting wafer (14, 144) at the exposed first peripheral edge when said pouch (12) is detached from a coupled position with said mounting wafer (14, 144)."

VII. The arguments of appellant I and of the respondent relevant to the present decision can be summarized as follows:

Added subject matter; Article 100(c) EPC

The claims of all requests comprised the term "for *coupling engagement with*" and "*couples against*". Apart from the fact that both terms seemed to have a different meaning rather than being synonymous, the term "*couples against*" was not found anywhere in the application as originally filed. Consequently, the subject matter of claim 1 of all requests extended beyond the content of the application as filed and thus contravened Article 123(2) EPC.

Inventive step; Article 100(a) EPC

Except for the material the ostomy pouch envelope was formed of, document D1 as the closest prior art disclosed all the technical features of the ostomy system according to claim 1 of the main and first auxiliary requests (D1, Figures 1 to 4). The selection of a thermoplastic material for the pouch envelope was, however, self-evident and commonly known to the skilled person. Paragraph [0026] of the patent specification confirmed this finding stating that the pouch was formed of a known envelope (18) of flexible thermoplastic material made in accordance with known techniques in the art of ostomy construction. Besides a pouch envelope of flexible thermoplastic material was known from document D3, column 4, lines 26 to 30. Vis-à-vis the technical disclosure of document D1 taken in combination with the skilled person's general knowledge or with D3, claim 1 of the main and first auxiliary requests did not comprise technical features justifying an inventive step.

Turning to claim 1 of the second auxiliary request, the claimed ostomy system differed from D1 merely in that the periphery of the non-adhesive landing area was generally rectangular in shape with rounded corners. The shape of the periphery was, however, not a technical feature which helped to solve a particular technical problem. Even if the problem this differing feature may be said to solve was regarded as how to provide a periphery which was suitable for manual gripping, the problem was well known to the skilled person. As a matter of normal design procedure, the skilled person would consult D6, in particular Figure 1a, where he would immediately realise that differences between the shape of the landing zones on the wafer and

the pouch would result in one or more gripping tabs. Figure 1a of D6 further showed the combination of a circular shape and rectangular shape with rounded corners and, consequently, the person skilled in the art would have no difficulties in altering the peripheral shape of the landing zones in D1 accordingly in order to arrive at the solution specified in claim 1. The subject matter of claim 1 of the second auxiliary request thus did not involve an inventive step either.

VIII. The arguments of appellant II relevant to the present decision can be summarized as follows:

Added subject matter; Article 100(c) EPC

The terms "for coupling engagement with" and "coupled against" objected to by appellant I were identical in meaning. Both terms were supported by the originally filed application which disclosed for instance in claim 1, on page 2, line 5 and page 3, line 4, page 4, line 21 that the pouch and the wafer were adhesively coupled. The wording "coupling against" actually meant "coupled with" or "secured to" and was supported by the original description, page 12, lines 14, 15. It was evident also from Figures 1 and 2 showing that the pouch was secured to the mounting wafer. The amendment to the claims of all requests thus did not contravene the requirements of Article 100(c) EPC.

Inventive step; Article 100(a) EPC

Contrary to the position of appellant I and the respondent, there were several features in claim 1 of all requests which were not disclosed in document D1.

Firstly, D1 failed to disclose that the pouch envelope was formed of a flexible plastic material. Secondly, since the figures in D1 represented merely schematic drawings, D1 did not disclose that the pouch coupling means couples against the first and second positions of the non-adhesive landing area when the pouch and wafer are coupled. Thirdly, nothing in D1 showed a mounting wafer having an exposed first peripheral edge that could be gripped when the pouch was detached from the coupled position with the mounting wafer. Reading the patent specification as a whole, there was no doubt that the wording "when detached" was to be interpreted as the action of decoupling or disengaging both parts of the system rather than the state of detachment, as ruled by the opposition division in the impugned decision. By giving the term "when detached" a logical interpretation, the feature that the mounting wafer had an exposed edge was not found in D1.

As to claim 1 of the first auxiliary request, substantially the entire periphery of the exposed peripheral edge, which went all the way round the wafer, and its predetermined periphery were deflectable away from the body surface. This was not shown in D1 either. Contrary to the argument of appellant I and the respondent, the rectangular shape featuring in claim 1 of the second auxiliary request had the technical effect that manual gripping of the non-adhesive landing area was facilitated. If the exposed periphery was generally rectangular-shaped, four corners or four exposed tabs were created which were readily accessible by the wearer.

Although the schematic Figure 1 of D1 showed a wafer having a non-adhesive landing area (7) with some kind of an earlobe tab extending from the landing area, and Figure 2 showed a pouch having a protective cover layer comprising a similar tab, no comment on or explanation for the function of both tabs were found anywhere in D1. Hence D1 did not disclose a free part and a fixed part of the wafer landing area which both were coupled with the pouch.

As regards the ostomy system given in D6, the basic problem of detaching the pouch from the wafer addressed in D6 was different to that of the claimed system. D6 concerned mechanical clipping together and disengaging both parts in the manner of closing and opening a Tupperware® container rather than coupling both by an adhesive layer. Moreover, the landing area could not be seen as being rectangular with rounded corners. Rather, the non-adhesive landing area in D6, Figure 1a comprised a circular tab 8 with two cut edge portions. Consequently, the combination of D1 and D6, even if made, would not arrive at claim 1 of the second auxiliary request allowed by the opposition division.

Hence, the subject matter of claim 1 of all requests was novel and involved an inventive step over the prior art.

Reasons for the Decision

1. The appeals are admissible.

2. Inventive step; main and first auxiliary requests

2.1 Figures 1 to 4 of document D1 disclose an ostomy system comprising:

(a) an ostomy pouch (1) including a pouch envelope (3) defining a waste collection chamber (3) for body waste that passes through a stoma, a waste inlet opening (4) formed in said envelope for positioning around said stoma to permit passage of waste material from said stoma to said collection chamber (3), a flexible annular adhesive pouch coupling means (5) on said envelope at said waste inlet opening (4) for coupling with a body side mounting wafer (6), and

(b) a body-side mounting wafer (6) joinable to a body surface around a stoma, said body side mounting wafer (6) having an opening (6a) for a stoma and a non-adhesive landing area surface (7) on a front side of the mounting wafer for coupling engagement with the annular adhesive pouch coupling means (5), said non-adhesive landing area includes a first portion (inner portion of flange (7)) that is immovable with respect to a body surface around a stoma when said mounting wafer (6) is secured to said body surface, and a second portion (external diameter of the rim portion of flange (7) which protrudes beyond the layer of adhesive (8)) that is deflectable away from said body surface when said mounting wafer (4) is secured to said body surface, wherein the pouch coupling means (5) couples against the first and second portions of the non-adhesive landing area (7) when the pouch (3) and wafer (6) are coupled, and said non-adhesive landing area has an exposed first peripheral edge and said second deflectable portion (rim portion with tab of flange (7) of said non-

adhesive landing area (7)) is provided at said exposed first peripheral edge to permit manual gripping of said mounting wafer at the exposed first peripheral edge when said pouch (1) is detached from a coupled position with said mounting wafer (6).

Appellant II argued that document D1 failed to give any information as to the purpose and function of the tab which had no reference number in Figure 1. Therefore it was speculative which function the tab in Figure 1 of D1 was supposed to perform.

It is true that D1 remains silent on the purpose of the flap or tab depicted in Figure 1. However, given that the wearer when replacing the ostomy pouch is permanently faced with the problem of releasing and reattaching the ostomy pouch to the mounting plate, no reasonable explanation for the tab's existence other than that the exposed peripheral edge in the form of the tab is provided in order to permit manual gripping of the mounting wafer and to facilitate uncoupling of the pouch from the wafer could be found. The Board's understanding is confirmed by the passage in D1, page 2, last line to page 3, line 3 which addresses the action of detaching and states that the ostomy system should permit the user to remove and reinstall one or more bags repeatedly without any reduction of the life of the base plate (wafer).

It is also true that the figures in document D1 represent merely schematic drawings of an ostomy system. However, this does not mean that the figures do not disclose relations between the sizes of the ostomy pouch (1) and the body-side mounting wafer (2). In

particular, Figures 3 and 4 show that the outer radii of the base plate flange 7 and of the connecting elements (5), on the one hand, and the outer radius of the collar (7b) and the inner radii of the connecting elements, on the other hand, are identical, respectively. Therefore, D1 also discloses that the pouch coupling means (5) couples against the first and second positions (inner and outer part of flange 7) of the non-adhesive landing area, when the pouch and wafer are coupled.

A further technical feature not explicitly described in D1 is that the pouch envelope should be formed of a flexible plastic material. This feature is, however, considered self-evident since the selection of a flexible plastic material is quite common and falls within the normal competence of a person skilled in the art of ostomy pouches. In that respect, the patent specification itself confirms in paragraph [0026] that the pouch is formed of a known envelope of flexible thermoplastic material made in accordance with known techniques in the art of ostomy pouch construction. Besides, document D3 discloses a flexible plastic material that is suitable for that purpose (D3, column 4, lines 26 to 30). Hence, no inventive step can be attributed to the choice of a flexible plastic material for the pouch envelope.

- 2.2 Compared to claim 1 of the main request, claim 1 of the first auxiliary request further defines that the edge has a predetermined periphery and substantially the entire periphery of the non-adhesive landing area at said exposed first peripheral edge is deflectable away from the body surface.

In the Board's assessment, the outer position of flange (7) including the tab depicted in Figure 1 of D1 and extending from base plate flange 7 satisfies all these criteria since it has a predetermined periphery and in that the entire periphery is deflectable away from the body.

Consequently, the subject matter of claim 1 of the main and the first auxiliary requests does not involve an inventive step with respect to document D1 and the common general knowledge of a skilled person.

3. Second auxiliary request

3.1 Amendment to claim 1; Article 100(c) EPC

Appellant I and the respondent objected to the term "coupled against" featuring in the characterizing portion of claim 1 of the second auxiliary request. They argued that no support for this term was given in the application documents as filed and, therefore, an objection arose under Article 100(c) EPC. Moreover, both parties raised the question whether the terms "coupling against" and "coupling engagement" in claim 1 had the same meaning.

In the Board's understanding of the patent specification as a whole and having regard in particular to Figures 1 and 2, it is evident to the skilled practitioner that, after removing the outer protective silicone release paper, the adhesive face plate 50 of the pouch is "coupled with" or "coupled against" or "secured to" or brought "into coupling

engagement with" the non-adhesive first landing zone 74. All these terms are considered as being identical in meaning. They find inter alia support in the application as filed on page 1, lines 1, 2, page 2, lines 5, 11, page 3, lines 4, 10 and page 12, lines 14 to 16. Thus, the objection under Article 100(c) EPC is not justified.

3.2 Inventive step

Claim 1 of the second auxiliary request includes the feature that "the periphery being generally rectangular with rounded corners and the deflectable second portion of said non-adhesive landing area extending inwardly from said exposed first peripheral edge to a generally circular boundary within the confines of said exposed first peripheral edge and said second deflectable portion (102, 150) of said non-adhesive landing area is provided at said exposed peripheral edge to permit manual gripping."

Document D1 does not show a non-adhesive landing area whose deflectable periphery is generally rectangular with rounded corner, and neither do D3 or D6, the latter being concerned with a different type of coupling as is shown in Figure 2. Specifically, the two fitting portions 7 and 14 which consist of a pair of annular or ring-form projections or prominences (9) are pinched and pressed together in the manner of closing a Tupperware® container with a lid (D6, column 4, lines 10 to 12 and column 5, lines 45 to 50). Certainly, Figure 1a of D6 shows a non-adhesive landing area 4 comprising finger-grippable tab 8 which is circular shaped having two cut-off edge portions. However, the landing area 4

in D6, Figure 1a is not regarded as being generally rectangular with rounded corners as defined in claim 1 of the second auxiliary request. As to the function of this technical feature, the Board concurs with the position of appellant II in that the shape of the periphery is not a random choice but represents a technical feature in that the four corners or parts assist decoupling when the wearer has to replace the pouch.

Since the available state of the art does not suggest the claimed shape, let alone for the purpose described above, the subject matter of claim 1 of the second auxiliary request, which corresponds to auxiliary request 6 upheld by the opposition division, involves an inventive step.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner