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Datasheet for the decision of 20 January 2009

Case Number: T 0301/07 - 3.2.02

Application Number: 97201073.0

Publication Number: 0800804

IPC: A61F 5/445

Language of the proceedings: EN

Title of invention:
Fabrication of customized ostomy devices

Patentee:
Bristol-Myers Squibb Company

Opponents:
01) Hollister Incorporated
02) Coloplast A/S

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 52(1), 56, 123(2)

Keyword:
"New subject-matter (no)"
"Inventive step (yes, third auxiliary request)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0301/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 20 January 2009

Appellant: (Opponent 01)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 12 December 2006 concerning maintenance of European patent No. 0800804 in amended form.

Composition of the Board:

Chairman: M. Noel
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. The appellants (opponents) lodged an appeal against the interlocutory decision of the opposition division relating to European patent No. 0 800 804.

II. The decision was dispatched on 12 December 2006. The appeals were received on 21 and 22 February 2007, respectively, and the fees for the appeals were paid on the day the respective appeal was filed. The statements setting out the grounds of appeal were received on 4 April and 20 April 2007, respectively.

III. The oppositions were filed against the whole patent and based on Article 100(a), (b), and (c) EPC 1973. The opposition division decided that the claims of the auxiliary request 4 then on file, and promoted to the main request, met the requirements the EPC.

IV. The following documents are of interest in the appeal procedure:

D1: DE-A-4 015 186
D5: DE-U-9 105 753
D8: US-A-5 074 852.

V. Oral proceedings before the Board were held on 20 January 2009. The appellant Hollister Inc. had informed the Board that it would not be attending. The following requests were submitted:

Both the appellants requested that the decision under appeal be set aside and that European patent No. 0 800 804 be revoked.

The appellant Coloplast A/S additionally requested that the dependent claims 6 to 53 of the third auxiliary request not be admitted since they were late filed and also objectionable under Article 123(2) EPC.

The respondent (patent proprietor) requested that the appeals be dismissed (main request) or that the patent be maintained on the basis of one of the auxiliary requests 1 to 4 filed at the oral proceedings.

VI. Claim 1 of the main request reads as follows: -

"A method for fabricating customized ostomy devices including a wafer (12, 18) and a collection pouch (14, 20) wherein the wafer is an adhesive wafer and the method comprises the following steps: measuring the surface or topography of the stomal area of the patient; recording information relating to the measurements of the stoma area, transforming the recorded information into electronic form; utilizing the electronic information to select the physical attributes of the ostomy device including physical attributes of the wafer (12, 18); and fabricating the ostomy device to have physical attributes selected in accordance with the measurement information, the step of fabricating comprising the sub-step of forming the wafer separated from the pouch to have said physical attributes for the wafer".

Claim 1 of the first auxiliary request reads as follows:

"A method for fabricating customized ostomy devices including a wafer (12, 18) and a collection pouch (14,

20) wherein the wafer is an adhesive wafer and the method comprises the following steps: measuring the surface or topography of the stomal area of the patient; recording information relating to the measurements of the stomal area; transforming the recorded information into electronic form and downloading into a computer; utilizing the electronic information to select the physical attributes of the ostomy device including physical attributes for the wafer (12, 18); and the computer causing fabrication equipment to select the appropriate materials and tooling and to guide the tools to fabricate the ostomy device to have physical attributes selected in accordance with the measurement information, the step of fabricating comprising the sub-step of forming the wafer separated from the pouch to have said physical attributes for the wafer".

Claim 1 of the second auxiliary request reads as follows:

"A method for fabricating customized ostomy devices including a wafer (12, 18) and a collection pouch (14, 20) wherein the wafer is an adhesive wafer and the method comprises the following steps: measuring the surface or topography of the stomal area of the patient; recording information relating to the measurements of the stomal area; transforming the recorded information into electronic form and downloading into a computer; utilizing the electronic information to select the physical attributes of the ostomy device including physical attributes for the wafer (12, 18); the computer selecting a tool for cutting the stoma receiving hole in the wafer and wafer outline and a tool for welding the pouch periphery; and fabricating

the ostomy device to have physical attributes selected in accordance with the measurement information, the step of fabricating comprising the sub-step of forming the wafer separated from the pouch to have said physical attributes for the wafer".

Claim 1 of the third auxiliary request reads as follows:

"A method for fabricating customized ostomy devices including a wafer (12, 18) and a collection pouch (14, 20) wherein the wafer is an adhesive wafer and the method comprises the following steps: measuring the surface or topography of the stomal area of the patient; recording information relating to the measurements of the stomal area; transforming the recorded information into electronic form; utilizing the electronic information to select the physical attributes of the ostomy device, including physical attributes for the wafer (12, 18); and fabricating the ostomy device to have physical attributes selected in accordance with the measurement information, and wherein the step of utilizing the electronic information comprises the step of selecting the surface contour of the adhesive wafer (12, 18) in accordance with said information and the step of fabricating the ostomy device comprises the step of forming the adhesive wafer (12, 18) with the selected surface contour separated from the pouch to have said physical attributes for the wafer".

VII. The parties argued as follows:

Appellant

Claim 1 of all requests included the feature "the step of fabricating the ostomy device comprises the step of forming the adhesive wafer with the selected surface contour separated from the pouch", for which there was no basis in the application as originally filed. The patent in suit did not rule out forming the adhesive wafer with given physical attributes while it was attached to the pouch. Figures 9 to 11 and 15 of the patent illustrated the wafer on its own but it was not known how this stage was arrived at, and paragraphs 22 to 28 of the patent, for example, also did not rule out working the wafer while it was attached to the pouch. This amendment took the parties by surprise since there was no indication that this would ultimately become the invention.

The claimed method (main request) was merely the automation of a known manual process as described in paragraphs 3 and 4 of the patent. This was in line with general trend and not inventive. The method of claim 1 differed from the method disclosed in D1 by three features: a) The use of an adhesive wafer b) transforming the recorded information into electronic form and utilizing this electronic information c) forming the wafer with selected physical attributes separated from the pouch. The corresponding partial problems were not related and each of these differences was known so the claimed method amounted to combining known steps for their known purpose.

D5 covered both one and two-piece devices and it disclosed the manufacture of adhesive wafers separate

from the bag. Thus, starting from D5, the only distinguishing feature of claim 1 was b) which, for the same reasons as given in the case of D1, was not inventive.

The new features of the auxiliary requests were disclosed in D1 or were well known. The selection of tools, etc was known technology (paragraphs 94 and 110 of the patent). The use of convex inserts and pastes to contour the wafer surface was admitted as being known in the patent (paragraphs 6 and 36) so that this feature of claim 1 of the auxiliary request was not inventive if claim 1 were to be broadly interpreted.

The respondent's argument regarding the convex inserts were new so the oral proceedings should be postponed.

Respondent

Throughout the patent the combination of the wafer attached to the pouch was referred to as a "device", whereas in the separated state they were referred to as a "wafer" and a "pouch", respectively. Paragraphs 22 to 24 of the patent, for example, described forming the wafer with the selected surface contour, so this was a clear and unambiguous disclosure to support the amendment at the end of claim 1.

Figure 1 was a general schematic of the claimed method and showed a laser cutting a wafer, no pouch was shown or mentioned in the description with reference to Figure 1. Figure 3 showed a wafer and a pouch separately, and Figures 9, 11, and 15 showed the wafers only.

The word "fabricating" in claim 1 was important because the invention was not concerned with a method of adaptation but of fabrication. Prior art ostomy devices were fabricated with standard attributes of the wafer which each individual could customise himself, as disclosed in D1 and D5.

The features b) and c) did have a synergy because in combination they allowed fabrication of ostomy devices under computer control. The reference in D1 to computer control concerned only the operation of the punching tool, for which purpose there was no need to store any information. If D1 were read so that the entire process was under computer control, then D1 was not an enabling disclosure.

D5 started from existing devices and adapted them for individual use, it did not relate to a process of fabricating a wafer with certain attributes. D5 did not disclose the steps of recording information, transforming the information into electronic form, utilizing the electronic information to select the physical attributes of the ostomy device, and fabricating the ostomy device to have physical attributes selected in accordance with the measurement information.

D1 and D5 did not disclose the essence of the invention including the steps of measuring the patient, recording information, transforming it into electronic form, utilising it, downloading into a computer, etc. The advantage of the combination of steps claimed was that

the device could be fabricated fully customised rather than being pre-formed and later adapted by the user.

The use of a wafer with a surface contour (third auxiliary request) enabled the device to better fit the user.

Reasons for the decision

1. The appeals are admissible.

2. *Amendments*

For the reasons given below the Board is satisfied that the feature "the step of fabricating the ostomy device comprises the step of forming the adhesive wafer with the selected surface contour separated from the pouch" is adequately supported by the application as originally filed.

The description of the patent corresponds to the original description, so for the sake of convenience passages of the patent rather than the application will be cited. The patent relates to an ostomy device, which is defined in paragraph 4 as "The basic device includes a collection receptacle or pouch connected to an adhesive coated wafer". Original claim 1 also relates to ostomy devices including an adhesive wafer and a collection pouch. The entire patent consistently mentions a "device" when talking of a pouch attached to a wafer (e.g. paragraphs 21, 88, and 89), and refers to "a wafer" or "a pouch" when talking of the individual components themselves.

The patent is self-consistent in this respect. For example the description with respect to Figures 9 to 11 discusses working on a wafer, and these Figures illustrate a wafer only, without a pouch. Paragraph 89 states that a controller directs each operation and fabricates the desired number of wafers and pouches of the selected materials and causes the wafers, pouches and accessories to be packed and shipped. This is also an indication that the wafer is made separately from the pouch. There is no contradiction of this view with the totality of the patent.

For these reasons the amplification of granted claim 1 by this feature is allowable under Article 123(2) EPC.

3. *Interpretation of D1*

The opening passages of D1 state that the invention relates to a method of adapting the connection opening of a traditional stoma emptying device to a stoma, and claim 1 of D1 also relates to "A method of adapting the connection opening of a stoma emptying device to a stoma".

Towards the end of the description of D1 (column 4, lines 7 and 8) there is the statement that it is conceivable within the scope of the invention that the adaptation process be carried out controlled by computer. This passage refers to "the adaptation process" which, in light of the above paragraph, refers to the entire process. Thus, the cited passage in column 4 means that the entire process could be carried out under computer control.

The appellant argued that if the cited passage is given this interpretation then D1 is not an enabling document. This argument is not persuasive given that, at the priority date of the patent in suit, manufacturing processes under computer control were routinely performed in the medical industry and no inventive step is required to automate the prior art methods. This is supported by the fact that the patent in suit itself gives no details of the computer control, it simply employs known technology, not only as regards tools and materials (see point 5. below), but also regarding computer control.

4. *Inventive step main request*

4.1 In light of the above D1 discloses all the steps of claim 1 except for the steps a) The use of an adhesive wafer and c) forming the wafer with the selected physical attributes separated from the pouch. This analysis was accepted by the respondent, except that it argued that the feature b) (transforming the recorded information into electronic form and utilizing this electronic information) also provided a difference. The respondent also accepted that feature a) did not involve an inventive step.

The feature c) is not technically related to feature a) and may be inspected separately for inventive step. The Board is of the view that feature c) (forming the wafer with the selected physical attributes separated from the pouch) does not involve an inventive step. Especially in the case of two-piece ostomy devices it is clear to the person skilled in the art that the

wafer can be worked more easily when it is detached from the pouch than when the two are attached together since the pouch would then interfere with operations performed with the wafer, or some protection would need to be provided for the pouch (see D1). It would be obvious for the person skilled in the art that working the wafer separated from the pouch would simplify the adaptation process. The separate working of a wafer is also well known in the art as exemplified by D8.

Claim 1 of the main request does not involve an inventive step, accordingly.

4.2 The respondent argued that the presently claimed method is fundamentally different from the methods of D1 and D5 in that the present method is for fabricating of an ostomy device whereas the prior art methods are for adapting an already fabricated device to suit an individual. The Board considers this to be an artificial distinction since the point when fabrication ends and adaptation begins is a matter of definition.

According to the description of the patent with reference to Figures 4 to 6 a card having a small starter hole 42 could be trimmed to the exact size and shape required by the user to fit his/her stoma (paragraph 76). This may be considered to comprise the step of adapting a given sheet 38, which is then used by a computer to fabricate the device. Thus, the whole fabrication process involves adaptation at some stage and whether the adaptation is performed during the measuring stage or during the fabricating stage is equivalent, no inventive step is involved in selecting the one or the other stage.

5. *Inventive step first and second auxiliary requests*

Claim 1 of these requests include the steps of downloading the recorded information into a computer and utilizing the electronic information in the computer to cause fabrication equipment to select the appropriate materials and tooling and to guide the tools to fabricate the ostomy device, or to select a tool for cutting the stoma receiving hole in the wafer and wafer outline and a tool for welding the pouch periphery. In short the process is computer-controlled.

In a process under computer control it is a safe assumption that as many process steps as possible would be under computer control, including the selection of appropriate materials and tools, as well as their guidance for performing routine tasks such as cutting and welding. That the patent uses known technologies for their known purpose is indicated in paragraphs 94 and 110 of the patent. No details of the technologies are given because they are well known.

Thus, these claims describe the automation of a process which was previously performed manually, and that is not considered to involve an inventive step.

6. *Inventive step third auxiliary request*

Claim 1 of the third auxiliary request includes the steps of selecting the surface contour of the adhesive wafer in accordance with recorded information and forming the adhesive wafer with the selected surface contour. The surface contour of the wafer enables it to

conform with skin surface irregularities such as folds, crevices and depressions (see paragraph 95 of the patent).

Clearly this affords a closer fit of the device to a stoma and, therefore, a better seal thereof together with better patient comfort. Such modification of a wafer is not disclosed or suggested in the prior art and involves an inventive step, accordingly.

The appellant's argument that the convex inserts of the prior art, mentioned in paragraphs 6 and 36 of the patent in suit, correspond to this feature of claim 1, is not convincing. A convex insert would not alter the surface contour which word, in the context, implies an irregular shape for conforming with irregularities of the skin surface. Also, the paste referred to in these passages is not clearly for altering the surface contour of the wafer.

Therefore, claim 1 of the third auxiliary request involves and inventive step.

7. *Dependent claims*

The appellant objected to dependent claims 6 to 53 of the third auxiliary request on the grounds that they were late filed, i.e. at the oral proceedings, and because deletion of claim 4 results in combinations of features not originally disclosed.

The opposition division upheld claims 1 to 54 of the fourth auxiliary request, which included claims 7 to 54, corresponding to claims 6 to 53 of the third auxiliary

request presently on file. In response to the appeals the respondent filed, by letter dated 1 November 2007, sets of claims of which the third auxiliary request had the features relating to surface contours. The letter requested that the patent be upheld as amended in the manner described in the interlocutory decision in opposition proceedings, and auxiliary requests were submitted in the event that the main request could not be maintained.

For convenience the claims filed with that letter included only those pages which were amended and, in the absence of an express statement that the remaining dependent claims were abandoned, the Board's understanding is that the remaining dependent claims were to be appended to those filed with said letter.

Claims 7 to 54 were always on file, consequently, and their being appended to claims 1 to 5 of the allowed third auxiliary request does not amount to their being late filed.

Another consequence of this is that any objection to the dependent claims under Article 123(2) EPC is a late-filed objection. In order to examine the claims thoroughly under Article 123(2) EPC the Board would have to remit the case to the opposition division for consideration of this objection, which would delay a final decision on the case inordinately. The Board decides not to admit this objection, accordingly.

The Board leaves it to the department of the first instance only to adapt the description to the claims of the third auxiliary request.

8. Postponement of oral proceedings

The appellant requested postponement of the oral proceedings because the subject-matter of claim 1 of the third auxiliary request, which was upheld at the oral proceedings, had not been searched and the arguments of the respondent concerning the surface contour of the adhesive wafer were presented for the first time at the oral proceedings.

The Board refuses this request because the third auxiliary request corresponds to the sixth auxiliary request filed with the respondent's response to the appeal, over a year before the oral proceedings. The appellant has had adequate time both to search this claim and to consider the inventive merits of all its features.

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 the first instance to maintain the patent on the basis of claims 1 to 53 of the third auxiliary request filed during the oral proceedings, a description to be adapted to the claims, and drawings as granted.

The Registrar The Chairman

D. Sauter M. Noel