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Datasheet for the decision of 13 March 2012

Case Number: T 0325/10 - 3.2.08

Application Number: 02779226.6

Publication Number: 1429696

IPC: A61F 5/448, A61F 5/441, A61F 5/443

Language of the proceedings: EN

Title of invention:
An ostomy appliance

Patent Proprietor:
Coloplast A/S

Opponent:
Hollister Incorporated

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 54(1)(2), 56, 83

Keyword:
"Allowability of amendments - yes"
"Sufficiency of disclosure - yes"
"Novelty - yes"
"Inventive step - yes"

Decisions cited:
-

Catchword:
-

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Case Number: T 0325/10 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 13 March 2012

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

Representative:
Nilausen, Kim
c/o Coloplast A/S
Holtedam 1
DK-3050 Humlebaek (DK)

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

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

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 15 December 2009 revoking European patent No. 1429696 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

I. By its decision posted on 15 December 2009, the opposition division revoked the European patent EP 1 429 696. On 15 February 2010 the appellant (patent proprietor) filed a notice of appeal against this decision and paid the appeal fee on the same day. The statement of grounds was received on 26 April 2010 (the 25 April being a Sunday).

II. The appellant requested that the decision under appeal be set aside and the opposition be rejected or the patent be maintained on the basis of one of the auxiliary requests A or B filed with the grounds of appeal.

The respondent (opponent) requested that the appeal be dismissed.

III. Independent claim 1 as granted reads:

"An ostomy appliance comprising a body side member (3)

comprising an adhesive wafer for securing the appliance to the user's skin,

said wafer having a hole (7) for receiving a stoma (5),

wherein the body side member comprises first substantially annular coupling means (2) for releasable attachment of a separately exchangeable receiving bag to the body side ostomy member for receiving secretions from the stoma,

said receiving bag comprising matching second substantially annular coupling means,

wherein the body side member comprises a separate sealing member for sealing against the stoma,

wherein the separate sealing member is in the form of a disc (1) having a centre hole (4) for accommodating the stoma (5) and

wherein at least the surface of the disc facing the skin of the user comprises a mass of a skin-friendly adhesive,

wherein the disc has a maximum outer diameter corresponding to the inner diameter of the first annular coupling means and

wherein the centre hole (4) of the disc (1) has a diameter smaller than the diameter of the stoma-receiving hole (7) of the body side member

ensuring that the disc (1) covers all of the surface of the adhesive wafer facing away from the user located between the first annular coupling means and the stoma **(feature K)**,

characterised in that

the disc is made from a material that may be detached,

rinsed with water without detergents (**feature M**) and

reapplied (**feature N**)."

The designation of the features K, M and N has been introduced by the Board.

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

D1: EP-A-0 998 247
D6: WO 98/53771
D8: US-A-4 831 070
D18: US-A-5 827 528

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

(a) Allowability of the amendments

The meaning of the verb "to rinse" intrinsically implied the use of water without a detergent. Moreover, this term had to be understood taking into consideration the whole disclosure of the original application, which disclosed water as the only solvent used for rinsing.

Hence feature M could be derived directly and unambiguously from the original application and claim 1 complied with the requirements of Article 123(2) EPC.

(b) Sufficiency of disclosure

The patent in suit related to a sealing disc for an ostomy device, which was defined by its functional features. Since guidance in the selection of a suitable material was given by providing one example, namely a silicone, the patent disclosed one way of carrying out

the invention and therefore complied with the requirements of Article 83 EPC (1973).

(c) Novelty

Neither D1 nor D6 disclosed all the features of claim 1.

Figure 18 of D1 and Figure 5 of D6 showed a radial gap between the sealing disc and the left part of the coupling means. Hence the two documents did not disclose feature K of claim 1.

Moreover, even if the material of the discs according to D1 and D6 tolerated water, this did not intrinsically imply that they could be rinsed with water without detergent (feature M). Furthermore, neither of the two documents disclosed sealing discs which could be reapplied after having been rinsed (feature N).

Therefore, the subject matter of claim 1 was novel with respect to D1 and D6.

(d) Inventive step

Features M and N addressed the problem of extending the service time of the body side member of the ostomy device. The skilled person would not even take D8 into consideration when looking for a solution for this problem, since this document did not address this problem and did not refer to a sealing disc but rather to an adhesive positioned between the wafer and the skin (see column 8, lines 40 to 48).

Hence the subject matter of claim 1 also involved an inventive step.

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

(a) Allowability of the amendments

The original application dealt with the issue of cleaning and rinsing of the sealing disc in several passages. However, it never disclosed the subject matter of feature M, which requires that the disc is made of any material that may be "rinsed in water without detergents".

Page 5, lines 13 and 14 of the application as published referred to a disc which may be **rinsed**, but without specifying with what solvent. Since it was possible to "rinse" an object using different solvents with or without detergents, this verb on its own did not imply intrinsically the use of water without detergents as required by feature M.

The application further disclosed the use of **water** on page 5, line 21 and on page 7, lines 1 to 4; however, these passages referred to cleaning and not to rinsing and did not specify that no detergents were to be used.

Page 7, lines 14 to 15 of the application described indeed discs which can be cleaned by rinsing with water "**without having to rely on the use of a detergent**". However, this way of rinsing was disclosed exclusively in combination with a disc made of silicone. Since claim 1 did not specify the material of the disc,

omitting this feature led to an intermediate generalisation and was contrary to the requirements of Article 123(2) EPC.

(b) Sufficiency of disclosure

It was correct that the description disclosed silicone as an example of a material for the sealing disc which was able to satisfy the requirements of functional features M and N. However, not all silicones fulfilled the functional features of the claim. Since the patent did not define the properties leading to the choice of suitable silicones, the skilled person would need to select a suitable material from the broad range of silicones by trial and error. Since this amounted to an undue burden, the patent did not disclose the invention in such a way that it could be carried out by the skilled person.

(c) Novelty

D1 and D6 disclosed all the features of claim 1. Particularly, Figure 5 of D6 and Figure 18 of D1 disclosed a disc which covered the whole surface of the adhesive wafer facing away from the user located between the first annular coupling means and the stoma (feature K).

Since both claim 1 of D1 and claim 9 of D6 foresaw that the sealing disc had a cohesion sufficient to allow it to be removed in one piece, and since the disc had to be resistant to the exudes of the stoma, they inherently had to be resistant to water. As shown in D18 (see column 14, lines 39 to 20), the presence of

hydrocolloids in an adhesive did not imply that they were not resistant to water or changed their shape significantly when exposed to it. Hence, despite containing hydrocolloids, the discs according to D1 and D6 were suitable for being rinsed in water and reapplied to the wafer (features M and N).

Therefore, the subject matter of claim 1 was not novel.

(d) Inventive step

The subject matter of claim 1 differed from the ostomy appliance according to D1 or D6, by features K, M and N. These features were not functionally linked and hence addressed different technical problems.

Extending the sealing disc up to the coupling means (feature K) did not have any technical effect, did not solve any technical problem and hence could not involve any inventive activity.

The problem addressed by features M and N was the provision of an alternative material inherently having the properties of these features. The skilled person looking for an alternative adhesive material would take D8 into consideration since it related to mouldable adhesives suitable for ostomy appliances (see column 1, lines 11 and 12). The adhesive of D8 was a silicone based pressure sensitive adhesive which did not disintegrate in water (see column 2, lines 47 to 59). Since, as described in the patent in suit, silicone adhesives were suitable for being rinsed in water and reapplied, the application of the adhesive according to D8 to the device of D1 or D6 would lead the skilled

person in an obvious way to the subject matter of features M and N.

Hence the subject matter of claim 1 did not involve an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Allowability of the amendments

It is correct that the original application does not disclose the exact wording of feature M which requires that the disc may be "rinsed with water without detergents". Therefore, in order to assess whether or not the subject-matter of claim 1 extends beyond the application as filed, it has to be determined whether the skilled person would consider this feature as being necessarily implied by the patent application as a whole.

The verb "to rinse" is generally understood as washing out or clean with clean water and implicitly with no detergent. Only in specific technical areas is it used in the sense of washing with a solvent different from water or washing with water and a detergent. Due to the different possible interpretations of the verb, it is necessary to consider the description in order to construe the meaning of the word in the sense of the invention.

The only solvent specified in the original application is water (see page 5, line 21; page 7, lines 3, 14 and 23) and no other solvent is either disclosed or suggested.

It is correct that the use of water is disclosed on page 5, line 21 in combination with the verb "to clean" and not "to rinse". However, since both verbs have to be understood in the sense of "to free from dirt, filth or impurities" they can be interchanged and this passage therefore discloses the rinsing of the sealing disc with water.

Moreover, the application never addresses or suggests the use of any detergent in combination with the rinsing of the sealing disc. It is correct that the application specifies that no detergent is used only when addressing the rinsing of a disc made of silicone (see page 7, lines 14 and 15). However, there is no reason why the skilled person would assume from the description as a whole that sealing discs made of a material different from silicone were supposed to be rinsed with water and a detergent.

Since the verb "to rinse" can be understood in the light of the description only as cleaning with water and without any detergent, the wording of feature M, requiring "rinsing with water without detergents" is merely tautologous.

Since the subject matter of feature M was at least implicitly disclosed in the original application, claim 1 fulfils the requirements of Article 123(2) EPC.

3. Sufficiency of disclosure

Article 83 EPC (1973) establishes that the invention shall be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Sufficiency of disclosure must be assessed on the basis of the application as a whole, namely the description, claims and any drawings supplemented by the common general knowledge of the person skilled in the art.

In the present case it is undisputed that the description of the patent in suit discloses at least one material - silicone - which complies with the requirements of the characterising features of claim 1 (see column 5, lines 35 to 39 and 51 to 57).

The Board concurs with the respondent that not all silicones are suitable for making a sealing ring of an ostomy appliance.

However, the disclosure of the patent is aimed at a skilled person who, when selecting a material for the disc, would only consider those silicone-based adhesives with the desired characteristics and would exclude those which are obviously unsuitable.

The selection of those silicones which fulfil the requirements of feature M from amongst known silicones does not represent an undue burden for a skilled person, since it does not require more than routine work. Therefore, the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4. Novelty

4.1 D1 and D6 disclose (see particularly Figures 17 and 18 of D1 and Figures 4 and 5 of D6):

An ostomy appliance comprising a body side member comprising an adhesive wafer (2) for securing the appliance to the user's skin, said wafer having a hole for receiving a stoma, wherein the body side member comprises first substantially annular coupling means (18) for releasable attachment of a separately exchangeable receiving bag to the body side ostomy member for receiving secretions from the stoma, said receiving bag comprising matching second substantially annular coupling means, wherein the body side member (5) comprises a separate sealing member for sealing against the stoma, wherein the separate sealing member is in the form of a disc having a centre hole for accommodating the stoma and wherein at least the surface of the disc facing the skin of the user comprises a mass of a skin-friendly adhesive (see page 5, lines 22 to 23 of D1; page 8, lines 8 to 10 of D6), wherein the disc has a maximum outer diameter corresponding to the inner diameter of the first annular coupling means and wherein the centre hole of the disc has a diameter smaller than the diameter of the stoma-receiving hole of the body side member the disc is made from a material that may be detached (see page 7, lines 4 to 5 of D1; page 11 lines 15 to 20 of D6).

4.2 Figure 18 of D1 and Figure 5 of D6 both show on the left hand side a radial gap between the sealing disc

and the coupling means. It is correct that on the right side the sealing disc appears to extend up to the coupling means; however, at least a part of the wafer's surface is not covered by the sealing disc. Since feature K of claim 1 requires that the disc covers the entire surface of the wafer located between the coupling means and the stoma, the ostomy appliances according to D1 and D6 do not comprise this feature.

The sealing discs according to D1 (see claim 1) and D6 (see claim 9) are made of materials comprising hydrocolloid components. They are supposed to resist exudates from the stoma and hence water and show a sufficient cohesion to allow them to be removed in one piece from the ostomate's skin without leaving remaining adhesive. Therefore, it can be assumed that they do not disintegrate when brought into contact with water.

However, a material which does not disintegrate upon contact with water is not necessarily intrinsically suitable for being rinsed in water in order to remove dirt and impurities. Therefore, neither D1 nor D6 disclosed feature M of claim 1.

Moreover, neither of these documents discloses a disc intended to be reapplied and made of a material suitable for this purpose (feature N). A material which does not disintegrate in water is not intrinsically suitable to be reused, as is evident for the adhesives used in D1 and D6, which swell under the influence of humidity (see page 6, lines 6 to 9 of D6) and therefore cannot be reused.

It is correct that D18 discloses adhesives comprising hydrocolloids which do not swell substantially due to the absorption of water (see column 14, lines 39 to 50). However, these values relate to the specific composition of the adhesives of D18, which are different from those used in D1 and D6, the latter relying precisely on the swelling characteristics of the adhesives in order to ensure sealing effects (see e.g. page 12, lines 6 to 9 of D6).

4.3 Since D1 and D6 do not disclose features K, M and N of claim 1 the subject matter of claim 1 is novel over the devices disclosed in these documents.

5. Inventive step

5.1 The ostomy appliances according to D1 or D6 represent the most relevant prior art.

Starting from these ostomy devices, the technical object to be achieved by the present invention is the extension of the service time of the body side member - which comprises the adhesive wafer and the sealing disc - and thus the reduction of the frequency of stressing the skin around the stoma (see column 3, lines 3 to 6).

In order to achieve this object, the ostomy appliance according to claim 1 comprises features M and N.

5.2 None of the cited prior art documents discloses or suggests rinsing the sealing disc with water without detergents and reapplying it to the adhesive wafer. On the contrary, both D1 and D6 require that the sealing

disc is detached, disposed of and exchanged for a new one when its lifetime has ended (see e.g. D6, page 17, lines 17 to 19 and claim 7).

5.3 It is correct that D8 discloses a silicone-based pressure-sensitive adhesive suitable for ostomy seal use which does not disintegrate in water.

However, since D8 does not address the problem underlying the patent in suit, the skilled person would not have any reason to take its teaching into consideration for solving it.

Moreover, D8 fails to suggest the use of an adhesive for a seal ring which can be reused after having been rinsed. On the contrary, since some of the preferred embodiments of D8 disclose adhesives including water-soluble hydrocolloid gums, this document rather suggests that the adhesive is not suitable for repeated use but that it has to be discarded and replaced after the first time it has been detached.

5.4 Hence the subject matter of claim 1 also involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The opposition is rejected.

The Registrar: The Chairman:

V. Commare T. Kriner