

**Internal distribution code:**

- (A)  Publication in OJ  
(B)  To Chairmen and Members  
(C)  To Chairmen  
(D)  No distribution

**D E C I S I O N**  
**of 14 September 2004**

**Case Number:** T 0201/02 - 3.2.6

**Application Number:** 96304868.1

**Publication Number:** 0756854

**IPC:** A61F 13/02

**Language of the proceedings:** EN

**Title of invention:**

Wafer having adhesive skin barrier layer and production method therefor

**Patentee:**

Hollister Incorporated

**Opponent:**

Coloplast A/S

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 54(2), 56

**Keyword:**

"Novelty (yes)"

"Inventive step (yes)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0201/02 - 3.2.6

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.6  
of 14 September 2004

**Appellant:** Coloplast A/S  
(Opponent) Holtedam 1  
DK-3050 Humlebaek (DK)

**Representative:** Beetz & Partner  
Patentanwälte  
Steinsdorfstrasse 10  
D-80538 München (DE)

**Respondent:** Hollister Incorporated  
(Proprietor of the patent) 2000 Hollister Drive  
Libertyville  
Illinois 60048-3781 (US)

**Representative:** Kensett, John Hinton  
Saunders & Dolleymore  
9 Rickmansworth Road  
Watford  
Hertfordshire WD18 0JU (GB)

**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 20 December 2001  
rejecting the opposition filed against European  
patent No. 0756854 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** P. Alting van Geusau  
**Members:** G. Pricolo  
R. T. Menapace

## Summary of Facts and Submissions

I. The appeal is from the decision of the Opposition Division posted on 20 December 2001 to reject the opposition filed against European patent No. 0 756 854, granted in respect of European patent application No. 96304868.1.

In the decision under appeal the Opposition Division considered that the subject-matter of the independent product claim 1 and method claim 4 was novel and also involved an inventive step over the cited prior art represented by documents

D1: US-A-4 867 748;

D2: EP-A-340 945;

D3: Woebcken, Wilbrand, "Erreichbare Maßgenauigkeiten bei Spritzgußteilen", in "Industrie-Anzeiger, Kunststoffe-verarbeitung und Anwendung", 92. Jg. Nr. 102, pages 2459 to 2465;

D4: Wilgenbus: "Spritzprägen von Formartikeln", in "Spritzgießen technischer Gummi-Formteile", VDI-Verlag, Düsseldorf, 1981, pages 162 to 171;

D5: Bangert, Hartmann: "Eigenschaften und Verarbeiten von LCP" in: "Neue Werkstoffe und Verfahren beim Spritzgießen", VDI-Verlag, Düsseldorf, 1990, pages 1 to 39;

- D6: Knappe, Lampl: "Zum optimalen Zyklusverlauf beim Spritzprägen von Thermoplasten", Kunststoffe 74 (1984) 2, pages 79 to 83.
- II. The appellant (opponent) lodged an appeal, received at the EPO on 19 February 2002, against this decision and simultaneously paid the appeal fee. The statement setting out the grounds of appeal was received at the EPO on 26 April 2002.
- III. In an annex to the summons for oral proceedings pursuant to Article 11(2) of the Rules of Procedure of the boards of appeal the Board expressed its preliminary opinion that, as concerned the alleged lack of novelty objection relied upon by the appellant, it would appear that D1 did not directly and unambiguously disclose an adhesive wafer having an annular outer zone where the molecules of the barrier layer had uniform radial orientation in radial directions over an arc of 360° about a central zone. However, considering granted method claim 4, which was not restricted to the manufacture of an adhesive wafer having all the features defined in claim 1, a method of making a wafer by means of a compression moulding process in which a mound of skin barrier material was displaced radially in directions extending 360° about the original location of deposit of said mound in the mould appeared to be known from D2.
- IV. Oral proceedings took place on 13 September 2004.
- The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained on the basis of the claims 1 to 3 filed during the oral proceedings, with the description and drawings as granted.

V. Claim 1 reads as follows:

"1. An adhesive wafer comprising (a) a thin barrier layer (11) of soft, pliant, adhesive material having particles of one or more hydrocolloids dispersed therein and having upper and lower surfaces, (b) a flexible cover layer (13) extending over one of said surfaces of said barrier layer, and (c) a removable release sheet (12) extending over the other of said surfaces of said barrier layer; wherein said wafer has a central zone (23) and an annular outer zone (22); characterised in that said material of said barrier layer in said outer (22) zone is of generally uniform molecular orientations in radial directions over an arc of 360° about said central zone (23) and is of substantially uniform tensile strength when measured in all of said radial directions."

VI. In support of its requests the appellant relied essentially on the following submissions:

D1 disclosed an annular adhesive wafer having bevelled edges. The latter were formed by pressing a blank between a plate and a mould. During the pressing step, adhesive material was forced to flow radially; as a consequence the molecules of the adhesive material in the bevelled zone were oriented in radial directions in a generally uniform manner over an arc of 360°. Still in accordance with the teaching of D1, the bevelled

wafer could also be obtained by a die-casting process in which a mass of adhesive was injected in a mould between two siliconized sheets. D1 did not disclose where the adhesive was injected into the mould, but the skilled person would only consider the possibility of injecting it from a central opening of the mould. Thus a wafer with adhesive having generally uniform molecular orientations in radial directions over an arc of 360° was inevitably obtained. Therefore, the claimed subject-matter was not novel over D1. Also D2 destroyed the novelty of the claimed subject-matter because it disclosed a method of manufacturing an adhesive wafer in which an adhesive mass was compression moulded between two sheets of silicone release paper. The thus obtained adhesive wafer was necessarily provided with an outer zone of generally uniform molecular orientations in radial directions over an arc of 360° about a central zone.

In any case, the subject-matter of claim 1 lacked an inventive step. The users of adhesive wafers in accordance with D1 would notice the non-uniformity of physical properties of the wafers, in particular because it affected wearing comfort. For example, the users of ostomy pouches equipped with the wafers would remark that when these leaked, it was because the physical properties of the adhesive wafers were non-uniform. Thus, the skilled person would obviously take into consideration the technical problem of improving the uniformity of physical properties of the wafer known from D1 and in doing so would focus on the properties of the adhesive layer. In order to solve this problem, the skilled person would turn to D3, or D4 or D5, all of which disclosed the solution in

accordance with claim 1 of the patent in suit, consisting in providing the adhesive material with generally uniform molecular orientations in radial directions over an arc of 360°.

VII. The respondent essentially argued as follows.

The skilled person would not derive directly and unambiguously from either D1 or D2 the feature of claim 1 regarding the alignment of the molecules of the adhesive material in a radial direction. In particular, there was no indication in D1 concerning the amount of bevelling that could result in generally uniform molecular orientations in radial directions. Uniform molecular orientations were also not obtained in D2 because after the step of compression moulding an adhesive mass between two sheets of silicone release paper the thus obtained laminate structure was die cut into a desired shape. Furthermore, there was no indication in D1 of any disadvantages caused by the non-uniformity of physical characteristics of the adhesive material, nor was there any evidence that such disadvantages were ever remarked in use. Thus, since the acknowledgment of the problem to be solved by the claimed invention was new itself and there was no basis for the skilled person to even consider improving the adhesive wafer of D1, the claimed subject-matter involved an inventive step.

## Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The patent in suit is amended only by way of deletion of the method claims 4 to 19. Product claims 1 to 3, the description and the drawings are identical to those of the patent as granted. Therefore, the amendments do not give rise to objections under Article 123(2) and (3) EPC.

3. *Novelty*

3.1 D1 discloses an adhesive wafer in accordance with the preamble of claim 1, comprising a thin barrier layer (sealing pad 4) of soft, pliant, adhesive material having particles of one or more hydrocolloids dispersed therein and having upper and lower surfaces (column 3, lines 27 to 33), a flexible cover layer (5) extending over one of said surfaces of said barrier layer, and a removable release sheet (protective cover 6) extending over the other of said surfaces of said barrier layer (column 3, lines 34 to 37); wherein said wafer has a central zone and an annular outer zone (Fig. 2).

The teaching of D1 consists in providing a dressing (i.e. adhesive wafer) which is bevelled along its outer edges (see claim 1). According to D1, the dressing can be manufactured in various ways and in particular by first providing a starting blank consisting of adhesive material and cover layer (see column 5, lines 44,45) and then bevelling the starting blank by pressing it



between a plane bottom plate and a mould (column 5, lines 35 to 50) where a protective cover (release sheet) is present (column 5, lines 51, 52). Since D1 is silent about how the starting blank is manufactured, nothing can be said about the orientations of the molecules of adhesive material in said starting blank. During the bevelling operation, the adhesive material of the starting blank is displaced in order to form the bevelled edges, as correctly argued by the appellant. However, there is no basis to conclude that a necessary consequence of the bevelling operation is to produce a zone of generally uniform molecular orientations in radial directions. In fact, the molecules of adhesive material in the starting blank might well have random orientations and the re-arrangement of the molecules during the pressing (bevelling) step, the intensity of which is not further described, might not be sufficient to change the random orientations into generally uniform radial orientations. According to a second alternative disclosed in D1, the dressing can be manufactured by a die-casting process (see column 5, line 53 to column 6, line 9) comprising the steps of leading a web of material for the cover layer and a web of material for the release sheet across an injection casting mould which has a hollow space between the two sheets corresponding to the intended shape of the dressing, and casting the adhesive mass at a suitable temperature. However, since D1 does not specify where the inlet for injecting the adhesive is provided, nothing can be said about the orientations of the molecules in the finished dressing. In this respect, the appellant's argument according to which the skilled person would necessarily dispose such inlet in the centre of the mould is speculative. In fact, injecting

the adhesive from a side of the mould is a possibility which the skilled person would seriously take into consideration because the adhesive must be injected between the web of cover layer material and the web of release sheet material. Moreover, there is no evidence that the process of injection casting results in a preferential orientation of the molecules.

It follows that D1 does not disclose the features of the characterizing portion of claim 1 according to which the material of the barrier layer in said outer zone is of generally uniform molecular orientations in radial directions over an arc of 360° about said central zone and is of substantially uniform tensile strength when measured in all of said radial directions.

- 3.2 Using the wording of claim 1, D2 discloses (Figs. 1, 2) an adhesive wafer comprising a thin barrier layer (12) of soft, pliant, adhesive material having particles of one or more hydrocolloids dispersed therein and having upper and lower surfaces, a flexible cover layer (14) extending over one of said surfaces of said barrier layer, and a removable release sheet (18) extending over the other of said surfaces of said barrier layer (page 4, lines 35 to 40). D2 further discloses to produce the wafer by compression or injection moulding (page 4, lines 16 to 19 and page 66, lines 25 to 27) or by extrusion (page 9, lines 34, 35). However, the compression or injection moulding step is carried out to produce a sheet of stock material comprising an adhesive layer disposed between two sheets of silicone release paper, and the desired wafer shape is cut from this sheet of stock material (page 6, lines 27 to 32).

Thus, even admitting that the compression or injection moulding step results in uniform radial orientations of the molecules of adhesive of the sheet of stock material, the fact that the wafers are cut from said sheet implies that such orientations are no longer present in the finished wafer, unless, but this has no basis in the disclosure of D2, the shapes are cut in a manner suitable (e.g. concentric annular shapes) for maintaining such orientations in the finished wafer.

Therefore, the subject-matter of claim 1 is novel over the disclosure of D2.

3.3 Since also the other available prior art does not disclose an adhesive wafer having all the features of claim 1, its subject-matter is found to be novel (Article 52(1) and 54(2) EPC).

4. *Inventive step*

4.1 The problem underlying the patent in suit is to provide adhesive wafers having more uniform physical characteristics (see column 2, line 58 to column 3, line 16), such as strength of the barrier material both prior to and following hydration, tendency to shrink in storage, rate of absorption or erosion, the routes of saturation, swelling and/or leakage.

4.2 Starting from the adhesive wafer known from document D1, which undisputedly represents the closest prior art, this technical problem is effectively solved by means of the distinguishing features defined in the characterizing portion of claim 1 (see above point 3.1), according to which the material of the barrier layer in

an outer zone is of generally uniform molecular orientations in radial directions over an arc of 360° about a central zone and is of substantially uniform tensile strength when measured in all of said radial directions.

- 4.3 D1 does not disclose that the adhesive wafers should have uniform physical characteristics in radial directions and that if this is not the case inconveniences would arise during use. On the basis of the disclosure of D1 there is therefore no reason for the skilled person to even consider the posing of the above mentioned technical problem.

The appellant essentially argues that the user and the skilled person would note that the properties of existing wafers vary depending on the direction in which these properties are measured and that the skilled person would then consider to provide uniform orientations of the molecules of adhesive material in radial directions. However, even if the skilled person would note that the properties of existing wafers vary depending on the direction in which these properties are measured, there is no indication in the available prior art represented by documents D1 to D6 that could suggest that such non-uniformity is due to the manner in which the molecules of adhesive material are oriented, and thus due to the manufacturing process since the orientations of the molecules depend on it.

In fact, D3 relates generally to injection moulding of plastics and discloses (Fig. 3) that the molecules of injection moulded thermoplastic material are oriented in radial directions about the central injection

orifice whilst those of duroplastic materials are oriented in directions perpendicular to the radial directions. However, D3 is mainly concerned with the dimensional precision obtainable with the moulding process (see the paragraph bridging pages 2459 and 2460) and is silent about the influence of molecular orientations on the physical properties relevant for adhesive wafers, such as the strength of the barrier material both prior to and following hydration, or the tendency to shrink in storage.

Also D4, which generally describes (page 163) an injection compression moulding method, is silent about the influence of molecular orientations on the physical properties relevant for adhesive wafers.

D5 refers to liquid crystal polymers and discloses that the injection moulding or extrusion process have as an effect the orientation of molecules (page 2, left column, last paragraph). However, apart from the fact that the adhesive material of the adhesive wafer of D1 is not a liquid crystal polymer, there is no indication in D5 that would suggest that radial uniform orientations of the molecules of the adhesive material would advantageously influence the physical properties of interest for adhesive wafers.

For these reasons, the subject-matter of claim 1 is not rendered obvious by the prior art and consequently is found to involve an inventive step (Article 56 EPC).

4.4 Therefore, independent claim 1 together with the dependent claims 2 and 3 as filed during the oral proceedings, the description and the drawings of the patent as granted, form a suitable basis for maintenance of the patent in amended form.

## **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the following documents:

**claims:** 1 to 3 filed during the oral proceedings of 14 September 2004;

**description:** columns 1 to 13 of the patent as granted;

**drawings:** figures 1 to 18 of the patent as granted.

The Registrar:

The Chairman:

M. Patin

P. Alting van Geusau