BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 5 August 2010

Case Number: T 0635/08 - 3.3.09

Application Number: 99303539.3

Publication Number: 0955347

IPC: C09J 7/02

Language of the proceedings: EN

Title of invention:
Method for adhering substrates using adhesive devices containing silicone gels

Applicant:
Dow Corning France S.A.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 53(c), 54, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Method for treatment of the human or animal body by therapy or surgery (no)
"Novelty, Inventive step (yes)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0635/08 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 5 August 2010

Appellant: (Applicant)
Dow Corning France S.A.
Le Britannia 20
Boulevard Eugene Deruelle
F-69432 Lyon Cedex 3 (FR)

Representative:
Gillard, Richard Edward
Elkington and Fife LLP
Thavies Inn House
3-4 Holborn Circus
London EC1N 2HA (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 26 November 2007 refusing European application No. 99303539.3 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
F. Blumer

Summary of Facts and Submissions

I. European patent application No. 99 303 539.3 filed on 6 May 1999 in the name of Dow Corning France S.A. was refused by decision of the examining division issued in writing on 26 November 2007.

II. The examining division's decision was based on the set of claims 1 to 12 as originally filed. Claims 1, 7, 8, 10, 11 and 12 read as follows:

"1. In a method for adhering a first substrate to a second substrate with an adhesive device, the improvement comprising the use of an adhesive device comprising:
a carrier sheet, said carrier sheet having at least two surfaces;
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the first substrate; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the second substrate."

"7. The method according to any of the previous Claims in which the first substrate is a prosthesis and the second substrate is a human or an animal body."

"8. A substrate having an adhesive device for adhering it to a second substrate comprising:
a substrate having a surface to be adhered to a second substrate; and

on the surface of the substrate to be adhered to the second substrate, an adhesive device comprising:
a carrier sheet, said carrier sheet having at least two surfaces;
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the substrate; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the second substrate,
wherein the first continuous layer of silicone gel of the adhesive device is adhered to the surface of the substrate to be adhered to a second substrate."

"10. A method for adhering a prosthesis to a human or an animal body comprising:
positioning an adhesive device between the prosthesis and the human or animal body; and
compressing the adhesive device between the prosthesis and the human or animal body, wherein the adhesive device comprises:
a carrier sheet, said carrier sheet having at least two surfaces,
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the human or animal body."

"11. The use of an adhesive device for adhering a first substrate to a second substrate, wherein the adhesive device comprises:
a carrier sheet, said carrier sheet having at least two surfaces;
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the first substrate; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the second substrate."

"12. The use according to Claim 11 wherein the first substrate is a prosthesis and the second substrate is a human or animal body."

III. In its decision the examining division held that Claims 7, 10 and 12 pertained to a method of treatment of the human or animal body by therapy or surgery which was excluded from patentability according to Article 52(4) EPC 1973. It argued in particular that the term "prosthesis" covered both external and internal prostheses and included, as disclosed in the application as filed, devices such as cannulas, tubes or surgical drapes which were used in therapy and surgery.

The examining division also denied novelty for the subject-matter of Claims 1, 8 and 11 over document:

D2 JP-A 10 095072 - Database WPI Section Ch, week 199825 Derwent Publications Ltd., AN 1998-279820, XP002236875;

and denied inventive step for the subject-matter of Claims 1, 8, 10 and 11 vis-à-vis a combination of:

D3 WO-A 94/24964 with
D4 CA-A 2 101 509.

IV. On 23 January 2008 the applicant (hereinafter: the appellant) filed an appeal against the examining division's decision. The prescribed fee was paid on the same day.
The statement of grounds of appeal was submitted on 18 February 2008. Enclosed with the grounds of appeal were sets of claims according to a main request and auxiliary requests 1 to 3, which sought to overcome the objections of the examining division. In particular, the limitation in the newly filed claims that the prosthesis was adhered to the skin of a human or animal body overcame the objection under Article 52(4) EPC 1973. The appellant emphasised that only the aspect of the adherence of the prosthesis to the skin of a human or animal body was relevant to the current invention, regardless of what other activities or aspects might apply to the prosthesis itself, which was not material to the invention as claimed.

V. In a communication dated 25 June 2010 the board indicated that it shared the appellant's view that the method of adhering the prosthesis to the skin of a human or animal body was not excluded from patentability under Article 53(c) EPC.

VI. On 5 August 2010 oral proceedings were held before the board.

With regard to novelty and inventive step the board, in addition to the above-cited documents, made reference to document:

D7 WO-A 96/09076,

which was cited in the application as filed.

In response thereto the appellant withdrew all requests filed in the written proceedings and submitted - as a single request - a set of nine claims according to auxiliary request 4 and description pages adapted thereto. Independent Claims 1, 7, 8 and 9 read as follows:

"1. A method for adhering a first substrate to a second substrate with an adhesive device comprising the use of an adhesive device comprising:
a carrier sheet, said carrier sheet having at least two surfaces;
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 1000 to 4500 g/m^2; said gel having sufficient tack to adhere to the second substrate; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the second substrate,

wherein the first substrate is a prosthesis and the second surface is the skin of a human or an animal body."

"7. A substrate having an adhesive device for adhering it to a second substrate comprising:
a substrate having a surface to be adhered to a second substrate; and on the surface of the substrate to be adhered to the second substrate, an adhesive device comprising:
a carrier sheet, said carrier sheet having at least two surfaces;
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the substrate; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the second substrate,
wherein the first continuous layer of silicone gel of the adhesive device is adhered to the surface of the substrate to be adhered to a second substrate,
and wherein the substrate is a prosthesis and the second substrate is the skin of a human or animal body."

"8. A method for adhering a prosthesis to the skin of a human or an animal body comprising:
positioning an adhesive device between the prosthesis and the skin of the human or animal body; and
compressing the adhesive device between the prosthesis and the skin of the human or animal body, wherein the adhesive device comprises:

a carrier sheet, said carrier sheet having at least two surfaces,
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the skin of the human or animal body."

"9. The use of an adhesive device for adhering a first substrate to a second substrate, wherein the adhesive device comprises:
a carrier sheet, said carrier sheet having at least two surfaces;
on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the first substrate; and
on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the second substrate
wherein the first substrate is a prosthesis and the second substrate is the skin of a human or an animal body."

VII. The relevant arguments of the appellant provided in writing and at the oral proceedings may be summarised as follows:

(a) Novelty

None of the documents of the prior art dealt with the adhesion of a prosthesis to the skin of a human or animal body via an adhesive device comprising a carrier sheet bearing on both its surfaces a continuous layer of a silicone gel. The silicone rubber disclosed in D2 and the tacky silicone layer on the back of the bearer strip 3 for attachment of the breast prosthesis to the user according to the teaching of D3 differed considerably from a silicone gel used in the claimed invention. Although silicone rubbers and silicone gels were principally based on the same molecular structure, namely a linear Si-O-Si chain containing 99% dimeric (D)-units, they differed in their degree of crosslinking via alkylenic bonds, which was defined via the ratio [H]/[Vinyl] (RHV). The RHV of a silicone gel was $\leq$ 0.8 and considerably lower than the RHV of $\geq$ 1.5 for a silicone rubber. This considerable gap between silicone gels and silicone rubbers was responsible for a tacky surface of a silicone gel, in contrast to the non-tacky silicone rubber surface.

Owing to their greater softness, silicone gels were accessible to the cone penetration test, which was not applicable to silicone rubbers. The above-mentioned differences between a silicone gel and a silicone rubber were common general knowledge of a skilled person.

D7, referred to by the board in the oral proceedings, disclosed an adhesive device comprising a carrier sheet and layers of a silicone gel on both sides of the carrier sheet. This adhesive device was the basis of a scar dressing which was to be fixed via one silicone gel layer to the skin of a human body in accordance with the invention. The other layer, however, which is distal from the wearer's skin was covered by a liquid-impermeable top sheet which could not be subsumed under the term "prosthesis".

(b) Inventive step

Document D3 was representative of the closest prior art because it pertained to the same problem, namely the adhesion of a (breast) prosthesis to the skin of a human body.
It emerged from Figure 3 of D3 and its explanation in the description that the tacky silicone layer provided on the back side of the bearer strip (3) was not defined as a silicone gel layer.

In contrast to D3, the carrier sheet of the adhesive device according to the claimed invention was provided with silicone gel layers on both sides which allowed tailoring the adhesive strength of the gel on the one side of the carrier used against the wearer's skin and on the other side used against the prosthesis. This made it possible to easily peel off the adhesive device from the skin without pain and, on the other hand, ensured that sufficient adhesion of the prosthesis

could be maintained without causing damage to the prosthesis when removed. Example 1 of the application as filed demonstrated that 75 cm^2 of an adhesive device according to the claims could be used to adhere a 1 kg breast prosthesis on a vertical surface for 48 hours.

Also, a combination of D3 with D7 would not lead to the invention because the skilled person would not take an adhesive device designed for adhering a scar dressing to the wearer's skin into account when looking for adhesion of a prosthesis to the skin of a body.

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of Claims 1-9 filed as "fourth auxiliary request" during the oral proceedings before the board and the description as amended during the oral proceedings before the board.

Reasons for the Decision

1. The appeal is admissible.

2. *Formal matters*

With regard to Article 84 EPC the appellant has convincingly argued (point IV) that the term "silicone gel" defines a silicone subclass which can be characterised by clear structural and physical properties which are known to a skilled person.

Independent Claims 1, 7, 8 and 9 are based on Claims 1, 8, 10 and 11 as filed where the feature that the first substrate is a prosthesis is supported by Claims 7, 9 and 12 as filed and that the second substrate is the skin of a human or an animal body is clearly and unambiguously derivable from page 5, line 32, to page 6, line 4, of the application as filed where it is indicated that removal of the prosthesis would be from the skin. Dependent Claims 2-6 correspond to Claims 2-6 as filed.

Thus, the claims according to the fourth auxiliary request meet the requirements of Articles 84 and 123(2) EPC.

3. *Method for treatment of the human or animal body by therapy or surgery - Article 53(c) EPC*

Claims 1, 8 and 9 pertain to the adhesion of a prosthesis to the skin of a human or animal body. The term "prosthesis" indicated in the above claims embraces, inter alia, devices which can be used for medical purposes, such as breast prostheses, catheters, cannulas etc. (page 9, lines 23 to 31, of the application as filed). The claimed invention, however, is limited to an external fixation of the prosthesis, with the consequence that the final result of the claimed measures is merely the adhesive contact between the prosthesis and the skin of the body, which does not include a specific therapeutic or surgical effect. Therefore, the subject-matter of Claims 1, 8 and 9 is not excluded from patentability under Article 53(c) EPC.

4. *Novelty*

The subject-matter of Claims 1, 7, 8 and 9 is novel over the prior art because none of the pertinent documents explicitly disclose the adhesion of a prosthesis to the skin of a human or animal body via an adhesive device having a carrier sheet and on its opposite surfaces two layers of a silicone gel, whereby the silicone gel layer of the first substrate is adhered to the prosthesis and the silicone gel layer of the second surface is (to be) adhered to the skin of the body.

D7 discloses a hypertrophic scar dressing which includes silicone gel on that side of the dressing which lies against the user's skin when worn. In particular, a flexible carrier sheet is embodied within the silicone gel such that the gel forms continuous layers on both sides of the carrier material, i.e. a carrier sheet has on its opposite surfaces two layers of a silicone gel (Claim 1 in conjunction with page 3, paragraph 1, and Figure 1). The combined thickness of the two silicone layers is suitably 0.3-0.6 mm (page 7, lines 29-30). While one silicone gel layer is adhered to the skin of the body, the silicone gel layer of the opposite surface (distal to the wearer's skin) is adhered to a top sheet. The primary function of the top sheet is to prevent the dressing from sticking to clothing or other objects that are liable to come into external contact with an applied dressing. The top sheet also contributes towards increasing the wear strength, tensile strength and tear strength of the dressing, and in the majority of cases it is beneficial when the top sheet has a small coefficient of friction

against clothing or other materials with which the dressing can be expected to come into contact. The top sheet will preferably also have a high vapour permeability, so that moisture is able to pass from the skin and through the top sheet. The top sheet will also be highly flexible and will suitably comprise a liquid-impervious plastic film, preferably film that has a high vapour permeability (page 7, lines 1-14). Such a function cannot be subsumed under the term "prosthesis". Consequently, the claimed subject-matter is novel over D7.

D2, referred to in the decision under appeal, relates to tapes per se and discloses a two-side silicone coated tape. Reference is made in the abstract to a silicone resin or rubber composition. These are different materials to silicone gels, as would be apparent to the skilled person (see also point VII(a)). Finally, D2 is not directed to adhering prostheses.

5. *Inventive step*

5.1 The claimed invention

The invention is concerned with the use of a double-sided adhesive device comprising on each side a silicone gel layer for adhering a prosthesis to the skin of a human or animal body. By modifying the tackiness of the silicone gels it is possible to tailor the adhesion to specific end uses. In particular, sufficient adhesion strength should be provided in order to ensure that the prosthesis remains attached to the body; on the other hand, tackiness should be not so strong that excessive numbers of skin cells are removed

when the adhesive device is removed from the body (page 1, lines 4-7, page 2, line 27, to page 3, line 6, and page 5, line 32, to page 6, line 15, of the application as filed).

5.2 The closest prior art

The board concurs with the appellant that D3 represents the closest prior art.

D3 is directed to a breast prosthesis having a bearer strip (3), which for attachment to the breast of the user is provided with a permanently tacky layer (Claim 1, page 1, first paragraph) which can be a tacky silicone layer (page 5, second full paragraph). The other side of the bearer strip (3) provides a method for connecting it to the breast prosthesis. This is achieved preferably by a strip-like permanent adhesive, but may be done in a releasable manner using a conventional burr fastener (such as a Velcro fastener) or a releasable adhesive material (page 5, first full paragraph, Figure 3).

Thus, the bearer strip (3) disclosed in D3 corresponds to the adhesive device referred to in the claims. However, D3 does not disclose that the bearer strip is covered on both surfaces with a silicone gel.

5.3 The problem to be solved

The experimental evidence provided in Examples 1 and 2 of the application as filed shows that the silicone gel layer allows adherence of a 1 kg external breast prosthesis on a vertical surface for 48 h (Example 1),

and tailoring the tackiness of the silicone gel over a wide range (Example 2, in particular Table 1).

Therefore, the problem to be solved by the claimed invention over D3 is seen in the provision of an adhesive device for adhering a prosthesis to the skin of the wearer which can be adapted in tackiness, in order to allow, on the one hand, a safe fixation of various prostheses, different in weight and shape, to the skin and, on the other hand, its easy removal from the skin without damaging the skin cells.

This problem is solved by a carrier sheet of an adhesive device, which is covered on both surfaces with a silicone gel.

5.4 Obviousness

D3 itself makes no mention of a silicone gel, and hence the skilled person would have no motivation to use such a material. D3 also does not consider using a double-sided tape with silicone gel on both sides in order to provide the adhesive properties of the silicone gel and the structural properties of the carrier sheet.

Although D7 discloses the attachment of a wound dressing to the skin of the user via a carrier sheet which is coated on both surfaces with a silicone gel layer which has sufficiently low adhesive strength to prevent pain and removal of skin cells when the dressing is peeled off (page 10, last paragraph), there is no indication that the adhesive strength of the silicone gel layer on the opposite surface of the carrier can be tailored over a wide range in order to

make the carrier available for specific applications on the skin of a user, other than the fixation of the top sheet of a wound dressing.
Therefore, the skilled person was not induced to consider the adhesive device according to D7 as an alternative system for the fixation of a prosthesis in general, let alone a breast prosthesis according to D3 to the skin. In particular, a relatively high-weight breast prosthesis transmits peeling forces to the adhesive connection during movement of the user. In fact, the analogous application of the concept of adhering a top sheet to a wound dressing to adhering a prosthesis to the skin of a human or animal body appears to be based on hindsight.

Therefore, the claimed subject-matter is not made obvious by D3 alone or by a combination of D3 with D7.

6. For the reasons set out in points 2 to 5, the claims according to the fourth auxiliary request are allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent in the following version:

Description:
Pages 6, 7, 8, 12, 13, 14 and 15 as originally filed;
Pages 1, 2, 2a, 3, 4, 5, 9, 10 and 11 as filed during the oral proceedings before the board;

Claims:
Claims 1 to 9 filed as fourth auxiliary request during the oral proceedings before the board.

The Registrar The Chairman

R. Schumacher W. Sieber