

**Internal distribution code:**

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

**Datasheet for the decision  
of 4 December 2007**

**Case Number:** T 0681/06 - 3.2.02

**Application Number:** 95927442.4

**Publication Number:** 0954342

**IPC:** A61F 5/448

**Language of the proceedings:** EN

**Title of invention:**

Ostomy appliance and wound drainage device

**Patentee:**

E.R. Sqibb & Sons, Inc.

**Opponent:**

Coloplast A/S  
Hollister Incorporated

**Headword:**

-

**Relevant legal provisions:**

-

**Relevant legal provisions (EPC 1973):**

EPC Art. 83, 84, 100(b)(c), 123(2)

**Keyword:**

"Unallowable broadening (main and first to fourth auxiliary requests (yes), fifth auxiliary request (no))"

"Sufficiency and clarity of fifth auxiliary request (yes)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0681/06 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 4 December 2007

**Appellant:** E.R. Squibb & Sons, Inc.  
(Patent Proprietor) Lawrenceville-Princeton Road  
Princeton  
New Jersey 08543-4000 (US)

**Representative:** Holmes, Miles Keeton  
Novagraaf International SA  
25, Avenue du Pailly  
CH-1220 Les Avanchets - Geneva (CH)

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

**Representative:** Simonsen, Jan Lyngberg  
Inspicos A/S  
Bøge Allé 5  
P.O. Box 45  
DK-2970 Hørsholm (DK)

(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 27 February 2007  
revoking European patent No. 0954342 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** S. Chowdhury  
M. Vogel

## **Summary of Facts and Submissions**

- I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 0 954 342. The decision was dispatched on 27 February 2006.

The appeal was received on 9 May 2006 and the fee for the appeal was paid on the same day. The statement setting out the grounds of appeal was received on 10 July 2006.

The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step of the claimed subject-matter), Article 100(b) EPC, and Article 100(c) EPC. The opposition division held that claim 1 of the main and first, second, and third auxiliary requests then on file did not comply with Article 123(2) EPC and that, although claim 1 of the fourth and fifth auxiliary requests then on file did comply with Article 123(2) EPC, they did not comply with Article 83 EPC, and revoked the patent, accordingly.

- II. Oral proceedings were held on 4 December 2007.

The appellant requested that the decision under appeal be set aside and that the Board decides that the main request or any of the auxiliary requests 1 to 6, all filed on 2 November 2007, meets the requirements of Articles 123(2) and 83 EPC and that the case be remitted to the opposition division.

The respondents (opponents) requested that the appeal be dismissed.

III. Claim 1 of the main request reads as follows:

"An ostomy appliance or wound drainage device comprising:

(a) a receptacle (8);

(b) a single pair of first and second coupling devices, said first coupling device (4) having a first surface operatively engaged to the receptacle and an opposed surface for releasably engaging the second coupling device to form a releasable fluid tight seal therewith; and

(c) said second coupling device (6) having a first surface for operative contact with a patient's skin (16) and an opposed surface for releasably coupling to the first coupling device, at least one of the respective opposed surfaces of said first (4) and second (6) coupling devices having thereon a single layer of a water-washable adhesive composition which provides releasable and resealable fluid-tight engagement of said first and second coupling devices, while the second coupling device remains in operative contact with the patient's skin (16),

wherein said adhesive composition is water-washable (i) to enable contaminants to be removed from the surface of the adhesive by washing with water and (ii) without retaining cleaning implement fibres on the surface of the adhesive,

said adhesive composition is hydrophobic and is resealable after washing, and said adhesive composition is an elastomeric composition having a modulus of elasticity sufficient to enable waste particles to be

readily removed therefrom, and having an internal viscosity low enough to enable water-washing and high enough to provide tack".

Claim 1 of the first auxiliary request has the additional feature that the adhesive composition is insoluble in water.

Claim 1 of the second auxiliary request has the further feature that the adhesive composition includes a thermoplastic elastomer, the thermoplastic elastomer being an acrylic adhesive.

Claim 1 of the third auxiliary request has the additional feature, over claim 1 of the first auxiliary request, that the adhesive composition has a modulus of elasticity of from about 1 to 100 psi.

Claim 1 of the fourth auxiliary request has the additional feature, over claim 1 of the second auxiliary request, that the adhesive composition has a modulus of elasticity of from about 1 to 100 psi.

Claim 1 of the fifth auxiliary request has the additional feature, over claim 1 of the first auxiliary request, that the adhesive composition has a modulus of elasticity of from about 1 to 100 psi and an internal viscosity of from about 1000 to 20,000 poises.

Claim 1 of the sixth auxiliary request has the additional feature, over claim 1 of the fifth auxiliary request, that the adhesive composition is solid and includes a thermoplastic elastomer, the thermoplastic elastomer being an acrylic adhesive.

Each claim 1 has its retinue of dependent claims.

IV. The parties arguments may be summarised as follows:

The appellant:

The original application clearly stated that the numerical ranges for internal viscosity and modulus of elasticity were merely preferred ranges (claim 8 and pages 9 and 13). The essential properties of the adhesive composition were defined functionally on page 8 and the preferred ranges followed this definition. Thus, the application as originally filed clearly contemplated water-washable adhesive compositions not limited to specific ranges of internal viscosity and modulus of elasticity.

The opponents had not provided any test results to prove that the rebounding ball method of determining the internal viscosity would not give consistent results. Instead of discharging their burden of proof they had simply attempted to pick holes. US-A-3 682 690 described the rebounding ball method, whose purpose was not to determine the absolute value of internal viscosity, but to compare a test material against a material of known internal viscosity. A ball of the latter material could be made of a high-molecular weight PVC (e.g. Geon 121) with a plasticizer, whose internal viscosity was equivalent to that of the plasticizer, which could be easily measured or obtained.

The respondents:

There were clear statements on page 9, lines 23 to 25 and page 10, lines 14 and 15 that the internal viscosity of the adhesive composition must be limited to a specific range for the invention to work. All other statements regarding these materials fell under this umbrella.

The term "internal viscosity" was a meaningless term and, in so far as it could be understood, the patent described no method of determining this property in a consistent manner. It was not possible to make up a ball of material having a given internal viscosity because once a plasticizer was mixed with a vinyl, for example, then the mixing ratio would determine the internal viscosity. This was demonstrated by the Examples 1 and 3 in US-A-3 682 690, in which the same plasticizer was used in the same mixing ratio, but small amounts of additives drastically affected the internal viscosity, and by Examples 1 and 2, in which the same materials were used in the same mixing ratio but gave very different internal viscosities. Hence this property was not defined by the plasticizer alone. Therefore, the rebounding ball method made no sense and the desire to make a ball with the required internal viscosity was mere wishful thinking.

Accordingly, the patent was enabled only for the three values of internal viscosity disclosed in US-A-3 682 690, and not for the entire range claimed in the fifth auxiliary request of the patent in suit.

US-A-3 682 690 stated that the adhesive composition must be a solid in order to be washable, and claim 1 without this limitation was objectionable.

### **Reasons for the decision**

1. The appeal is admissible.
2. *Article 100(c) EPC*
  - 2.1 The patent relates to ostomy appliances and wound drainage devices having coupling members releasably secured to each other through a washable adhesive composition. The adhesive must be readily washed by conventional cleaning implements such as tissues, cloths and the like and still provide a substantially contamination free surface, especially free of fibers and the like.

Claim 1 of each request requires the adhesive composition to be water-washable to enable contaminants to be removed from the surface of the adhesive by washing with water and without retaining cleaning implement fibres on the surface of the adhesive.

- 2.2 Support for the feature that the adhesive composition is water-washable is to be found in original claim 8 and on page 9 of the application (WO-A-96/03 167). However, this disclosure also requires the internal viscosity of the adhesive composition to be between about 1,000 and 20,000 poises (page 9, lines 23 to 25) to enable water-washing and at the same time provide tack, and it is also stated that "in general,



viscosities outside the range of from 1000 to 20,000 poises give inferior results" (page 10, lines 14 and 15).

- 2.3 The appellant has argued that original claim 8 and the sentence linking pages 8 and 9 clearly support the disclosure of a water-washable adhesive composition, without any restriction on the internal viscosity thereof. The Board takes the view, however, that the statement on page 9, that the range of 1,000 to 20,000 poises is merely a preferred range, is erroneous because it is trumped by the definitive statement later on page 9, that this is a required feature for washable tackiness, and that on page 10, that viscosities outside the range of from 1000 to 20,000 poises give inferior results.

This view is supported by the fact that the patent in suit employs adhesives used in US-A-3 682 690 (see page 8 of WO-A-96/03 167, page 8, lines 23 to 25), which states that this range of internal viscosity is an essential feature (US-A-3 682 690 column 3, lines 20-28 and column 4, lines 27-29 and 51-67).

- 2.4 For the above reasons the internal viscosity of the adhesive composition of between about 1,000 and 20,000 poises was originally disclosed as an essential feature of the invention in connection with its water-washing property, and the application as originally filed did not clearly and unambiguously disclose a water-washable adhesive composition for an ostomy appliance or wound drainage device without a restriction as to its internal viscosity.

Since claim 1 of each of the main request and the first to fourth auxiliary requests does not include this range of internal viscosity of the adhesive composition, each of these claims is objectionable under Article 123(2) EPC.

Claim 1 of the fifth auxiliary request includes the range of internal viscosity, discussed above, as well as the range of modulus of elasticity of the adhesive composition, and the feature that this is hydrophobic and insoluble in water. Therefore, this claim meets the respondents' objections under Article 83 EPC.

3. *Article 100(b) EPC - fifth auxiliary request*

3.1 The respondents have argued that "internal viscosity" is a meaningless expression. This argument is not persuasive in view of the fact that US-A-3 682 690 uses it extensively and explains how it relates to the physical properties of a material (column 4, lines 31 to 44). Moreover, manufacturers often furnish this figure for plasticizers (column 4, lines 70 to 72).

3.2 The requirement of claim 1, that the adhesive composition should have an internal viscosity of from about 1000 to 20,000 poises, means that any adhesive composition whose internal viscosity falls within this range may be used in the claimed device (so long as it also has all the other properties required by claim 1).

3.3 The question then arises as to how the internal viscosity of an adhesive composition is to be measured in order to see whether it is suitable for use in the invention.

One method of testing whether a composition's internal viscosity is within the allowable range, borrowed from US-A-3 682 690, is described at the end of page 10 of the application. A ball of the material in question is prepared, and its rebound is compared with a similar, reference ball made of a material whose internal viscosity is known. The reference ball is prepared from a mixture of a high-molecular weight polyvinyl chloride, such as Geon 121, with a plasticizer whose internal viscosity is known. The surfaces of the balls are dusted with talc, and the rebounds are compared, the greater the rebound, the lower the viscosity.

Thus, two reference balls having internal viscosities of 1,000 poise and 20,000 poise, respectively, are required, and the ball in question must have a rebound between the two reference balls.

The success of this test is based on the fact that materials such as neoprene and high molecular-weight vinyls have little internal viscosity of their own, and the viscosity of the plasticized material is a fairly accurate reflection of the viscosity of the plasticizer itself (WO-A-96/03 167 page 9, line 26 to page 10, line 1). Therefore, two balls made of Geon 121 together with a plasticizer having the required internal viscosities (1,000 poise and 20,000 poise) must be made in order to furnish the reference balls. This would be a straight forward matter for the person skilled in the art, given that manufacturers often furnish this figure for plasticizers.

The reason why the internal viscosities of the adhesives of Examples 1 and 3 of US-A-3 682 690 are so different is that they use PVCs of different molecular weight (respectively Geon 121 and 222). Example 2 uses a significant amount of a glycerol ester, which Example 1 does not, so their internal viscosities are not directly comparable.

- 3.4 The respondents' arguments regarding the temperature, the fall height, the weight and diameter of the ball, etc. are not convincing. Internal viscosity is an intrinsic property of a material and it seems plausible that extrinsic properties such as its weight, size, etc. would not affect an intrinsic property of the material. In the absence of a temperature indication it may be assumed that tests are performed at room temperature.

The respondents have not submitted any test results to prove that the rebounding ball method would give inconsistent results, or that the temperature, ball weight and size, fall height, etc. would crucially affect the results of this method of determining whether a material's internal viscosity fell within the desired range. Accordingly, their arguments are no more than unverified assertions.

4. *Article 84 EPC*

The respondents argued that claim 1 of the fifth auxiliary request was unclear because it was not clear which contaminants it referred to, which utensils were to be used for cleaning, how long the cleaning process should last, to what degree the fibres must be retained,

and how many fibres could be present on the surface before falling under the scope of the claim.

Moreover, they argued, for an adhesive composition to be washable US-A-3 682 690 said that it must be a solid. This, essential feature was lacking in this claim.

Claim 1 defines an ostomy appliance having releasably engageable coupling devices having thereon a water-washable adhesive composition. The construction of the device is adequately defined in functional terms and as constructional features and parameters, and the claim is clear in this respect. These features are for solving the stated problem, which is to enable contaminants to be removed from the surface of the adhesive by washing with water. The sorts of contaminants in question are those arising from the use of tissues, cloths, etc. during washing (page 6, lines 19 to 22) and the claim is clear in this respect also. It is not necessary to define the problem more precisely, e.g. by stating exactly which contaminants are meant, how many fibres may be retained, etc.

US-A-3 682 690 describes the mechanism, involving Van der Waals forces, by which the adhesive composition picks particles of dirt, fibres, etc. off a surface, and how water-washing neutralises these forces to leave a clean surface. For the adhesive composition to be water-washable the particles, fibres, etc. must not sink into the adhesive composition. However, this property of the adhesive composition is related to its modulus of elasticity, as defined at the end of claim 1, and is not dependent on the adhesive composition being a solid.

5. For the above reasons the Board decides that the fifth auxiliary request meets the requirements of Articles 123(2), 83, and 84 EPC.

6. *Article 100(a) EPC*

Since the opposition division has not given any opinion or decision on novelty or inventive step, the case is remitted to the department of the first instance to resume examination of the oppositions as to the requirements of Article 52(1) EPC.

In their written submissions during the appeal procedure the respondents had requested that late-filed documents D7, D8, and D13 to D15 be admitted into the procedure. Since these documents were not discussed during the oral proceedings before the Board, this matter is left to the discretion of the opposition division.

**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 for further prosecution on the basis of the fifth auxiliary request.

The Registrar

The Chairman

V. Commare

T. Kriner