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**Datasheet for the decision  
of 21 August 2014**

**Case Number:** T 0229/12 - 3.3.10

**Application Number:** 07762800.6

**Publication Number:** 1979016

**IPC:** A61L29/08, A61L29/14

**Language of the proceedings:** EN

**Title of invention:**

METHODS OF APPLYING A HYDROPHILIC COATING TO A SUBSTRATE, AND  
SUBSTRATES HAVING A HYDROPHILIC COATING

**Applicant:**

HOLLISTER INCORPORATED

**Headword:**

**Relevant legal provisions:**

EPC Art. 54, 123(2)

**Keyword:**

Amendments - added subject-matter (no)  
Novelty - (yes)

**Decisions cited:**

G 0010/93

**Catchword:**



**Beschwerdekammern  
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Case Number: T 0229/12 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 21 August 2014**

**Appellant:** HOLLISTER INCORPORATED  
(Applicant) 2000 Hollister Drive  
Libertyville, Illinois 60048 (US)

**Representative:** Høiberg A/S  
St. Kongensgade 59 A  
1264 Copenhagen K (DK)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 13 July 2011  
refusing European patent application No.  
07762800.6 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** P. Gryczka  
**Members:** J. Mercey  
C. Schmidt

## Summary of Facts and Submissions

- I. The present appeal lies from the decision of the Examining Division posted on 13 July 2011 to refuse European patent application no. 07762800.6.
- II. *Inter alia* the following documents were cited in the examination proceedings:
- (2) US-A-6 048 620 and
  - (3) US-A-5 670 558.
- III. The decision of the Examining Division was based on a single request comprising three independent claims 1, 14 and 15, wherein claim 1 was directed to a method, independent claim 14 to a substrate made according to the method of claim 1, and claim 15 to a substrate. In the appealed decision, the Examining Division held that the subject-matter of all claims was not novel over the disclosure of document (2), more particularly Examples 1 to 3 thereof, and that the subject-matter of claims 15 and 19 to 21 lacked novelty over the disclosure of document (3), more particularly over general parts of the description at column 2, line 6 to column 3, line 36, column 5, lines 14 to 16 and 32 to 35 and column 6, lines 38 to 58 thereof.
- IV. With a letter dated 18 July 2014, the Appellant (Applicant) submitted a main request and an auxiliary request, the main request consisting of thirteen claims, independent claims 1 and 13 reading as follows:
- "1. A method of applying a hydrophilic coating to a substrate comprising a medical device comprising:

providing a substrate having an outer, first layer with a surface, said first layer comprising at least in part a water-swellaable material;  
contacting the substrate surface with a solution to swell the water-swellaable material, said solution comprising at least one solvent selected from the group consisting of water, alcohols, and mixtures thereof, and a water-soluble polymer capable of being cross-linked to form a cross-linked, lubricious, hydrophilic coating; and  
cross-linking said water-soluble polymer to form an interpenetrating polymer network with the substrate surface, thereby forming a cross-linked lubricious, hydrophilic coating entangled with and securely anchored to the substrate surface."

"13. A substrate made according to the method of claim 1."

Claims corresponding to claims 15 to 21 of the request on which the contested decision was based were no longer present.

- V. The Appellant submitted that the amendments found support in the application as filed, and thus complied with the requirements of Article 123(2) EPC. More particularly, claim 1 was based on original claims 1, 2 and 5, together with page 2, lines 29 to 30 and page 4, lines 5 to 12 of the application as filed.

The Appellant argued that the subject-matter of claims 1 and 13 was novel over documents (2) and (3) because not all urethane-based copolymers were water-swellaable. With letter dated 18 July 2014, the Appellant filed documents (4) to (6):

- (4) Data sheet for NeoRez R981
- (5) US-A-5 264 242 and
- (6) WO-A-99 567 10

as evidence that the particular polyurethane polymers used in the first coating compositions of each of Examples 1 to 3 of document (2) were not water-swellaible.

With regard to document (3), although this disclosed that the matrix surface of a medical instrument swelled in a solvent, there was no disclosure, either in the general description, or in any of the examples, that the matrix would swell in water. Instead harsh organic solvents were always used, polymers which were swellaible in organic solvents not necessarily being swellaible in water.

- VI. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request, or, subsidiarily, on the basis of the auxiliary request, both requests submitted with letter dated 18 July 2014.
  
- VII. At the end of the oral proceedings, the decision of the Board was announced.

## **Reasons for the Decision**

1. The appeal is admissible.

### *Main request*

2. *Amendments (Article 123(2) EPC)*

- 2.1 Claim 1 is based on original claim 1, wherein the substrate is defined as comprising a medical device as in original claim 5, and the solution as comprising at least one solvent selected from the group consisting of water, alcohols, and mixtures thereof as in original claim 2. That the substrate has an outer, first layer is supported by page 2, lines 29 to 30 of the application as filed. Contacting the substrate surface with a solution to swell the water-swellable material and cross-linking the water-soluble polymer to form an interpenetrating polymer network with the substrate surface, thereby forming a cross-linked lubricious, hydrophilic coating entangled with and securely anchored to the substrate surface finds a basis on page 4, lines 5 to 12 of the application as filed.
- 2.2 Claim 13, which is directed to a substrate made according to the method of claim 1, is based on original claim 16 combined with the basis for claim 1 given above.
- 2.3 Dependent claims 2 to 9, 11 and 12 are based on original claims 3, 4, 6 to 10, 12, 14 and 15, respectively. Dependent claim 10 finds a basis on page 4, lines 14 to 15 of the application as filed.
- 2.4 Therefore, the amendments made to the claims do not generate subject-matter extending beyond the content of

the application as filed and the Board concludes that the requirements of Article 123(2) EPC are satisfied.

3. *Novelty*

Documents (2) and (3) are cited in the decision under appeal as anticipating the subject-matter of claims of the then pending request.

*Document (2)*

3.1 Document (2) discloses methods for making medical devices having a coating which show excellent lubricity when contacted with water. More particularly, in Examples 1 to 3, tubes and a balloon catheter are provided with two coatings. In Example 1, the first coating composition comprises NeoRez R981, which is a polyester-based aliphatic water-borne polyurethane; in Example 2 it comprises U21X, which is a polyester-based aliphatic polyurethane dispersion; and in Example 3 it comprises Bayhydrol LS-2033, which is a water-borne polyurethane stabilized by sulfonate groups. In each of these examples, the second coating is applied by dipping the coated device into an aqueous solution of an acrylic acid-acrylamide copolymer, the Appellant conceding that said polymer is capable of being cross-linked.

3.2 The question which thus needs to be answered is whether the first coating used in these examples comprises a water-swellaable material. There is no explicit disclosure in document (2) that the particular polymers employed in the first coating compositions are water-swellaable. Indeed to the contrary: in order for a material to be water-swellaable, it must be hydrophilic. However, throughout document (2) (see, for example,

column 6, line 15 and 63 to 65 and column 7, line 49), only the second polymeric coating is described as being hydrophilic, it being frequently referred to as **the** hydrophilic polymer (emphasis added), as opposed to the "polymer having organic functional groups", which is how the first polymeric coating is generally referred to.

- 3.3 In addition, the Appellant provided documents (4) to (6) as evidence that the three particular polyurethane polymers used in the first coating compositions of each of Examples 1 to 3 of document (2) were not water-swallowable. The Appellant argued that in view of the fact that these documents indicated that these polyurethane polymers were insoluble in water and described them for use in protective coatings, they could not be water-swallowable, because this would render them soft and less mechanically robust.
- 3.3.1 Document (4), which is a datasheet for NeoRez R981 describes it as being water and humidity resistant. If a compound is water-resistant, then it is *per se* not water-swallowable.
- 3.3.2 Document (5) describes polyurethanes for use in a scuff-resistant coating for articles such as shoes (see claims 1 and 2). The preferred coating forms a film which is not water soluble, U21X being recited as typically useful as the polyurethane ingredient (see column 2, lines 40 to 61). Since the film should remain effective in wetting conditions (see column 2, lines 46 to 48), then it is highly unlikely that said film is water-swallowable, as this would render it soft and less mechanically robust.



- 3.3.3 Document (6) discloses Bayhydrol LS-2033 as an example of a water-insoluble film-forming polymer for use as a polish for mammalian nails exhibiting long wear (see page 5, lines 9 to 10, page 6, lines 1 to 3 and page 7, line 8 from the bottom). Again, as argued for document (5), in view of this intended use and described protective properties, Bayhydrol LS-2033 would not be expected to be water-swellaible.
- 3.3.4 The Board therefore holds that the evidence provided by the Appellant suffices to render it plausible that the three polyurethane polymer first coatings of Examples 1 to 3 of document (2) are not water-swellaible. This evidence thus discharges the onus of the Appellant to rebut the assertion of the Examining Division in the contested decision that all urethane-based copolymers were water-swellaible, said assertion being based on the fact that the application in suit (see page 5, lines 13 to 16 and original claim 8) referred to the same family of polymers, namely urethane-based copolymers, as water-swellaible. The Board additionally notes here that this passage at page 5, lines 13 to 16 of the application in suit teaches that "Suitable water-swellaible materials include [...] **water-swellaible** urethane-based copolymers water-swellaible" (emphasis added), which does not imply that **all** urethane-based copolymers are water-swellaible.
- 3.4 Thus, the method of claim 1 and the substrate of claim 13 made by said method are both novel over the disclosure of document (2) in view of the fact that the substrate has a first layer comprising a water-swellaible material.
- 3.4.1 During oral proceedings before the Board, the Appellant conceded that the method of claim 1 of the present

invention did not necessarily exclude the formation of covalent bonds between the water-soluble polymer and the water-swellaible material, such that the Board holds that the absence of such bonding is not an additional difference between the substrate of present claim 13 and the coated medical devices of document (2).

*Document (3)*

3.5 Document (3) discloses according to its second aspect a medical instrument exhibiting surface lubricity when wetted, characterized by having a surface lubricating layer that is composed of a crosslinked water-soluble polymer. Said instrument is made by dipping a substrate of a medical instrument in a solution of a water-soluble polymer in a solvent which is swellaible onto the substrate, and heating at 40°C to form an interpenetrating network structure on the matrix surface of the medical instrument, whereby said polymer is securely fixed to the matrix, the matrix surface preferably swelling by a factor of 1-100% when immersed in the solvent (see column 2, line 46 to column 3, line 1). One example of the interpenetrating network structure is a structure of crosslinking between molecules formed by the mutual reaction of the reactive groups such as epoxy groups of a polymer in a matrix surface of a medical instrument such as urethane polymer (see column 7, lines 17 to 31).

3.5.1 However, although document (3) discloses that the matrix surface of the medical instrument may be of the kind that will swell in solvents (see column 7, lines 33 to 34 and point 3.5 above), it does not specifically disclose water as one of these solvents. At column 11, lines 10 to 15, examples of the solvent that can swell the matrix are described as including toluene, xylene,

benzene, tetrahydrofuran, dioxane, hexane, methylene chloride and mixed solvents based on these solvents, with suitable solvents being selected in accordance with the properties of the specific matrix used. From the harshness of the solvents cited as being suitable for swelling the matrix, together with the absence of water, it cannot be concluded that the matrix materials disclosed in document (3) would be swellable in water. In addition, the Examples of document (3) do not explicitly disclose matrix surfaces which are water-swellable and in any case, none disclose a medical device.

The Appellant submitted that polymers which are swellable in organic solvents are not necessarily swellable in water. Thus although document (3) recites *inter alia* polyurethanes as being an exemplary polymeric material for the matrix of the medical instrument (see column 5, lines 32 to 35 and column 7, lines 30 to 31), the former passage of document (3) having been cited in the contested decision against the novelty of certain substrate claims, it has already been shown in connection with document (2) (see points 3.3 to 3.3.4 above), that not all urethane-based polymers are water-swellable.

3.6 Thus, the method of claim 1 and the substrate of claim 13 made by said method are both novel over the disclosure of document (3) in view of the fact that the substrate has a first layer comprising a water-swellable material.

3.7 Therefore, the Board concludes that the subject-matter of claims 1 and 13, and by the same token that of the dependent claims, is novel within the meaning of

Articles 52(1) and 54 EPC over the disclosures of documents (2) and (3).

4. *Remittal*

Having so decided, the Board has not taken a decision on the whole matter, since the decision under appeal dealt exclusively with novelty. Proceedings before the Boards of Appeal in *ex-parte* cases are primarily concerned with examining the contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons), fresh issues normally being left to the Examining Division to consider after a referral back, so that the Appellant has the opportunity for these to be considered without loss of an instance. Special circumstances leading to another conclusion were not given in the present case. The Board thus considers it appropriate to exercise its power conferred on it by Article 111(1) EPC to remit the case to the Examining Division for further prosecution on the basis of the claims according to the main request in order to enable the Examining Division to decide on the outstanding issues.

**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 for further prosecution on the basis of the main request filed with letter dated 18 July 2014.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated