

Internal distribution code:

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

**Datasheet for the decision
of 9 December 2021**

Case Number: T 0344/18 - 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

Patent Proprietor:

HOLLISTER INCORPORATED

Opponents:

Coloplast A/S
Dentsply IH AB

Headword:

Hydrophilic coating / Hollister

Relevant legal provisions:

EPC Art. 54

Keyword:

Novelty - (no) - all requests

Decisions cited:

T 0229/12

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0344/18 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 9 December 2021

Appellant: HOLLISTER INCORPORATED
(Patent Proprietor) 2000 Hollister Drive
Libertyville, Illinois 60048 (US)

Representative: FRKelly
27 Clyde Road
Dublin D04 F838 (IE)

Respondent: Coloplast A/S
(Opponent 1) Høltedam 1
3050 Humlebaek (DK)

Representative: Kornum, Martin Rahbek
Coloplast A/S
Corporate Patents
Høltedam 1
3050 Humlebæk (DK)

Respondent: Dentsply IH AB
(Opponent 2) Aminogatan 1
431 21 Mölndal (SE)

Representative: Lind Edlund Kenamets
Intellectual Property AB
Östra Hamngatan 17
411 10 Göteborg (SE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 24 November
2017 revoking European patent No. 1979016
pursuant to Articles 101(2) and 101(3) (b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: M. Kollmannsberger
F. Blumer

Summary of Facts and Submissions

I. The patent proprietor's appeal lies from the decision of the Opposition Division to revoke European Patent No. 1 979 016 under Articles 101(2) and 101(3)(b) EPC.

II. The patent was granted after an appeal (T 229/12) against a decision of the Examining Division to refuse the patent application.

The patent was then opposed under Articles 100(a)(b)(c) EPC for lack of novelty and inventive step, insufficient disclosure and unallowable amendments.

The Opposition Division concluded that the claims of the granted patent contained subject-matter extending beyond the application as originally filed (Article 123(2) EPC). Neither could the patent be maintained based on any of the pending auxiliary requests. The first auxiliary request was not admitted under Rule 80 EPC. The second to fourth auxiliary requests lacked novelty over D1. The fifth and sixth auxiliary requests likewise contravened Article 123(2) EPC. The patent was thus revoked.

III. Of the documents cited during the proceedings the following is of importance for the present decision:

D1: WO98/58990

IV. The appellant (patent proprietor) requests the impugned decision to be set aside and the patent to be

maintained as granted. As auxiliary request he requests the maintenance of the patent in amended form based on the claim sets filed as auxiliary requests 1-3 together with the statement of grounds of appeal.

V. The respondents 1 and 2 (opponents 1 and 2 respectively) request the appeal to be dismissed. Furthermore, respondent 1 requests the appellant's auxiliary request 2 not to be admitted into the appeal proceedings.

VI. Independent claim 1 of the granted patent reads:

"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."

Independent claim 13 of the granted patent reads:

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

Claim 1 of auxiliary request 1 differs from claim 1 of the granted patent in the last process step, as follows:

"cross-linking said water-soluble polymer to form an interpenetrating polymer network with the substrate surface, when the water-swella-ble substrate is in a swollen state, thereby forming a cross-linked, lubricious, hydrophilic coating entangled with and securely anchored to the substrate surface."

Claim 1 of auxiliary request 2 differs from claim 1 of the granted patent in that two additional process steps are introduced before the last step and reads:

"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-swella-ble material;

contacting the substrate surface with a solution to swell the water-swella-ble 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

holding contact between said substrate surface and said solution for a period of time to swell the substrate surface and to entangle the water-soluble polymer with the swollen substrate surface, and then
—
drying the substrate; and then

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."

Claim 1 of auxiliary request 3 corresponds to auxiliary request 2, in which the step "drying the substrate" is omitted.

The product-by-process claims of the auxiliary requests are unamended compared to claim 13 of the granted patent.

VII. In its ground of appeal and in the further course of the appeal proceedings the appellant contested the decision of the Opposition Division. In particular it argued that neither the claims of the granted patent nor the claims of the auxiliary requests contained amendments extending beyond the application as filed. Moreover, the claimed process as well as the claimed products were novel over D1, in particular because the claims of the patent required the formation of an interpenetrating polymer network. Such a network was not disclosed in D1.

VIII. In their replies to the patentee's appeal and in the further course of the appeal proceedings the respondents defended the decision of the Opposition Division. The claims of the granted patent as well as the claims of the auxiliary requests extended beyond the content of the application as originally filed. Neither the claimed processes nor the claimed products were novel over D1. In particular, in D1 an interpenetrating polymer network was formed in the same way as required by the claims of the patentee's requests. Furthermore, the claims lacked novelty also over other cited documents. Moreover, the claimed processes were insufficiently disclosed in the description of the patent. Auxiliary request 2 differed in wording from the corresponding request pending before the Opposition Division and should not be admitted into the proceedings under Article 12(4) RPBA 2007.

IX. On 27 August 2020 the Board issued a communication under Article 100(2) EPC informing the parties about its preliminary opinion on the disputed issues.

In particular, the Board was of the preliminary opinion that none of the appellant's requests appeared allowable due to lack of novelty over D1.

X. On 28 January 2021 the parties were summoned to oral proceedings to take place on 9 December 2021.

XI. In view of the ongoing COVID-19 pandemic, oral proceedings were held in form of a video-conference. The proceedings were attended by the appellant and by

respondent 1; respondent 2 had informed the Board beforehand that it would not be represented.

At the oral proceedings the parties confirmed their requests, as set out in points IV and V above. At the end of the oral proceedings the Board announced its decision.

Reasons for the Decision

1. The appeal is admissible.

Appellant's Main Request - patent as granted

2. The claimed invention

The claims are directed to a method for providing a substrate comprising a medical device with a hydrophilic coating. The hydrophilic coating becomes lubricious when activated with water and thus reduces friction when the device is introduced into the body, see [0001], [0002].

The method aims at securely anchoring the coating to the substrate surface. In order to achieve this, the intention is to form an interpenetrating polymer network involving the surface of the substrate and the hydrophilic coating. Such a network is formed by swelling the substrate surface in an aqueous or alcoholic solution containing a cross-linkable water soluble polymer so that the polymer physically entangles with the swollen substrate surface. Thereafter, the entanglement is fixed by cross-linking

the polymer, e. g. by means of curing using UV light, , see [0009], [0010].

Such a process is defined in claim 1; the resulting product is defined in claim 13.

3. Novelty over D1 (Article 54 EPC)

3.1 D1 is likewise dealing with hydrophilic coatings of medical devices, in particular catheters.

In example 5 of D1 a PVC catheter is dipped into an alcohol containing solution comprising polyvinylpyrrolidone (PVP), hydroxypropylcellulose (HPC) and a curing agent. After drying for 1 minute, the catheter is again dipped into an PVP containing alcoholic solution, dried and cured using UV light.

In example 6 of D1 a primer coating layer of cross-linked PVP is formed on a catheter tube. In a second step the coated tube is dipped again in an alcoholic PVP containing solution, dried and cured using UV light.

3.2 The Opposition Division held that example 5 of D1 anticipates the process of claim 1, see point II.4.6.1 of the reasoning. The Opposition Division's decision on novelty was given for then pending auxiliary requests 2-4 but it applies by analogy also to the broader claims of the granted patent. The Board agrees, for the reasons set out below, and additionally considers example 6 of D1 novelty destroying.

3.3 Claim 1 of the granted patent requires three physical activities as process steps, namely *providing a*

substrate having an outer layer comprising a water swellable material, *contacting* this substrate with an aqueous or alcoholic solution containing a cross-linkable polymer and *cross-linking* the polymer.

- 3.3.1 In D1 a substrate is provided that contains a layer comprising a water swellable material on its surface. This water swellable material is the PVP containing layer which, in example 5, additionally contains HPC or, in example 6, is cross-linked.

The appellant argued that the PVP layer in D1 is not water swellable. It referred to page 7 lines 20-24 and page 8 lines 5-9 of D1. These passages describe that the first PVP layer has a higher degree of cross-linking than the second layer, leading to reduced swelling of the inner layer. Thus, in the view of the appellant the first layer, corresponding to the outer layer defined in present claim 1, does not contain a water swellable material.

However, as the respondents correctly pointed out, "reduced swelling" does not mean that the material does not swell at all. As set out in [0019] of the patent specification, *swelling* is defined as an increase of at least 0.5% in at least one dimension when immersed in water for a period of approximately 90 minutes. Even a water swellable material having a reduced swelling ability inevitably falls into this broad definition; the appellant has not provided any technical arguments or data why this would not be the case.

In any case this argument only applies to example 6 of D1 since in example 5 the PVP layer is not cross-linked before the dipping step and thus clearly water swellable.

Thus, the first step of the claimed process is disclosed in examples 5 and 6 of D1.

- 3.3.2 The second step of the claimed process requires this substrate to be contacted with a solution comprising water or an alcohol and a water soluble polymer capable of being cross-linked. In D1, the substrates are dipped in an alcoholic PVP containing solution. PVP is a water soluble polymer capable of being cross-linked.
- 3.3.3 The third process step required by the claim is to cross-link the water-soluble polymer. This is done in D1 by exposing the catheters to UV-light, thereby inducing cross-linking of the polymer.
- 3.3.4 Thus, the claimed process steps as such (*providing, contacting, cross-linking*) are described in D1. Also the purpose of the method as defined in the claim ("*A method of applying a hydrophilic coating to a substrate comprising a medical device*") is disclosed in D1.
- 3.4 The claim furthermore defines some results that should be obtained by the process steps. In particular, the second step is carried out "*to swell the water swellable material*" and the cross-linking is done "*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*".
- 3.5 In the appellant's view in D1 there is no swelling of the water swellable material and, more importantly, no interpenetrating polymer network is formed with the substrate surface.

- 3.6 The feature "water swellable material" has been discussed above. The cross-linked PVP layer of example 6 is, at least to some extent, water swellable, and the swelling capability of the PVP/HPC layer in example 5 has not been contested.

The water swellable layer is contacted with the alcoholic solution containing the water-soluble polymer by dipping. Swelling will occur. D1 does not specify the dipping time, but neither does the claim define any dipping time or any other measure that would have to be taken in order to achieve a specific state of swelling.

- 3.7 It is uncontested that D1 does not use the term "interpenetrating polymer network". Thus, there is no explicit disclosure of such a network.

On the other hand, the process steps defined in claim 1 of the patent are also carried out in examples 5 and 6 of D1. The question thus is whether in D1 an interpenetrating polymer network is formed between the two PVP layers as required by the claim, or, to put it the other way around, whether the claimed process leads to a product that is distinguishable from the products obtained in D1.

- 3.7.1 The appellant has referred to the disclosure at the bottom of page 12 of D1 which refers to figure 1 and explains that a two-layer arrangement is formed, the inner layer having a higher degree of cross-linking than the outer part. The appellant argued that the teaching of D1 was to get away from an interpenetrating polymer network, as set out on page 2 of D1, due to its low abrasion resistance; also other passages in D1 referred to the formation of a two-layer arrangement in D1.

However, as the respondent brought forward, the intention of the authors of D1 is not the decisive issue for assessing novelty. In the Board's view what matters is what is actually done in D1 and whether the patent claims are distinguishable therefrom.

- 3.7.2 The patent does not contain any structural characterization of the interpenetrating polymer network formed. The formation of the network is inferred from the way the coating process is carried out and from the anchorage of the hydrophilic layer to the substrate.

For proving the coating anchorage to the substrate an abrasion test protocol is established in [0038]. The combination of high abrasion resistance and low friction coefficient shows a good anchorage of the coating to the substrate.

However, also examples 5 and 6 in D1 are said to have a high abrasion resistance and a low friction coefficient. Thus, it cannot be concluded that the physical properties of the coatings imply a difference in structure between the coatings of the claims and those of D1.

The appellant has argued that, since in example 5 of D1 it is stated that the friction coefficient of the coating is equivalent to that obtained in examples 1 and 2, having a one-layer arrangement only, it could be concluded that the second layer does not form an interpenetrating network with the first layer. However, in the Board's view such a conclusion cannot be drawn. In the absence of any comparison between a claimed coating and a coating according to D1 the disclosure of

D1, i. e. that the coatings have a high abrasion resistance, must be taken as such.

Thus, D1 uses the same means and therefore must achieve the same results as the process claimed in the patent. Assuming that an interpenetrating polymer network is formed in the claimed process, it must be formed in the same way in the processes disclosed in D1.

- 3.7.3 The Opposition Division considered example 5 of D1 to be novelty destroying because of the formation of an interpenetrating polymer network between the cross-linked primer PVP layer and the HPC, see point II 4.6.1. of the impugned decision.

With respect to this finding the appellant has argued that the HPC does not participate in any interpenetrating network. It was referred to page 6, lines 13-16 in D1 where it is stated that the saturated polymer, i. e. HPC, is not taking part in the cross-linking.

On the other hand, the Board observes that according to the last paragraph of the same page the HPC is entangled in the cross-linked network. This could well be seen, as was done by the Opposition Division, as an interpenetrating polymer network. Furthermore, even if one followed the appellant's view in this respect, there would still be a network between the first and the second PVP layer, as discussed above.

- 3.7.4 It has also been argued that D1 does not relate to two *different* polymers forming an interpenetrated polymer network. However, the claim only specifies that an "*interpenetrating polymer network with the substrate surface*" is formed. Neither the claim nor the

specification restrict the meaning of *interpenetrating polymer network* to two different polymers.

- 3.8 In summary, claim 1 of the patent does not specify any technical feature that could provide a distinction over the processes carried out in D1.

The materials and solvents used ("*water swellable material*", "*water soluble polymer capable of being cross-linked*", "*solution comprising at least one solvent selected from the group consisting of water, alcohols, and mixtures thereof*") are indistinguishable from D1. The physical process steps (*providing, contacting, cross-linking*) are the same. The purpose of the method ("*applying a hydrophilic coating to a substrate comprising a medical device*") is the same. *Swelling* is done in the claimed process in the same way than in D1. The formation of an *interpenetrating polymer network* is proven in the patent specification using the same physical parameter as in D1, at least in a qualitative way.

The process of D1 being carried out in the claimed way using claimed materials must thus yield the same result as claimed.

- 3.9 The claimed preparation process being indistinguishable also product claim 13 does not define novel subject-matter.

The appellant has defended novelty of the product claim based on the formation of an *interpenetrating polymer network*. However, this feature is not distinguishing the process claim from D1, see above, so it neither renders the product claim novel.

4. Thus, the appellant's main request cannot be granted.

Auxiliary requests

5. Novelty - auxiliary requests

- 5.1 The process claim of auxiliary request 1 further defines that the cross-linking step is carried out when the substrate is in a swollen state.

The process claims of auxiliary requests 2 and 3 further define the contacting step as being sufficiently long to swell the substrate surface and to entangle the water soluble polymer with the substrate surface. Auxiliary requests 2 additionally requires a drying step after this contacting step.

- 5.2 It has not been shown that these additional features result in a change of the structure of the product formed compared to the claims of the granted patent. Regarding auxiliary request 1, the the cross-linking being done with the substrate in a swollen state or not does not change the structure of the final product, which may be dried anyway. This applies equally to the drying step before the cross-linking in auxiliary request 2. As furthermore pointed out by the respondents, the added requirement in auxiliary requests 2 and 3 concerning the length of the contacting step must have been fulfilled also in the process defined in the claims of the granted patent, otherwise no interpenetrating polymer network can be formed at all.

5.3 Thus, the product-by-process claims of the auxiliary requests define the same product as claim 13 of the granted patent. The appellant did not submit any arguments to the contrary, it relied on the interpenetrating polymer network as a distinguishing feature.

5.4 Since the product claim of the granted patent is not novel over D1 this applies equally to the product claim of the auxiliary requests.

5.5 The appellant's auxiliary requests are thus not allowable already for this reason alone.

Other objections concerning admissibility or allowability of these requests need not be addressed.

6. Since none of the appellant's requests is allowable the appeal has to be dismissed

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated