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**Datasheet for the decision
of 23 October 2018**

Case Number: T 0136/15 - 3.3.10

Application Number: 06117208.6

Publication Number: 1745807

IPC: A61L29/04, A61L29/14

Language of the proceedings: EN

Title of invention:

Urinary catheter

Patent Proprietor:

Dentsply IH AB

Opponents:

Coloplast A/S
Hollister Incorporated

Headword:

Relevant legal provisions:

EPC Art. 100 (a), 100 (b)

Keyword:

Grounds for opposition - insufficiency of disclosure (no) -
lack of patentability (no)

Decisions cited:

T 0409/91, T 0435/91, T 0398/01, T 0249/05

Catchword:



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Case Number: T 0136/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 23 October 2018

Appellant: Hollister Incorporated
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 12 November
2014 rejecting the opposition filed against
European patent No. 1745807 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
 T. Bokor

Summary of Facts and Submissions

I. The appellant (opponent 2) lodged an appeal against the decision rejecting the oppositions against European patent No. 1 745 807.

II. Two notices of opposition had been filed on the grounds of insufficiency of disclosure (Article 100(b) EPC) and lack of inventive step (Article 100(a) EPC).

III. The documents forming part of the opposition proceedings include the following:

D1: US 4,616,064

D2: WO 97/49437

D3: US 6,017,577

D8: EP 1 149 598 A2

D11: Morrison and Boyd, Organic Chemistry, Fifth Edition, Newton, 1987, pages 1251-1252

D12: US 2003/0065091 A1

D13: WO 90/13021

A2: Dryflex® TPE Compounds

A6: Dryflex®s Injection Moulding

A7: WO 2001/073403

The following documents were filed during these appeal proceedings:

D16: LaPorte, Hydrophilic Polymer Coatings for Medical Devices, Lancaster 1997, Chapter 9

D17: Xanthos, Interfacial Agents for Multiphase Polymer Systems: Recent Advances, Polymer Engineering and Science, mid-November 1998, vol. 28, No. 21, pages 1392-1400

D18: Willis, Favis, Processing-Morphology Relationships of Compatibilized Polyolefin/Polyamide Bends: Part I: The Effect of an Ionomer Compatibilizer on Blend Morphology, Polymer Engineering and Science, mid-November 1998, vol. 28, No. 21, pages 1416-1426

- IV. The opposition division concluded that the claimed invention was sufficiently disclosed for it to be carried out by a person skilled in the art. Document D2 was the closest prior art. The problem underlying the claimed invention was how to modify the substrate of D2 in order to provide a further urinary catheter not being PVC and having an improved low-friction surface and better water-retention properties. The solution, which was characterised by a substrate containing a blend with defined amounts of a polyolefin and a polyamide or polyurethane having molecules with active hydrogen(s), was not obvious in view of the prior art.
- V. Claim 1 of the main request, which is the patent as granted, reads as follows:

"A urinary catheter comprising a substrate forming an elongate shaft, having on its surface, on at least an insertable part thereof, a hydrophilic surface layer providing low-friction surface character of the medical device when wetted by a wetting fluid, wherein the substrate is made of a polymer blend comprising a polyolefin and a polymer having molecules with active hydrogen(s), wherein the polymer having molecules with active hydrogen(s) is at least one of polyamide and polyurethane, and wherein the polymer blend comprises at least 80 weight percent polyolefin or polyolefin with intermixed medical oil and/or paraffin, and in the range of 2-20 weight percentage of the polymer having

molecules with active hydrogen(s)."

VI. The arguments of the appellant were relevant for the present decision were as follows:

The claimed invention was not sufficiently disclosed for it to be carried out by a person skilled in the art. The polymers forming the blends required by claim 1 were not compatible and for that reason not suitable for manufacturing catheters. The examples disclosed trademarked material for the preparation of the catheters and thus could not be relied on for disclosure of the claimed invention under Article 83 EPC. The feature required by claims 8, 9, 16 and 17 could only be achieved by systems containing a divalent hydrogen. The feature "hardness Shore A" of claim 3 did not allow the blends contemplated by the claimed invention to be determined.

Document D3, which related to coated catheters, was the closest prior art, as document D2 did not address the problem of low-friction.

If D2 were nevertheless considered closer, the problem of how to provide a non-PVC urinary catheter having lower friction than one having a polyolefin-only substrate could not be considered credibly solved by the features of claim 1, as the comparative data in the patent in suit had been obtained with Dryflex® and Meliflex®, whose composition was not disclosed.

The appellant acknowledged that if the board were not to accept its arguments with respect to the trademarked material Dryflex® and Meliflex®, Tables 1 to 3 of the patent in suit showed that the problem as formulated above was credibly solved by the catheter of claim 1.

Document D3 disclosed that amino groups on the surface of a polyolefin could react with isocyanate groups and form cohesive bonds to maintain a hydrophilic coating affixed to a catheter substrate. D1 disclosed blends having mechanical properties comparable to PVC. With this knowledge, the skilled person would use the blends of D1 as substrates for hydrophilic coatings and thus arrive at the claimed catheters. For this reason, they were not inventive.

VII. The arguments of the respondent (patent proprietor) where relevant for the present decision were as follows:

Catheters made of the blends required by claim 1 were already state of the art (D1, D18). Coated catheters were also known (D2, D3). The skilled person would thus find no difficulty in carrying out the invention.

Document D2, which disclosed urinary catheters and dealt with the problem of low friction, was closer than D3 to the claimed invention. The problem underlying the claimed invention was how to provide a non-PVC urinary catheter with lower friction than one having a polyolefin-only substrate, while maintaining comparable mechanical properties. The solution to this problem was the claimed catheter characterised by having a substrate blend containing 2-20 weight percent of a polymer having active hydrogen(s) selected from polyurethane and polyamide. The problem was credibly solved having regard to Tables 1 to 3 of the patent in suit, and the state of the art did not contain any pointer at the claimed solution. Thus, it was inventive.

VIII. Opponent 1 withdrew its appeal and became party as of right in these appeal proceedings. It informed the board that it would not be attending the oral proceedings, which took place on 23 October 2018.

IX. The final requests of the parties were as follows:

- The appellant requested that the decision under appeal be set aside and European patent No. 1 745 807 be revoked.
- The respondent requested that the appeal be dismissed, or alternatively, that the decision under appeal be set aside and the patent be maintained in an amended form on the basis of auxiliary requests A to G filed by letter dated 26 March 2018.

It further requested non-admission of documents D16, D17 and D18.

- Opponent 1 as party of right did not make any substantive requests.

X. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Documents D16, D17 and D18

2. These documents were filed by the appellant with the statement of grounds of appeal.

The respondent requested that the board hold these documents inadmissible under Article 12(4) RPBA.

The board decided not to hold document D18 inadmissible under Article 12(4) RPBA. This document was filed in order to further support the argument of the appellant with respect to lack of sufficiency of disclosure arising from miscibility issues, which was already part of the opposition proceedings and had been rejected by the opposition division.

The admissibility of document D17 was not discussed during the oral proceedings. However, D17 did not require a formal admission. For the purpose of the present appeal, the teaching of D17 is similar to that of D18 and only confirms the knowledge of the board.

As document D16 is not relevant for the present decision, it is not necessary to elaborate further on its admissibility.

Sufficiency of disclosure

3. The requirements of sufficiency of disclosure are met only if the claimed invention can be performed by a person skilled in the art without undue burden, using common general knowledge and having regard to the information in the patent in suit (T 409/91, OJ 1994, 653, Reasons 3.5; T 435/91, OJ 1995, 188, Reasons 2.2.1).
4. Leaving out the indications concerning the purpose of the technical features from claim 1 of the patent in suit, it remains that the invention defined in claim 1 is directed to a urinary catheter having a substrate made of a polymer blend and a hydrophilic layer on its

surface. The polymer blend required by claim 1 contains at least 80 % by weight of a polyolefin or a polyolefin with intermixed medical oil and/or paraffin, and 2-20 % by weight of a polymer having molecules with active hydrogen(s) being at least one of polyamide and polyurethane.

5. Catheters made of polymer blends required by claim 1 are known (D1, D18); catheters containing hydrophilic coatings are also state of the art (D2, D3).

6. The appellant argued, however, that the claimed invention was not sufficiently disclosed for the following reasons:

6.1 Polymers' miscibility

6.1.1 Claim 1 requires a blend of a polyolefin and a polymer having molecules with active hydrogen(s) which is at least one of a polyamide and polyurethane. However, it was known from D8, D12, D17 and D18 that polyolefins were not miscible with polyamides or polyurethanes.

Document D8 disclosed that polymeric materials should be compatible in order to obtain a catheter having good properties. The examples of compatible polymers were mixtures of only hydrophobic polymers and mixtures of only hydrophilic polymers, and did not include the mixtures required by claim 1, namely hydrophobic polymers (polyolefin) mixed with hydrophilic (polyamide, polyurethane).

Document D12 disclosed compatible polyurethane-polyolefin blends containing 5-95% of thermoplastic polyurethane. Paragraph [0012] of D12 disclosed that a low amount of polyurethane led to a continuous

polyolefin phase with discrete polyurethane domains dispersed. Such material did not have the required mechanical properties [0042], was not suitable for urinary catheters, and did not have a uniform surface to which a coating could adhere.

Lastly, documents D17 and D18 disclosed that few polymers formed truly miscible blends and proved that blends such as those required by claim 1 could only be obtained after extensive research.

As only compatible polymers were suitable for manufacturing catheters, and the patent in suit did not disclose the required steps in order to render a blend of these polymers compatible, the appellant concluded that the claimed invention was not sufficiently disclosed to be carried out.

6.1.2 However, the board finds that the prior art cited by the appellant fails to prove that the blends as defined in claim 1 are not suitable for urinary catheters.

Document D8 merely discloses blends which are compatible, but does not mention any of the blends required by claim 1.

Document D12 teaches that the miscibility of polymers can be enhanced by adding a compatibiliser [0042]. Even if the argument of the appellant that only miscible blends could be used in the claimed invention were followed, D12 already teaches the skilled reader how to solve that issue.

Similarly, D17 and D18 also teach the skilled reader how to achieve good mechanical properties using polymer

blends, for example by adding compatibilisers.

- 6.1.3 Document D1 discloses catheters made of blends required by claim 1 (see examples 89 to 92) having suitable mechanical properties, regardless of whether the polymers are miscible or not.

The board thus fails to see a miscibility problem which would prevent the skilled person from preparing a blend of a polyolefin and a polyamine or polyurethane as required by claim 1.

6.2 "Covalent bond to active hydrogen in the substrate"

- 6.2.1 Claims 8 and 9 require that the urinary catheter has a hydrophilic surface layer which is adhered to the substrate by a polyurea network, whereby said polyurea network forms a covalent bond to said active hydrogen(s) in the substrate. Claims 16 and 17 contain, respectively, the features of claims 8 and 9 in the context of a method for producing a urinary catheter.

- 6.2.2 The appellant argued that the urinary catheter of claims 8 and 9, and the method for producing it of claims 16 and 17, were not sufficiently disclosed for it to be carried out by a person skilled in the art.

Since claims 8, 9, 16 and 17 required forming "a covalent bond to said active hydrogen(s) in the substrate", said hydrogen must remain covalently linked to the substrate and would thus be divalent, which is not possible.

- 6.2.3 However, claims 8, 9, 16 and 17 merely require a network that
- adheres to the substrate, and

- is covalently bound to an active hydrogen (from the polyamide or polyurethane of the substrate).

If the network is adhered to the substrate by addition of a -NH- moiety of a urethane or amide group to an isocyanide, the hydrogen from said -NH- forms a covalent bond with the newly formed urethane group (D11, page 1252, line 4), and the coating is adhered by a polyurea network to the substrate, as required by claims 8 and 16. The same argument applies to the reaction of a -NH- group with, for example, an epoxide or an anhydride (claims 9 and 17).

The board thus fails to see why the conditions set by these claims could not be fulfilled unless a divalent hydrogen would be formed.

The skilled reader would immediately disregard the interpretation made by the appellant and necessitating a divalent hydrogen, since such embodiment is chemically not feasible and paragraph [0011] discloses that these hydrogen(s) are prone to react with other substances and thus leave their position in the molecule.

- 6.2.4 The appellant argued that if the hydrogen(s) in the polymer would leave the molecule, there was no moiety to which the network could adhere.

However, such adherence can be obtained by covalently linking the network required by claims 8, 9, 16 and 17 to a heteroatom previously linked to an active hydrogen.

6.2.5 For these reasons, this argument of the appellant is not convincing either.

6.3 Hardness Shore A

6.3.1 The appellant argued that the feature "hardness Shore A" in claim 3 was an arbitrary parameter, used mostly for control purposes, which was dependent on a large number of different factors. As the patent in suit did not provide any method for determining the "hardness Shore A" required by claim 3, the appellant concluded that the claimed invention was not sufficiently disclosed.

However, the mere possibility of obtaining different values for one parameter by using different tests is a clarity issue, which would only put into question a patent's disclosure if, for that reason, the skilled person would not be in a position to carry out the invention. The board considers this not to be the case, as claim 3 only requires a substrate having a specific hardness Shore A, which is not an uncommon parameter, regardless of which measurement method is used. There is no evidence on file that the blends required by claim 1 could not have a hardness Shore A value as defined in claim 3.

This argument is thus not convincing.

6.4 Trademarked material in the examples of the patent in suit

6.4.1 The appellant argued that the examples of the patent in suit failed to provide a way to carry out the invention, as the polymers used were defined only by means of trademarked material (Dryflex®, Meliflex®).

The former could have different compositions (A2, A6), whereas the latter could contain polyamide in addition to polyolefin (A7, page 12, lines 17-18).

The appellant cited T 398/01 and T 249/05 in support of its case.

In T 398/01, the board dealt with the situation of lack of clarity due to the presence of trademarked material as a feature of the claim.

In T 249/05, the board had to examine, in the context of novelty, whether or not the trademarked material of the state of the art disclosed an SBS copolymer with the degree of hydrogenation required by that invention.

The facts of these decisions were not the same as those of the present case, and none of them relate to the issue of sufficiency of disclosure.

Inventive step

7. Claim 1 is directed to a urinary catheter comprising a substrate and a hydrophilic surface layer. The substrate of the claimed catheter is made of a polymer blend comprising more than 80 weight percent of a polyolefin, which can contain intermixed medical oil and/or paraffin, and 2-20 weight percent of a polymer having molecules with active hydrogen(s), which is at least one of polyamide and polyurethane.

The claimed catheter aims at providing a non-PVC urinary catheter having good mechanical properties and reduced friction.

8. Closest prior art

8.1 At the oral proceedings before the board, the appellant argued that document D3 was the closest prior art. The respondent considered, in line with the opposition division's decision, that D2 was closer to the claimed invention.

8.2 The appellant argued that the patent in suit was not restricted to urinary catheters [0001], [0002], [0026], [0063] and, for this reason, other medical tubing, such as that of D3, could be used as the starting point for the assessment of inventive step.

Document D3 related to catheters suitable for being in contact with body fluids. The purpose of D3 was to provide low-friction catheters, which was also the aim of the claimed invention. According to column 1, lines 11-13, the catheters of D3 had slippery coatings which adhered tenaciously to the substrate. Column 1, line 59 onwards mentioned the issue of adhesion of the coating.

In contrast, document D2 sought a non-PVC catheter having no shrinkage and was not concerned with low friction (page 2, lines 18-20 of D2).

Thus, by relating to the same problem, document D3 came closer to the claimed invention.

8.3 However, document D2 refers to the problem of adhesion of the hydrophilic coating (page 3, line 19) and low friction (page 1, lines 19-21). D2 thus addresses a facet of the problem underlying the claimed invention.

In addition, it was not disputed at the oral

proceedings before the board that urinary catheters must have a diameter and length within specific limits. Not every catheter for medical application is therefore suitable for use as a urinary catheter. For this reason, the urinary catheters of D2 (page 1, line 10; examples) have more features in common with those of claim 1 than the catheters of D3.

As D2 and D3 both relate to the problem of adhesion of the hydrophilic coating, but the urinary catheters of D2 have more technical features in common with those of claim 1, D2 comes closer than D3 to the claimed invention.

- 8.4 Document D2 discloses two embodiments: urinary catheters having a PEBAX substrate (i.e. containing a polyester-polyamide block copolymer, see examples 1 to 3) and those having a polyolefin substrate (example 4).

It was not disputed at the oral proceedings that the latter embodiment comes closer to the claimed invention.

9. Technical problem underlying the invention

The respondent defined the technical problem underlying the claimed invention as how to provide a non-PVC urinary catheter having lower friction than one having a polyolefin-only substrate, while maintaining comparable mechanical properties.

10. Solution

The solution to this technical problem is the claimed urinary catheter having a polyolefin substrate and a

hydrophilic coating, characterised in that the substrate is a blend containing 2-20 weight percent of a polymer having active hydrogen(s) selected from polyurethane and polyamide.

11. Success

11.1 The respondent relied on the results obtained in Tables 1 to 3 of the patent in suit to show that the problem formulated in the preceding point had been credibly solved by the features of claim 1.

Experiments A-0 and B-0 were comparative and related to coated catheters whose substrate consisted of polyolefin only. Experiment A-5/10 showed that 5 to 10% of polyurethane led to improved water retention (Table 1), lower friction force (Table 2), and friction coefficient after wetting (Table 3) compared with Experiment A-0. Similar results were obtained in the experiments of series B by catheters containing 5 %, 10 % and 15 % weight to volume of polyamide (Experiments B-5, B-10 and B-15), compared to those having only polyolefin (B-0).

11.2 The appellant argued that it had not been shown that the problem as formulated above was credibly solved, as the data in Tables 1 to 3 of the patent in suit had been obtained with trademarked polymers whose composition was not known.

Dryflex®, which was the material used in experimental series A, was a designation which included many different polymers, as shown by evidence A2 and A6. It was thus not possible to ascertain which blends had been tested.

Meliflex® contained polyamide in addition to polyolefin (A7, page 12, lines 17-18). Thus, the experiments of series B did not provide a comparison to the urinary catheters of document D2 either.

11.3 However, the patent in suit indicates that the experiments of series A and B were carried out using polyolefin material [0044]. The board sees no reason to doubt it, even if not every commercial blend under the brands Dryflex® and Meliflex® were made of polyolefin only. This argument is thus not convincing.

11.4 The comparison provided in Tables 1 to 3 shows that the problem underlying the claimed invention was credibly solved by the claimed urinary catheters, which have lower friction than those having an olefin substrate.

12. It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious from the prior art.

12.1 The appellant argued in this respect that document D3 disclosed coatings covalently attached to catheter substrates (column 20, lines 41-43) by the reaction of amino and isocyanate groups.

Column 10, lines 39-46 of D3 disclosed the chemistry involved, according to which isocyanate groups formed cohesive bonds with reactive chemical functional groups such as hydroxyl, urethane, urea, amide, carboxyl and carbonyl. Said functional groups could be present in the original substrate polymer, or could have been affixed to a polymeric plastic or rubber substrate by oxidative or plasma treatment.

Plasma treatment of polyolefins such as polyethylene

allowed amino groups to be affixed to them, thereby facilitating the reaction with a polyurethane prepolymer containing terminal isocyanate groups (column 11, lines 35-37 and 47-53).

With this knowledge, the skilled person would turn to a document such as D1, which discloses tubes for delivering or removing liquids from the body and for use as catheter shaft materials (column 1, lines 23-25) made of blends that have the mechanical characteristics of PVC (column 3, lines 44-46).

Examples 89, 90 and 92 of D1 related to blends containing 3% of PTUA 102, PTUE 302 and PTUE 202, which were polyurethane/polysiloxane polymers (column 2, lines 39-46); and example 91 contained 3% of PTA 1201, which was a polyamide/polysiloxane polymer (column 1, lines 46-48).

The skilled person would recognise that substrates made of these blends, which were good alternatives to PVC according to D1, would allow a better attachment of the hydrophilic surface layer by having reactive -NH- groups (D3) and thus arrive at the claimed invention without using inventive skills.

A further pointer to this combination was that the blends of document D1 showed reduced spallation (column 1, lines 55-56), which was identified as a problem in document D2 (page 3, line 13).

Lastly, the appellant argued that using blends as a substrate was an obvious option taking into account the common general knowledge of the person skilled in the art, as reflected in document D18, which disclosed that the mechanical properties of a blend resembled those of

the main component (Figure 4).

12.2 The board does not find the arguments of the appellant convincing, for the following reasons:

12.2.1 Document D3 proposes, as a solution to the problem of adhesion of the hydrophilic surface layer, affixing very reactive amino groups to the surface of the polymer by plasma treatment (example 3; column 11, lines 10-53).

In contrast, the claimed invention does not rely on amino groups, but on urethane or amide groups for adhering the hydrophilic layer.

Document D3 teaches modifying the surface of the polyolefin substrate, but does not mention or contain a pointer to the blends of polymers, which is the claimed solution.

12.2.2 Document D1 relates to blends, some of which have functional properties similar to plastisiced PVC (column 3, lines 44-46).

However, not every composition of D1 represents an alternative to PVC, as D1 also relates to compositions similar to polysiloxanes (column 4, line 5) and soft elastomers (column 4, line 27). Blends taught as alternatives to PVC (column 3, line 41 to column 4, line 2) are made of polysiloxane/polycarbonate block copolymers, whereas the claimed solution requires polyurethane or polyamide.

Thus, even if the skilled person were to combine the teaching of documents D1 and D2 in seeking a blend having the mechanical properties of PVC, they would not

have arrived at the claimed invention.

- 12.2.3 Examples 89 and 90 of D1 (Table 8) have tensile and elongation values which correspond to those of the PVC-alternatives in column 3, lines 44-46. The appellant argued that the skilled person, searching for a PVC alternative, would turn to these examples having the required mechanical properties.

However, the problem to be solved starting from D2 is that of increasing the adherence of the hydrophilic coating layer so that friction is reduced. The skilled person seeking a catheter with the desired mechanical properties but not aiming at diminishing friction would turn to D1.

Further, the blends of document D1 have a low coefficient of friction with human skin per se (column 1, lines 22-23). There is no reason why the skilled person would attach a hydrophilic coating to a blend according to D1, which already has the desired friction properties.

- 12.2.4 Lastly, with respect to the arguments of the appellant relying on D18, it is not in dispute that blends of polymers are state of the art. The issue is whether or not the skilled person would use the blends required by claim 1 in order to solve the problem underlying the present invention. D18 only relates to mechanical properties, not to reducing friction, and thus does not contain a pointer to the claimed solution either.

- 12.2.5 There is thus no pointer in the prior art to the claimed invention, as the skilled person, trying to reduce the friction of the urinary catheters of D2, would have arrived at the blends required by claim 1

only with the benefit of hindsight.

As the skilled person seeking a catheter with less friction would not have any motivation to replace the substrate of the urinary catheters of D2 with any of the blends disclosed in document D1, the urinary catheter of claim 1, and by the same token the method of claim 12 for producing such catheter are inventive within the meaning of Article 56 EPC.

13. Conclusion

The grounds under Article 100(a) and (b) EPC do not preclude the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated