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Datasheet for the decision of 28 September 2011

Case Number: T 0468/09 - 3.2.02

Application Number: 01114582.8

Publication Number: 1145729

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:
A ready-to-use urinary catheter assembly

Patentee:
Coloplast A/S

Opponents:
(1) Hollister Limited
(2) Dansac A/S

Headword:
-

Relevant legal provisions:
EPC Art. 100(b)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Sufficiency of disclosure (yes)"

Decisions cited:
T 0881/95

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0468/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 28 September 2011

Appellant: (Patent Proprietor)	Coloplast A/S Holtedam 1 DK-3050 Humlebaek (DK)
Representative:	Inspicos A/S Kogle Allé 2 P.O. Box 45 DK-2970 Hørsholm (DK)
Respondents: (Opponent 1)	Hollister Limited 21 Holborn Viaduct London EC1A 2DY (GB)
Representative:	Anderson, Robert J. Hogan Lovells International LLP Atlantic House Holborn Viaduct London EC1A 2FG (GB)
(Opponent 2)	Dansac A/S Lille Kongevej 304 DK-3480 Fredensborg (DK)
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 11 December 2008 revoking European patent No. 1145729 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 20 February 2009 against the decision of the Opposition Division posted on 11 December 2008 to revoke the patent for insufficient disclosure. The fee for the appeal was paid at the same time and the statement setting out the grounds for appeal was received on 21 April 2009. Opponent III withdrew his opposition on 5 January 2009.

II. Following documents are cited in the present decision:

D7: Report of Mogens Swanum dated 15.09.05,
D26: EP-A-586 324,
D27: EP-A-217 771,
D28: WO-A-94/16747,
D29: Solemn declaration by Mogens Swanum dated 21.04.2009,
D30: WO-A-00/30696,
D31: WO-A-00/30575,
D32: Coloplast Continence Care Lab Report, "Accelerated aging experiments and Friction measurements of coated and noncoated PVC catheters" dated 21.04.2009,
D33: Coloplast Continence Care Lab Report, "Friction measurements of coated PVC catheters" dated 13.02.2010.
Annex 2: Excerpt from a brochure published by the patentee in 1988/89.
Annex 8: Karl J. Hemmerich "General Aging Theory and Simplified Protocol for Accelerated Aging of Medical Devices, Medical Plastics and Biomaterials" dated July 1988.

III. Oral proceedings were held on 28 September 2011.

IV. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the sets of claims according to the main request or to one of the first to the third auxiliary requests, all filed with the statement of grounds of appeal dated 21 April 2009, after the Board's assessment of compliance with the Articles 100(b) and 83 EPC. On an auxiliary basis, the appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the above-cited set of claims.

He further requested that Mr Swanum be heard as a witness under Article 117(1)(d) EPC with regard to the events and technical issues which led to the invention and the circumstances explained by him in his declarations D7 and D29, and that an expert opinion be obtained under Article 117(1)(e) EPC on the suitability, for storage in a pre-wetted condition, of hydrophilic coated catheters which were known at the priority date of the patent in suit.

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

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

"A urinary catheter assembly comprising at least one urinary catheter (1) having on at least a part of its surface a hydrophilic surface layer (6) intended to

produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7, 16, 29, 34, 42, 46, 51, 51') made of a gas impermeable material and having a cavity (11, 18, 39, 48, 53) for accommodation of the catheter (1, 58, 69), characterized in that the cavity accommodates said liquid swelling medium for provision of a ready-to-use catheter assembly."

VI. The appellant argued essentially as follows.

The gist of the claimed invention was to provide an assembly for intermittent catheterisation, wherein the catheter could be withdrawn from the package in a condition which was suitable for insertion into the urethra. In order to put the invention into practice, the skilled person had to provide the urinary catheter with a hydrophilic surface layer, a package made of a gas impermeable material, to place the catheter and a liquid swelling medium in the package and to close the package.

Urinary catheters with hydrophilic surface layers were known at the priority date of the patent in suit, and so were gas-impermeable packages. On the basis of the disclosure of the opposed patent and his common general knowledge, the skilled person would have no difficulty in carrying out the catheter assembly in the claimed manner, no matter if the liquid swelling medium were to be placed in direct contact with the catheter surface or in a storage body from which it was released. The subject-matter of claim 1 of the main request covered both embodiments and did not require storage of the

catheter for years. The stability of the catheter coating was not an essential feature in the present patent.

The opponents had provided no technical evidence to establish that the catheters mentioned in paragraph [23] of the patent (documents D26, D27, D28), or the catheters commonly available at the priority date of the patent were unsuitable for being stored within a package in direct contact with a liquid swelling medium.

From the results of the patentee's experiments presented in D32 and D33 and from Mr Swanum's statement in D29, it was clear that the Opposition Division's interpretations of D7 and Annex 2 were wrong and that its conclusions could not be followed. Sufficiency of disclosure had to be assessed primarily on the basis of the disclosure of the contested patent itself.

Documents D29 to D33 should be admitted into the proceedings as additional evidence in response to the Opposition Division's decision. In particular, D33 was prompted by the opponent's objections raised against the accelerated ageing tests provided in D32. The laboratory report D32 proved that catheters commonly available at the priority date of the patent actually worked, i.e. preserved their low friction characteristics after storage in water for the proposed shelf life of the catheters.

Though D26 to D28, cited in paragraph [2] of the patent, did not suggest storing of the catheters in wetted conditions, these documents did not indicate

that the catheters and their coatings might not be suitable in such a situation. In order to establish insufficiency of disclosure, the burden of proof was upon the opponents.

Should the Board still have doubts about Mr Swanum's declarations D7 and D29 concerning the circumstances which led to the invention or the suitability of catheters known at the priority date for long-term wetted storage, the Board was requested to consider taking evidence by hearing Mr Swanum as a witness and by obtaining an expert opinion under Article 117(1) EPC.

No further experiments had been conducted by the appellant to evaluate the effects of long-term storage of the known cathethers in pre-wetted conditions because Mr Swanum had experienced brown colouring and opaqueness of the PVC catheters, which was not accepted by users, as stated in D29. However, the mere fact that new developments were initiated by the patentee in 1996 (Annex 2) did not deprive the earlier technology of enablement. A drawback of an aesthetic nature did not render the catheter technically unsuitable. Moreover, the provision of Article 100(b) EPC did not require the invention to be carried out in the best mode.

VII. Respondent 1 (opponent 1) argued as follows.

The documents filed belatedly by the appellant should not be admitted into the proceedings. In particular, the experiments submitted in D33 were irrelevant and unreliable since they did not show that catheters stored for up to 5 years in a liquid swelling medium

would still be usable and since these experiments had not been made using coatings existing at the filing date of the contested patent. The results showed limited friction measurements, but did not show that the coating maintained its consistence throughout the time.

The appellant's request for taking of evidence from Mr Swanum as a witness or for obtaining an expert opinion under Article 117(1) EPC should be refused since the appellant had failed to indicate the factual details to be proven and Mr Swanum had already made his views clear in his previous declarations D7 and D29. Moreover, taking further evidence or obtaining an opinion would necessitate adjournment of the oral proceedings and additional time for the opponents to reply, which would amount to an abuse of procedure.

The invention as claimed was restricted to the embodiments in which the coating was in contact with the liquid swelling medium (water) from the time of manufacture until use of the catheter, which could be up to 5 years later. It was essential that the coating be capable of being stored for the duration of this period without deterioration. Although not specified in claim 1, the recommended time period was, however, implicit.

The subject-matter of claim 1 did not include the embodiment in which coating and liquid were kept apart until immediately before use, by confining the liquid in a spongy body.

At the time the patent was filed, a skilled person was not able to produce without undue burden a hydrophilic catheter coating that could withstand wet storage for the required shelf life, i.e. avoiding deterioration of the coating. The patent was silent on how to solve this problem with the coating, namely how to provide a pre-wetted catheter assembly which could be stored for up to 5 years, typically 36 months, thus resulting in a long term preservation of the low friction surface characteristic of the catheter until its use.

The evidence provided by the appellant clearly showed that the prior art coatings were not suitable. None of the catheters disclosed in documents D26 to D28 referred to in paragraph [2] of the patent was intended for wet storage. There was no indication in the patent of how the hydrophilic coating catheter could be made.

It resulted from the declaration D7 by Mr Swanum that a coating remaining stable in water for the time of the shelf life of the catheter was not available. The appellant simply did not know how to make a hydrophilic catheter which could be stored in wetted conditions for three years. The recent declaration D29 of Mr Swanum that the previous catheters did not withstand immersion in water due to a brown colour and opaqueness observed on a PVC catheter, was an unacceptable attempt to change the facts. D30, filed 2 years after the opposed patent, made it clear that the above problems still had not been solved 2 years later. Annex 2, which was the appellant's own publication, was consistent with Mr. Swanum's declaration D7 and confirmed that there was a problem with the hydrophilic coating which could not be solved without undue burden. The appellant's

experiments D32 and D33 were not reliable, as mentioned above. Moreover, it was not established that the catheters used in the experiments and those available at the filing date of the patent were identical, or that an accelerated ageing experiment was appropriate as far as durability was concerned.

Respondent 2 (opponent 2) argued as follows.

In Annex 2, which was aimed at healthcare professionals, there was a clear statement that it proved complicated to develop a catheter coating which remained smooth after immersion in water for an extended period of time.

Mr Swanum's statement in D29 that the alleged problem was the discolouring of the PVC catheter due to long term immersion in water, was purposely misleading, since in D7 Mr Swanum was undoubtedly referring to the smoothness of the coating when he stated that it was not suitable for a long storage in wetted condition. It was further stated that in 1996 Coloplast had no experience in hydrophilic surface coatings at all. Therefore, the prior art catheters referred to as documents D26 to D28 in paragraph [2] of the patent were not suitable.

The appellant's experiments provided in D32 were not relevant since there was doubt on the impartiality of the test and there was no evidence that the tested catheters were the same as the ones available in 1996. Moreover, there was doubt whether the process of accelerated ageing used in the experiments was appropriate, since the information given in Annex 8

rather dissuaded from using a temperature above 50°C for ageing tests if PVC was involved, which was the material used for the tested catheters.

In claim 1 of the main request it was specified that the catheter assembly comprised a package with a cavity in which both the catheter and the swelling liquid were accommodated. This meant that the catheter was constantly in contact with the liquid and that the hydrophilic coating was constantly immersed in the wetting liquid until use of the catheter.

However at the filing date of the contested patent no hydrophilic coating existed which could withstand being immersed for a long time, as acknowledged in Annex 2 and D30 and confirmed by Mr Swanum's declaration D7. Since there was no disclosure in the patent of the type of coating used for the catheter, the described embodiment could not work and was not enabling. Article 83 EPC was not complied with since the claimed subject-matter could not be carried out without undue burden over the whole range of the claim.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of documents D29 to D33*

During the appeal proceedings the appellant requested that documents D29 to D33 be admitted into the proceedings, which was contested by respondent 1, albeit only in relation to D33.

In the Board's judgement the laboratory report D33 is admissible under Article 13(1) RPBA since, although submitted belatedly, this document was filed to supplement and confirm the results previously presented in the laboratory report D32 in an attempt to overcome the respondent's objections. Moreover, both reports are regarded by the Board as useful to assist a proper understanding of the invention and its development.

The other documents D29 to D32 were regularly submitted by the appellant with its statements of grounds for appeal in order to counter the reasons of the Opposition Division's decision which led to the revocation of the patent. They are therefore also admitted in accordance with the provisions of Article 12(1) and (2) RPBA.

3. *Taking of evidence*

The Board holds that Mr Swanum had already produced detailed declarations (D7, D29) and sufficient information on the common general knowledge, the circumstances surrounding his contribution to the invention as an employee at Coloplast and the suitability for storage of coated catheters in a pre-wetted condition at the time the patent application was filed, so that taking further evidence from him as a witness did not seem to be expedient. Also, an expert opinion did not appear to be necessary, since the ample information provided in the numerous documents already on file were sufficient to allow the Board to decide on the matter of sufficiency of disclosure. Therefore, the

appellant's request for taking of further evidence is refused.

4. *Sufficiency of disclosure*

4.1 Article 100(b) EPC states that an opposition may be filed on the ground that the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The requirement is the same as for Article 83 EPC, which addresses the European patent application before grant.

It is established case law that sufficiency of disclosure must be assessed on the basis of the patent specification as a whole, including the description and the claims. Moreover, the disclosure is only regarded as sufficient if it allows the invention to be performed in the whole range claimed, i.e. for all embodiments falling within the ambit of the claimed subject-matter.

4.2 Essentially, claim 1 of the main request defines a urinary catheter assembly comprising a urinary catheter and a catheter package;

- the urinary catheter has on its surface a hydrophilic surface layer (coating);
- prior to use, the hydrophilic surface layer is brought into contact with a liquid swelling medium to produce a low-friction surface;
- the catheter package is made of a gas impermeable material and has a cavity;

– the cavity accommodates the catheter (preamble of claim 1) and the liquid swelling medium (characterising portion of claim 1) for provision of a ready-to-use catheter assembly.

Claim 1 of the main request covers the two embodiments which are disclosed in the patent specification.

4.3 In a first embodiment, shown in Figures 1 and 2, the catheter package 7 is formed by two sheets 8 and 9 of gas impermeable material welded together along a seam 10 (joint) so as to define a cavity 11 for accommodating a catheter tube 2 and a compartment 12, spaced apart from the cavity by an transitional section 13 (see paragraphs [11] to [12] and [21] to [22]) for accommodation of a liquid swelling medium confined in a storage body 14 made of a spongy or gel-like material (see paragraphs [23] and [30]).

The catheter and the spongy body are arranged in the package prior to welding the sheets of gas impermeable material together, in order to form the urinary catheter assembly. This clearly means that the package 7 encloses both the cavity and the compartment (see paragraphs [12] and [24]).

Prior to use of the catheter, the hydrophilic surface layer 6 (coating) is prepared for activation of its low friction character by squeezing the liquid out of the body in order to allow it to flow into the cavity and to bring the catheter into a ready-to-use condition (see paragraph [25]).

This first embodiment, therefore, corresponds point by point to the wording of claim 1 in suit and, contrary to respondent's 1 assertion, falls within the scope of said claim. In particular, the hydrophilic coating of the catheter which is accommodated in the cavity is activated "prior to use" by treatment with the liquid swelling medium (preferably water - see paragraph [69]) within the cavity for provision of a "ready-to-use" catheter assembly.

This embodiment can readily be carried out on the basis of the information given in the above-quoted passages of the description. This was not contested by the respondents either.

4.4 In a second embodiment, not shown in the figures, the spongy body 14 is not used. The liquid is introduced into the package during the assembly operation, prior to the welding of the joint. In this case, the compartment for the liquid swelling medium is integrated with the cavity for accommodation of the catether, the coating being prepared and activated immediately after completion of the production process when the liquid has been introduced into the package (see paragraphs [13] and [29]).

This embodiment is made possible due to the gas impermeable characteristic of the material of the package. As explained in paragraph [10] of the patent, this should be understood as a material sufficiently tight to avoid diffusion by evaporation of the liquid, so as to prevent the coating from drying out and to preserve its low friction character for a long time (see paragraphs [13] and [29]). A period exceeding the

shelf life of the catheter is recommended, which could be up to 5 years but is typically 36 months.

It should be noted here that the disclosed range is not limited at the lower end and therefore does not exclude much shorter periods of e.g. a few months, though such interpretations should be ruled out which do not make any technical or commercial sense, such as a zero length period or a period of a few days. Moreover, the time period of 36 months is given as an example ("typically"; "recommended"). The important matter is to keep the coating activated and the catheter in a ready-to-use condition "at all times" (see paragraph [29]), i.e. within the time period corresponding to the above defined range.

Claim 1 does not mention any duration for the preservation of the coating, i.e. the period between the time of activation of the coating and the time at which a catheter is used. Therefore the subject-matter of claim 1 also covers the second embodiment since "prior to use" corresponds in that case to the activation of the coating at the time the catheter assembly is produced. From that time onwards, the catheter assembly is "ready-to-use", in accordance with the wording of a claim 1.

4.5 As can be derived from the patent specification, the problem underlying the claimed solution is principally to avoid diffusion by evaporation of the liquid swelling medium in order to protect the activated coating from drying out (see paragraphs [10], [13] and [29]). This result is achieved by the gas impermeable characteristic of the material constituting the package,

not by a characteristic of the coating. Therefore, the respondent's arguments based on maintenance of the coating stability and of its coherence over time by avoiding its dissolution in the liquid are irrelevant and not convincing.

The same is true for the problem formulated by the Opposition Division of avoiding the coating reacting with the material inside the bag or dissolving into water.

4.6 It results therefrom that all the discussions about the characteristics of the coating appear to be irrelevant for the assessment of sufficiency of disclosure and of the reproducibility of the catheter assembly as claimed. The same applies to the document cited by both parties in support of their arguments regarding the properties of the coating.

Having regard to the broad definition of claim 1 and given that the gas impermeable material of the package provides sufficient tightness against evaporation of the liquid for a period of time which could vary considerably ("up to five years"), the known catheters referred to in paragraph [2] of the patent specification could be suitable in any case and on the basis of this disclosure the invention can be carried out, even if such catheters may suffer from some other deficiencies. Article 100(b) EPC does not require that the best mode be performed.

Where a disadvantage of an invention could (possibly) prevent its use, this is not an obstacle to reproducibility provided that the otherwise desired

result was achieved by the technical teaching disclosed in the patent (see also T 881/95 of 25 June 1997, not published). This is obviously the case here since the only problem addressed by the contested patent is confined to preventing evaporation of the liquid from the package and subsequent drying of the catheter coating, and this is solved by the provision of an appropriate material for the package. The coating stability of a catheter immersed for a long period of time is not an issue. Under the circumstances, it matters little whether, at the priority date of the contested patent, catheter coatings capable of withstanding water storage over a long period of at least 36 months were available or not.

4.7 For the foregoing reasons, the requirements of Article 100(b) EPC are satisfied.

5. *Remittal*

Since the decision to revoke the patent, which is the subject of the present appeal, was based on an objection of insufficiency of disclosure (Articles 100(b) EPC) which now is removed, the Board finds it appropriate to remit the case to the department of first instance for further prosecution of the case, as requested by all parties.

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 set of claims according to the main request filed on 21 April 2009.

The Registrar: The Chairman:

D. Hampe M. Noël