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Datasheet for the decision of 18 December 2008

Case Number: T 1574/05 - 3.2.02

Application Number: 97918923.0

Publication Number: 0923398

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) Willy Rüsch GmbH
2) AstraZeneca AB (withdrawn)
3) Hollister Limited
4) Manfred Sauer GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 113(1), 114(1)(2), 123(2), 54(3)(4), 56, 87(1)

Relevant legal provisions (EPC 1973):
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Keyword:
"Admissibility of the requests"
"Right to be heard - no procedural violation"
"Priority rights"
"Novelty and inventive step - yes (main request)"
"Remittal to the first instance"

Decisions cited:
G 0002/98

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1574/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 18 December 2008

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 22 December 2005 revoking European patent No. 0923398 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: M. Noel
M. J. Vogel

Summary of facts and submissions

I. In its decision of 22 December 2005, the opposition division revoked European patent No. 0 923 398 for lack of novelty of the subject-matter of claim 1 then on file vis-à-vis

D11 JP-A-55-12265, and
D11A English translation of D11.

In an *obiter dictum*, the first instance additionally held that there was no inventive step vis-à-vis the combination of documents

D8 US-A-3 967 728,
D12 CN-A-1 106 744, and
D12A English translation of D12

II. The appellant (proprietor of the patent) lodged an appeal on 7 December 2005 and paid the appeal fee on the same day. A statement setting out the appeal grounds was submitted on 5 April 2006.

III. Opponent 02 withdrew its opposition by the letter dated 26 August 2003. It is therefore not a party to these proceedings.

Opponent 01 withdrew its opposition by the letter dated 5 January 2009, that is after the oral proceedings held before the Board. Therefore, it still was a party at the time the present decision was announced.

IV. Oral proceedings were held on 18 December 2008. The opponent 01 was not represented. At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed at the oral proceedings before the opposition division on 6 December 2005 or, in the alternative, on the basis of the first to fifth auxiliary requests, all filed with the grounds of appeal on 5 April 2006, or on the basis of the sixth or seventh auxiliary requests, all filed with the letter of 15 September 2008.

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

V. In addition to the documents cited above (see section I), the following documents are of relevance to this decision:

D25 WO-A-97/26937, and
D25P SE-9600276-1 (priority document of D25).

VI. Claim 1, according to the main request, reads:

"A urinary catheter assembly comprising at least one urinary catheter (1, 58, 69, 77, 81, 102) 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 (16, 29, 34, 42, 46, 51, 51', 101) having a

cavity (39, 53, 57, 74) for accommodation of the catheter (1, 58, 69, 77, 81, 102), characterized in that:

the package (16, 29, 34, 42, 46, 51, 51', 101) is closed, made of a liquid tight material, and includes a compartment (25, 31, 35, 40, 47, 54, 54', 56, 63, 64, 71, 78, 82, 89, 95, 105) having walls of a gas impermeable material,

the compartment (25, 31, 35, 40, 47, 54, 54', 56, 63, 64, 71, 78, 82, 89, 95, 105) is separated from the cavity (39, 53, 57, 74) for accommodation of the catheter (1, 58, 69, 77, 81, 102), and

the swelling medium is confined in said compartment (25, 31, 35, 40, 47, 54, 54', 56, 63, 64, 71, 78, 82, 89, 95, 105) in a liquid state until the intended use of the catheter for provision of a ready-to-use catheter assembly."

VII. The appellant submitted the following arguments:

All of the requests filed at the appeal stage were admissible because the main request was identical to the version revoked by the opposition division, and auxiliary requests 1 to 5 were filed with the statement setting out the grounds of appeal with the view to overcome the reasons given in the contested decision. Auxiliary requests 6 and 7 were filed belatedly, but as a precaution and in reasonable time, before the oral proceedings.

The opposition division committed a procedural violation by not respecting the appellant's right to be heard

under Article 113(1) EPC. In the annex to the summons to the oral proceedings the opposition division pointed out that D11 was not novelty destroying. Therefore the patent proprietor refrained from commenting on D11/D11A during the oral proceedings. However, surprisingly the opposition division changed their opinion on D11 and revoked the patent for lack of novelty without informing the patent proprietor about their new interpretation of D11.

The decision under appeal was based on lack of novelty. However, in an *obiter dictum* the opposition division additionally denied an inventive step with respect to documents different from those used for the novelty assessment. If the case was remitted to the first instance, it would therefore be appropriate to change the composition of the opposition division to rule out any risk of partiality.

The amendments to claim 1 did not introduce new subject-matter. The term "separated" and the expression "liquid tight material" were supported by the application as filed, in particular by claim 19. The term "closed" could be derived from the drawings and also the expression "without opening the package", mentioned several times in the description, showed that the package was closed.

D25 could at best be considered under Article 54(3) EPC. In one embodiment disclosed in this document, the hydrophilic urinary catheter was contained in a bag which was closed. However, it was not derivable with certainty from the priority document D25P whether the inlet of the urine collection bag was open or closed.

Consequently, the embodiment of D25 according to which the bag was said to be closed was not entitled to the priority date of document D25P. It resulted therefrom that D25 did not belong to the prior art.

D11/D11A disclosed a therapeutic catheter which had drug release capabilities, but the hydrophilic cross-linked resin layer described therein did not absorb enough water to give the catheter sufficient lubricity to produce a low-friction surface. The sole purpose of the layer was to administer a therapeutic drug solution. Moreover, the catheter assembly did not have a compartment separate from the cavity housing the catheter, and the liquid contained in the cavity was not a swelling medium. The subject-matter of claim 1 was therefore novel vis-à-vis this document.

D8 disclosed a lubricant pouch separated from the cavity housing the catheter, in order to keep the user's fingers free of lubricant when lubricating the catheter.

D12/D12A disclosed a high water-containing elastomer shaped catheter which was kept until use in a plastic bag containing a sterilisation liquid for storage (hibitane). However, since the catheter had no coating and the liquid was not a swelling medium, it could not produce a low friction surface. Besides, the mechanical properties of the catheter did not change during use. Furthermore, the catheter package of D12/D12A did not have a compartment separated from the cavity, since the storage fluid was already contained in the cavity for the catheter. Therefore the problem of preparing the catheter by activation of the coating layer just before use did not arise in the device of D12/D12A. Under these

circumstances, the provision of a pouch according to D8 in the catheter of D12/D12A would be the result of an *ex post* analysis and would not lead in an obvious way to the subject-matter of claim 1.

Furthermore, none of D8 and D12/D12A disclosed a catheter with a hydrophilic surface layer to be activated by a swelling medium. Therefore, also when starting from D8, a combination with D12/D12A would not result in the claimed catheter.

The subject-matter of claim 1, therefore, involved an inventive step when faced with any combination of D12A and D8.

VIII. The respondents submitted the following arguments:

All the requests, including the main request, were filed after the opposition's time-limit. They were therefore filed late and as such inadmissible. In particular the auxiliary requests 6 and 7 were filed without good reason shortly before the oral proceedings.

D11/D11A was duly considered during the oral proceedings before the opposition division and the appellant was given an opportunity to comment on it. Therefore his right to be heard had been respected.

Since claim 1 had been amended, also formal aspects had to be considered. The term "separated" was unclear because it could mean either "independent" or "in two different places". The term "closed" was not supported by the application as filed. Nor could it be deduced with certainty from the expression "without opening the

package" used in the description. Moreover, this expression was restricted to some embodiments set out in the application, so that the generalisation represented by the introduction of the term "closed" into claim 1 was not justified. Furthermore, "the package is closed" represented a functional feature, not a structural feature of the catheter assembly. Consequently, all these amendments lacked clarity and extended the claimed subject-matter in contravention of the requirements of Articles 84 and 123(2) EPC.

The priority document D25P disclosed a urine collection bag having a closed upper inlet. The bag had to be closed first for sterilisation purposes and secondly for wetting the catheter before use, by shaking the bag containing the wetting fluid released from the sachet. Therefore, the priority date of D25P was validly claimed in D25.

D11/D11A disclosed a catheter whose coating was made of a hydrophilic resin. All the resins mentioned in this document had hydrophilic properties in common and were able to produce a low-friction surface when they were brought in contact with water. D11/D11A therefore necessarily increased lubricity in addition to diffusing a therapeutic drug. According to opponent 03, the terms "casing" and "cavity" used in D11A were synonymous and denoted simply the space surrounding the catheter and its coating, and according to opponent 04, the "casing" was separated from the "sealed cavity" containing the therapeutic drug solution, as stated in claim 1 of the document. Therefore, the subject-matter of claim 1 at issue lacked novelty vis-à-vis the catheter disclosed in D11/D11A.

D12/D12A disclosed a catheter made entirely of highly hydrophilic material, as was the case for the embodiment mentioned in paragraph [28] of the contested patent. D12/D12A also aimed at providing improved surface lubricity. Since the catheter and the surrounding storage liquid were contained in a packing bag, a problem of gas impermeability of the packing bag material arose, first vis-à-vis the gas used for sterilisation and then vis-à-vis the gas produced by the evaporation of the storage liquid. D8 suggested separating the liquid by keeping it in a compartment independent of the cavity housing the catheter. The subject-matter of claim 1 was therefore suggested by the combination of D12A and D8.

Starting from D8, the problem to be solved was to keep the user's hands free of lubricant when manipulating the catheter. D12A suggested replacing the lubricant with water, subject to providing the catheter with a hydrophilic coating. Such a measure was obvious for the skilled person, taking into account his general knowledge.

Reasons for the decision

1. The appeal is admissible.

2. *Admissibility of the various requests*

The main request corresponds to the version of the claims refused by the opposition division, leading to the revocation of the patent. This request forms the

legal framework on which the appeal is based, and is therefore admissible.

Auxiliary requests 1 to 5 were filed with the statement of grounds of appeal as fallback positions. Since this has to be considered as a normal behaviour of a losing party, auxiliary requests 1 to 5 are admissible under Article 114(1) EPC.

Auxiliary requests 6 and 7, however, were filed late in the appeal stage, i.e. after the summons to oral proceedings, and without convincing reasons. The Board has therefore decided not to admit these requests under Article 114(2) EPC.

3. *Procedural matters*

3.1 The appellant contends to have been taken by surprise because he first learned of the opposition division's interpretation of claim 1 in the contested decision. Moreover, the first instance had acknowledged the novelty of the subject-matter of claim 1 vis-à-vis D11/D11A in the notification annexed to the summons to oral proceedings. As a result, the appellant had not been able to reply to this change of the first instance's opinion contrary to the requirements of Article 113(1) EPC.

However, on reading the minutes of the oral proceedings (see page 6), the Board notes that the parties discussed the novelty of the subject-matter of claim 1 vis-à-vis D11/D11A during the oral proceedings before the opposition division. The framework of the discussion had been set out in the communication dated 7 April 2005

annexed to the summons to oral proceedings of 6 December 2005. This communication shows that the interpretation of D11/D11A was to be discussed. There is no mention or suggestion that the subject-matter of claim 1 was novel vis-à-vis D11A. The Board concludes that the decision was properly taken at the oral proceedings, having heard the parties in accordance with Article 113(1) EPC, and that there was no procedural violation.

3.2 Although the contested decision is based on the lack of novelty of the subject-matter of claim 1 vis-à-vis D11/D11A, the decision also contains an *obiter dictum* to the effect that inventive step is lacking vis-à-vis the combination of D12 and D8.

Although such *obiter dicta* do not form part of the reasons for the decision, they are permissible where they can help to prevent remittal of a case to the first instance if the grounds for the contested decision are overturned. But they certainly do not constitute a prejudgement of the case by the first instance, necessitating a change in the composition of the division concerned in case of remittal. In other words, these *obiter dicta* do not carry an *a priori* risk of partiality.

4. *Amendments*

Claim 1 of the main request is a combination of claims 1 and 19 of the patent as granted. Claim 19, which is identical to the version as filed, states that "the compartment is separated from the cavity". Consequently the term "separated" is supported by the application as filed. In the light of the description and drawings it

is clear that "separated" means a physical separation between the compartment and the cavity. Since this term was contained in a granted claim, and since clarity is not a ground for opposition, clarity does not require consideration.

The expression "a liquid tight material" is supported by the application on page 12, lines 4 and 5, and its technical meaning is explained on page 3, lines 20 to 26.

The term "closed", which describes the state of the "catheter package", can be derived directly and unambiguously from the drawings and the text corresponding to the different embodiments of the invention. For example, as shown in Figures 1, 7, 9 and 12 the "package" 7, 29, 34 and 51, respectively, is formed by two sheets of impermeable thermoplastic film material welded together (see application, page 7, line 33 to page 8, line 4). Therefore the package is closed. The way the package is then opened is explained on page 9, lines 23 to 28 with reference to Figure 3: a peel-off joint permitting easy separation of plastic film sheets 8 and 9. Furthermore, the expression "without opening the package", used repeatedly throughout the description (application, page 13, line 13; page 16, lines 11 and 24, and page 19, line 7) indisputably proves that the package is closed until the catheter is used, i.e. as long as the hydrophilic surface layer has not been activated by the swelling medium contained in the compartment.

Therefore the amendments to claim 1 do not go beyond the content of the application as filed, and thus comply with Article 123(2) EPC. Moreover, as these are added

features, the protection conferred has not been extended, thus also complying with Article 123(3) EPC.

5. *Novelty*

The novelty of the subject-matter of claim 1 according to the main request has been contested vis-à-vis the disclosure of D25 and D11/D11A.

5.1 D25 is an earlier European application published after the priority date of the contested patent. It is therefore prior art under Article 54(3) and (4) EPC, provided that its priority date is valid, i.e. that priority document D25P discloses the same invention as that described in D25 (Article 87(1) EPC).

D25 discloses a wetting apparatus for wetting a hydrophilic catheter having a water-containing sachet 6 incorporated in a urine collection bag 1 (see Figure 1). The collection bag is provided with an inlet 14 for introduction of the catheter 3 (see page 10, lines 6 to 7). Alternatively, the bag may be provided with a closed end in place of the inlet 14 (see page 11, lines 26 to 27). Therefore, there is no doubt that D25 discloses a closed package as recited in Claim 1 in dispute.

Priority document D25P is much more succinct. In the one and only drawing, the "inlet" has no reference number. The side view does not enable to ascertain whether the inlet is open or closed. While the bag described in D25P is sterilised using the same sterilising gas (ethylene oxide) (see page 3, lines 19 to 21) as that used in D25, the sterilisation operation alone does not allow to conclude with certainty whether the "bag" is open or

closed, since it depends principally on the meaning of the term "sterilisation", which is not further defined in the document.

Under established case law, a claimed feature may be entitled to a priority date only if it is derivable directly and unambiguously from the priority document (G 2/98). A document should therefore not be interpreted on the basis of additional evidence or general knowledge going well beyond the scope of the document to be interpreted. This is particularly true with respect to the interpretation of the expression "sterile conditions" mentioned in D25P, from which it thus cannot be deduced that the bag is closed.

As a consequence, D25 is not entitled to the priority date of D25P, and does not belong to the state of the art.

5.2 D11/D11A discloses (see Figure 1) a urinary catheter 1 contained in a sterile plastic bag 9, comparable to the package of the catheter assembly according to the invention. The catheter has a hydrophilic resin coating 2 which is compatible with human tissues, in order to reduce the pain caused by insertion of the catheter. This layer of hydrophilic resin is impregnated with a therapeutic drug solution to treat a patient by drug diffusion. Therefore, a reduction in friction, inherent to the nature of the impregnated coating is also present, so that the provision of a low-friction surface is also disclosed by D11/D11A.

The coated catheter 1 is contained in a tube 3 which constitutes a casing. The first way of using the

catheter is to have the manufacturer fill the therapeutic-drug solution tube and to store the plastic sterile bag 9, containing the tube, in an unchanged condition until the catheter is used (as in examples 1 and 2 of D11A). The second method is to leave it to the doctor to inject the solution into the tube using a syringe, just before the catheter is used (see page 3, second paragraph and paragraph running from page 6 to 7). In both cases, the therapeutic drug solution is contained in "a casing having a sealed cavity" (see page 7, lines 9 to 10 and page 8, second paragraph, line 8). These two alternatives are summarised in claim 1 of D11A (page 1 and page 2, third paragraph). It results therefrom that "casing" and "sealed cavity" denote actually the same thing, i.e. a cavity for accommodation of the catheter having a hydrophilic surface layer within the meaning of claim 1 in dispute.

To compare the device of D11/D11A with the subject-matter of claim 1, it should be noted that the catheter assembly according to claim 1 at issue is clearly defined in a state prior to preparation of the catheter, i.e. before the hydrophilic layer is activated by the "swelling medium". In that state, the swelling medium is contained in a compartment separated from the cavity containing the coated catheter.

In D11/D11A, before the therapeutic drug solution has been introduced into the tube 3 (cavity) the swelling medium is absent from the package. In that case, a compartment within the meaning of the present patent does not exist in D11/D11A. Once the therapeutic drug solution is introduced into the casing (tube 3) of D11/D11A in accordance with one of the two alternatives

mentioned above and the liquid impregnates the catheter coating, the liquid is not in a compartment separate to the cavity but in the cavity itself. Moreover, this situation does not correspond to the state of the catheter assembly as claimed, where no swelling medium has yet entered the cavity around the catheter. So in both of the above situations a swelling medium confined in a compartment, which is separated from the cavity is not disclosed by D11/D11A. Consequently, the subject-matter of claim 1 is novel vis-à-vis the device of this document.

6. *Inventive step*

D12/D12A discloses a high water-containing elastomer shaped urinary catheter having excellent lubricity, i.e. which will not attenuate after long exposure to atmosphere. The catheter is obtained by moulding an appropriate material made from e.g. a polyvinyl alcohol, and heat treating said shaped catheter. After sterilisation, the medical catheter is sealed in a polyethylene packing bag containing sterilising liquid (saline solution with hibitane) for storage (see page 8, penultimate paragraph).

The catheter assembly of D12/D12A has no compartment within the meaning of the present patent, since the solution that gives the catheter its lubricant properties is completely contained within the cavity for the catheter. The D12/D12A catheter is already impregnated and ready to use, while the catheter according to claim 1 in dispute is defined before its preparation state, i.e. before the coating is activated (see point 5.2 above). In this state, the swelling

liquid is separated from the cavity and does not yet surround the catheter, as indicated by the terms "intended" and "prior to use" in the preamble of claim 1 and "until the intended use" in the characterising portion.

Starting from D12/D12A, the skilled person had no reason to separate the liquid solution from the cavity containing the catheter, because in this storage state the package is already ready to use and perfectly satisfactory. Consequently, the objective problem to be solved by the invention, i.e. to prepare a catheter just before use, is not relevant for the device of D12/D12A. Therefore D8, which discloses a catheter package comprising a lubricant-fluid compartment separated from the cavity containing the catheter, is of no use for and incompatible with the subject-matter of D12/D12A.

Conversely, if the skilled person starts from the teaching of D8, which discloses a structural combination more or less comparable to that of claim 1, i.e. an assembly comprising a compartment for a lubricant, separated from a cavity housing a catheter to be lubricated just before use, he would not arrive at the subject-matter of claim 1 by combining this teaching with the disclosure of D12/D12A. The catheter disclosed in D12/D12A has no hydrophilic surface layer to be activated just before use of the catheter. If the skilled person provided the layer according to D12/D12A in the assembly according to D8 he would also provide the saline solution in the cavity for the catheter and abandon the compartment for a lubricant.

Hence, the subject-matter of claim 1 is not suggested by the combination of D12A and D8 and therefore involves an inventive step within the meaning of Article 56 EPC.

7. *Remittal*

Since the decision under appeal is principally based on lack of novelty of the subject-matter of claim 1 according to the main request vis-à-vis D11, and, auxiliarily, on lack of inventive step vis-à-vis the combination of D12A and D8, the Board deems it appropriate to remit the case to the first instance for further prosecution on the basis of the other document combinations cited by the parties against the inventive step of the subject-matter of claim 1, and in order to give to the appellant the benefit of two levels of jurisdiction.

The opposition division should also consider the requests for correction of the minutes of the first-instance oral proceedings. These requests made by the respondents at the appeal stage were not considered by the Board since such a correction is within the competence of the first instance.

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.

The Registrar: The Chairman:

D. Sauter T. Kriner