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Datasheet for the decision of 16 October 2007

Case Number: T 1516/05 - 3.2.03

Application Number: 97870177.9

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Language of the proceedings: EN

Title of invention:
Cryoprobe based on a Peltier module

Patentee:
Dewaegenaere, Levi

Opponent:
N.V. GymnaUniphy

Headword:
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Relevant legal provisions:
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Relevant legal provisions (EPC 1973):
EPC Art. 56

Keyword:
"Inventive step (yes)"

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-

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Case Number: T 1516/05 - 3.2.03

D E C I S I O N
of the Technical Board of Appeal 3.2.03
of 16 October 2007

Appellant: (Opponent)	N.V. GymnaUniphy Passweg 6A BE-3740 Bitzen (BE)
Representative:	Gross, Felix Patentanwälte Maikowski & Ninnemann Postfach 15 09 20 D-10671 Berlin (DE)
Respondent: (Patent Proprietor)	Dewaegenaere, Levi Huldenkens 2 B-2970's Gravenwezel (BE)
Representative:	Duxbury, Stephen Arnold & Siedsma Advocaten en Octrooigemachtigden Sweelinckplein 1 NL-2517 GK Den Haag (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 4 October 2005 rejecting the opposition filed against European patent No. 0840078 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: J.-P. Seitz
Members: C. Donnelly
Y. Jest

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division, posted on 4 October 2005, rejecting the opposition against European Patent No. 0840 078.

II. The contested patent relates to a "cryoprobe" or "cooling probe" which, in particular, can be used for thermal treatment of the skin of the human or animal body. The main purpose of the cryoprobe is to replace ice cubes and other cooling media traditionally used in such treatments.

Claim 1 as granted reads:

"A cryoprobe comprising:

- a Peltier module (22) with a cold side and a hot side;
- an electrical power supply (34) connected to said Peltier module;
- a cooling head (23) mounted at said cold side;
- a heat dissipation element (24) mounted at said hot side;
- a reservoir (25) for a thermally conductive fluid in contact with said heat dissipation element (24);
- a hollow cylindrical housing (21);

is **characterised in that** said cooling head (23) is provided with a circular groove (89) having a circular O-ring (90) for sealing and thermally insulating between said cooling head (23) and said housing (21) whereby on assembly the cooling head (23) is pushed into position in the housing (21)."

III. The opponent (appellant) filed a notice of appeal on 2 December 2005 and requested that the impugned decision be set aside and the patent revoked in its entirety. In the grounds of appeal filed on 3 February 2006, the appellant cited the following documents as state of the art:

(i) documents cited from the opposition proceedings:

D1: DE-A-4125535
D2: Websters Third New International dictionary, Merriam Webster Inc. 1993, page 1592
D3: US-A-5097828
D4: GB-A-2286660;
D5: EP-A-108 242
D6: US-A-4389316;
D7: DE-U-9306669;

(ii) documents cited for the first time in the grounds of appeal:

D8: WO-A-9316667 (also cited in the search report);
D9: DE-A-3309093 (also cited in the search report);
D10a: Kopie DIN-Norm 3771 part 1 and part 5;
D10b: Extract from "Introduction to DIN Standards" ("Einführung in die DIN-Normen"), Klein , 13th edition 2001, Beuth Press, Berlin-Vienna-Zürich.

IV. In reply, the patentee (respondent) requested by letter of 23 June 2006 that the appeal be dismissed. Further, it was requested that D8 and D9 not be admitted into the proceedings. A request for remittal to the

opposition division was made should it be decided to admit these documents.

Both parties made auxiliary requests for oral proceedings to be held.

V. On 11 June 2007 the Board issued a communication pursuant to Article 11(1) RPBA annexed to the summons to oral proceedings. In particular, the Board pointed out that certain features of the device of D7 seemed to differ in concept with that of the contested patent.

In response to the invitation to oral proceedings the respondent filed auxiliary requests 1 to 8 with letter of 20 August 2007. By letter of 17 September 2007 the appellant, as well as making further comments concerning claim 1 as granted, took position with respect to these further requests.

Oral proceedings were held on 16 October 2007.

VI. The arguments put forward by the parties concerning the contentious issues are summarised below.

(a) *Admission of documents D8 and D9 into the proceedings and remittal to the opposition division*

Appellant

Documents D8 and D9 are cited in the European search report and D8 is cited in the description of the contested patent at page 3, lines 18 to 19. The content of these documents can, thus, be no surprise to the

respondent. Moreover, both documents have been cited in the grounds of appeal together with a complete reasoned argument as to their pertinence.

It must also be pointed out that infringement proceedings are pending before a national court (Belgium) and this must also speak against remittal to the opposition division given the inevitable delay that this would entail.

Respondent

Documents D8 and D9 were filed late and should not be admitted into the proceedings since the appellant had had adequate time to file them during the opposition proceedings. The opposition division has not had the occasion to give its opinion on the pertinence of these documents and it is normally accepted that such matters be considered by two instances.

(b) *Inventive Step (Article 56 EPC)*

Appellant

The nearest prior art can be taken as either D7 or D8 since these documents disclose devices which tackle the same problem as the device of the contested patent and have the greatest number of common features. D3 on the other hand describes a device wherein there is no heat transfer into a reservoir of cooling fluid since the housing of D3 is open to the environment. The cooling effect of the device according to D3 would therefore be very small such that there would be no condensation and hence, the problem of improving the sealing between the

cooling head and housing to avoid the ingress of moisture would not arise.

The subject-matter of claim 1 as granted lacks an inventive step in view of:

(i) D8 in combination with D2 or the skilled person's general knowledge; or
(ii) D7 in combination with the skilled person's general knowledge according to D2.

(i) *D8 in combination with D2*

Claim 1 as granted can be broken down into the following features:

(a) A cryoprobe comprising:

(b) - a Peltier module (22) with a cold side and a hot side;
(c) - an electrical power supply (34) connected to said Peltier module;
(d) - a cooling head (23) mounted at said cold side;
(e) - a heat dissipation element (24) mounted at said hot side;
(f) - a reservoir (25) for a thermally conductive fluid in contact with said heat dissipation element (24);
(g)- a hollow cylindrical housing (21);

is characterised in that

(h) said cooling head (23) is provided with a circular groove (89) having a circular O-ring (90)
(hi) for sealing and

(hii) thermally insulating between said cooling head (23) and said housing (21)
(j) whereby on assembly the cooling head (23) is pushed into position in the housing (21).".

D8 describes all the features (a) to (g) of the preamble. In order for the device of D8 to function a heat-dissipating element of some kind must be provided, otherwise the heat would just build up in the Peltier element instead of being transported to the fluid in the reservoir. The skilled person would see that this vital function is fulfilled by the part of the Peltier module in contact with the reservoir, hence, feature (e) is also described in D8. In particular, the claim does not require that feature (e) be a separate element and, even if it did, such a constructional difference would fall within the scope of normal design activity.

Thus, the distinguishing features are (hi),(hii) and (j) which relate to the O-ring and the mounting of the cooling head.

The objective technical problem to be solved can only be seen to be one of how to thermally insulate and seal the cryoprobe from the environment in order to protect the inner workings of the device, especially with a view to preventing the formation of condensation on the inside of the probe-tip.

It is irrelevant whether this problem is mentioned in the contested patent or not since, when applying the problem-solution approach, the objective problem is defined as a function of the technical effect of the distinguishing features of the claimed device when

compared with the nearest prior art. In this case the only difference is an O-ring assembly.

It is generally known and accepted amongst mechanical engineers that the most common and simple technique for insulating and sealing two cylindrical parts is to interpose an O-ring between them.

Thus, the application of an O-ring in the manner specified in the characterising portion of claim 1 to solve this problem represents nothing more than a standard solution which is merely part of the skilled persons general knowledge.

Consequently, the subject-matter of claim 1 does not involve an inventive step.

(ii) *D7 in combination with the skilled person's general knowledge according to D2.*

With the exception of feature (g), D7 describes all the features of the preamble of claim 1. However, the selection of a round or cylindrical housing does not require any inventive activity on the part of the skilled person since the Peltier module can be fitted in one just as well as the other. The selection of the outer housing shape is merely a question of preference depending on the circumstances, since it is easier to manufacture a cylindrical as opposed to a shower-head shape, a cylindrical housing would be an obvious choice and is furthermore hinted at by D8. The sealing arrangement for the cooling head would be adjusted according to the choice made. As already explained above in relation to D8, when using a cylindrical

housing, the application of an O-ring in the manner specified in the characterising portion of claim 1 represents nothing more than a standard solution which is merely part of the skilled persons general knowledge.

Respondent

(i) D8 in combination with D2 or the skilled person's general knowledge;

D8 does not disclose features (e), (hi),(hii) and (j) of claim 1.

In D8 the cold reservoir 18 for the thermally conductive fluid functions as a heat accumulator and is placed in direct contact with the Peltier module. There is no separate heat dissipation element to improve the dissipation from the hot side as required by feature (e).

It should be noted that feature (j) is particularly relevant since it indicates that it is by the O-ring that the pushing into position in the housing is possible, i.e. the O-ring ensures that the cooling head is positioned in the housing such that the Peltier module mounted on the cooling head is mounted floating with respect to the housing. By mounting the cooling head in the housing using an O-ring, the shock transmission between the Peltier element and housing is decreased, thus protecting the Peltier module even if the cooling head bounces on a solid surface.

It would not be obvious for the skilled person to use O-rings in the device of D8 since it is intended for a fundamentally different purpose to that of the contested patent. The device of D8 is intended to be used in treatments normally carried out using liquid nitrogen, e.g. the freezing of papilloma or lesions (see D8, page 1, lines 16 to 30). Such operations require the application of extremely low cryogenic temperatures for short periods of time over a small skin area. In contrast thereto, the device of the contested patent is intended to replace ice-cubes traditionally used in physiotherapy treatment (see the contested patent description page 2, lines 46 to 47). This type of treatment is carried out for prolonged periods of time at temperatures equating to that of melting ice and over larger surface areas.

The device of D8 would therefore never suffer from a problem of condensation since any water vapour would immediately freeze. Furthermore, the cooling head is removed between treatments to allow recharging, thus there cannot be any build-up of condensation since the inside of the head is frequently exposed.

(ii) D7 in combination with the skilled person's general knowledge according to D2.

As well as not disclosing the features of the characterising portion of claim 1, D7 also does not show:
- a cooling head at the cold side of the Peltier element since a heat transfer element is interposed between the two;

- a reservoir according to feature (f) since fluid only flows through the heat-exchanger;
- a cylindrical housing according to feature (g) since the housing is spherical.

Also, insulating material is provided between the Peltier module/heat-transfer element assembly and the housing without leaving any apparent space. Hence, the problem of water condensation and any other sealing problems would not arise. Even if there were some kind of problem, the shape of the housing would preclude the use of an O-ring.

In conclusion neither of the lines of argument presented by the appellant is convincing and in view of the above analysis of D8 and D7, it must be remarked that D3 in fact represents the nearest state of the art since this document is used in physiotherapy for the same type of treatment in a similar temperature range and has the most common technical features.

Reasons for the Decision

1. *Admission of documents D8 and D9 and remittal to the opposition division*

The Board considers that documents D8 and D9 should be admitted into the procedure since they have been cited in the grounds of appeal and the European search report. Further, D8, which is the only document of the two relied upon in any detail by the appellant, is also cited in the description of the contested patent at page 3, lines 18 to 19. Thus, the subject-matter and

relevance of these documents cannot have come as a surprise to the respondent.

The appellant has also stated that infringement proceedings are pending before a national court and that this must also speak against remittal to the opposition division given the inevitable delay that this would entail.

In these circumstances, the Board considers that it is not in the interests of an economic procedure to remit the case to the opposition division.

2. *Most relevant prior art*

The respondent has suggested that D3 is the most relevant prior art. However, the appellant does not share this view and has presented convincing arguments as to why D7 or D8, as opposed to D3, are more relevant art (see above: paragraph VI (b)). The Board sees no reason to dispute the appellant's opinion in this respect and would additionally note that, although this device shows an O-ring between what could be interpreted as a cooling head (54) and a housing (30), the groove for holding the O-ring is formed in a screw-on extension ("face-cap" 32) to the housing which on assembly holds the cooling head in position in the housing as opposed to the configuration specified in the characterising part of claim 1.

Accordingly, the Board will concentrate upon the lines of argument based on D8 and D7 presented by the appellant in the written procedure and further detailed at the oral proceedings.

Inventive step

2.1 *(i) D8 in combination with D2 or the skilled person's general knowledge;*

D8 describes both active and passive cryoprobes as well as various types of charging stand for charging both the power supply and the thermal reservoir prior to fitting the cooling head.

D2 is merely a dictionary definition of an O-ring and does not give any extra indications to the skilled person.

Figures 2 and 4 of D8 relate to active cryoprobes positioned in a charging-stand, the device of figure 2 comprises a single Peltier element whereas that of figure 4 comprises two in cascade. The active cryoprobes are first charged in the stands with the cold side of the Peltier element (semiconductor thermoelectric heat pump 30) arranged to cool the fluid in the cold reservoir. The probes are then removed from the stand and a cooling head is fitted to the Peltier end of the housing. The current can be switched to flow in either direction to the Peltier element which means that extremely low temperatures can be achieved if the hot side is cooled by the cold reservoir.

Thus, when the active cryoprobe is removed from the stand it comprises:
- a Peltier module (30) with a cold side and a hot side;
- an electrical power supply (40) connected to said Peltier module;

- a cooling head (16) mounted at said cold side (see page 5, lines 23 to 34);
- a heat dissipation element mounted at said hot side;
- a reservoir (18) for a thermally conductive fluid in contact with said heat dissipation element ;
- a hollow cylindrical housing (12).

With respect to the above analysis the Board would remark that the wording of the claim does not mean that the heat dissipation element mounted at said hot side must necessarily be separate. As pointed out by the appellant, the heat from the hot side of the Peltier must somehow be dissipated into the fluid of the thermal reservoir otherwise the device would not function efficiently enough to achieve the extreme levels of cold required by the treatments this particular probe is intended for. Accordingly, the Board is of the view that the hot side of the Peltier element must be constructed so as to be capable of transferring and dissipating heat to the fluid in the cold reservoir, thus fulfilling the role of a heat dissipation element within the meaning of the claim.

Hence, with reference to the feature breakdown proposed by the appellant, the device according to claim 1 differs therefrom in that:

(h) said cooling head is provided with a circular groove having a circular O-ring
(hi) for sealing and
(hii) thermally insulating between said cooling head and said housing
(j) whereby on assembly the cooling head is pushed into position in the housing.

The features (h), (hi) and (hii) directly concern the mounting and function of the O-ring. However, the functional feature (j) cannot simply be dismissed as being technically irrelevant since it at least determines that the cooling head is the male member in a male-female coupling arrangement which must allow the cooling-head to be pushed into position. Nevertheless, this feature does not necessarily mean that the cooling head is "mounted floating" in the housing as contended by the respondent since it could be pushed into position and then held there by some mechanism.

According to the granted patent, the O-ring in the circular groove of the cooling head is "for sealing" (see page 4, line 56). However, it can also be accepted that it contributes, along with other O-rings, to a good thermal insulation which is "the key for good operation of the cryoprobe" (see page 5, lines 31 to 32). It is also common general knowledge that O-rings are primarily used for sealing purposes (also see D2).

The sealing provided by the O-ring is with respect to the penetration of outside contaminants rather than to prevent leakage of reservoir fluid, which is the main purpose of O-ring 37 in groove 85 (see description, page 9, lines 20 to 24 and figure 15A).

Thus, the objective technical problem to be solved is seen to be one of how to protect the cryoprobe from the ingress of contaminants from the outside environment whilst preventing heat leakage to the housing.

Faced with this problem it must be assessed whether the skilled person would modify the apparatus of D8 by incorporating the features (h), (hi), (hii) and (j).

The respondent is correct in indicating that the device of D8 is primarily intended to replace treatment normally carried out using liquid nitrogen, e.g. the freezing of papilloma or lesions (see D8, page 1, lines 16 to 30), which typically require the application of extremely low temperatures for short periods of time over a small skin area.

There is also no doubt that the cooling head ("probe tip 16) must be removed to allow charging of the device such that it can achieve these low temperatures. Further, it would be normal hygiene practice for a new probe tip to be used for each patient subjected to this type of treatment, indeed the act of having to remove the probe tip in order to carry out recharging of the device would be a significant security feature in such procedures. The probe tip or cooling head of D8 is thus probably a disposable item or at the very least one capable of being removed and sterilised before reuse.

Hence, since the cooling head of the device according to D8 is not intended to remain in place, the skilled person would reasonably assume that it is also not expected to function as a protective element for the other parts. Further, the device of D8 would not suffer from a problem of condensation build-up since any water vapour would immediately freeze and be removed when the cooling head is replaced between treatments to allow recharging.

Consequently, the skilled person would undertake any necessary improvements to ensure protection of inner workings of the device once the probe tip removed.

Given the requirement to achieve very low temperatures for short time periods, the main function of any connector device would be to ensure good thermal contact between the heat pump (Peltier module) 30 and the cooling head (probe tip 16) rather than prevent ingress of contaminants. In order to reduce costs and ensure correct functioning, any elements intended to minimise heat-loss to the housing would be incorporated into the housing itself rather than the probe tip since the addition of an O-ring in a groove would only increase the cost of a disposable item or render more difficult the sterilisation of reusable one.

The authors of D8 do not attach much significance to the method by which the cooling head ("probe tip 16) is attached, merely indicating that it may be by "any number of attachment means known in the art. These are stated to include but are not limited to screw threads or snap-lock connectors" (see page 5, lines 8 to 9), but there is no indication as to whether the cooling head should form the male or female member.

Thus, it would not be obvious for the skilled person to modify the cooling head ("probe tip 16") of D8 by the features (h), (hi), (hii) and (j).

2.2 *(ii) D7 in combination with the skilled person's general knowledge according to D2.*

D7 describes a

a cryoprobe comprising:
- a Peltier module (4) with a cold side (10) and a hot side(9);
- an electrical power supply (1) connected to said Peltier module;
- a cooling head (7,8)
- a heat dissipation element (12) mounted at said hot side;
- thermally conductive fluid in contact with said heat dissipation element (12) (see page 2, lines 12 to 14)
-a reservoir provided for the thermally conductive fluid (element 12 is also capable of containing thermally conductive fluid);
- a hollow housing (3);
- whereby on assembly the cooling head (7,8) is pushed into position in the heat transfer element (5)(see page 2, lines 6 to 8).

The device according to claim 1 differs therefrom in that:
(i) -the housing is cylindrical;
(ii) -said cooling head is provided with a circular groove having a circular O-ring for sealing and thermally insulating between said cooling head and said housing; and
whereby on assembly, the cooling head is pushed into position in the housing (as opposed to the heat transfer element) so that it is mounted at the cold side of the Peltier element.

The objective technical problem can thus be seen to be one of how to simplify the manufacture of a cryoprobe housing whilst ensuring protection against ingress of

contaminants from the outside environment and preventing heat leakage to the housing.

In the construction according to D7, the Peltier element (4), the heat transfer/reservoir unit (5), cooling head (7,8) and heat dissipator (12) form an assembly which is surrounded by insulating material (11).

Thus, in D7, cooling heads of different diameters are fitted into the heat transfer element with which they must have good thermal contact, but which is itself insulated from the housing by means of an insulating layer.

Consequently, in order to obtain the device according to the subject-matter of claim 1 the skilled person would have to carry out at least the following steps:

(i) decide to change the shape of the housing from a spherical to cylindrical;
(ii) abandon the idea of internal insulation to prevent heat loss to the housing and contribute to holding and protecting the inner elements of the device;
(iii) fit the cooling head directly into the housing from which it must be insulated as opposed to into an intermediate heat transfer element with which it must be in good thermal contact;
(iv) modify the cooling head by forming a circular groove in it to hold an O-ring in order to carry out step (iii).

Even if the skilled person should decide to adopt a cylindrical housing in an attempt to solve the above

problem, the Board can see no reason to proceed further with steps (ii), (iii) and (iv) since the provision of the internal insulating layer already provides a full solution to the problem of contaminant ingress and protection of the inner parts of the device. The undertaking of the further steps would only be contemplated with the benefit of hindsight.

Thus, also when taking D7 as the most relevant prior art the skilled person would not obtain the subject-matter of claim 1 in an obvious manner.

In conclusion, the subject-matter of claim 1 as granted involves an inventive step and, thus, meets the requirements of Article 56 EPC.

Claims 2 to 9 as granted describe further embodiments of the device according to claim 1 and thus also meet the requirements of Article 6 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

Registrar: Chairman:

A. Counillon J. P. B. Seitz