

Internal distribution code:

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

**Datasheet for the decision
of 28 October 2008**

Case Number: T 1311/06 - 3.2.02

Application Number: 99924794.3

Publication Number: 1182966

IPC: A61B 5/0408

Language of the proceedings: EN

Title of invention:
A skin electrode

Patentee:
MEDICOTEST A/S

Opponent:
Unomedical A/S

Headword:
-

Relevant legal provisions:
EPC Art. 52(1)

Relevant legal provisions (EPC 1973):
EPC Art. 54(1)(2), 56

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 1311/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 28 October 2008

Appellant: Unomedical A/S
(Opponent) Engmosen 1
DK-3540 Lyngø (DK)

Representative: Elmeros, Claus
Højberg A/S
St. Kongensgade 59A
DK-1264 Copenhagen K (DK)

Respondent: MEDICOTEST A/S
(Patent Proprietor) Rugmarken 10
DK-3650 Olstykke (DK)

Representative: Rasmussen, Torben Ravn
Internationalt Patent-Bureau A/S
Rigensgade 11
DK-1316 Copenhagen K (DK)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 22 June 2006
rejecting the opposition filed against European
patent No. 1182966 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division relating to European patent No. 1 182 966, rejecting its opposition to the grant thereof. The decision was dispatched on 22 June 2006.

A notice of appeal against this decision was filed on 21 August 2006 and the appeal fee was paid on the same day. The statement of grounds was submitted on 23 October 2006.

II. The opposition was filed against the entire patent and based on Article 100(a) EPC 1973 (lack of novelty and inventive step). As part of its case the opponent alleged public prior use of the claimed device.

The opposition division decided that public prior use had not been proved and that the patent met the novelty and inventive step requirements of the EPC, and rejected the opposition, accordingly.

III. Oral proceedings were held before the Board on 28 October 2008, at which the following requests were submitted:

The appellant requested that the decision under appeal be set aside and that the European patent No. 1 182 966 be revoked.

The respondent (patentee) requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of one of the first to third

auxiliary requests filed with its letter dated 26 September 2008.

IV. The following documents were of particular interest in the appeal procedure:

- D7: US-A-5 624 415
- D24: Material coding Form, dated 23/05/96
- D26: Drawing No. R700, title "Defibrillation Pad Set (Pace)", dated 28/9/91
- D27: Process Sheet Issue Record
- D28: Material coding Form, dated 8/11/96
- D29: Material coding Form, dated 7/11/96
- D32: EP-A-0 836 864
- D34: "Material call up", dated 1 5 Sept. 96
- D35: "Material Specification"
- D36: Telefax from Jung+ Lindig, dated 16.08.98
- D37: Certificate of Analysis from Butterworth Laboratories.

V. Independent claim 1 of the patent as granted reads as follows: -

"An electrode for establishing electrical contact with the skin, comprising an electrically conductive metallic layer having a high sensitivity to acid and an electrically conductive gel attached to said metallic layer, thereby providing an interface between said gel and said metallic layer, characterized in that the pH of the electrically conductive gel is between 0 and 4 so as to provide corrosion of said metallic layer, whereby a number of ions are etched from said metallic layer, thereby generating a concentration of metallic ions at the interface between the gel and said metallic

layer sufficient to contribute to the availability of current carriers when a current is impressed on the electrode."

Claims 2 to 18 are dependent on claim 1.

VI. The parties argued as follows:

Appellant

D26 described and showed the construction of the defibrillator pad R700 which was sold to customers before the priority date of the patent in suit, and which used a foil FL 16 and a conductive hydrogel GL 01. According to D34 the foil FL 16 had the part number 20-X001, and this was a tin foil according to D35 and D36. The gel GL 01 was the same as the gel 12 GL 01 (see D27) which, according to D24, D28, and D29, was also the same as the gel LT-3300. This gel was analysed by Butterworth Labs. Ltd. and shown to have a pH value of 2.4 or 2.6 (D37).

Therefore, the defibrillator pad R700 of D26 comprised a tin foil and a conductive hydrogel having a pH value within the range defined in claim 1 of the opposed patent, and anticipated the claimed device.

Starting from D32 a problem could be formulated which was the same as that of the opposed patent, i.e. to provide a low interface resistance. The problem was well known to the person skilled in the art, and its solution was also indicated in D32, viz. to provide a hydrogel having a pH value less than 4. Moreover, the combination of an electrode and a hydrogel having a pH

value less than 4 was suggested by D7 which related to a neighbouring field and would have been considered by the skilled person. The pH value in D32 could be reduced without the need for further modification of the device. Claim 1 did not involve an inventive step, accordingly.

Respondent

D26 specified that a "foil" FL16 was used, but D34 mentions a foil 10-FL16. Therefore, although D35, which is dated some years later, said that the latter was a pure tin foil, it was not clear that this was the same foil as that used in D26.

D26 used the gel GL 01, but this was deleted according to D27, and it was not clear when the deletion occurred. The prefix "12" in the designation 12-GL 01 was also problematic since it indicated that this could be a different product to GL 01.

Therefore, neither the nature of the foil nor of the gel used in D26 were clear, so that public prior use had not been satisfactorily proven.

Starting from D32 as the closest prior art document, there was no incentive to invoke D7 because this related to a remote field. Even if D7 were to be invoked it did not suggest that the metal should be corroded. A cathode reservoir would inhibit corrosion rather than promoting it.

Reasons for the decision

1. The appeal is admissible.
2. *Public prior use*

The established practice of the EPO is to require an allegation of public prior use to be proved "up to the hilt" and the evidence provided should establish beyond reasonable doubt that the public prior use as alleged actually did take place. It must be clearly established when the use occurred, the circumstances of the use, and what exactly was used.

The Board is satisfied, and the respondent accepts, that the defibrillator pad R700 was sold to customers before the priority date of the patent in suit, and that it used a foil FL 16 and a conductive hydrogel GL 01. The allegation of public prior use falters, however, in that it is not proven beyond reasonable doubt that the former is a tin foil and that the latter has a pH value of between 0 and 4.

No evidence is provided that the gel GL 01, used in D26, is the same in composition as the gel 12-GL 01 mentioned in D27, which is said to be deleted, or the same as 12-GL 17 and 12-GL 18, which are said to have been added. Moreover, the analysis of D37 relates to 12-GL 11, which is yet another designation. It seems reasonable to suppose that a change of designation would only occur if there were a change in some property of the gel, but it is not clear which property changes with the change of designation, the changed property could be the composition.

Consequently, it has not been proven that the gels GL 01, 12-GL 01, 12-GL 11, 12-GL 17, and 12-GL 18 have the same composition, so the pH value of the gel used in D26 has not been proven to lie between 0 and 4.

Similarly, no evidence is provided to link the foil FL 16 of D26 with the foil 10-FL 16 of D34 to D36. The latter indicate that the foil 10-FL 16 corresponds to part no. 20-X001 which is a pure tin foil but in the absence of a clear link between FL 16 and 10-FL 16 it may not be assumed that the latter also comprises a pure tin foil. Consequently the nature of the foil used in D26 is also unclear.

For these reasons it is not clear exactly what the nature of the electrode used in the product of D26 was. Prior use of the claimed electrode has not been established to the necessary criteria, accordingly.

3. *Novelty*

The appellant withdrew its objection of lack of novelty at the oral proceedings, so this is no longer an issue.

4. *Inventive step*

- 4.1 The parties and the Board concur that D32 is the closest prior art document and that it discloses all the features of the preamble of claim 1.

The characterising feature of the claimed device is that the pH of the electrically conductive gel is

between 0 and 4, whose purpose is to provide corrosion of the metallic layer.

- 4.2 The technical problem to which the characterising feature relates is to lower the impedance at the interface between the gel and the metallic layer (see the patent in suit, paragraph [0020]).
- 4.3 No prior art document suggests such a measure for improving the impedance properties of an electrode, for which reason claim 1 involves an inventive step.
- 4.4 The document D7 does not relate to an electrode, which term, in normal parlance, refers to a passive conductor, normally a metal contact, which transfers a signal into or out of a body which it contacts, without amplification or distortion of the signal. D7 does not relate to such an electrode, it relates to an electrotransport delivery device having a cathodic reservoir and an anodic reservoir for the transdermal delivery of drugs. This device is not clearly capable of transferring signals without distortion and attenuation and is, therefore, not an electrode in the classical meaning of this term. For this reason D7 cannot be considered to be in a neighbouring field and the person skilled in the art has no reason for consulting this document when faced with the present problem.
- 4.5 Nevertheless, even if the person skilled in the art were to consult this document he would not learn how to solve the present problem.

The device of D7 has an anode electrode and a cathode electrode. The document states that the anodic reservoir should be buffered to a pH of about 4 to 10, whereas the cathodic reservoir should be buffered to a pH of about 2 to 4 (see the abstract). However, no corrosion occurs at a cathode because this is protected against corrosion by the negative potential impressed upon it.

Therefore, this document does not teach the use of a conductive gel having a pH value of between 0 and 4 in order to corrode the metallic layer which it contacts.

4.6 For the foregoing reasons claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

V. Commare

T. Kriner