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**Datasheet for the decision
of 7 September 2006**

Case Number: T 0420/04 - 3.2.02

Application Number: 95919215.4

Publication Number: 0759724

IPC: A61B 5/0488

Language of the proceedings: EN

Title of invention:

Method and apparatus for analysing uterine activity

Applicant:

THE BOARD OF REGENTS, THE UNIVERSITY OF TEXAS

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 84

Keyword:

"Late-filed claims (not admissible)"

"Clarity - (no)"

Decisions cited:

G 0009/91, T 0427/99, T 0840/93

Catchword:

-



Case Number: T 0420/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 7 September 2006

Appellant: THE BOARD OF REGENTS, THE UNIVERSITY OF TEXAS
SYSTEM
201 West 7th Street
Austin, Texas 78701 (US)

Representative: W.P. Thompson & Co.
Coopers Building
Church Street
Liverpool L1 3AB (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 20 October 2003
refusing European application No. 95919215.4
pursuant to Article 97(1) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 20 October 2003 to refuse European patent application No. 95 919 215.4.

The grounds of refusal were that Claims 1 to 5 on file referred to diagnostic and/or therapeutic methods which were not susceptible of industrial application, and the subject-matter of claim 6 did not involve an inventive step.

- II. On 31 October 2003 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 20 February 2004 a statement of grounds of appeal was filed. The statement included claims of a main request and first to sixth auxiliary requests.

By letter dated 7 August 2006, and following a communication from the Board annexed to the summons to oral proceedings and setting out preliminary objections to the claims, the appellant filed a single set of new claims replacing the above claims.

- III. Independent claims 1 and 6 of these claims read as follows:

"1. A method of indicating pre-labor, labor or non-labor in a patient by characterizing uterine electrical activity, comprising:
applying action potential measuring electrodes (17) to an abdominal or vaginal surface (16) of a patient (11);

storing electromyographic signals, including action potentials, produced by said electrodes; stimulating a vagina of said patient while said electromyographic signals are being stored; analyzing uterine activity indicating parameters from action potentials within said stored electromyographic signals; and characterizing uterine activity of said patient based on said parameter analysis.

6. An apparatus for recording and analyzing uterine electrical activity from the abdominal or vaginal surface (16) of a patient, comprising:
at least one action potential measuring electrode (17) applicable to an abdominal or vaginal surface (16) of a patient (11) under analysis; the apparatus being characterised by:
an analog-to-digital converter (21), connected to said at least one electrode (17), for converting electromyographic signals, including action potentials produced by electrode into digitized data indicative of said electromyographic signals and action potentials;
a memory for storing said digitized data;
means for stimulating a vagina of said patient whilst said electromyographic signals are being stored; and
a programmed computer (22) for analyzing uterine activity including parameters from action potentials represented by said stored digitized data and comparing said digitised data with stored values, and
for providing an indication of uterine electrical activity of said patient under analysis as a function of said uterine activity indicating parameters."

Claims 2 to 5 and 7 are dependent claims.

- IV. Further sets of claims were filed by letter dated 30 August 2006 and by telefax on 6 September 2006, respectively.
- V. The appellant requests that the decision under appeal be set aside and that the application be granted on the basis of claims 1 to 7 filed by telefax on 6 September 2006.

The appellant additionally requests that the appeal fee be reimbursed.

- VI. Oral proceedings took place on 7 September 2006. The appellant did not attend the oral proceedings as announced in its facsimile of 6 September 2006.
- VII. In its written submissions the appellant argued that the expression "stimulating the vagina" was clear to the person skilled in the art and, moreover, was clearly explained in the description. Also, given the literature which discussed this concept the skilled person would comprehend the meaning of this expression.

Similarly, there were many documents detailing how uterine activity was characterised since such regimes had already been referenced in the prior art. Thus the person skilled in the art would understand the expression "characterising uterine activity".

Reasons for the Decision

1. The appeal is admissible.
2. *Late filed claims*
 - 2.1 The communication from the Board on 22 March 2006 set out preliminary objections to the claims and informed the appellant that it had the opportunity to file observations no later than one month before the oral proceedings in order to give the Board sufficient time to prepare for the oral proceedings on 7 September 2006. The Board further pointed out that late filed arguments, facts, and evidence may not be admitted into the appeal proceedings (cf. Case Law of the Boards of Appeal of the EPO, 2001, VI-F 5).
 - 2.2 The appellant duly filed a new set of claims by letter dated 7 August 2006. However, further sets of claims were filed by letter of 30 August 2006 and on 6 September 2006, i.e. on the eve of the oral proceedings, respectively.
 - 2.3 As has been stated in the decision G 9/91 (OJ EPO 1993, 408, point 18 of the reasons) the purpose of the appeal procedure in inter partes proceedings is mainly to give the losing party the possibility of challenging the decision of the first instance. The same principle applies in principle in ex parte proceedings.

Accordingly, Article 10b of the "Rules of procedure of the Boards of Appeal" points out that any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's

discretion. The discretion shall be exercised in view of inter alia the current state of the proceedings and the need for procedural economy.

Furthermore, the case law of the Boards of Appeal indicates that admission of late filed requests into the proceedings is a matter of discretion of the Board of Appeal, and is not a matter of right of the appealing party (see decision T 840/93, OJ EPO 1996, 335, point 3.1 of the reasons; T 427/99, point 3 of the reasons).

2.4 The late-filed claims were filed over five months after the Board's communication and shortly before the oral proceedings. Since they are not clearly allowable, nor has the appellant attempted to justify their late filing, the claims filed by letter of 30 August 2006 and on 6 September 2006 are not admitted, and only the claims filed by letter of 7 August 2006 will be considered in this decision since they were filed as a procedural reaction to the communication of the Board.

3. *The application*

The application relates to a method and apparatus useful for determining the contractility of the uterus by recording spontaneous, mechanically or electrically stimulated, or drug-evoked electrical activity of the myometrium of the uterus from the abdominal or vaginal surface. In the method electrodes are applied to the abdominal or vaginal surface of a patient, electromyographic signals produced by the electrodes are stored while the vagina is stimulated, and the

signals are then analysed in order to characterize uterine activity of the patient based on the analysis.

4. *Claim 1*

- 4.1 The Board considers the expression "characterizing uterine activity of said patient based on said parameter analysis" in claim 1 to be unclear in the context. The purpose of the analysis of the action potentials is to indicate pre-labor, labor, or non-labor in a patient. However, the application does not make clear which criteria are to be used to classify the action potentials as indicating pre-labor, labor, or non-labor.

On page 13 there are tabulated normal values for action potentials and bursts of action potentials for labor patients. For non-labor patients it is stated that "considerably lower values for the measured parameters for action potentials and bursts of action potentials are considerably lower than the values presented in the above tables" [sic except for added emphasis]. This is not a clear criterion for distinguishing between the two cases. As regards pre-labor patients, the application is totally silent as to which values of the potentials would indicate a pre-labor condition.

Therefore, this feature of claim 1 is a definition by result rather than a definition of those features which would enable the desired result to be attained, and is unclear, accordingly.

- 4.2 An essential feature of the method and apparatus claims is the step of stimulating the vagina of the patient

while the electromyographic signals are being stored. The stimulation of the vagina, according to the description of the application, may either be electrical, mechanical or pharmacological, for example through the cutaneous introduction of oxytocin to the patient (see page 6, lines 26 to 29 of WO-A-95/31932).

The application does not state clearly what the vaginal stimulation achieves, but it appears, from page 6, lines 23 to 25 and page 17, lines 17 to 21, to have something to do with the conduction of EMG signals to the uterus. Claim 1 (and for that matter the entire application) does not indicate the intensity of stimulus which is necessary to affect the conduction of signals and to elicit signals at the abdominal or vaginal surface (for example, the dosage and concentration of oxytocin), yet there must be some intensity threshold below which acting on the vagina would not be sufficient to affect the signal conduction but be considered as stimulating the vagina.

The significance of the step of stimulating the vagina is all the more suspect since the only concrete examples of this are given on page 6, line 29 and page 16, lines 1 to 6, but this is in connection with rats, and the concentration, dosage, etc. are not given. In the examples on pages 8 to 13, which example relates to "patients" (as does claim 1), the step of vaginal stimulation does not feature at all.

For these reasons the expression "stimulating the vagina" is unclear in the claims.

5. *Claim 6*

The above arguments also apply to claim 6. In particular the description and claim 6 are silent as to which criteria the apparatus is to employ in order to perform the step of "providing an indication of uterine electrical activity of said patient under analysis as a function of said uterine activity indicating parameters".

6. Therefore, claims 1 and 6 do not meet the clarity requirement of Article 84 EPC, accordingly.

6.1 The appellant's arguments regarding the clarity of the claims are not accepted since the concept of "characterising uterine activity" in order to indicate pre-labor, labor or non-labor in a patient was not known in the prior art. Since it forms the basis of the present application, there must be a clear disclosure of how uterine activity is characterised, but there is no disclosure in this respect, either in the application, or in the prior art. Similar arguments apply in respect of the expression "stimulating the vagina", this expression is not explained in the context of "characterising uterine activity".

7. *Reimbursement of the appeal fee*

The appellant has furnished no arguments in this respect and the Board sees no reason to allow this request.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

V. Commare

T. K. H. Kriner