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D E C I S I O N
of 29 June 2001

Case Number: T 0964/99 - 3.4.1

Application Number: 95924591.1

Publication Number: 0766577

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:

Device and method for sampling of substances using alternating polarity

Applicant:

CYGNUS, INC

Opponent:

-

Headword:

Device and method for sampling of substances using alternating polarity/CYGNUS, INC

Relevant legal provisions:

EPC Art. 52(4)

Vienna Convention on the Law of Treaties Art. 31(1)

Keyword:

"Diagnostic method (yes: main request, first and second auxiliary requests)"

"Remittal to the department of the first instance (third auxiliary request)"

Decisions cited:

G 0005/83, T 0116/85, T 0385/86, T 0083/87, T 0400/87,
T 0655/92, T 0082/93, T 0530/93, T 0329/94, T 0035/99

Headnote:

1. The expression "diagnostic methods practised on the human or animal body" in Article 52(4) EPC or the equivalent expressions "Diagnostizierverfahren, die am menschlichen oder tierischen Körper vorgenommen werden" and "méthodes de diagnostic appliquées au corps humain ou animal" in the other two official languages should not be considered to relate to methods containing all the steps involved in reaching a medical diagnosis.
2. According to the principle, well-established in the case law of the Boards of Appeal, that the EPC has to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context (Article 31(1) Vienna Convention on the Law of Treaties), Article 52(4) EPC is meant to exclude from patent protection all methods practised on the human or animal body which relate to diagnosis or which are of value for the purposes of diagnosis.
3. A step of iontophoretically sampling a substance from the living human or animal body for diagnostic purposes has to be considered a diagnostic method within the meaning of Article 52(4) EPC.



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Boards of Appeal

Chambres de recours

Case Number: T 0964/99 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 29 June 2001

Appellant: CYGNUS, Inc.
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Redwood City, CA 94063 (US)

Representative: Hallybone, Huw George
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 25 August 1999
refusing European patent application
No. 95 924 591.1 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
M. G. L. Rognoni

Summary of Facts and Submissions

- I. European patent application No. 95 924 591.1 (publication No. 0 766 577) was refused by a decision of the examining division dispatched on 25 August 1999 on the ground that the subject-matter of claim 1 then on file was excluded from patentability under Article 52(4) EPC.
- II. The appellant lodged an appeal against the decision on 15 September 1999 and paid the prescribed fee on the same day. The notice of appeal also included the statement of grounds of appeal.
- III. In oral proceedings held on 3 August 2000 at the request of the appellant, the pertinence of Article 52(4) EPC to the method claims on file as well as some aspects of lack of clarity (Article 84 EPC) were discussed. At the end of the oral proceedings, the appellant was given the opportunity to file further submissions and new requests so that a decision of the Board could concentrate on the issue of Article 52(4) EPC.
- IV. The discussion was continued in second oral proceedings held on 27 March 2001 and concentrated on the aspects of whether the subject-matter of the method claims constituted a diagnostic method performed on the human or animal body or a treatment by surgery. At the end of the oral proceedings the proceedings were closed.
- V. The appellant requested that the decision under appeal be set aside and the case remitted to the examining division for examination on the basis of the following

documents:

Main request

Claims: 1 to 35 filed on 5 October 2000;

Description: pages 7 to 10, 12, 14, 15, 17, 18, 20, 23 to 30 as published;
pages 16 and 22 filed on 7 January 1997;
pages 13, 19 and 21 filed on 17 May 1999; pages 1 to 4, 11 filed on 4 July 2000; and page 6 filed on 5 October 2000. Page 5 as published has been deleted.

Drawings: sheets 1/11 to 11/11 as published.

First auxiliary request

Claims 1 to 35 filed on 5 October 2000 with the description and Figures as for the main request.

Second auxiliary request

Claims 1 to 27 filed in the oral proceedings on 27 March 2001 with the description and Figures as for the main request.

Third auxiliary request

Claims 1 to 15 filed on 5 October 2000 as then second auxiliary request with the description and Figures as for the main request.

VI. Independent claim 1 of the **main request** reads as follows:

"1. A method of sampling a substance or substance metabolite from a human or an animal body and analysing the concentration of the substance or substance metabolite, which comprises the steps of:

- (a) placing at least one sampling chamber at a collection site on a surface tissue of the human or animal body,*
- (b) extracting the substance or substance metabolite through the surface tissue into the sampling chamber by conducting electrical current through the tissue in a first polarity between two electrodes in electrical contact with the surface tissue, at least one of the electrodes being in electrical contact with the surface tissue at or adjacent to the sampling chamber collection site,*
- (c) analysing the sampling chamber for the concentration of the substance or a substance metabolite,*
- (d) reversing polarity to apply electrical current between the two electrodes in a second polarity to reverse reactions caused by the electrical current in the first polarity, and*
- (e) repeating steps b) to d)."*

Further independent claims 21 and 33 of the **main request** are directed to an iontophoretic sampling

device and a substance monitor, respectively.

Claim 1 of the **first auxiliary request** corresponds to claim 1 of the main request and is specifically directed to the sampling of glucose or a glucose metabolite by extracting the glucose or glucose metabolite through the skin by electrodes which do not penetrate into or beneath the skin and by analysing the concentration of the glucose or glucose metabolite.

Claim 1 of the **second auxiliary request** is based on claim 1 of the first auxiliary request, step (c) thereof, namely analysing the sampling chamber for the concentration of the glucose or glucose metabolite, being deleted.

The **third auxiliary request** comprises only device claims.

VII. As regards the question whether the method claims of the main request and the first and second auxiliary requests are to be considered as constituting a diagnostic method practised on the human or animal body within the meaning of Article 52(4) EPC, the appellant's submissions may be summarised as follows:

An exclusion clause, such as Article 52(4), first sentence, EPC, had to be narrowly construed (cf. for instance **T 385/86** (OJ EPO 1988, 308), headnote 3 and point 3.2 of the reasons).

The case law was clear and consistent on what would qualify as a method of diagnosis. A pertinent decision in this respect was **T 385/86 supra**, which had been

widely accepted and confirmed in subsequent decisions **T 83/87**, **T 400/87** and **T 530/93** (not published in OJ EPO). According to **T 385/86** (cf. points 3.2, 3.3 and 3.4.1 of the reasons), *"the only diagnostic methods to be excluded from patent protection are those whose results immediately make it possible to decide on a particular course of medical treatment. This means that to answer the question whether a method is a diagnostic method for the purposes of Article 52(4), first sentence, it is necessary to ascertain whether the method claimed contains all the steps involved in reaching a medical diagnosis. Methods providing only interim results are thus not diagnostic methods in the meaning of Article 52(4), first sentence, even if they can be utilised in making a diagnosis."* Diagnosis was found to comprise the phase of recording the case history, examining and data gathering phases, the phase of comparing the data with normal values and recording any significant deviation (symptom) and, finally, the phase of attributing the deviation to a particular clinical picture (deductive medical decision phase). The deciding board had held that even if only one of the last three steps was lacking, there was no diagnostic method but at best a method of data acquisition or data processing that could be used in a diagnostic method. Thus, what was decisive was whether the nature of the disease was already immediately clear from the very value of a parameter obtained from the examination of the body. Decision **T 83/87** confirmed this finding specifically for a method of determining the concentration of blood sugar on a living body.

Although the sampling of substances from a body had not been the subject of previous considerations of the

Boards of Appeal, the principles developed in **T 385/86** and applied in **T 83/87** did not rely on an evaluation of the factual situation to be decided in these cases. Therefore, even if the factual basis of the present case differed to some extent from that of the existing case law, the findings therein as to what would qualify as a diagnostic method within the meaning of Article 52(4) EPC had to be respected. A clear distinction had to be made between a diagnostic method meeting the criteria developed by the established case law and a method of gathering data which at best provides an interim result in the course of a diagnosis.

In the present case, the taking of a sample from a body in a non-invasive manner merely constituted a method of collecting data and thus did not qualify as a method of diagnosis according to the principles developed in **T 385/86**. The present case was in fact parallel to decision **T 83/87** dealing with a method of operating an implanted blood glucose sensor for which the deciding board had held that the measurement of a value representative of the sugar concentration, albeit being used in the context of diagnosing, merely gave an intermediate result which could not provide a diagnosis directly in the sense of recognition of a pathological condition. The same applied for the claimed methods according to the main request and first auxiliary request, which also provided for the determination of the concentration of a desired substance, such as glucose, but did not provide enough information to effect a diagnosis or directly and alone to suggest a course of treatment. The knowledge of the concentration of a blood glucose level did not permit either a diagnosis of diabetes or even of hypo- or hyper-

glycaemia. Even for a patient who was already known to suffer from diabetes, a single reading of the blood glucose level alone was not sufficient to decide on the course of a treatment to be taken. Hence, if the Board was inclined to consider the method claims on file as relating to a diagnostic method to be excluded from patent protection, such finding would be contrary to the existing case law.

Moreover, the step of analysing the sample chamber for the concentration of the extracted substance was performed by purely technical means outside the body. The method claims of the second auxiliary request even did not comprise a step of analysing for the glucose concentration.

Finally, the application of electrodes to the skin and the passing of low iontophoretic currents through the skin had no significant or lasting effect on the body. Moreover, executing the claimed methods did not involve any risk for the health of a person treated nor did it require any medical knowledge. Thus the claimed methods could be performed by any person and did not require the participation of a medically qualified professional.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

Amendments

2. The amendments made to the independent method claims of the main request and the first and second auxiliary requests serve to clarify the non-therapeutic purposes of the steps of conducting electrical currents in opposite polarities. The Board is satisfied that the amendments have a basis in the originally filed application documents and thus comply with the requirements of Article 123(2) EPC.

Exclusion from patentability (Article 52(4) EPC)

- 3.1 Article 52(4) EPC excludes from patent protection methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. The policy behind the exclusion of such methods is clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents (cf. **T 116/85** (OJ EPO 1989, 13), point 3.7 of the reasons).
- 3.2 The reasons for the present decision are concerned with considerations relating only to the exclusion from patentability of diagnostic methods. Thus, the Board does not consider it necessary to discuss herein the arguments put forward in the course of these proceedings relating to methods for treatment of the human or animal body by surgery or therapy.
- 3.3 In **T 385/86** *supra* (cf. points 3.2, 3.3 and 3.4.1 of the reasons), the Board, having considered the historical origins of the exclusion made by Article 52(4) EPC with respect to diagnostic methods in the light of the travaux préparatoires to the Munich Diplomatic Conference, held:

"All this shows that the first sentence of Article 52(4) EPC is intended to exclude from the possibility of patent protection only methods of therapeutic treatment, so that no-one can be hampered in the practice of medicine by patent legislation. Like any exclusion clause, Article 52(4), first sentence, must be narrowly construed, a fact underscored by the statement in the second sentence that the exclusion from patentability does not apply to products for use in such methods. The Board is therefore convinced that the only diagnostic methods to be excluded from patent protection are those whose results immediately make it possible to decide on a particular course of medical treatment. This means that to answer the question whether a method is a diagnostic method for the purposes of Article 52(4), first sentence, it is necessary to ascertain whether the method claimed contains all the steps involved in reaching a medical diagnosis. Methods providing only interim results are thus not diagnostic methods in the meaning of Article 52(4), first sentence, even if they can be utilised in making a diagnosis.

The systematic list of the steps leading to a diagnosis contained in the relevant literature includes recording the case history, observing, palpating and auscultating various parts of the body and carrying out numerous medical and technical examinations and tests - the examination and data gathering phases - and comparing the test data with normal values, recording any significant deviation (symptom) and, finally, attributing the deviation to a particular clinical picture (deductive medical decision phase) - cf. Brockhaus Enzyklopädie, Vol. 4, 1968, page 684; The New

Encyclopaedia Britannica, Macropaedia, 1977, Vol. 5, page 684; La Grande Encyclopédie Larousse, 1973, Vol. 7, page 3833. Even if only one of the last three steps is lacking, there is no diagnostic method but at best a method of data acquisition or data processing that can be used in a diagnostic method.

For a case where the result of the measures claimed is a quantitative expression of an isolated physical variable, the board arrived at the conclusion that "what is decisive is whether the nature of the disease is already immediately clear from that very value".

3.4 Apparently the reasoning in decision **T 385/86** *supra* on the aspect of diagnostic methods rests on two observations (cf. point 3.2 of the reasons):

- that Article 52(4) EPC was intended to exclude from the possibility of patent protection only methods of therapeutic treatment, so that no one could be hampered in the practice of medicine by patent legislation,
- and that Article 52(4), first sentence, being an exception, must be narrowly construed, a fact underscored by the statement in the second sentence that the exclusion from patentability does not apply to products for use in such methods.

For these reasons, the then deciding board arrived at the conclusion that the only diagnostic methods to be excluded from patent protection were those whose results immediately made it possible to decide on a particular course of medical treatment and that

therefore a method was a diagnostic method for the purpose of Article 52(4) EPC only if it contained **all the steps involved in reaching a medical diagnosis** (emphasis added).

- 3.5 This line of reasoning equates the meaning of the expression "diagnostic methods practised on the human or animal body" in Article 52(4) EPC with the conventional meaning of the term "diagnosis" and thus implies that "diagnostic methods" cover activities which are not normally practised on the body but predominantly involve **mental acts**, *i.e.* activities of non-technical nature performed by a medical professional, such as the steps of comparing the data with normal values and recording any significant deviation and of attributing the deviation to a particular clinical picture.

Though the above interpretation of the wording of Article 52(4) EPC would exclude from patentability procedures providing a more or less complete diagnosis as the result of a fully automated operation of technical devices, a strict adoption of the principles set out in **T 385/86** would lead to the conclusion that typical diagnostic procedures practised on the human body, like percussion, auscultation or palpation could, in principle, be patentable because they do not constitute a complete diagnosis and certainly do not fall within the further medical categories of surgery and therapy referred to in Article 52(4) EPC. However, the Board considers that it would go against the spirit of Article 52(4) EPC to interpret its provisions in such a way that "manual procedures" of physical examination essential for making a diagnosis and executed by a medical practitioner would not constitute

an exception to patentability.

3.6 Moreover, the Board wishes to note that the restrictive interpretation of the patent exemption for diagnostic methods adopted by **T 385/86** amounts to setting a different standard for diagnostic methods than that established for methods of surgery or therapy, the latter being excluded from patent protection if they comprise only a single step of a surgical or therapeutic nature (cf. for instance **T 35/99** (OJ EPO 2000, 447) and **T 82/93** (OJ EPO 1996, 274)). It is thus not surprising that literature on patent law considers the interpretation of the law by **T 385/86** as resulting in a practical dissolution of the legislative exclusion of diagnostic methods (cf. R. Moufang: "Methods of medical treatment under patent law", 24 IIC, no. 1, 1993, 18-49, at 46 and 47).

3.7 Furthermore, the appellant's view that the case law on diagnostic methods has consistently adopted the restrictive interpretation of **T 385/86** is not correct.

In **T 329/94** (OJ EPO 1998, 241, cf. point 4 of the reasons) withdrawal of blood from a living body was considered to fall under the exclusion of Article 52(4) EPC, if it could be regarded as a step of a diagnostic method, for example with a view to a blood analysis for determining the cause of a disease.

In **T 655/92** (OJ EPO 1998, 17, cf. headnotes 2 and 3; and points 5.2 and 5.3 of the reasons) a method including a step of parenteral administration of a diagnostic contrast agent was considered a diagnostic method within the meaning of Article 52(4) EPC. This

finding was derived from distinctions in the factual basis of the case as compared with that of **T 385/86**. The board in **T 655/92** noted in particular that *"unlike the processes of the previous cases, the present diagnostic process, when considered in its totality, comprises at least one step essential for the desired diagnostic result, which cannot fall under the exclusive responsibility of the technician skilled in NMR technology. While for a process whose steps as a whole are non-medical but technical it is legitimate not to derive the in vivo diagnostic character from its final diagnostic purpose, this does not apply to a process for a diagnostic purpose which is to be implemented in its essential steps by medical staff or under the responsibility of a doctor. A different interpretation would be in clear conflict with the spirit of Article 52(4) EPC."*

- 4.1 It is not contested by the Board that, in order to arrive at a medical diagnosis, all the steps referred to by the appellant and indicated in point 3.3 of the reasons in **T 385/86** *supra* are required, including a symptom recording phase and a deductive medical decision phase. However, for the reasons given in points 3.5 and 3.6 above, the Board is of the opinion that the expression "diagnostic methods practised on the human or animal body" in Article 52(4) EPC or the corresponding expressions "Diagnostizierverfahren, die am menschlichen oder tierischen Körper vorgenommen werden" and "méthodes de diagnostic appliquées au corps humain ou animal" in the other two official languages of the EPC should not be considered to relate to methods containing all the steps involved in reaching a medical diagnosis.

4.2 According to the Oxford English Dictionary (second edition, Oxford University Press, 1999) "diagnosis" means the "determination of the nature of a diseased condition" or the "identification of a disease by careful investigation of its symptoms and history" and also the "opinion resulting from such investigation", whereas "diagnostic" means "of or pertaining to diagnosis" or "of value for the purposes of diagnosis". Hence, the straightforward meaning of "diagnostic methods" would be "methods pertaining to, or of value for the purposes of, diagnosis". Within this meaning, any medical activity concerning the gathering of information in the course of establishing a diagnosis qualifies as a diagnostic method. A corresponding differentiation exists in the German language between the meanings of the terms "Diagnose" and "Diagnostik" (cf. Roche Lexikon Medizin, 3. Auflage, Verlag Urban & Schwarzenberg, 1993), the latter being used as a generic term for medical activities ("Diagnostizierverfahren") relating to the examination and collection of data required in establishing a diagnosis. In the French language, the term "diagnose" means "connaissance qui s'aquiert par l'observation des signes diagnostiques" and "diagnostic" means "action de determiner une maladie d'après ses symptômes" (cf. Le Petit Robert, Dictionnaires Le Robert, 1990). Although the term "diagnostic" as such may be interpreted as encompassing all steps required for reaching a medical diagnosis, it appears that it can also define an individual step of a diagnostic examination when used in the expression "méthodes de diagnostic". Thus, the French text of Article 52(4) EPC does not favour an interpretation limiting the exception to patentability to methods encompassing **all** steps required for reaching a medical diagnosis.

4.3 The medical art knows of a broad spectrum of diagnostic methods applied by the medical practitioner ranging from general observations of the appearance of a patient and purely manual interventions, such as palpation or auscultation, to diagnostic techniques utilizing sophisticated physical instruments and chemical or bio-chemical tools. Diagnostic methods can be classified in two categories: those which are practised **on the living body** and those whose performance takes place **outside the body**. It appears from the wording of Article 52(4) EPC that the legislator has intended to exclude from patent protection only methods "practised on the human or animal body", whereas for instance extra-corporal laboratory tests would be patentable.

4.4 For these reasons and adopting the principle, well-established in the case law of the Boards of Appeal, that the EPC has to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context" (Article 31(1) Vienna Convention on the Law of Treaties, cf. **G 5/83** (OJ EPO 1985), 64, points 4 and 5), the Board is of the opinion that Article 52(4) EPC is meant to exclude from patent protection all methods **practised on the human or animal body** which **relate to diagnosis or which are of value for the purposes of diagnosis**.

5.1 All method claims on file comprise the step of sampling a substance from a living human or animal body.

One significant and specific commercial embodiment of the claimed methods is the analysis of blood glucose as it has been found that the levels of glucose below the

skin correlate with the level of glucose in the blood. The sampling of glucose relieves diabetes patients, who require a more or less continuous monitoring of their blood glucose levels, of the painful procedure of pricking a finger several times a day in order to obtain a blood sample for analysing the blood glucose level. Further envisaged applications include optimization of the blood level of an administered drug during a chemotherapeutic regimen (cf. page 12, lines 18 to 20 of the original description) and the sampling of therapeutically introduced metabolites, anaesthetics or psychotherapeutically acting agents (page 12, line 28 to page 13, line 2 of the description). All of these examples concern activities exercised in the course of a medical treatment of patients and serve particularly for diagnostic purposes.

5.2 In the Board's view, the taking of a body sample for the purpose of a medical examination belongs to a fundamental diagnostic activity, regardless of the technical means used, be it a spatula for taking a swab or smear, a syringe for taking a blood sample, or, as in the present case, a iontophoretic current forcing a substance through the skin. For these reasons, the claimed step of sampling a substance relates to diagnosis and constitutes in this context an essential diagnostic measure **practised on the living human or animal body**. Consequently, the subject-matter of the method claims on file has to be considered a diagnostic method within the meaning of Article 52(4) EPC.

6.1 In order to arrive at this judgment, it is immaterial that the claimed methods could be performed by a patient himself and that their execution would not have

a significant impact on the body nor involve a serious health risk. What is decisive is the fact that all method claims on file comprise the step of taking of a body sample for the purpose of diagnosis and that such a step is to be regarded as an essential activity pertaining to diagnosis and practised on the living body.

6.2 It is in this respect that the present case is factually distinguished from decisions **T 385/86**, **T 83/87**, **T 400/87** and **T 530/93**.

In case **T 83/87**, the claimed method does not comprise any step which is explicitly practised on the human or animal body. In fact, the method exclusively defines steps concerning the internal operation of an electro-catalytic sugar sensor when analysing a bodily fluid, using certain electrodes operated with a specific sequence of potentials. The other three cases all relate to nuclear magnetic resonance (NMR) procedures which, although performed on a living body, only define steps which concern the technical operation of exciting and detecting resonance signals and thus fall in terms of design and performance within the exclusive competence and responsibility of the technician skilled in NMR technology.

As a matter of fact, none of the methods judged in the above decisions comprises a step which would have to be attributed to basic medical activities exercised on the human or animal body. Thus, although the present decision does not adopt the approach chosen in former decisions **T 385/86**, **T 83/87**, **T 400/87** and **T 530/93**, it does not question the fact that a process, the claimed steps of which amount to nothing more than the

(internal) operation of a technical device and thus without exception fall within the competence and under the exclusive control of a technician, may be regarded as patentable, even if it generates and detects physical signals on a living body and its results may be evaluated for diagnostic purposes. In fact, the method claims on which the aforementioned decisions were taken, can be considered (and could have been formulated) as containing only steps which concern the control and internal operation of a technical device, in the specific cases either a tomographic NMR machine or an electro-catalytic sensor, so that no specific step of diagnostic character can be recognized.

In contrast thereto, in the present case, the crucial step of diagnostic character is the extraction of a body substance for diagnostic purposes, which is to be considered as constituting an elementary diagnostic activity performed under the ultimate responsibility of a physician.

7. In conclusion, the main request as well as the first and second auxiliary requests, in seeking protection for diagnostic methods within the meaning of Article 52(4) EPC, are not allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of the first

instance for further examination on the basis of the third auxiliary request (cf. point V above).

The Registrar:

The Chairman:

R. Schumacher

G. Davies