

Patentability of Diagnostic Methods under the EPC: A new Referral to the Enlarged Board of Appeal by the President of the EPO

Dr. FRANZ-JOSEF ZIMMER and DR. ULRIKE LANGHEINRICH

INTRODUCTION

In contrast to US patent law, which allows patent protection for methods of treatment of the human body^{1a}, the patentability of methods for treatment by surgery or therapy and diagnostic methods practised on the human or animal body is excluded according to Article 52(4) of the European Patent Convention (EPC). Article 52(4) EPC, first sentence, reads as follows:

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1.

Article 52(4) EPC represents one of the exemptions from the general clause in Article 52(1) EPC, which reads as follows:

European patents shall be granted for any inventions which are susceptible of industrial application, which are new and involve an inventive step.

The wording of Article 52(4) EPC implicitly recognizes that the methods outlined in paragraph (4) are susceptible of industrial application as a matter of reality, however, it provides that they "are not regarded as" inventions susceptible to industrial application, by way of legal fiction¹. Thus, Article 52(4)

^{1a} Although U.S. law allows for such patents to issue, it was amended in 1996 to protect doctors and health care providers against actions for infringement by the holders of such patents, 35 U.S.C. § 287(c) (2004).

EPC takes precedence over article 57 EPC,¹ which states:

An invention shall be considered as susceptible of industrial application if it can be performed or used in any kind of industry including agriculture.

The provision of Article 52(4) in the EPC is based on the fundamental consideration that persons using surgical, therapeutic, or diagnostic methods as part of a medical treatment of humans or animals should not be hampered by patents¹. Only non-commercial and non-industrial medical and veterinary activities should be free from restrictions due to patent law². As explained above, medical treatments are regarded as non-commercial activities by way of fiction.

THE RECENT REFERRAL TO THE ENLARGED BOARD OF APPEAL

Recently, on December 29, 2003, the President of the European Patent Office (EPO) has referred points of law to the Enlarged Board of Appeal relating to the interpretation of the term "diagnostic methods practised on the human or animal body" within the meaning of Article 52(4) EPC³.

The Referral is mainly based on the divergence between the interpretation of this term in decisions **T 385/86**⁴ and **T**

¹ Decision of the Technical Board of Appeal T 116/85; cf. OJ EPO 1989, 13 ff.

² Decision of the Enlarged Board of Appeal G 5/83; cf. OJ EPO 1985, 64 ff.

³ http://www.european-patent-office.org/dg3/g_dec/pdf/g012004.pdf

⁴ Decision of the Technical Board of Appeal T 385/86; cf. OJ EPO 1988, 308 ff.

964/99⁵, both of the Technical Board of Appeal 3.4.1. The case is pending under G 01/04. The Referral, together with the full translations in the other two official languages, is scheduled to be published in OJ EPO No. 5/04.

Until the Enlarged Board of Appeal has issued its decision in this case, all proceedings before the EPO first-instance departments where the decision depends entirely on the Enlarged Board of Appeal's decision, will be suspended.

The questions referred to the Enlarged Board of Appeal are the following:

1a. Are "diagnostic methods practised on the human or animal body" within the meaning of Article 52(4) EPC (hereinafter: "diagnostic methods") only those methods containing all the procedural steps to be carried out when making a medical diagnosis, i. e. the examination phase involving the collection of relevant data, the comparison of the examination data thus obtained with the standard values, the finding of any significant deviation (a symptom) during that comparison and, finally, the attribution of the deviation to a particular clinical picture (the deductive medical decision phase), or

1b. is a claimed method a "diagnostic method" even if it only contains one procedural step that can be used for diagnostic purposes or relates to the diagnosis?

2. If the answer to question 1b is in the affirmative: Does the claimed method have to be usable exclusively for diagnostic purposes or relate exclusively to the diagnosis? According to which criteria is this to be assessed?

3a. Is a claimed method a "diagnostic method" if

i) it contains at least one procedural step considered as essential for a "diagnostic method" and requiring the presence of a physician (Alternative 1), or

ii) it does not require the presence of a physician but presupposes that a physician bears the responsibility (Alternative 2), or

iii) all procedural steps can also or only be practised by medical or technical support staff, the patient himself or an automated system (Alternative 3)?

3b. If the participation of a physician (by being present or by bearing the responsibility) is decisive, does the physician have to participate in the procedural step practised on the body, or does he only have to participate in any procedural step considered as essential for a diagnostic method?

4. Does the requirement "practised on the human or animal body" mean that the procedural steps take place in direct contact with the body and that only such steps practised directly on the body can provide a method with the character of a diagnostic method, or is it sufficient if at least one of the procedural steps is practised directly on the body?

THE DIVERGENT DECISIONS

Prior to discussing the actual divergence between the two decisions T 385/86 and T 964/99, facts underlying both cases are summarized. Further decisions were issued by different Technical Boards of Appeal of the EPO which then followed the one or other of the two cases.

1. Decision T 385/86 – Method for the non-invasive determination of measurement values inside a living

⁵ Decision of the Technical Board of Appeal T 964/99; cf. OJ EPO 2002, 4 ff.

body /Bruker⁴ (the “all steps approach”)

Claim 1 of the European patent application, published as No. EP-A-0095124 and being the basis for decision T 385/86, read:

1. A method for the non-invasive determination of chemical and/or physical conditions inside a whole, intact, living animal or human body using magnetic resonance with a homogeneous, steady magnetic field and a high-frequency magnetic field, in which high-resolution magnetic resonance measurements are carried out on individual areas of the body and freely-selectable measuring points at any desired location within the living body are examined using local magnetic resonance (LMR) restricted to selectable areas of the body's volume, characterised in that the temperature within the selected areas of volume is determined from a parameter of the nuclear magnetic resonance spectrum measured.

The main request was refused by the Examining Division on the basis of Article 52(4) EPC, because claims 1 and 2 would be directed to a diagnostic method practised on the human or animal body. The applicants filed an appeal of this decision on July 1986.

In 386/86, the Technical Board of Appeal stated that the first sentence of Article 52(4) EPC should, like any exclusion clause, be narrowly construed. Therefore, the only diagnostic methods to be excluded from patent protection should be those whose results would make it immediately possible to decide on a particular course of a medical treatment (see item 3.2 of the reasons). Methods providing only interim results would therefore not be regarded as

diagnostic methods in the meaning of Article 52(4) EPC. An immediate decision, according to the Board, can only be obtained if the method claimed would contain all the steps involved in reaching a medical diagnosis. These are:

(1) Examination and data gathering phases, including recording the case history, observing, palpating and auscultating, technical and medical examination and tests,

(2) Establishing of symptoms by comparing the test data with normal values, recording any significant deviation, and

(3) Deductive medical decision phase, wherein the deviation recorded is attributed to a particular clinical picture (see item 3.3. of the reasons).

In the case under decision the requirement that a diagnostic method in the sense of Article 52(4) EPC must contain all steps necessary for obtaining a diagnosis was not fulfilled, because, in the Board's view, the claimed method would only result in a quantitative expression of an isolated physical variable, which does not indicate immediately a diagnosis. It remained to be shown that the measure values differ significantly from a value regarded as normal, i.e. non-pathological, and the deviation had to be attributed to a certain clinical picture (see items 3.4 and 3.4.1 of the reasons).

Further, in the Board's view, the criterion “practised on the body” was not fulfilled. Under item 4.1, the Board concluded from the requirement of a narrow construction of Article 52(4) EPC that both the examination (measurement of actual value) and establishing the symptoms on the basis of the examination results, hence the deviation measured from the norm, must be

carried out on a living body. In the case under decision, however, the data obtained would be visible on a data carrier detached from the body only after further technical measures which would take place outside the body. Any further step which as a result of comparison with a norm would reveal an abnormal deviation, would not require the patient's presence.

The practice of a diagnostic method on the human or animal body in the meaning of Article 52(4) EPC, first sentence, EPC, would presuppose that even a deviation from a norm that must be regarded as a symptom is directly discernible on the body itself (see items 4.2 and 4.3 of the reasons). Examples would be an allergy test in which the abnormal deviation can be detected from a change to the skin, a method in which scarlet-fever spots are directly observed or an endoscopic examination carried out to ascertain liver damage (item 4.3 of the reasons).

Further, according to the Technical Board, since the examination phase does not require the presence of a doctor, the measures claimed would be susceptible of industrial application, just like laboratory tests carried out on blood or tissue samples. A method involving interaction with the human or animal body is susceptible of industrial application if it can be used with the desired result by a technician without specialist medical knowledge and skills, according to T 385/86 (see item 3.5.2 of the reasons).

None of the three basic requirements, established by the Board (all steps involved in diagnosis must be part of the claimed method, examination and establishing symptoms must be practised on the body, participation of a physician is necessary during examination), were fulfilled in the case under decision in order to categorize the

method as a diagnostic method in the meaning of Article 52(4) EPC. Thus, the method claimed was regarded as being susceptible to industrial application and therefore not excluded by Article 52(4)EPC.

In the Referral, it is noted that the interpretation of the term "diagnostic method" as applied by the Board in T 385/86 was in accordance with several earlier decisions of the Technical Boards of Appeal of the EPO, and that later decisions would have confirmed this view.

Further, the narrow interpretation of the term "diagnostic method" as applied in T 385/86 would also be applied in the practice of the EPO in the "Guidelines for Examination in the EPO" (C-IV, 4.2.1., December 2003, page 52), which reads as follows:

"Diagnostic methods likewise do not cover all methods related to diagnosis. Methods for obtaining information (data, physical quantities) from the living human or animal body are not excluded by Art. 52(4) EPC, if the information obtained merely provides intermediate results which, on their own, do not enable a decision to be made on the treatment necessary. Generally, such methods include X-ray investigation, NMR studies, and blood pressure measurements (see 385/86, OJ 8/1988, 308)."

2. Decisions based on T 385/86

In this section, examples are provided of claims to methods that have been regarded as patentable under Article 52(4) EPC because they only provide interim results and would not allow an immediate decision on a diagnosis. The corresponding decisions all refer to decision T 385/86 in their reasons.

2.1. Decision T 83/87⁶ refers to a method for the detection of glucose in the body fluid in the presence of interfering foreign substances by use of an implanted sensor. The basis for the decision were seven claims, the only independent claim, read as follows:

An improved method for measuring the sugar content of a fluid, in particular glucose in a body fluid, in the presence of interfering foreign substances by means of an electrocatalytic sugar sensor which includes a test electrode having a membrane arranged in front of it, said method including the steps of applying potentiostatically to said electrode a reactivation potential and a test potential and measuring and evaluating a current flowing during a test period with a set time delay to determine sugar content, said improvement including the step of: applying a reduction potential for a period of time shorter than said test period to said test electrode to reduce the effect of said interfering foreign substances, said reduction potential being more negative than said test potential and being applied after the application of said reactivation potential and prior to the application of said test potential.

The Technical Board agreed with the Division of lower instance in that the data points could be used in the scope of diagnosis. However, by citing decision T 385/86, the Board concluded that in this case, without reference to values regarded as normal and an attribution of a possible deviation from the norm to a disease condition, the data points itself would not lead to an immediate recognition of a pathological condition (see item 3.2 of the reasons).

⁶ Decision of the Technical Board of Appeal T 83/87; unpublished, <http://legal.european-patent-office.org/dg3/biblio/t870083du1.htm>

2.2 A nuclear magnetic resonance method, NMR, was the basis for decision T 400/87⁷.

Claim 1 read as follows:

A method of deriving image information from an object using nuclear magnetic resonance signals comprising subjecting the object to a continuous magnetic field along an axis and carrying out the following steps:

1) selectively exciting nuclear spins in a selected plane in the presence of a first gradient (Gy+) of the static magnetic field, the direction of said first gradient being perpendicular to said plane;

2) applying the said first gradient of the magnetic field in the reverse direction after step 1) to rephase the excited nuclear spins across the thickness of the selected plane;

3) applying a second gradient (Gx-) to the static magnetic field during the period of time of step

2) the direction of the second gradient being orthogonal to the direction of the first gradient, to dephase the spins along the direction of the said second gradient as a preliminary to the subsequent read-out step;

4) applying a third gradient (Gz) to the static magnetic field, the direction of the third gradient being orthogonal to the directions of both the first and second gradients;

5) reversing the direction of the second gradient after step 3) and maintaining said reversed gradient (Gx+) while reading out the resultant free induction decay signal from the object; and then successively repeating the above

⁷ Decision of the Technical Board of Appeal T 400/87; unpublished, <http://legal.european-patent-office.org/dg3/biblio/t870400eu1.htm>

sequence of steps, there being a recovery interval between said successive repetitions of the above sequence of steps characterised in that the said step 4) is applied during the period of time (4) of said steps 2) and 3) to phase encode the excited nuclear spins, and in that the above sequence of steps 1) to 5) is repeated at different values of the amplitude of the third gradient (GZ) while keeping constant the period of time (4) in which step 4) is applied."

Claims 2 to 6 are referred back to Claim 1.

In the reasons, the Board stated that the method to which claim 1 refers to would provide a spatial spin-density distribution in selected planes that would allow the localization of an eventual pathological deviation only after a comparison with normal values. Since a further step would be necessary in order to attribute a localized deviation to a particular clinical picture, claim 1 would only comprise the examination and data gathering phase of diagnosis, thus providing only interim results.

Further, the claimed method could be implemented without specialist medical knowledge, according to the Board, because the magnetic fields would not leave any harmful side-effects in the living matter. Finally, a possible deviation from the norm would be only discernible from diagrams and not from the human or animal body itself. For the reasons above and by referring to T 385/86, the Board then decided that the method would not represent a diagnostic method in the meaning of Article 52(4) EPC (see items 3.1 to 3.3 in the reasons).

2.3. An NMR method for producing a sequence of images throughout the cardiac cycle was the subject matter of

claim 1 in the case under decision of T 530/93⁸. Claim 1 read as follows:

A method for producing images with an NMR imaging system of a human heart at selected cardiac phases of its functional cardiac cycle, comprising the steps of:

(a) repeatedly executing an NMR fast scan pulse sequence at regular time intervals throughout a functional cycle to acquire a subset of NMR data, said execution being asynchronous with respect to said functional cycle to produce NMR data at each of a plurality of times within the functional cycle, and said NMR pulse sequence including a position encoding gradient pulse;

(b) detecting the start of each cardiac cycle and deriving therefrom phase angles of the cardiac cycle which vary linearly as a function of time between starts of successive cycles;

(c) correlating the NMR data acquired during the execution of each NMR fast scan pulse sequence with the phase angle of the functional cycle at the time the NMR data is acquired;

(d) repeating steps (a), (b) and (c) for a plurality of functional cycles with a different position encoding gradient pulse employed during each functional cycle to produce other subsets of NMR data;

(e) reconstructing an image at a selected phase angle of the functional cycle by interpolating between the corresponding correlated NMR data within each subset of acquired NMR data to produce a set of NMR data interpolated to said selected phase angle which is employed to produce the image; and

⁸ Decision of the Technical Board of Appeal T 530/93; unpublished, <http://legal.european-patent-office.org/dg3/pdf/t930530eu1.pdf>

repeating step (e) at a plurality of successive phases [read: phase] angles of the functional cycle to produce a plurality of images which depict the heart at successive phase angles of its functional cycle.“

In the opinion of the Technical Board the claimed method would only comprise the data gathering phase of a diagnosis and only provide interim results which would require a further step in order to attribute the data to a particular clinical picture, and therefore, by referring to T 385/86, would not represent a diagnostic method in the meaning of Article 52(4) EPC.

2.4. A method for the use of a vaginal discharge collector was also not regarded as a diagnostic method by a Technical Board of the EPO (T 1165/97)⁹, by reference to T 386/86, because a direct decision on a particular course of a medical treatment was not possible. The steps of providing a collector, placing it, collecting discharge therein, retrieving and disposing of it would not fulfil this condition because on the sample thus collected, not even data would be gathered (see item 4.3 of the reasons).

2.5. A method for locating lung malignancies by injection of radioactive copper complexes was the subject matter of claims 8-11 in the application on which decision T 629/98¹⁰ was based. The original claim 8 for example read as follows:

A method for treating lung cancer, comprising the step of injecting a sample of the ⁶⁷Cu complex of 5, 10, 15, 20-tetrakis (4-carboxyphenyl)-porphinato

into the bloodstream of a patient to be treated.

According to the Board, the medical application, e.g. in claim 8, represents a diagnostic method practiced on the human body which provides an immediate clinical picture and allows to determine the presence or absence of lung malignancies in a patient to whom the substance is administered. However, according to established case law, a patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic or diagnostic application (“second medical use” claims). The Board then concluded that the new claims, formulated as second medical use claims, would not longer raise issues under Article 52(4) EPC as did the originally filed method claims. The new claim 8 read as follows:

Use of the ⁶⁷Cu complex of 5, 10, 15, 20-tetrakis (4-carboxyphenyl)porphinato in the preparation of a substance to be administered to a patient for the diagnosis of lung cancer, whereby an image is formed from the emitted gamma radiation for locating sites of lung malignancies.

Methods which fulfil the criteria, developed in decision T 385/86, for being regarded as a diagnostic method in the meaning of Article 52(4) EPC, were for example the following:

2.6. A method for the determination of bone density for evaluation of an x-ray photograph of a bone was the subject matter of the case on which decision T 775/92¹¹ was based. Claim 1 read as follows:

⁹ Decision of the Technical Board of Appeal T 1165/97; unpublished, <http://legal.european-patent-office.org/dg3/pdf/t971165eu1.pdf>

¹⁰ Decision of the Technical Board of Appeal T 629/98, <http://legal.european-patent-office.org/dg3/pdf/t980629eu1.pdf>

¹¹ Decision of the Technical Board of Appeal T 775/92; unpublished, <http://legal.european-patent-office.org/dg3/biblio/t920775eu1.htm>

A method for providing bone densities My'i for the evaluation of an X-ray photograph or a bone, comprising the steps of:

(a) determining a bone pattern by measuring the photodensities along a line substantially perpendicular to the longitudinal axis of the bone of an X-ray photograph of a long shank bone of a limb;

(b) smoothing and symmetrizing the bone pattern to modify the same; and

(c) determining bone densities My'i, by establishing, from the modified bone pattern, a bone model having an elliptical bone cross-sectional external shape with a ratio of the major axis to the minor axis of more than 1 but not more than 1.4 and having a zonate bone cortex consisting of a plurality of cross-sectional zones of which the densities thereof are stepwise reduced toward the centre of the elliptical bone cross-section.

According to the Board, the expression "evaluation of an X-ray photograph" in claim 1 would be so vague and general that it could also cover the case where a diagnosis is being made (see item 10 of the reasons). It would appear that this expression could be so interpreted that the said final data distributions of the bone densities according to steps (c) for example were evaluated by e.g. a doctor by comparing these distributions of the bone densities with model distributions in order to find out the status of a patient with regard to ageing or bone densities. Thereby, not only interim results would be provided, but a deviation to a particular clinical picture would be possible such that a doctor could start a medical treatment. Hence, the claim could be interpreted such that all three steps of a diagnostic method were included.

2.7. Another example for a method which would not only provide interim results but could lead to diagnosis was the basis for the decision T807/98¹². The subject matter was a method for the *in vivo* detection of abnormalities in electrophysiological signals of an organ affected by a functional disorder. Claim 1 read as follows:

Process for detecting a series of abnormal dysfunction-conditioned events among a multiplicity of normal events in an electrophysiological signal (IS) of an organ exhibiting a dysfunction, which process exhibits the following process steps:

(a) the signal (IS) is compared, with respect to a signal parameter (t), with a defined treshold value (t_D), which the signal (IS) exceeds upon the occurrence both of a normal and of an abnormal event,

(b) for each event, the maximum value (t_T) of the signal parameter (t) is measured, characterized in that

(c) for the event which occurred respectively last and a defined number of events which occurred in succession directly before the latter, a characteristic quantity (S) corresponding to the statistical distribution of the measured maximum values (t_T) is determined, and

(d) the determined characteristic quantity (S) is compared with a defined value (DVA).

According to the Board, the claimed method, characterized by data gathering and comparison steps, would fulfil all the criteria of a diagnostic method in the sense of decision T 385/86. In contrast to the case in T 385/86, in the present

¹² Decision of the Technical Board of Appeal T 807/98; unpublished, <http://legal.european-patent-office.org/dg3/pdf/t980807du1.pdf>

case, the Board stated that the claimed method would comprise a step in which a comparison is made and a pathological deviation could have been determined by a corresponding output signal. The quantitative values were transformed to a corresponding signal providing the qualitative information, whether a disease, e.g. an arrhythmia, does exist or not. An output signal would be provided as soon as the disease is recognized. Importantly, the negative statement, that a certain disease is excluded was explicitly regarded as a diagnosis. Further, the claimed method was practiced on the body and a physician would finally assume the responsibility for the method. For all these reasons the method was excluded from patentability (see item 2.2. and 2.3 of the reasons).

3. Decision T 964/99 – Device and method for sampling of substances using alternating polarity /Cygnus (the “one step approach”)

According to the Referral, decision T 964/99⁵ would not be in accordance with the principles developed in decision T 385/86 and later decisions based thereon. In the application on which decision T 964/99 was based, a non-invasive method for the iontophoretic sampling of a substance through the skin was claimed. Claim 1 read as follows:

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 the 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) – (d).

In the reasons of the decision, the Board first cited the principles developed in T 385/86, and then interpreted and criticised the former decision. The term “diagnostic methods practised on the human or animal body” in Article 52(4) EPC would have been equated in T 385/86 with the conventional meaning of the term “diagnosis” and would imply that “diagnostic methods” would cover activities which predominantly involve mental acts (e.g. comparing of data, recording of deviations, attribution to a clinical picture). Further, by a strict adoption of the principles set out in T 385/86, typical diagnostic procedures practised on the human body, like percussion, auscultation or palpation could, in principle, be patentable, because they would not constitute a complete diagnosis (see item 3.5 in the reasons).

Importantly, the Board in T 964/99 further stated that the restrictive interpretation of the patent exemption for diagnostic methods adopted by T 385/86 would set 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 (see item 3.6 of the reasons).

Citing decisions T 329/94¹³ and T 655/92¹⁴, the Board stated that the restrictive interpretation of T 385/86 had not been consistently adopted, because in these cases also only one step essential for the desired diagnostic result and for which a doctor assumes the responsibility would be sufficient for an exclusion from patentability (see item 3.7 of the reasons). Under item 4.1 of the reasons, the Board explicitly stated that the expression “diagnostic methods practised on the human or animal body” in Article 52(4) EPC should not be considered to relate to methods containing all the steps involved in reaching a medical diagnosis.

By analysing the term “diagnosis” and “diagnostic”, the Board concluded that 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. Therefore, Article 52(4) EPC would be 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 (see item 4.4 of the reasons). Thus, a method comprising at least a single step of diagnostic character would be sufficient according to this statement to regard a method as a diagnostic method.

¹³ Decision of the Technical Board of Appeal T 329/94; cf. OJ EPO 1998, 241 ff.

¹⁴ Decision of the Technical Board of Appeal T 655/92 ; cf. OJ EPO 198, 17 ff.

In the claimed method all activities would serve a diagnostic purpose and the taking of a body sample for the purpose of a medical examination would belong to a fundamental diagnostic activity, regardless of the technical means (e.g. spatula, syringe, iontophoretic current) used (items 5.1 and 5.2. of the reasons). Importantly, the Board noted that it would be immaterial if 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 (item 6.1 of the reasons).

The Board in T 964/99 then provided arguments that decisions T 385/86, T 83/87, T 400/87 and T 530/93 are factually distinguished from the present case (see item 6.2 of the reasons).

In T 83/87 (see above), for example, the claimed method would not comprise any step which is explicitly practised on the human or animal body. In fact, the method would exclusively define steps concerning the internal operation of an electro-catalytic sugar sensor.

In the other three cases, all related to NMR techniques and performed on the living body, the claimed methods would only define steps which would concern the technical operation of exciting and detecting resonance signals and thus would fall under the exclusive competence and responsibility of the technician skilled in the NMR technology. These methods might be regarded as patentable even if they generate physical signals on a living body and the results could be evaluated for diagnostic purposes.

Therefore, in view of the Board in T 964/99, none of the methods judged in the above decisions would comprise a step necessarily attributable to basic medical activities exercised on the human or animal body (see item 6.2 of

the reasons). In contrast, in the case under decision, the crucial step of diagnostic character would be the extraction of a body substance for diagnostic purposes, which was considered as constituting an elementary diagnostic activity performed under the ultimate responsibility of a physician and therefore would not be patentable.

According to the Referral, some later decisions would already have shown first hints for a deviation in the interpretation of the term “diagnostic method” as defined in T 385/86.

4. Decisions deviating from the reasoning of T 385/86

In the application being the basis for decision T 329/94 a method was claimed for facilitating blood extraction with the help of a stimulating agent. Claim 12 read as follows:

A blood extraction assistance method for facilitating sustained venous blood flow through a human limb towards a venous blood extraction point (14), the method comprising engaging means (200, 100) in tactile manner with a lower portion of the limb, characterized in that said means is limb stimulus means (200, 100) and in that the method includes selectively activating the limb stimulus means to provide a stimulus to the limb when sustained venous blood flow to the blood extraction point (14) is desired, and deactivating the limb stimulus means when sustained venous blood flow to the blood extraction point (14) is not desired.

The Board first noted that a blood extraction method considered *per se* would fall under the exclusion of Article 52(4) EPC in three ways if it could be considered as a step of a method of treatment by surgery, by therapy or as a diagnostic method. However, according

to the Board, the purpose of the claimed subject-matter has to be defined in accordance with the patent application, as understood in the light of the description and drawings.

According to the Board, the purpose of the main request would be to facilitate sustained venous blood flow to a blood extraction point. It would matter little whether the measure would be performed by a medical practitioner or another person having medical knowledge or under the supervision of such a person. Much more important in order to decide if the claimed method is objectionable under Article 52(4) EPC would be the purpose and inevitable effect of the feature under consideration (item 5 of the reasons). In the case under decision, the Board concluded that the purpose of the claimed method was not of a diagnostic, therapeutic or surgical nature, but merely of a technical nature, with the sole aim of improving the efficiency of taking blood from a donor. The method would be clearly distinguishable from a therapeutic or diagnostic effect (item 8 of the reasons). Therefore, the exemption from patentability was denied. Thus, in contrast to T 385/86 the emphasis in this decision was clearly on the purpose of the method.

Decision T 606/96¹⁵ refers to a multi step process for the selection of radiolabeled antibodies for *in vivo* cancer diagnosis and therapy. Claim 1 read as follows,

A method for selecting at least one monoclonal antibody component, the monoclonal antibody component comprising at least one member from the group consisting of whole monoclonal antibodies and monoclonal antibody fragments, for use in preparing

¹⁵ Decision of the Technical Board of Appeal T 606/96 ; unpublished, <http://legal.european-patent-office.org/dg3/pdf/t960606eu1.pdf>

a patient specific monoclonal antibody-based compound for use in in vivo cancer detection or therapy of a specific patient, comprising the following steps:

(a) preselecting a panel of at least two monoclonal antibody components, the monoclonal antibody components predetermined to be specific to tumour associated antigens of a cancer type to be detected or treated;

(b) obtaining a solid tumour specimen, which has been obtained from a specific patient, of the cancer type to be detected or treated;

(c) allowing the preselected panel of monoclonal antibody components to bind to tumour associated antigens present in the specific patient's solid tumour specimen;

(d) independently determining which, if any, of the monoclonal antibody components in the preselected panel bind to tumour associated antigens present in the specific patient's solid tumour specimen; and

(e) selecting at least one monoclonal antibody component, if the selected monoclonal antibody is determined in step (d) to bind to tumour-associated antigens present in the specific patient's solid tumour specimen for use in preparing a compound for use in in vivo cancer detection or therapy for the specific patient.

By citing decision T 82/93¹⁶, the Board first noticed that a multi-step process would be considered to relate to a method for treatment or diagnosis of the human body if it comprises at least one such step, thereby interpreting Article 52(4) EPC similar as in decision T 964/99. However, in the case under

decision the Board agreed with the appellant that none of steps (a) to (e) of claim 1 would be a step of treatment or diagnosis of the human body (see item 3 of the reasons).

In T 310/99¹⁷ the Board referred to the principles developed in T 964/99. The claimed method in the application to which the decision refers to was a method with which the risk for fetal Down syndrome can be determined. Claim 1 read as follows:

An in vitro screening method for determining if a pregnant woman is carrying a fetus with Down syndrome comprising: assaying a pregnant woman's blood for free human beta chorionic gonadotropin (hCG), the results of the assay being indicative of increased risk of fetal Down syndrome.

The Board referred to decision T 964/99, according to which all methods practised on the human or animal body which relate to diagnosis or would be of value for the purposes of diagnosis would be excluded from patent protection. Then, the Board denied the presence of a diagnostic method in the meaning of Article 52(4) EPC in the present case because the methods would not be practised on the body of a pregnant woman but on a sample of her blood and no sampling step was included. Further each claim would explicitly mention that it relates to an *in vitro* method. Moreover, the activities could be undoubtedly carried out by a laboratory assistant without requiring the intervention of a physician and finally it would be immaterial if a physician is involved in steps prior to or after the steps of the claimed method (see item 13-15 of the reasons).

¹⁶ Decision of the Technical Board of Appeal T 82/93; cf. OJ EPO 1996, 274 ff.

¹⁷ Decision of the Technical Board of Appeal T 310/99; unpublished, <http://legal.european-patent-office.org/dg3/pdf/t990310eu1.pdf>

5. Differences between decision T 386/86 and T 964/99

In the Referral, three main differences between decisions T 385/86 and T 964/99 have been revealed, concerning (a) the interpretation of the term “diagnostic method”, (b) the interpretation of the term “practised on the human or animal body” and (c) the necessity of the presence of a physician in a diagnostic method.

5.1. The term “diagnostic method” – all steps are required for diagnosis versus one step only required

The Board in T 385/86 has construed the term “diagnostic method” narrowly by equating the terms “diagnosis” and “diagnostic method.” Thereby, **all** steps involved in reaching a diagnosis are required in order to constitute a “diagnostic method” in the sense of Article 52(4) EPC, whereas methods comprising only a single diagnostic step for example would not be excluded from patentability. Thus, methods such as percussion or auscultation would in principle be patentable by applying the principles developed in T 385/86. In contrast, the Board of Appeal in decision T 964/99 explicitly stated that the term “diagnostic method” should not be considered to relate to methods containing all steps involved in obtaining a medical diagnosis. Instead, it would be sufficient to define a method as a diagnostic method if the claimed method would comprise **one** step (i.e. at least one step) which serves diagnostic purposes or would be related to diagnosis and would be an essential diagnostic activity pertaining to diagnosis and practised on the living body.

According to decision T 964/99 the standard set by decision T 385/86 for diagnostic methods would be different from that for surgical and therapeutic methods, the latter being already

excluded if they comprise at least one surgical or therapeutic method step (for surgical methods, see T 182/90¹⁸, item 2.5.1 of the reasons; for therapeutic methods, see T 820/92²⁰, item 5.5 of the reasons).

In the President’s opinion as expressed in the Referral it appeared to be justified to regard diagnostic methods in the same manner as surgical and therapeutic methods as all three types of methods are exempted by the same stipulation of Article 52(4) EPC. This would mean that only a single step with diagnostic character in a claimed method would render it non-patentable under Article 52(4) EPC. The basis for this wide interpretation of the term “diagnostic method” as already long applied to “surgical” and “therapeutical methods” would be that, for a given patient, the optimal or only available treatment could not be applied if even a single part or step thereof - and most treatments comprise several steps - was covered by patent protection (see item 7 of decision T 35/99)²⁰. In view of the President

“a member of the health care professions could not carry out a diagnostic method on a patient if even a single necessary method step would be protected by patents” (Referral, page 17, last sentence).

Further, the Referral considers that, depending on which approach of the two decisions further decisions will be based, methods related to diagnosis may or may not be patentable. This argument is supported by stating that the non-allowed method claims in T 964/99 would be patentable by applying the

¹⁸ Decision of the Technical Board of Appeal T 182/90, cf. OJ EPO, 1994, 641 ff.

¹⁹ Decision of the Technical Board of Appeal T 820/92, cf. OJ EPO, 1995, 113 ff.

²⁰ Decision of the Technical Board of Appeal T 35/99; cf. OJ, EPO 2000, 447 ff.

principles developed in T 385/86 since the step of attributing the measured deviation to a particular disease would be missing and further, the analysis of the samples was not performed on the body.

In case the Enlarged Board will decide that in future methods comprising at least one step related to diagnosis are excluded from patentability, the exact circumstances fulfilling this criterion have to be determined. For example, it has to be analyzed whether the value for diagnosis or the relation to diagnosis should be derivable from the patent claims themselves or if it is sufficient if the purpose and the relation could be derived implicitly or explicitly from the application in total. And further, an answer must be given as to whether or not an implicitly disclosed purpose is sufficient. For example, if a computer tomography method is claimed for the examination of food the skilled person in the art might derive that this method is also useful for tumour diagnostics; would this possibility of application already exclude the claimed method from patentability?

For the Technical Board discussing the claims in T 964/99 it was sufficient to exclude the method from patentability because the relation to diagnosis was described in the specification only and not in the claims.

5.2. Participation of a physician – mandatory versus not mandatory

According to the Board, the basis for the decision was that the NMR method of T 385/86 could be implemented by a person skilled in NMR in a commercial laboratory environment without specialist medical knowledge or skills. Further, the effect on the living matter would be of a technical nature and would not constitute an invasion of the living substance nor lead to any permanent changes in the

body matter (item 3.5.1. of the reasons). The technician would be able to produce a working basis for the doctor's subsequent activity of diagnosis. Therefore, according to T 385/86 a method involving an interaction with the human or animal body would be susceptible to industrial application, if it could be used with the desired result by a technician without specialist medical knowledge and skills (see 3.5.2 of the reasons).

The President then concludes from T 385/86 that a method could be considered as a diagnostic method if it contains at least one step which could only be carried out by a doctor (Referral p. 21, last paragraph).

According to the Referral, criteria for the required involvement of a physician might be whether the claimed method would be characterized by an invasion on the living substance or would lead to any permanent changes of the body matter. Further, the final step of making a diagnosis based on the examination phase and method steps like the setting of default values (e.g. selection of radiation dosage), auscultation, placing a catheter, taking biopsies etc. would be methods which can only be practised by a doctor.

In contrast, according to decision T 964/99, it would be immaterial for the exclusion of a method as a diagnostic method whether the claimed method could be performed only by the patient himself, a technician or by a physician; if the method contained at least one step of an essential diagnostic activity it should be excluded. According to the Referral, this decision would be in agreement with the definition of "therapeutic methods" (see for example T 116/85²¹); in particular it should not be

²¹ Decision of the Technical Board of Appeal T 116/85, OJ EPO, 1989, 13

decisive who practices the method in order to judge whether the method in question is a “diagnostic method.”

5.3. All steps versus one step “practiced on the human or animal body”

According to decision T 385/86, Article 52(4) EPC requires that both the examination phase and the establishment of symptoms must be carried out on a living human or animal body. In other words, the actual data should be directly readable from parts of the body itself and the deviation must be directly discernible on the body itself, respectively (see items 4.1 – 4.3 of the reasons). Typical examples fulfilling this prerequisites would include an allergy test, a method in which scarlet-fever spots are directly observed, or an endoscopic examination carried out to ascertain liver damage (item 4.3.1 of the reasons). In the case discussed in T 385/86 the data obtained by NMR methods would only be visible outside the body in a high-resolution resonance spectrum which appeared on a screen or plotter and also the pathological deviation was not directly discernible on the body. Further, the pathological deviation was not directly discernible on the body. According to the approach developed in decision T 385/86 the criterion “practised on the human or animal body” would also be denied for methods imaging tissues from the body via ultrasound, for electrocardiographic methods, electro- and magnetic encephalography methods and the method which was the subject-matter of decision T 964/99 (analysis of the sample in the laboratory). In all these cases the respective results of the examination would not be directly readable on the body itself.

Since in the claimed method of T 964/99 only the sampling step was performed on the body (which at the same time was

the step with diagnostic character) it is concluded in the Referral that, according to this decision, not all steps must be practiced on the body in order to exclude a method from patentability. Rather one step in a method practised on the body would be sufficient for an exclusion from patentability. In the Referral, the President notes, that this interpretation would be in accordance with the case law concerning surgical or therapeutic methods. In T 964/99 typical examples are listed which fulfil the prerequisite “practised on the body” (e.g. the taking of a sample from the living human or animal body, percussion, auscultation and palpation).

In the Referral the question arose as to how much interaction with the body is necessary in order to fulfill the requirement “practised on the body”? For example, would the application of radiation be a method “practised on the body”? Would the mere presence/appearance of a body be sufficient to regard a method as non-patentable under Article 52(4) EPC? Finally it has been asked if it would be a necessary, in order to exclude a method from patentability, that the step which is related to diagnosis and constitutes an essential activity of diagnosis is at the same time the step practised on the living human or animal body?

6. Summary and Outlook

The differences between the two cases discussed may be briefly summarized as follows: first, according to T 385/86 a method only constitutes a “diagnostic method” if it comprises all steps necessary for a medical diagnosis. In contrast, in T 964/99, one step with diagnostic character could be sufficient to regard the method as “diagnostic method”. Second, whereas in T 385/86 a physician must be involved in at least one step of the “diagnostic method”, this is not a prerequisite in T 964/99. Third,

both the examination phase and the phase in which the symptoms are established must be practiced on the body according to T 385/86. In contrast, only one step with diagnostic character practiced on the body is sufficient in T 964/99 to regard a method as a “diagnostic method.”

Importantly, until the Enlarged Board of Appeal has issued its decision in this case, all proceedings before the EPO first-instance departments where the decision depends entirely on the Enlarged Board of Appeal’s decision, will be suspended

According to established case law of the EPO, methods are excluded from patent protection if they comprise only a single step of a surgical or therapeutical nature (see for example T 775/97, T 1005/98, T 35/99, T 606/96, T 820/92). Importantly, the President states that “it appears to be justified to treat the diagnostic methods as equal with surgical and therapeutical methods”. In view of the case law in the field of therapy and the fact that some legal and socio-ethical aspects apply not only to therapeutic and surgical but also to diagnostic methods there are good chances that the Enlarged Board of Appeal will interpret the term “diagnostic method practiced on the human or animal body” according to T 964/99, thereby raising the bar for obtaining patents in the field of diagnosis.