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To the Chairman of the Enlarged
Board of Appeal
Mr. Messerli

**Ref.: Referral by the President of the EPO to the Enlarged Board of Appeal
based on two divergent decisions of the Boards of Appeal**

Related to: T 385/86, OJ EPO 1988, 308 ff. – BRUKER and others
T 964/99, OJ EPO 2002, 4 ff. – CYGNUS, INC. and others

In order to ensure a uniform application of the law and due to its fundamental importance I herewith refer the following points of law to the Enlarged Board of Appeal according to Art. 112 (1) b) EPC, pertaining to the interpretation of the term “diagnostic method practised on the human or animal body” in the meaning of Article 52(4) EPC:

- 1a) Do only those methods which comprise **all** steps necessary for establishing a medical diagnosis (i.e. the examination phase including data gathering, the comparison of the data obtained with the normal values, the establishment of a significant deviation (of a symptom) by this comparison, and finally the attribution of the deviation to a certain clinical picture (the deductive medical decision phase)) constitute “diagnostic methods practised on the human or animal body” within the meaning of Article 52(4) EPC (in the following “diagnostic methods”) or
- 1b) is a “diagnostic method” already present if the claimed method comprises **only one** method step which is of value for **diagnostic purposes** or **relates to diagnosis**?
- 2) If the question in 1b) is affirmed: Must the claimed method be exclusively applicable for diagnostic purposes or be exclusively related to diagnosis? Which criteria are needed to obtain a judgment?
- 3a) Is a “diagnostic method” already present, if
 - i. the claimed method contains at least one step which is regarded as a fundamental step of a “diagnostic method”, requiring the personal presence of a physician (alternative 1), or
 - ii. the claimed method, although not requiring the personal presence of a physician, requires that a physician assumes the responsibility (alternative 2), or

- iii. all method steps can be practised even or also by medical or technical help, by the patients themselves, or by an automated system (alternative 3)?
- 3b) If the participation of a physician (through physical presence or by assuming responsibility) is decisive, must the physician then participate in that method step which is practised **on** the body, or must the physician participate in only any of the steps regarded as a fundamental step of a diagnostic method?
- 4) Does the requirement “practised on the human or animal body” mean that the steps are carried out in direct contact with the body, or can only those steps which are directly practised on the body attribute a diagnostic character to a method, or is it sufficient if at least one of the method steps is directly practised on the body?

Overview of the reasons

I.	Introduction	3
II.	The divergent decisions of the Boards of Appeal	3
	1. The decision T 386/86 , OJ EPO 1988, 308 ff.- Non-invasive determination of measure values/BRUKER.....	3
	2. The decision T 964/99 , OJ EPO 2002, 4 ff.- CYGNUS,INC.....	8
III.	The divergence between the decisions T 386/86 and T 964/99	12
	1. The term “diagnostic method”.....	12
	a) The diagnostic purpose and the relation to diagnosis, respectively.....	14
	b) The requirement of a participation of a physician.....	16
	2. The feature “practised on the human or animal body”.....	19
IV.	Divergent decisions of two Boards of Appeal in the meaning of Article 112 (1) EPO	22
V.	Assurance of a uniform application of law and the fundamental significance of a point of law	24

Reasons for the Referral

I. Introduction

This Referral relates to the interpretation of the term “diagnostic methods practised on the human or animal body.” According to Article 52(4) EPC, sentence 1, these methods are not considered to be industrially applicable like the “methods of surgery or therapeutic treatment of the human or animal body” in the meaning of Article 52(1) and 57 EPC, even if the requirements of the latter Article are fulfilled in principle. According to Articles 52(4) EPC, sentence 2, this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

The patentability of inventions related to medical methods is regulated in part rather differently by the various patent systems. These differences can be attributed to the fact that the way in which a legislator approaches this topic is dependent on basic considerations, in which a number of legal, social, cultural, and particularly ethical factors play a role.

The provision 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 patents (**T 116/85**, OJ EPO 1989, 13, item 3.7 of the reasons; **T 386/86**, OJ EPO 1988, 308, item 3.2. of the reasons; **T 24/91**, OJ EPO 1995, 512, item 2.4. of the reasons, **T 665/92**, OJ EPO 1998, 17, item 5.3. of the reasons; **T 329/94**, OJ EPO 1998, 241, item 3 of the reasons; **T 35/99**, OJ EPO 2000, 447, item 6 of the reasons; **T 964/99**, OJ EPA 2002, 4, item 3.1 of the reasons; **T 807/98** unpublished, item 2.1 of the reasons; with regard to therapeutic treatments: **T 82/93**, OJ EPO 1996, 274, item 1.2. of the reasons). However, only non-commercial activities in the field of medical and veterinary medicine should be free from restrictions due to patent law (**G 1/93**, OJ EPO, 1985, 60, item 22 of the reasons). Therefore, the exclusion clause in Article 52(4) EPC is based on social-ethical considerations and contemplations in the context with public health (cf. **T 24/91**, item 2.4 of the reasons). Human diseases should not be commercialized such that the physician can freely decide at any time on suitable measures to eliminate a disease or to recognize a disease by examination procedures (see *Schulte*, Patentgesetz mit EPÜ, 6. Auflage 2001, § 5, Rd. 16.).

II. The divergent decisions of the Boards of Appeal

1. The decision **T 385/86**, OJ EPO 1988, 308 ff. – Non-invasive determination of measure values/BRUKER

In **T 386/86**, the Technical Board 3.4.1. analyzed the meaning and intention of Art. 52(4) based on the history of the origins of the Article and came to the conclusion that the first sentence of Art. 52(4) is intended to exclude only those methods from the possibility of

patent protection, which serve healing purposes, such that no one could be hampered in the practise of medicine by patent legislation. Like any exclusion clause, Art. 52(4), first sentence, should be narrowly construed, which would be further emphasized by sentence 2. The Board was convinced that only those diagnostic methods whose results immediately make it possible to decide on a particular course of medical treatment should be excluded from patent protection. Therefore, to answer the question whether a method is a diagnostic method in the sense of Article 52(4), first sentence, it has to be determined whether the claimed method contains **all** the steps necessary for obtaining a medical diagnosis. Methods providing only interim results are thus not diagnostic methods in the meaning of article 52(4), even if they can be utilized in making a diagnosis (item 3.2 of the reasons; emphasis added).

The Board then stated: “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** phase - 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**); ... 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” (item 3.3. of the reasons; emphasis added).

With regard to the requirement “practised on the human or animal body” and by referring to Article 52(4) which, because it is an exclusion clause has to be narrowly construed, the Board held that both the examination (measurement of actual value) and establishing the symptom on the basis of the examination results – hence the deviation measured from the norm – must be carried out on a living human or animal body (item 4.1 of the reasons). Therefore, Article 52(4) EPC would presuppose that even the measure values obtained and the deviation from a norm that must be regarded as a symptom should be directly discernible on the body itself (items 4.2 and 4.3 of the reasons).

The subject matter of the application, which was the basis for decision **T 385/86**, was a method for the non-invasive determination of chemical and/or physical conditions, namely of the temperature or of the pH value within the whole, undamaged, living animal or human body, by use of magnetic resonance (method of localized magnetic resonance). The claimed method provided a measure value, which was readable in a high-resolution resonance spectrum, appearing on a screen or a plotter paper at the final step of the diagnostic device.

Based on the principles developed, the Board did not consider this method to be a “diagnostic method” in the meaning of Article 52(4) EPC because the claimed method did not contain all steps involved in reaching a medical diagnosis. Rather, the method would be a patentable measurement process, according to the Board, because the measure values obtained by the claimed method would not provide an immediate diagnosis. The Board, however, conceded that the measure values would implicitly contain useful

information, but it was decisive for the Board that the presence or absence of a disease was not explicitly recognizable on the basis of the determined values. In the present case, it remained to be shown that the measure values differed significantly from a value regarded as normal, i.e. non-pathological, and the deviation had to be attributed to a certain clinical picture. Only if these operations of differentiations and comparison were to be incorporated into the claim would the claimed method of measuring a physical variable become a diagnostic method regardless whether these operations were performed by a doctor or by a computer (item 3.4.1 and 3.4.2 of the reasons).

Further, in the Board's view, the criterion "practised on the body" was not fulfilled. The data obtained would be only visible on a data carrier detached from the body after further technical measures which take place outside the body. Any further step which is a result of comparison with a norm reveals an abnormal deviation, would not require the patient's presence. Further, the deviation from the normal value, which must be regarded as a symptom, would not be directly discernible on the body itself. It is not sufficient, in view of the Board, that merely any investigation into the state of a human or animal body be carried out for medical purposes. The condition ascertained must of itself demonstrate the pathological deviation. A measure value would be an absolute value which only would reveal any irregularity when compared with a norm. It would be only the comparison and the explicit indication of how great the deviation must be to be characteristic of a particular disease or group of diseases that make the measuring method a diagnostic one (items 4.2 and 4.3 of the reasons).

The elaborations on the term "diagnostic method" were in accordance with the earlier decisions issued to that point by the Technical Board 3.2.1.. In **T 61/93**, **T 208/83**, **T 18/84** and **T 45/84** (all unpublished), the Board already required that a "diagnostic method" in the meaning of Article 52(4) should contain not only the examination phase, constituting the basis for the diagnosis, but also an indication of the diagnosis, representing the result. In **T 45/84**, in particular, the Board held "that a diagnostic method would only be present if it leads to a concrete result of a diagnosis and that further ... neither the result of the diagnosis as such nor the method of examination, being the basis for the result, should be equated with the diagnostic method. Thus, a method should be regarded as a "diagnostic method" only in those cases in which both requirements are fulfilled." (item 2 of the reasons).

A number of decisions confirmed the interpretation of the term "diagnostic method" in the sense of Article 52(4), outlined in **T 385/86**, referring to a method containing **all** steps necessary for reaching a medical diagnosis.

Decision **T 83/87** of the Technical Board 3.4.1 (unpublished) referred to a method for the detection of glucose in the presence of interfering foreign substances by a sensor. The Board concluded that although the data points obtained by use of the implanted glucose sensor could be used within the scope of reaching a diagnosis, they would not immediately provide a diagnosis in the sense of recognition of a pathological condition.

The claimed method would only provide interim results and therefore would not be regarded as a diagnostic method (item 3.2 of the reasons).

In decision **T 400/87** (unpublished) the Technical Board 3.4.1 concluded, by referring to decision **T 385/86**, that a nuclear magnetic resonance method (NMR) practised on the human body would not fall under the exclusion of patentability in the sense of Article 52(4) EPC. The method would comprise, according to the Board, only the examination and data gathering phase of a diagnosis. Methods which would provide only interim results would not constitute diagnostic methods in the meaning of article 52(4) EPC, even if they could be utilized in making a diagnosis. Further, a possible deviation from the norm would be discernable from these diagrams but not from the human or animal body itself" (item 3.1 and 3.3 of the reasons).

In the application, on which decision **T 775/92** (unpublished) of the Board 3.5.1 was based, a method was claimed, comprising several steps for determining bone density for evaluation of an X-ray photograph of a bone. The Board held that the term "evaluation of an X-ray photograph" appeared so vague and generally formulated that it could also include a diagnostic application. This expression could be interpreted in such a way that the said final data distributions of the bone densities, obtained with the claimed method, would be evaluated, for example, by a doctor, who would compare these distributions with model distributions in order to find out the status of a client with regard to aging of bone diseases. Such an evaluation would not only provide interim results but would also localize a deviation from a particular clinical picture and thereupon allow the doctor to start a medical treatment. The Board concluded that the method claimed must be regarded as a diagnostic method which would fall under the exclusion from patentability according to Article 52(4) EPC (item 10 of the reasons).

The subject-matter of decision **T 530/93** (unpublished) was related to a method for the generation of images of a human heart by use of an NMR imaging system. In this decision, the Technical Board 3.4.2 explicitly referred to the established case law, according to which methods which only contain the data gathering phase of a diagnosis and would only provide interim results requiring a further step in order to attribute the data to a particular clinical picture would not be regarded as diagnostic methods in the meaning of Article 52(4) EPC (item 4 of the reasons).

Further, in decision **T 1165/97** (unpublished), in which a method for the use of a vaginal discharge collector was under consideration, the Technical Board 3.2.6 denied the presence of a diagnostic method in the sense of Article 52(4) EPC. Only those methods would be excluded from patentability, the results of which would enable a direct decision on a particular course of medical treatment. Therefore, the claimed method should contain all steps involved in reaching a medical diagnosis. The latter was not the case in the method evaluated because data had not even been gathered (item 4.3. of the reasons).

The claims on which decision **T 629/98** (unpublished) of the Technical Board 3.3.4 were based, were formulated in the “second medical use” format and referred to a preparation for administration to a patient. Therefore, the Board evaluated whether the preparation could be used in a method excluded from patentability according to Article 52(4) EPC. The Board confirmed the presence of a diagnostic method based on the criteria developed in **T 385/86** because the method would allow to determine the presence or absence of lung malignancies in a patient to whom the substance was administered. Therefore, the claimed method would constitute a diagnostic method practised on the human body which would provide an immediate clinical picture (item 3 of the reasons).

The Technical Board 3.3.4 followed the principles of decision **T 385/86** also in its decision **1038/00** (unpublished). The method of the case under decision was carried out on a sample such that the Board concluded that the claimed method is not practised “on the human or animal body” (item 6 of the reasons).

The criteria developed in **T 385/86** also provided the basis for decision **T 807/98** (unpublished) of the Technical Board 3.2.2. In the application, which found basis of the decision, a method was claimed “for the detection of a sequence of unusual events due to functional disorder among a number of normal events in an electrophysiological signal, ... of an organ affected by a functional disorder”. The method was characterized by data gathering and comparison steps. Among others, the data points should be compared with a defined threshold value and set point. In the reasons, the Technical Board analyzed whether the claimed method would constitute a “diagnostic method”, based on decision **T 385/86**. The Board elaborated that in this decision the presence of a diagnostic method was denied because the obtained data points have not been compared with normal values and no significant deviation has been determined. In contrast, in the present case such a comparison is made and a pathological deviation could have been determined by a corresponding output signal. In **T 385/86**, merely quantitative values would be determined, whereas in the case to be evaluated the quantitative values were transformed to a corresponding signal providing the qualitative information, whether a disease, e.g. an arrhythmia, does exist or does not exist. An output signal is provided as soon as a disease is recognized; if there is no pathological condition, no output signal is generated. From the absence of the signal one could directly conclude with certainty, that the presence of a disease condition is excluded. The Board regarded the negative statement, that a certain disease is excluded, explicitly as a diagnosis (point 2.2. of the reasons). Further, the Board concluded that the assumption of a diagnostic method would be in accordance with **T 964/99** because the method is practised on the human or animal body referring to diagnosis. Moreover, the determination of a threshold value and a set point would be fundamental steps with a diagnostic character for the recognition of an arrhythmia, and should be regarded as basic diagnostic activities because the doctor would finally assume the responsibility for these steps (item 2.3. of the reasons).

The narrow construction of the term “diagnostic method” in the meaning of Article 52(4) EPC, as developed in **T 385/86**, was not only confirmed in the case law but also used in

the practise of the Office. The Guidelines for Examination in the European Patent Office therefore request (C-IV, 4.3, status of October 2001):

“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), 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 included X-ray investigation, NMR (nuclear resonance) studies, and blood pressure measurements (T 385/86, OJ 8/1988, 308).”

2. Decision T 964/99, OJ EPO 2002, 4 ff. –CYGNUS, INC.

The decision **T 964/99** of the Technical Board 3.4.1 is not in accordance with the principles set out in decision **T 385/86** and the further decisions based thereon. A non-invasive method of sampling a substance from the living human or animal body for analysis of the concentration of the substance was claimed in the application, constituting the subject-matter of this decision. In particular, the following steps were comprised:

- 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 iontophoretically through the surface tissue into the sampling chamber,
 - c) analyzing the sampling chamber for the concentration of the substance or a substance metabolite,
- and a step for reversal of the reaction.

In an auxiliary request directed to sampling of glucose or a glucose metabolites, the step of “analysis of the sampling chamber for the concentration of the substance or a substance metabolite” was not contained.

In the reasons, the Board first dealt with the decision **T 385/86**. In this context, it held “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 practioner would not constitute an exception to patentability” (item 3.5 of the reasons). Further, the Board asked to keep in mind that 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” (item 3.6. of the reasons).

Based on a semantic analysis of the meaning of the terms “diagnosis” and “diagnostic” and the respective corresponding expressions in the other two official languages, the

Board concluded “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**” (item 4.4 of the reasons).

The Board noted that all of the claimed methods in the application under decision comprised, as method step, the sampling of a substance from a living human or animal body. The specific embodiments disclosed in the description would concern activities exercised in the course of a medical treatment of patients and would serve particularly **diagnostic purposes** (item 5.1 of the reasons, emphasis added).

In the Board’s view, 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 used, be it a spatula, a syringe, or an iontophoretic current. For these reasons the claimed step of sampling a substance would relate to diagnosis and would constitute in this context an **essential diagnostic measure practised on the living human or animal body**. Consequently, the subject-matter of the claims relating to the method had to be considered as a diagnostic method within the meaning of Article 52(4) EPC (item 5.2 of the reasons, emphasis in part added).

In order to arrive at this judgment, the Board stated that it would be immaterial that the claimed methods could be carried out by a patient himself and that their execution would not have a significant impact on the body nor involve a serious health risk. What would be decisive is the fact that all method claims on file comprise, as method step, the removal of a sample out of the body for the **purpose of diagnosis** and that such a step would be regarded as an **essential activity pertaining to diagnosis and practised on the body** (item 6.1 of the reasons, emphasis added).

The Board denied the presence of a method which could be attributed to a basic medical activity exercised on the human or animal body by referring to an NMR technique as an example, which, although performed on the living human or animal body, would only define steps concerning the technical operation of exciting and detecting resonance signals. The steps would only concern the internal operation of a technical device. Therefore, they would fall, without exception, within the competence and under the exclusive control of a technician skilled in the NMR technology, such that the method would 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.” The method claims could be interpreted such that they would only comprise steps concerning the control and internal operation of a technical device, in the specific case a tomograph NMR machine, so that no specific step of diagnostic character would be recognizable (item 6.2 of the reasons).

However, in the application under decision, the crucial step with **diagnostic character** would be the extraction of a body substance for **diagnostic purposes**, which would have to be considered as constituting an **elementary diagnostic activity** performed

under the **ultimate responsibility of a physician** (item 6.2 at the end; emphasis added).

A number of decisions, based on **T 385/86**, preceded the decision **T 964/99**, some of which were already mentioned under I. However, among these earlier decisions a few appear to follow the principles developed, but in retrospect, with the background of decision **T 385/86**, reveal first hints for a deviation in the interpretation of the term “diagnostic method.”

In the decision **T 655/92** (OJ EPO 1988, 17) the Technical Board 3.3.2 analyzed whether an NMR imaging technique, carried out on the living body (in vivo) and involving the parenteral administration of contrast agents, would fall under the exclusion of Article 52(4) EPC. According to the Board, the claimed method constitutes an invasive method. Additionally, the intravenous injection of the substance administered would not be devoid of side-effects, some would be severe. The technique of intravenous injection would first involve the injection of a few drops to determine whether undesired side-effects appear. This task could only be within the responsibility of medical staff who had to recognize the earliest symptoms of the undesired side-effect and if necessary had to initiate the respective treatments. Therefore, the diagnostic process, when considered in total, would comprise at least one step essential for the desired diagnostic result that cannot fall under the exclusive responsibility of a technician. Although it would be legitimate for a process whose steps as a whole would be non-medical but technical to not derive the diagnostic character from its final diagnostic purpose, this would 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 (item 5.3. of the reasons). The fact that the specialist administering the contrast agent and the specialist which makes the final diagnosis could be different people shows that a diagnostic character in the meaning of Article 52(4) EPC could be recognized because of the diagnostic character of at least some steps of the method, independent of the final diagnostic activity, which in fact would not be a part of the claimed method (item 5.3. of the reasons).

A blood extraction assistance method facilitating sustained venous blood flow through a human limb towards a venous blood extraction point was claimed in the application which was the basis of the subject-matter in decision **T 329/94** of the Technical Board 3.2.2. The Board stated in this context that patent protection should be refused for a blood extraction method *per se*, since otherwise a large part of medical activities would be hampered. “As a matter of fact the withdrawal of blood would fall under the exclusion of Article 52(4) EPC three times if it could be regarded either as

- a step of a method for treatment by therapy, such as in connection with a dialysis method or with a retransfusion of blood after cleaning, or
- as a step of a method for surgical treatment when considering that taking blood requires the use of surgical instruments and the operation is performed on the structure of the organism..., or

- as a step of a diagnostic method, such as with a view to blood analysis for finding out the cause of a disease” (item 4 of the reasons).

It was the Board’s opinion that when determining whether the claimed features under consideration constitute medical or diagnostic activities, the purpose of the claimed subject-matter had to be defined in accordance with the patent application, as understood in light of the description and drawings. In this respect it would matter little whether the measure is performed by a medical practitioner or another person having medical knowledge under the supervision of such a person. This sole criterion would not be sufficient to decide whether the method step would be objectionable under Article 52(4) EPC, though the medical competence of the practitioner might be, at first sight, a useful indication. Much more important would be the purpose and inevitable effect of the feature under consideration (item 5 of the reasons). In the case under decision, the Board’s opinion was that the claimed method would be of a mere technical nature, with the sole aim of improving the efficiency of taking blood from a donor. This method would be clearly distinguishable from a therapeutic or diagnostic effect (see item 8 of the reasons). Therefore, the exclusion from patentability was denied.

In decision **T 609/96** (unpublished) of the Technical Board 3.3.4 the subject-matter was a method comprising several steps for the selection of at least one antibody component for the preparation of a patient specific monoclonal antibody-based compound for use in *in vivo* cancer detection or therapy. In the Board’s view a multi-step process is considered to relate to a method for treatment or diagnosis if it comprises at least one such step which relates to it. In the case under decision the Board agreed that none of the steps was a step of treatment or diagnosis of the human body (see item 3 of the reasons).

In decision **T 310/99** (unpublished), issued after decision **964/99**, the Technical Board 3.3.8 also applied the principles developed in **T 964/99**. Therein, a method was claimed which should indicate the risk of fetal down syndrome. Since the claimed methods have not to be practised on the body but on a blood sample and since the claims did not contain a sampling step, the Board denied the presence of a “diagnostic method” (see item 13 of the reasons). Further, the Board stated that the method undoubtedly could be carried out by a laboratory assistant without requiring the actual intervention of a physician (see item 14 of the reasons). It was immaterial for the Board whether the activities of the physician take place before or after the claimed steps (see item 15 of the reasons). Furthermore, the Board considered decision **T 385/86** to be non-applicable to the case under decision because different facts were the basis for **T 385/86** (“Decision **T 385/86**... relates to a different framework, the claims examined relating to a medical diagnosis in which not a sample of a body fluid but a whole, intact, living animal or human body is examined (using magnetic resonance). Consequently, decision **T 385/86**... is not applicable to the present case.”; see item 16 of the reasons).

III. The divergence between the guidelines for the interpretation of the term “diagnostic method” developed in decisions T 385/86 and T 964/99

The basis for both decisions of the Technical Board was that the exclusion from patent protection of the methods listed in Article 52(4) EPC resulted from the fundamental consideration that those who apply these methods in the practise of medicine on humans or animals should not be hampered by patents (see **T 385/86**, item 3.2 of the reasons; **T 964/99**, item 3.1 of the reasons). While pursuing the same goals of law, however, the term “diagnostic method practised on the human or animal body” in the sense of Article 52(4) was construed in different breath.

1. The term „diagnostic method“

In decision **T 385/86**, the term “diagnostic method” was very narrowly construed by the Technical Board. Only those diagnostic methods should be excluded from patentability whose results immediately make it possible to decide on a particular course of medical treatment. This would only be the case if the claimed method would contain **all** the steps involved in reaching a medical diagnosis. These are the steps of examination, determination of a significant deviation from the normal value and the attribution of the deviation to a particular clinical picture. Therefore, methods providing only interim results would not be diagnostic methods, even if the data can be utilized in making a diagnosis (see **T 385/86**, item 3.2 of the reasons; cf. also **T 83/87**, item 3.2 of the reasons; **T 400/87**, item 3.1 of the reasons; **T 775/92**, item 10 of the reasons; **T 530/93**, item 4 of the reasons; **T 1165/97**, item 4.3 of the reasons). If the result of the measures claimed would be a quantitative expression of an isolated physical variable, then it would be decisive if the measurement itself allowed the immediate recognition of the disease and therefore immediately provided the diagnosis (see item 3.4 of the reasons; cf. also **T 629/98**, item 3 of the reasons). Additionally, in **T 807/98** it was stated more precisely that not only the specific positive determination of a disease, but also the negative statement, that a certain disease can be ruled out would be considered a diagnosis (item 2.2. of the reasons).

By applying this narrow interpretation, it follows that methods which only comprise a single step necessary for a medical diagnosis are not excluded from patentability under Article 52(4). This applies even if this single step claimed is an essential part of the diagnosis.

In decision **T 964/99**, the Technical Board explicitly stated that by using the guideline set out in **T 385/86**, methods would be excluded from patentability which would provide a more or less complete diagnosis as the result of a fully automated operation of technical devices. On the other hand, it had to be concluded that 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 and would certainly not fall within the further medical categories of surgery and therapy referred to in Article 52(4) EPC. It would go against the spirit of Article 52(4) 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 (see **T 964/99**, item 3.5 of the reasons).

The literature on patent law also considers the interpretation of law in **T 385/96** as resulting in a practical dissolution of the legislative exclusion of diagnostic methods (see Moufang, *Medizinische Verfahren im Patentrecht*, GRUR Int. 1992, 10 ff., 23; *Methods of Medical Treatment Under Patent Law*, IIC 1993, 18 ff.; 46 f.).

Deviating from the interpretation of the terms in **T 385/86**, the Board in **T 964/99** explicitly stated that the term “diagnostic method practised on the human body” and the corresponding expressions in the two other official languages, respectively, should **not** be considered as to relate to methods containing **all** the steps involved in reaching a medical diagnosis (see guiding principle 1 and item 4.1 of the reasons: emphasis added). In particular, the French text of the Article 52(4) would not favor an interpretation limiting the exception to patentability to methods encompassing all steps required for reaching a medical diagnosis (item 4.2 of the reasons).

Instead, in the Board’s view, 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). Accordingly, it would be sufficient for approving the exclusion from patentability under Article 52(4) if the claimed method would comprise only **one** step which **serves diagnostic purposes** or is **related to diagnosis** and could be considered as an activity practised on the human or animal body (see item 5.1, 5.2 and 6.1 of the reasons; emphasis in part added).

With regard to the request in **T 385/86** that for the presence of a diagnostic method all steps of a medical diagnosis must be contained, the Board in **T 964/99** explicitly stated that a different standard would be set for diagnostic methods than for methods of surgery or therapy (see item 3.6 of the reasons). The latter are excluded from patent protection if they comprise only **a single** step of a surgical or therapeutic nature (for surgical methods, see **T 775/97**, item 2.5 of the reasons; **T 1005/98**, unpublished, item 2.4 of the reasons; **T 35/99**, item 8 of the reasons; **T 182/90**, OJ EPO 1994, 641, item, 2.5.1 of the reasons; for therapeutic methods, see **T 606/96**, item 3 of the reasons; **T 820/92**, OJ EPO 1995, 113, item 5.5 of the reasons; **T 82/93**, item 1.4 of the reasons). Accordingly, a single surgical step in a multi-step method for treatment of the human or animal body would confer a surgical character on that method (see **T 182/90**, item 2.5.1 of the reasons). The basis for the broad interpretation of surgical and therapeutical methods is based on the consideration that the optimal or only available treatment could not be administered even if a single part or step thereof would be covered by patent protection (see **T 35/99**, item 7 of the reasons).

Therefore, it appears to be justified to apply the same standards for diagnostic methods as for surgical and therapeutic methods. A member of the health care professions could

not practise also the diagnostic method on a patient if only a single necessary step is protected by patents.

Altogether, it can be stated that the term “diagnostic method” is much more narrowly construed in decision **T 385/86** than in decision **T 964/99**. Therefore, depending on which of the two approaches further decisions are based, the judgement of patentability for certain claimed methods would lead to different results. If, for example, the guidelines developed in **T 385/86** would be applied to the claimed method in **T 964/99**, it probably would not be considered a “diagnostic method” in the sense of Article 52(4) EPC and at least this provision would not contravene the issuance of a European patent. The step of attributing the measured deviation to a particular disease would be missing in the claimed method of the main request comprising only the sampling step and the analysis of the substance. Additionally, the examination phase would be missing in the claimed method of the auxiliary request, referring only to the sampling of a substance or a metabolite. Based on the data obtained it would not be immediately possible “to decide on a particular course of a medical treatment” (**T 385/86**, item 3.2 of the reasons). Moreover, the claimed method in **T 964/99** would also probably not be regarded as a diagnostic method according to the criteria developed in decision **T 385/86** because the analysis of the extracted body fluid was carried out outside the body, i.e. not **on** the human or animal body (see also item III.2, below).

a) The diagnostic purpose and the relation to diagnosis, respectively

According to decision **T 385/86**, it would be decisive for the qualification as a diagnostic method that the result of the claimed method allows an immediate decision on the medical treatment. This would only be the case if the claimed method would comprise all steps involved in reaching a medical diagnosis. If the claimed method provides only interim results, and if therefore no differentiation and comparison steps are included in order to detect a pathological deviation, the claimed method would not constitute a diagnostic method in the meaning of Article 52(4). The Board explicitly states that this interpretation also applies if the interim results obtained can be utilized for diagnosis (same in **T 61/83**, **T 208/83**, **T 18/84**, **T 45/84**, **T 83/87**, **T 400/87**, **T 775/92**, **T 530/93**, **T 1165/97**).

Therefore, the Board equated the term “diagnostic method” with “diagnosis” because the recognition, distinction, and determination of a pathological condition as well as the attribution of the deviation to a particular clinical scenario must be necessary components of such a method.

In conclusion, by this narrow interpretation, it would be possible that a diagnostic method, not accessible for patent protection under Article 52(4) EPC, could be transformed to a patentable measurement process under certain circumstances, especially if the step of comparison is omitted. The question whether the measurement process serves a diagnostic purpose appears to be irrelevant according to this approach.

In contrast, according to **T 964/99**, methods could fall under Article 52(4) if they only contain **one** step which is of **value for diagnosis** or which is **related to diagnosis** and which is considered to constitute an essential activity of diagnosis carried out on the living human or animal body (compare also to **T 696/96**, item 3 of the reasons).

Decision **T 964/99** did not explicitly discuss if the value for diagnosis or the relation to diagnosis of the claimed method in question should be derivable from the patent claims themselves or if it is sufficient if the purpose and the relation can be derived implicitly or explicitly from the application in total. If the second alternative is affirmed, then the next question arises if a “diagnostic method” would also be present if the application documents implicitly or explicitly disclose a non-diagnostic purpose, in addition to the diagnostic purpose, in other words, if the method would not be **exclusively** applicable to a diagnostic purpose but would also be industrially applicable. The following constellations could occur:

The patent claim itself could be restricted to the definition of the method steps, without defining the purpose of the examination in detail. In the description, diagnostic as well as non-diagnostic applications might be explicitly disclosed. It is also conceivable that either diagnostic or non-diagnostic applications are discussed and that the respective other use would immediately come to the mind of the skilled man while reading the application, such that a broad scope of the claim would be supported by the description.

The patent claim could, for example, be directed to the optical computer tomography method for examination of tissue structures with an uneven geometry of the surface and in the description, the diagnosis of tumors in humans as well as the examination of food from a distance could be mentioned explicitly as a possible use of the method. Another example would be a method for the determination of the penetrability of tubes, which, according to the description, could be used for the examination of the transport ways (vascular bundles) in plants but which also, according to the knowledge of a skilled man, could be useful for diagnostic purposes, such as the examination of blood vessel penetrability in the human body for the purpose of diagnosis of a heart attack. It is also imaginable that the step decisive for recognizing a diagnostic method is not contained in the claim itself but necessarily precedes the method. Insofar as such a step could be the administration of a substance, like a contrast agent bearing health risks, a possible claim could read as: “Method for imaging the stomach, in which a contrast agent has been administered...”

In the application, which was the basis of decision **T 964/99** and in which a method was claimed for sampling a substance out of the body and for determining the concentration of this substance, there was no direct reference to the diagnostic purpose in the claims. Therefore, for an exclusion from patentability according to Article 52(4), it appears to be not necessary that the purpose of diagnosis can be directly derived from the patent claims. On the other hand, according to the Board, all concrete embodiments in the description would concern activities exercised in the course of a medical treatment of a patient and in particular would serve for diagnostic purposes (see item 5.1 of the

reasons). In the case under decision, the relation to diagnosis could at least be derived from the disclosure of the application as the whole.

Further, there is a need for clarification of how a situation should be judged when there is no explicit relation to diagnosis in the totality of the application documents, and whether, in view of the skilled man, the claimed method would also be applicable to the field of diagnostics. The decision **T 329/94** appears to suggest the requirement of an explicit reference. In order to determine whether the features under consideration constitute a diagnostic method, the **purpose of the claimed subject-matter** should be defined **in accordance** with the description and drawings (item 5 of the reasons, emphasis added). Consequently, a method which also serves diagnostic purposes but is not explicitly disclosed in the application and could only be derived implicitly by the skilled man, would not constitute a “diagnostic method” in the meaning of Article 52(4).

b) The requirement of a participation of a physician

By applying the guidelines, developed by its own, the Technical Board in decision **T 385/86** concluded that the claimed method would not be a diagnostic method excluded from patentability according to Article 52(4) because it did not comprise **all steps** involved in reaching a medical diagnosis. Nevertheless, the Board further asked, “based on the assumption that the first sentence of Article 52(4) EPC is intended to prevent a doctor from being hampered in the practise of medicine by patent legislation”, if the claimed method which did not comprise all the steps necessary for making a medical diagnosis still would not be considered as susceptible to industrial application because it “only can be carried out by a doctor in the exercise of his healing skills” (item 3.5 of the reasons).

Based on four arguments the Board concluded in the case under decision that a **person skilled** in nuclear spin resonance spectroscopy could implement the measures claimed in a commercial laboratory environment without **specialist medical knowledge or skills**. The effect on living matter is of technical nature, so the impact of these technical measures does not constitute invasion of the living substance nor lead to any permanent changes in the body matter (see item 3.5.1 of the reasons, emphasis added). The claimed methods would **not include measures having the character of medical treatment or requiring a doctor to carry them out**. In fact, the technician using the method claimed would be able, quite independently, to produce a working basis for the doctor’s subsequent activity of diagnosis. Since the examination phase does not require the presence of a doctor who, moreover, has at his disposal a piece of equipment detached from the living body, the measures claimed are susceptible to industrial application, just like laboratory tests carried out on blood or tissue samples taken from the body. A method involving **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 item 3.5.2 of the reasons, emphasis added: cf. **T 400/87**, item 3.2 of the reasons).

Therefore, it can be concluded from **T 385/86** that a method can constitute a diagnostic method if it contains at least **one** step which could be carried out **exclusively by a doctor**. Criteria for this requirement would be whether the method claimed is characterized by an invasion in the living substance or leads to any permanent changes of the body matter. Claimed method steps which, at least nowadays, can only be practised by a doctor are for example the evaluation whether a specific diagnostic method is suitable for a patient and the selection of the diagnostic method. Moreover, methods not fully automated fall under these criteria, like placing a catheter, taking biopsies, palpation (insofar that it is not automated) or examinations wherein the doctor, due to his or her education and experience, already obtains results relevant for diagnosis during the examination phase (e.g. auscultation). Finally, making a diagnosis based on the examination results is a step which is carried out exclusively by a physician, insofar that no automation had taken place (for example if the absence of a certain technical signal excluded the presence of a specific disease, see for example **T 807/98**).

According to decision **T 385/86**, it appears that the presence of a diagnostic method, in those cases in which not **all** steps necessary for reaching a diagnosis are claimed, must also be denied if all steps could be practised by a **technically skilled man of the art** without specialist medical knowledge and skills or by the patient himself. Thus, according to this decision, the mere **possibility** that a technician uses the method would prevent the intervention of the exclusion according to Article 52(4) EPC. Therefore, the Board would follow the narrow construction of Article 52(4) EPC as it is emphasized at various places in the decision (see item 3.2 and 4.1 of the reasons).

According to decision **T 964/99**, Article 52(4) should be applied if the claimed method comprises one step which is carried out because of its diagnostic value and which is regarded an essential activity of diagnosis practised on the living human or animal body. In order to arrive at this judgment, it would be immaterial for the Board that the claimed methods could be performed by a patient himself and that the execution would not have a significant impact on the body nor involve a serious health risk (see item 6.1 of the reasons). This means, according to **T 964/99**, that even those methods which are used by a person without medical knowledge and skills should also be regarded as “diagnostic methods” in the meaning of Article 52(4). In **T 385/86**, in contrast, the consideration that all steps are practised by other persons than physicians prevented that the method claimed was regarded as a diagnostic method excluded from patentability (see item 3.5.2 of the reasons).

If not all steps necessary for diagnosis are claimed in a method and therefore constitutes a diagnostic method, it follows from **T 385/86** that only those methods in which at least one step must be carried out by a physician are excluded from patent protection. According to **T 385/86**, in order to regard the claimed method as a “diagnostic method,” it appears to be of essential significance that the physician is personally involved in using the method. On the other hand, a method carried out by the patient himself would not prevent the method from being regarded as a “diagnostic method,” according to **T 954/99**.

It would be in agreement with the definition of “therapeutic methods” in the meaning of Article 52(4) EPC that it should not be decisive which person the method practises in order to judge about the presence of a “diagnostic method”. The exclusion clause might also be applied if the method cannot only be practised by the physician but also by the technical staff who are not specialists in medical skills (see **T 116/85**, OJ EPO 1989, 13 item 4.3 of the reasons; for surgical therapies, see also **T 182/90**, item 2.2 of the reasons, **T 24/91**, OJ EPO 1995, 512, item 2.4 of the reasons).

Therefore, in the first place, it is not important who is practising the method, according to **T 964/99**. It appears to be more significant that one of the steps is practised for the purpose of diagnosis and is regarded as an essential activity of diagnosis. In this context, the Board asked for the presence of a **specific step with diagnostic character** (see item 6.2 of the reasons, emphasis added). In the Board’s view, the crucial step of diagnostic character would be the extraction of a body substance for diagnostic purposes, which would be considered as constituting an **elementary diagnostic activity** performed under the **ultimate responsibility of a physician** (see item 6.2 of the reasons, emphasis added). Previously, the Board defined that 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 used (see item 5.2 of the reasons). This approach was confirmed in **T 807/98**. There, it has been considered as decisive that the claimed method contains fundamental steps of diagnostic character which are regarded as elementary diagnostic activity since the physician takes the ultimate responsibility for them (see item 2.3 of the reasons).

Thus, while in **T 385/86** it was further analyzed if at least one step is contained which had to be practised by the doctor himself, the approach in **T 964/99** differs insofar as the character of the activity should be decisive. The personal presence of the doctor practising the method should not be a necessary requirement. It appears to be at least sufficient if there is one step for which the doctor takes the responsibility. Already in decision **T 655/92**, the Board came off of the necessity of a personal collaboration of the doctor. It was decisive for the Board that the method should contain one step which only can be carried out **by medical staff or under the responsibility of a physician** (see item 5.3 of the reasons).

In this context, the question arises in which situations can such a responsibility of a physician be assumed. Indications might be health risks for patients attributed to the use of the method (see **T 655/92**, item 5.3 of the reasons, compare a similar approach applied to the surgical methods, **T 24/91**, item 2.4 of the reasons). By the use of a technical device on humans one has to think about the setting of the default values, for example the intensity of the radiation doses or the selection of the body part on which the method is applied. In **T 807/98**, for example, the determination of the threshold value and the set point, with which a functional disorder of the heart could be identified, has been regarded as a step which only can be practised after receiving instructions by a physician (see item 2.1 of the reasons).

Decision **T 964/99** might possibly be understood in such a way that a method would also constitute a “diagnostic method” according to Article 52(4) EPC if a physician does not necessarily take the responsibility for one of the steps. The Board stated that the methods claimed could also be practised by the patient himself and that their execution would not have a significant impact on the body nor involve a serious health risk (see item 6.1 of the reasons). In the methods claimed in **T 964/99**, one of the embodiments, mentioned in the description, was related to the determination of glucose in the blood, which, accordingly, could be practised by self-controlling diabetes patients.

Applying this wide construction, it appears to be a decisive criterion whether a specific method step with a **diagnostic character** is contained. Such a diagnostic character usually appears to be present if a physician practises this method step personally or if he assumes the responsibility for that step. Even if neither of these two alternatives were present a step of diagnostic character might still be acknowledged.

It is uncertain whether such interpretation is allowed with regard to decision **T 310/99**. In this decision it was not only analyzed who was involved in practicing the method. Since the claimed methods undoubtedly could be carried out by a laboratory assistant without the participation of a doctor (“actual intervention of a physician”), the presence of a diagnostic method was denied (see item 14 of the reasons). It was not evaluated if a step of diagnostic character was nevertheless present.

Further, it needs to be clarified whether the participation of persons in a method is decisive for judging a diagnostic method, or if it only indicates that the claimed method, if practised by a physician or must be carried out under the responsibility of a physician, normally falls under the exclusion of Article 52(4) EPC (for surgical therapies, see **T 24/91**, item 2.4 of the reasons).

2. The feature “practised on the human or animal body”

In **T 385/96**, following the narrow construction of Article 52(4) EPC, the feature that the “diagnostic method must be practised on the human or animal body” was interpreted in such a way that all steps characterizing a diagnostic method must be practised on the human or animal body themselves. This led to the requirement, according to the Board, “that where the facts show a particular subject-matter to be covered by the first sentence of Article 52(4) EPC both examination (measurement of actual value) and the establishment of the symptoms on the basis of the examination results (hence the deviation measured from the norm) must be carried out on a living human or animal body” (item 4.1 of the reasons). Accordingly, the actual values obtained and deviations from the norm regarded as symptoms must be **directly readable from parts of the body itself** and must be **directly discernible on the body itself**, respectively (see item 4.2 and 4.3 of the reasons; emphasis added; cf. **T 400/87**, item 3.3 of the reasons; **T 1038/00**, item 6 of the reasons).

As examples for such methods practised directly on the body, the Board listed in decision **T 385/86**, among others, an allergy test in which the abnormal deviation can be detected from a change to the skin; a method for determining the patency of a body duct whereby liquid is injected into the uterus with a catheter and the pressure build-up in the uterus is observed; a method in which scarlet-fever spots are directly observed or photographed; or an endoscopic examination carried out to ascertain liver damage (see item 4.3.1 of the reasons).

The method under decision, in contrast, resulted in measure values only visible outside the body in the high-resolution resonance spectrum that appears on a screen or plotter page in the final stage of the diagnostic apparatus. The data thus obtained would therefore be visible on a data carrier detached from the body only after further technical measures which take place outside the body. Accordingly, the presence of the body was not required in these further steps. Therefore, the Board considered the criterion “practised on the body” as not fulfilled in this case (item 4.2 of the reasons).

Further, in the opinion of the Board, this criterion was not fulfilled in the case under decision also because the pathological deviation was not directly discernible on the body. According to the Board, it would not be sufficient that merely any investigation into the state of a human or animal body would be carried out for medical purposes. The condition ascertained must of itself demonstrate the pathological deviation. It would only be the comparison and the explicit indication of how great the deviation must be to be characteristic of a particular disease that make the method a diagnostic one. Thus a radiographic examination with X-rays does not make the internal condition discernible on the body itself but only on a screen after the X-ray quanta have been converted into visible fluorescent light outside the body. Even then, a pathological condition could only be ascertained after the density structure has been compared with normal values (item 4.3.2 of the reasons).

According to the approach developed in **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 using a corresponding device, as well as for electrocardiography methods and electro- and magnetic encephalography methods. The respective results of the examination would not be directly readable on the body itself in these cases.

For fulfilling the criterion “practised on the ... body,” it is decisive, according to **T 385/86**, that the recording of the measure values and the establishment of a pathological deviation are both practised on the living human or animal body itself. All the steps defining a “diagnostic method” must therefore be practised directly on the body itself. Conversely, this means that if only one step of the diagnostic steps is practised outside the body, the criterion “practised on the ... body” will not be fulfilled. In such a case the exclusion of Article 52(4) EPC would not apply.

It appears that the result of an interaction of the body with a diagnostic examination means must be directly discernible on the body, according to decision **T 385/86**. The

intensity and quality of this interaction does not appear to be decisive for the Board in this decision, with regard to the feature “practised on the ... body.”

If the principles developed in **T 385/86** were to be applied to the method which was the subject-matter of decision **T 964/99**, the criterion “practised on the human or animal body” would not be fulfilled. In this decision, a substance was extracted iontophoretically through the skin surface of a human or animal body into a sampling chamber and the concentration of the substance was determined outside the body in the sampling chamber.

In **T 964/99**, however, the Board stated that the medical art would know 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 biochemical tools. Diagnostic methods could be classified in two categories: those which are practised **on the living body** and those whose performance takes place **outside the body**. Only “methods practised on the human or animal body” would be excluded from patentability according to Article 52(4) EPC, whereas for instance extra-corporal laboratory tests would be patentable (item 4.3 of the reasons).

Regarding the question under which prerequisites the feature “practised on the ...body” is fulfilled, it is noted, that in **T 964/99** the taking of a sample occurred from of a living human or animal body. Further, the Board defined that percussion, auscultation and palpation as examples for typical diagnostic methods practised on the human body (see item 3.5 of the reasons). From this statement one could conclude that the feature “practised on the ...body” is fulfilled if a direct contact with the body exists.

However, the question arises, if it could also be sufficient to fulfill the criterion “practised on the ... body” if another way of an interaction with the human body is claimed. One could think of, for example, non-invasive methods, which could, for example, by use of radiation be useful for measuring and analytic purposes providing the basis for a diagnosis. In **T 964/99**, no further explanations are given with regard to the quality and intensity of an interaction in order to fulfill the criterion of the feature “practised on the ... body.” Therefore, according to the wording of Article 52(4) EPC (“practised on the human or animal body”), the mere presence of a human or animal body could be sufficient such that the appearance of the animal or human body could also be implied with this expression. It appears as if the Technical Board 3.5.1 in its decision **T 775/92** the Board had applied this interpretation, since it considered an interaction with a body from a distance also as a diagnostic method (see item 10 of the reasons).

Moreover, the method, being the subject-matter of the decision in **T 964/99**, comprised steps which had to be carried out “on the human and animal body” (placement of the sampling chamber on the body surface, extraction of the substance through the surface tissue) as well as outside the body (analysis of the concentration of the substance in the

sampling chamber with technical means). The taking of a body sample from a living human or animal body for the purpose of a medical examination would belong, according to the Board, to a “fundamental diagnostic activity” and regarded this step as an “essential activity pertaining to diagnosis and practised on the living body” (item 5.2 and 6.1 of the reasons). Since the claimed method contained this method step, it was considered to constitute a “diagnostic method” in the meaning of Article 52(4) EPC.

Therefore, from this decision, it can be concluded that obviously not all steps must be practised on the body in order to affirm the exclusion from patentability of a diagnostic method practised on the human or animal body. Rather, it appears to be sufficient that **one** such step is practised on the human or animal body. Such an interpretation appears to be also in accordance with the case law concerning surgical or therapeutic methods.

In **T 964/99**, the step with diagnostic character was at the same time that step which was practised “on the human or animal body.” Therefore, the question arises if this connection is a prerequisite or if, under certain circumstances, a method would also constitute a “diagnostic method practised on the human or animal body” if in a multi-step process, not the step which is related to diagnosis and constitutes an essential activity of a diagnosis is “practised on ... the body” but another. With regard to decision **T 807/98**, it appears as if the step with “diagnostic character” could also be practised outside the body. In this decision, the fundamental step with diagnostic character and regarded as essential diagnostic activity comprised the determination of the threshold value and the set point, for which the physician would finally assume the responsibility (item 2.3 of the reasons). Determining the values would correspond to a measure which is not directly discernible on the living human or animal body, but rather is carried out with the device used.

IV. Divergent decisions of two Boards of Appeal in the meaning of Article 112(1) b) EPC

According to its wording, Article 112 (1) b) EPC requires that “two Boards of Appeal have given different decisions on a point of law.”

The present two divergent decisions **T 385/86** and **T 964/99** came from the same Technical Board in the sense of the schedules of responsibility, namely Board 3.4.1. Nonetheless, they have to be understood as divergent decisions in the meaning of Article 112 (1) b) EPC:

Other Technical Boards, in decisions **T 775/92**, **T 530/93**, **T 1165/97**, **T 629/98** and **T 807/98**, followed decision **T 385/86**. All these decisions relate in their content to the former decision **T 385/86** and made use of the arguments therein. Accordingly, decision **T 964/99** (another Board of Appeal followed (**T 310/99**)) also diverges from the decisions of other Boards in the sense of the schedules of responsibility. The divergence, described here, was mainly outlined on the basis of the decisions **T 385/86** and **T 964/99**, since both decisions developed different approaches for the exclusion from

patentability which could result in a concrete individual case, as for example that which was the basis for decision **T 964/99**, could lead to different results. Moreover, the Technical Board 3.4.1. explicitly distanced itself in its decision **T 964/99** from the approach supported in **T 385/96** (see especially reasons 4.1).

Additionally, the Technical Board 3.4.1 came to its decisions **T 385/86** and **T 964/99** with completely different team members. In case of divergent decisions of the Legal Board of Appeal, the Enlarged Board of Appeal allowed a submittal of the president in its opinion **G 4/98** (OJ EPO 2001, 131, item 1.2 of the reasons). It was decisive that the effect of Article 112 EPC would be restricted improperly if the authorization for a Referral by the President would be defined by a restrictive interpretation of the term “two technical Boards,” based on the structure of the organization. In such cases, Referrals concerning the Legal Board of Appeal, which represents a single unit of organization, would not be possible. In the former situation, the Enlarged Board of Appeal allowed the Referral since the contradicting decisions were issued by different assemblies of the Board. With regard to the purpose and sense of Article 112 EPC, a comparable need could exist for clarification of which conception of legality should be decisive in those cases in which a Technical Board issues decisions in completely different assemblies. Accordingly, the term “Board of Appeal” in Article 112 (1) b) EPC could not only be understood as a Board with its name according to the schedule of responsibility (see *Schulte*, Patentgesetz mit EPÜ, 6. Auflage 2001, Anhang zu § 73, Art. 112 EPÜ, Rd. 42; *Günzel* in: *Benkard*, EPÜ, 2000, Artikel 112, Rd. 5).

The provision of Article 112 (1) b) EPC is based on the consideration that the President of the EPO should refer a point of law to the Enlarged Board of Appeal if divergent decisions of the Board of Appeal are issued, which lead to legal uncertainty, for example due to their different legal assessments requiring clarification. It should be immaterial whether these decisions have been issued by two different Boards of Appeal in the sense of the schedule of responsibility or of two Boards of Appeal in different assemblies or even of Boards of Appeals in partially or completely identical assemblies (same in *Schulte*, Patentgesetz mit EPÜ, 6. Auflage 2001, Anhang zu § 73, Art. 112 EPÜ, Rd. 42; see also *Joos*, in: *Singer/Stauder*, Europäisches Patentübereinkommen, 2. Auflage 2000, Artikel 112, Rd. 30 for a discussion that it should be decisive for an authorization for a Referral that two contracting decisions exist and not, if these decision have been issued by two Boards of a different organizational name). Article 112 EPC particularly serves, according to its wording, the aim of obtaining a uniform application of law (see also *Moser*, Münchner Gemeinschaftskommentar, 20. Lieferung, Art. 112, Rd. 28; *Paterson*, The European Patent System, 2001, 4/175, 187). If different principles are developed in the decisions of the Board of Appeals, leading to different results by applying them in a concrete individual case, then a substantial need for clarification in the office and public exists in order to determine which legal conception is decisive.

The present case does not appear to be about a development of the case law, but rather a divergence of jurisdiction. In decision **T 964/99**, the Board explicitly clarified that it would not apply the principle developed in **T 385/96** (and further confirming decisions)

but would apply another. It distanced itself completely from the interpretation of the term “diagnostic method” in the meaning of Article 52(4) EPC, as it was developed in decision **T 385/86** by using in **T 964/99** in guideline 1 and items 4.1 and 4.2 of the reasons nearly the identical wording of the definition developed in **T 385/86**, in order to provide a negative definition. Moreover, the Board stated, based on a number of examples, that certain methods would not be excluded from patentability in the sense of Article 52(4) EPC by applying the principles developed in **T 385/86**, which in the Board’s view would go against the spirit of this provision (see **T 964/99**, item 3.5 of the reasons). Thereby, the Board explicitly expressed its opinion that, on the contrary, the term “diagnostic method” needs not be understood in the way elaborated by the Board in decision **T 385/86** and therefore distanced itself consciously from the principles of interpretation established in **T 385/86**. Thus, the Board exceeded the limits of the development of case law. Additionally, the divergence between decision **T 385/86** and **T 964/99** results from the decision **T 807/98**, issued later. In this decision the Board 3.2.2 applied the principles of both decisions in parallel (see items 2.2 and 2.3 of the reasons) in order to decide if a method would constitute a diagnostic method, excluded from patent protection according to Article 52(4) EPC. In case of a development of the case law such an approach using two decisions in parallel would not have been necessary.

Accordingly, decisions **T 385/86** (and the decisions which followed it in its argumentation) and **T 964/99** diverge from another. Therefore, for the reasons of uniform legal certainty and clarity of law, a submittal of the president appears to be necessary, regardless of the fact that the different approaches have been developed by the same Board of Appeal in the sense of the schedule of responsibility.

V. Insurance of uniform application of law and the fundamental significance of a point of law

A Referral by the president of the EPO is only allowed for ensuring a uniform application of the law or if an important point of law arises.

The application of the principles of interpretation, as developed in decisions **T 385/86** and **T 964/99**, respectively, could lead to the same result in a concrete individual case. However, it is equally probable in the concrete individual case that a different judgment is reached with regard to the presence of a diagnostic method in the sense of article 52(4) EPC, depending on the approach applied. The Technical Board in **T 964/99**, for example, affirmed the presence of a diagnostic method within the meaning of Article 52(4) EPC. However, if the principles developed in **T 385/86** were applied to the method claimed in **T 964/99**, then no “diagnostic method” would be present (see above, items III.1 and III.2). The result, therefore, would be another. Further examples in which the application of both approaches would lead to different results are mentioned in **T 964/99** itself (see item 3.5. of the reasons). Depending on which principle the decision is based, a diagnostic method in the sense of Article 52(4) may or may not be present in a concrete individual case. Thus, the chance for issuing a patent would therefore depend on the selection of the principle of interpretation.

As already mentioned under II.1, the Guidelines for Examination of the European Patent Office follow decision **T 385/86** in the interpretation of that term. The practise of the office, therefore, is basically in accordance with that interpretation, even if the Board diverges from the Guidelines in exceptional cases (see Guidelines; General introduction, 1.2). In view of the Office, with regard to the interpretation in **T 964/99** and the confirmation in subsequent decisions, an urgent need exists for clarification to which approach one should follow in order to interpret the term “diagnostic method” in the sense of Article 52(4) EPC.

For European patent applicants, it is extremely important to know which principle of interpretation should be applied. They must know by which examination rules they have to comply, as the chance of the granting of a patent could substantially depend from the principle of interpretation being the basis for the decision.

A similar need for clarification as to which interpretation one should follow exists for the owners of patents, who, in special cases, stand to lose their patents in procedures of opposition proceedings and invalidation procedures since the chances of success of an appeal or a complaint can depend on the approach of interpretation to which it is followed.

A need for clarification of the term “diagnostic method” in the sense of Article 52(4) EPC also exists for the appellant in order to estimate the risks of costs for an appeal or a complained against the refusal of the appeal.

Therefore, a clarification by the Enlarged Board of Appeal about how to interpret the term “diagnostic method, practised on the human or animal body” in the meaning of Article 52(4) EPC, appears to be required for uniform application of law.

The question of which interpretation has to be followed also has a fundamental significance. The sense and purpose of the exclusion from patentability according to Article 52(4) EPC is to exclude methods which serve healing purposes from the possibility of patent protection. Nobody should be hampered in the practise of medicine by patents. The scope of this exclusion from patentability is therefore crucially dependent on the interpretation of the term “diagnostic method” as used in Article 52(4) EPC. The interpretations developed in T 385/86 on the one hand and in **T 964/99** on the other hand appear to differ in their scope. Accordingly, the Board stated in **T 964/99** that by applying the principles of **T 385/86**, typical diagnostic steps practised on the human body, such as percussion, auscultation or palpation, would be patentable in principle because they do not constitute a complete diagnosis and would, without fail, not fall under the further medical categories of treatment by surgery or therapy, as listed in Article 52(4) EPC. In the Board’s view, this would contradict the spirit of Article 52(4) EPC if its provisions would be interpreted such that certain “manual procedures” of the examination on the body, which are essential for diagnostic activity and are practised by a physician, would not be excluded from patentability (see item 3.5 of the reasons). The interpretation of the

term “diagnostic methods practised on the human or animal body” therefore determines the scope of patent rights, based on socio-ethical considerations.

Should the Enlarged Board feel that a supplement of this submittal would be appropriate, a corresponding indication is requested.

Ingo Kober
President