Opinion of the Enlarged Board of Appeal dated 16 December 2005
G 1/04

(Language of the proceedings)

Composition of the board:

Chairman: P. Messerli
Members: W. Moser
U. Kinkeldey
A. Nuss
J.-C. Saisset
M. Seppik
H. C. Thomsen

Headword: Diagnostic methods

Article: 4(3), 52(1), (2), (4), 57, 84, 112(1)(b) EPC
Rule: 29 EPC
Article: 53(c) revised EPC

Keyword: "Diagnostic methods under Article 52(4) EPC representing inventions excluded from patentability by means of a legal fiction" - "Proper construction of the terms 'diagnostic methods' and 'practised on the human or animal body' referred to in Article 52(4) EPC - requirements of clarity and legal certainty - difficulty of defining medical and veterinary practitioners on a European level within the framework of the EPC - essential features of a diagnostic method excluded from patent protection under Article 52(4) EPC - qualification of an activity as having a diagnostic character - requirements for a diagnostic method to be regarded as being practised on the human or animal body"

Headnote

I. In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:

(i) the diagnosis for curative purposes stricto sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise,

(ii) the preceding steps which are constitutive for making that diagnosis, and

(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

II. Whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC may neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medical or technical support staff, the patient himself or herself or an automated system. Moreover, no distinction is to be made in this context between essential method steps having diagnostic character and non-essential method steps lacking it.

III. In a diagnostic method under Article 52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes stricto sensu must satisfy the criterion "practised on the human or animal body".

IV. Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.

Summary of the proceedings

I. On 29 December 2003, the President of the EPO, making use of his power under Article 112(1)(b) EPC, referred the following point of law to the Enlarged Board of Appeal (English translation):

"1(a) 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

1(b) 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 1(b) 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?

3(a) 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)?

3(b) 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?"

II. In the reasons for his referral, the President of the EPO pointed to conflicting decisions of the boards of appeal on the above point of law and in essence put forward the following arguments.

(i) Decision T 385/86 (OJ EPO 1988, 308) held that the only methods to be excluded from patent protection as diagnostic methods were those whose result immediately made it possible to decide on a particular course of medical treatment. That, in turn, was only the case if the claimed method contained all steps involved in reaching a medical diagnosis, viz. examination, recording any significant deviation from the normal value, and attributing that deviation to a particular clinical picture. That meant that methods providing only interim results were not diagnostic methods, even if the results could be utilised in making a diagnosis. The consequence of such a narrow interpretation was that methods not containing all the steps involved in making a medical diagnosis were not excluded from patentability under Article 52(4) EPC.

(ii) Departing from the interpretation set out in decision T 385/86, decision T 964/99 (OJ EPO 2002, 4) held that the expression "diagnostic methods practised on the human or animal body" should not be considered to relate only to methods containing all the steps involved in reaching a medical diagnosis. Article 52(4) EPC was meant to exclude from patent protection all methods practised on the human or animal body which related to diagnosis or were of value for the purpose of diagnosis. Consequently, all that was needed to justify exclusion under Article 52(4) EPC was that the claimed method comprised one step which served diagnostic purposes or related to diagnosis and was to be regarded as an essential activity pertaining to diagnosis and practised on the living human or animal body.

(iii) As noted in decision T 964/99, the requirement in decision T 385/86 that for a method to be diagnostic it had to contain all the steps involved in reaching a medical diagnosis amounted to setting a different standard for diagnostic methods than for methods of surgery or therapy, the latter being excluded from patent protection if they comprised only one single step of a surgical or therapeutic nature.

(iv) Decision T 385/86 equated the expression "diagnostic method" with "diagnosis", in that detecting, distinguishing and identifying a pathological condition and attributing the deviation to a clinical picture had to be essential elements of such a method. As a result of so narrow an interpretation, a diagnostic method denied patent protection under Article 52(4) EPC could be converted to a potentially patentable measurement method essentially by omitting the comparison operation from the claim. By way of contrast, according to decision T 964/99, Article 52(4) EPC might even apply to methods comprising only one step which served diagnostic purposes or related to diagnosis and was to be regarded as an essential activity pertaining to diagnosis and practised on the living human or animal body. However, decision T 964/99 did not specifically examine whether the diagnostic purpose or relation to diagnosis of the step had to be clear from the claims themselves or whether it sufficed for this to be clear, explicitly or implicitly, from the application documents as a whole.

(v) In decision T 385/86 it was further considered whether, working on the assumption that the first sentence of Article 52(4) EPC was intended to prevent a physician from being hampered in the practice of medicine by patent legislation, the claimed method, although not containing all the steps involved in reaching a diagnosis, could still not be regarded as susceptible of industrial application because it could only be carried out by a physician in the exercise of his or her healing skills (point 3.5 of the Reasons). It was held that, apart from methods which were "diagnostic" because they contained all the steps involved in making a diagnosis, a method comprising at least one step that only a physician was able to perform could also be regarded as a diagnostic method. By way of contrast, in cases where not all steps involved in reaching a diagnosis were claimed, the presence of a diagnostic method was to be denied if all steps of the claimed method could be carried out by a technician without medical knowledge or skills, or by the patient himself or herself.

(vi) While decision T 385/86 called for a further test to establish whether there was at least one step that had to be performed by the physician himself or herself, decision T 964/99 made the character of the activity the deciding factor, and the personal presence of the physician, when the method was carried out, appeared not to be an essential precondition. Rather, decision T 964/99 could be construed to mean that a "diagnostic method" within the meaning of Article 52(4) EPC might be present even if a physician did not necessarily have to bear responsibility for any of the steps.

(vii) In this broad interpretation, the crucial criterion seemed to be whether a specific step of diagnostic character was included. As a rule, a step appeared to have a diagnostic character if a physician had to perform it in person or bore the responsibility for it. But, even if neither of these alternatives applied, a step could still have a diagnostic character. In the light of decision T 310/99 of 1 April 2003 (not published in the OJ EPO), however, it was not certain that such an interpretation was valid. That decision held that it was not just a question of who was involved in implementing the method. As the claimed method steps could "undoubtedly be carried out by a laboratory assistant without requiring the actual intervention of a physician", the method was not a "diagnostic method" (point 14 of the Reasons).

(viii) It therefore still seemed necessary to clarify whether the qualification of an activity as having a diagnostic character depended on who was involved or whether that was purely circumstantial to the extent that if the claimed method had to be performed by a physician or under his or her responsibility, it would normally come under the exclusion of Article 52(4) EPC.

(ix) In decision T 385/86, the criterion that the diagnostic method had to be "practised on the human or animal body" had been construed to mean that all the steps characterising a diagnostic method had to be performed on the human or animal body itself. Both examination (measurement of actual values) and establishing the symptoms on the basis of the examination results - hence the deviation measured from the norm - had to be carried out on a living human or animal body. Consequently, the actual values measured as well as the deviation from a norm that had to be regarded as a symptom had to be directly readable from parts of the body or directly discernible on the body itself (point 4.2 and 4.3 of the Reasons). Thus, according to decision T 385/86, the "on the body" criterion was not satisfied if at least a part of the diagnostic method was implemented outside the body being examined. The result of the interaction of the body with diagnostic examination equipment seemed to have to be directly readable on the body. By way of contrast, the intensity or quality of the interaction did not appear to be significant in terms of the criterion "practised on the body".

(x) From decision T 964/99 it might be concluded that the criterion "practised on the body" was in any case satisfied if direct contact with the body was involved. However, one might further ask whether, in order to satisfy this criterion, it might also be sufficient for there to be some other kind of interaction with the living body. One

might for example envisage non-invasive methods using radiation that could be performed for measurement and analysis purposes and that could form the basis for a diagnosis. Decision T 964/99 did not concern itself further with the quality or intensity of an interaction satisfying this criterion. According to the wording of Article 52(4) EPC ("practised on the human or animal body"), the mere presence of the human or animal body might potentially suffice, so even an assessment of the appearance of the human or animal body could be subsumed under it. This was the interpretation that seemed to have been applied in decision T 775/92 of 7 April 1993 (not published in the OJ EPO), which also classified a remote interaction with the body as a diagnostic method (cf. point 10 of the Reasons).

(xi) According to decision T 964/99, it seemed that not all steps needed to be performed on the body in order for a method to come under the exclusion from patentability of diagnostic methods practised on the human or animal body under Article 52(4) EPC. Rather, it appeared to suffice that one such step was performed on the human or animal body. Such an interpretation also seemed to be consistent with established case law on surgical and therapeutic methods.

(xii) In decision T 964/99 the step that had "diagnostic character" was also the one that was "practised on the human or animal body". This logically raised the issue whether this association always had to exist or whether under some circumstances a "diagnostic method practised on the human or animal body" might also be present if, in a multi-step process, the step practised on the body was not the step that related to diagnosis and constituted an essential diagnostic activity. As a matter of fact, in the light of decision T 807/98 of 25 April 2002 (not published in the OJ EPO), it seemed that the step having a "diagnostic character" might also be carried out outside the body.

III. Statements by third parties (*amicus curiae* briefs)

Statements were filed by the Fédération Internationale des Conseils en Propriété Industrielle (FICPI), the European Society of Human Genetics (ESHG), Mr Simon Kremer of Mewburn Ellis, European Patent Attorneys, London, Dr H.-P. Pfeifer on behalf of Roche Diagnostics, Philips Intellectual Property & Standards, Mr Andrew Sheard on behalf of Amersham plc, now trading as GE Healthcare, Bio-Sciences, Siemens AG, Praxis Dr med. Ulrich Kübler, Società Italiana Brevetti, and the Institute of Professional Representatives before the European Patent Office (epi). The arguments submitted in writing were *inter alia* as follows.

(a) Statements in favour of a narrow interpretation of the patent exemption for diagnostic methods under Article 52(4) EPC

(i) The diagnostic exception pursuant to Article 52(4) EPC had to be seen in the context of Article 4(3) EPC, which provided that it was the task of the EPO to grant patents. Any exception to this provision had therefore to be construed narrowly. The wording of Article 52(4) EPC excluded only diagnostic methods performed on the human or animal body. This wording had deliberately been chosen in order not to cover all diagnostic methods.

(ii) According to decision T 964/99, any method involving the taking of bodily samples was a diagnostic method excluded by Article 52(4) EPC, regardless of whether or not the samples were taken by a physician or the patient himself or herself. The delivering of a urine or saliva sample by a patient without medical intervention and the subsequent analysis of that sample by a commercial laboratory had thus been construed as a diagnostic method. Such a conclusion was inconsistent with the clear wording of Article 52(4) EPC.

(iii) It was not a fundamental aim of Article 52(4) EPC to ensure that physicians were able to perform diagnoses unfettered by patents. It expressly permitted new and effective diagnostic reagents and equipment to be protected by patents. Patents for such products inevitably protected methods for using them.

(iv) A diagnostic method was almost inevitably preceded by data gathering and analysis steps. Claims which recited some, but not all, of these steps should not be rejected under Article 52(4) EPC. The concern raised in decision T 964/99 that the exclusion under Article 52(4) EPC could be circumvented by missing out one of these steps was academic rather than real due to the practice of the EPO to insist that, in view of Articles 84 and 56 EPC, any claim had to recite all the essential features required to solve a technical problem.

(v) It was well-known that an important contribution to diagnoses performed by physicians in private practice and in hospitals was the determination of medical laboratory parameters. Most of these parameters were concentrations of molecules or cells in a body liquid (e.g. blood or urine) and normally determined *in vitro*. The sample (e.g. body fluid) was mixed with the reagents in a reaction vessel, and the detectable change was evaluated by the instrument which belonged to the system. Inventions relating to such *in vitro* determination of

medical laboratory parameters could in most cases be protected by product claims. But where method claims were appropriate, such methods should neither be excluded from patentability under Article 52(4) EPC, since none of the method steps was carried out on the body. Only if direct interaction with the body made a real difference whether the object of the invention was achieved, should a diagnostic method be regarded as falling within the exclusion under Article 52(4) EPC. Moreover, for the exclusion to operate, the entirety of the diagnostic method had to be practised on the body.

(vi) Recent developments of new analytical methods could lead to substantial improvements of analytical tools available to the medical profession. Some of these developments were such that the answers to the questions of the referral might be critical with respect to their possible exclusion from patent protection. These developments concerned integrated home-monitoring systems, non-invasive methods and decision support systems.

(vii) Modern analytical and diagnostic tools allowed the collection of a large amount of data about a particular patient. The decision whether these data had to be regarded as pathological was currently beyond the possibilities of automatic systems used in medical analyses. Rather, the physician evaluating such data had to have a comprehensive knowledge to draw correct conclusions from them. However, it was becoming more and more difficult for physicians to have the constantly increasing amount of required knowledge present by the time a decision was needed. The aim was therefore to provide decision support systems for the medical profession which "refined" the analytical and other diagnostic data by applying up-to-date factual knowledge. The questions of the referral could thus be critical for method claims covering the operation of such systems, because cases might exist where at least one step of data collection was performed on the body, and the decision support system performed a plurality of steps on the path to the final diagnosis.

(viii) A narrow interpretation of the diagnostic method exception under Article 52(4) EPC was therefore justified. A counterargument against a narrow interpretation was that most inventions in this field could be covered by product claims. However, product protection was not always possible. There were cases where the gist of the invention related to typical method features such as a particular sequence of steps or a particular timing. Moreover, some of the new and, from a medical point of view, highly interesting developments of medical analytics included interaction of body and instrument which were typically expressed by method claims.

(ix) The solution chosen in decision T 964/99 involved a strong risk to exclude inventions from patent protection which, in their nucleus, related to the automatic operation of a machine, but included steps which, at least theoretically, could be performed by a physician on the body of a patient.

(x) There was a need for legal certainty as to what the actual scope of the exclusion under Article 52(4) EPC was. The definition of the excluded scope should remain stable in time. This requirement was not met if the physician was an integral part of the definition of the concept of "diagnostic method", because this would lead to a dynamically changing definition of the scope of exclusion. As technology progresses, opinions in the healthcare industry might change as to whether a particular method needed to be applied by a physician having particular skills.

(xi) Analysis of a sample or of image information which in itself did not enable the distinction of a particular pathological or non-pathological state of the patient's body should be considered to be a technical achievement and, thus, not within the exclusion of Article 52(4) EPC. An actual diagnosis was only reached when, from the wide class of suspected pathologies, one had narrowed down into a comparatively detailed clinical picture enabling to ascertain which distinct pathology was at issue.

(b) Statements in favour of a broad interpretation of the patent exemption for diagnostic methods under Article 52(4) EPC

(i) The purpose of Article 52(4) EPC was to prevent patents in respect of certain methods pertaining to the treatment of humans and animals. From ethical considerations, the living human and animal body was not a suitable substrate for an industrial process. The work of a physician or other type of medical practitioner, including a medical geneticist, was not an industry, but a profession, and therefore was not industrially applicable. Methods which intruded too severely into the doctor-patient relationship were thus excluded from patenting.

(ii) The need to allow unfettered access to information, free worldwide contribution of knowledge related to genetic data and freedom to operate the diagnostic methods was in particular applicable to genetic diagnostic testing, having regard to the large number of persons involved in generating a reliable and accurate diagnostic test in this particular field. Hence, it should be a goal of the EPC to prevent the patenting of genetic diagnostic test methods whose success typically depended on a large-scale, communal effort, and where patenting could in a negative manner influence the preparedness of physicians throughout the world to co-operate.

(iii) Any explicit or implicit audio, visual or tactile contact which contributed to the final diagnostic result was a step in a diagnostic test as applied to the human or animal body. A diagnostic method including such a step was excluded from patentability under Article 52(4) EPC.

Reasons for the opinion

Admissibility of the referral

1. Both decisions T 385/86 and T 964/99 originate from Technical Board of Appeal 3.4.1. Article 112(1)(b) EPC provides for a referral by the President of the EPO when different decisions on a particular point of law have been given by two boards of appeal. However, it must be drawn into consideration that decisions T 775/92, T 530/93 of 8 February 1996 (not published in the OJ EPO), T 1165/97 of 15 February 2000 (not published in the OJ EPO) and T 807/98 of other technical boards of appeal adopted the findings of decision T 385/86. Hence, decision T 964/99 also diverges from decisions of other boards of appeal. In addition, decisions T 385/86 and T 964/99 were rendered by Technical Board of Appeal 3.4.1 in completely different compositions. Consequently, the referral is admissible.

Preliminary remark

2. Diagnostic methods practised on the human or animal body are normally carried out by practitioners in the fields of human and veterinary medicine, respectively. Consequently, these persons will be referred to by the term "medical or veterinary practitioners" hereinafter. The term "physician" used in the referral pertains rather to a practitioner in the field of human medicine.

The concept of diagnostic methods practised on the human or animal body

3. Article 52(4) EPC provides *inter alia* that "diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application". In view of answering the questions of the referral, it is necessary to define the terms "diagnostic methods" and "practised on the human or animal body". For the proper construction of these terms, the object and purpose of the provision, the various interests associated with diagnostic methods, and legal certainty constitute important aspects to be taken into consideration.

4. From the systematics of Article 52 EPC it follows that diagnostic methods practised on the human or animal body referred to in Article 52(4) EPC are inventions within the meaning of Article 52(1) EPC and thus also Article 57 EPC, which however, by means of a legal fiction, are regarded as not susceptible of industrial application. This is corroborated by the preparatory documents to the EPC (cf. Minutes of the Munich Diplomatic Conference, Minutes of Main Committee I, document M/PR/I, point 24). Article 52(4) EPC thus restricts the concept of industrial application in the field of medical and veterinary treatments and is to be regarded as *lex specialis* which takes precedence over Article 57 EPC (cf. T 116/85 (OJ EPO 1989, 13), point 3.5 of the Reasons). However, whilst the legislator has chosen the legal fiction of lack of industrial applicability, the exclusion from patentability of the above-mentioned methods under Article 52(4) EPC seems actually to be based on socio-ethical and public health considerations. Medical and veterinary practitioners should be free to take the actions they consider suited to diagnose illnesses by means of investigative methods. Consequently, the policy behind the legal fiction referred to above appears to be aimed at ensuring that those who carry out diagnostic methods as part of the medical treatment of humans or veterinary treatment of animals are not inhibited by patents (cf. T 116/85, point 3.7 of the Reasons).

5. The preparatory documents to the EPC do not elaborate on the term "diagnostic methods". However, according to the established jurisprudence of the EPO, it is accepted that the method steps to be carried out when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes include: (i) the examination phase involving the collection of data, (ii) the comparison of these data with standard values, (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase. In the judgment of the Enlarged Board of Appeal, there is no reason to deviate from this jurisprudence. However, the question to be answered in this context is whether the diagnostic methods referred to in Article 52(4) EPC comprise only the deductive medical or veterinary decision phase consisting in attributing the detected deviation to a particular clinical picture, i.e. the diagnosis for curative purposes *stricto sensu*, or whether they are also meant to include one or more of the preceding steps related to examination, data gathering and comparison.

5.1 Diagnosis in connection with the patent exemption for diagnostic methods practised on the human or animal body under Article 52(4) EPC is the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology. It includes a negative finding that a particular condition can be ruled out.

5.2 As the deductive medical or veterinary decision phase, diagnosis for curative purposes in itself is an intellectual exercise, unless, as a result of developments in the field of diagnostic technology, a device capable of reaching diagnostic conclusions can be used. As an intellectual exercise, pursuant to Article 52(2) EPC, the deductive decision phase is not regarded as an invention within the meaning of Article 52(1) EPC, whereas the method carried out by the device might well represent an invention within the meaning of this provision.

5.3 Since diagnostic methods referred to in Article 52(4) EPC are inventions within the meaning of Article 52(1) EPC (cf. point 4 above), it follows that, in a situation where the deductive medical or veterinary decision phase is a purely intellectual exercise, i.e. a step of a non-technical nature, such a method must necessarily further include preceding steps (cf. point 5 above) of a technical nature, in order to satisfy the requirements of Article 52(1) EPC. The subject-matter of a claim including technical and non-technical features may satisfy the requirements of Article 52(1) EPC if the non-technical features interact with the technical features in order to bring about a technical effect (cf. T 603/89 (OJ EPO 1992, 230), point 2.5 of the Reasons).

6. When it comes to determining the scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods which, in order to comply with Article 52(1) EPC, include preceding steps (cf. point 5.3 above), the following is to be considered.

A narrow interpretation of the scope of the exclusion presupposes that Article 52(4) EPC excludes diagnostic methods practised on the human or animal body only if all of the preceding steps which are constitutive for making a diagnosis as an intellectual exercise (cf. point 5.2 above) are performed on a living human or animal body (cf. T 385/86, point 4.1 of the Reasons), whereas a broad interpretation of said scope implies that this provision excludes all methods practised on the human or animal body which relate to diagnosis or which are of value for the purpose of diagnosis (cf. T 964/99, point 4.4 of the Reasons).

According to Article 4(3) EPC, it is the general task of the EPO to grant European patents. Moreover, Article 52(1) EPC lays down the fundamental maxim of a general entitlement to patent protection to the effect that, as a matter of principle, a European patent is to be granted for an invention which meets the requirements of that provision. It is true that there are exclusion clauses from patentability provided for in the EPC. It is also true that the frequently cited principle, according to which exclusion clauses from patentability laid down in the EPC are to be construed in a restrictive manner, does not apply without exception. However, the Enlarged Board of Appeal considers that the principle of a narrow interpretation of such exclusion clauses is to apply in respect of the scope of the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods.

6.1 As a starting point, Article 52(4) EPC mentions "diagnostic methods practised on the human or animal body". The provision does not make reference to particular steps pertaining to such methods, nor does it contain a wording such as "relating to diagnosis" or "of value for diagnostic purposes". Thus, the text of the provision itself already gives an indication towards a narrow interpretation in the sense that, in order to be excluded from patentability, the method is to include all steps relating to it. Furthermore, if the aim of the exclusion of such methods is to prevent medical or veterinary practitioners being inhibited by patents from taking the actions they consider appropriate to diagnose illnesses (cf. point 4 above), it will indeed be necessary to define the persons that are considered to be such practitioners. However, it is difficult, if not altogether impossible, to give such a definition on a European level within the framework of the EPC. From this it follows that, for reasons of legal certainty, which is of paramount importance, the European patent grant procedure may not be rendered dependent on the involvement of such practitioners. Since a comprehensive protection of medical and veterinary practitioners may be achieved by other means if deemed necessary, in particular by enacting legal provisions on the national level of the Contracting States of the EPC, introducing a right to use the methods in question, a narrow interpretation of the scope of the exclusion from patentability referred to above is therefore equitable. On the national level, it will also be more appropriate to define what a medical or veterinary practitioner is. Moreover, such a narrow interpretation is also justified by the fact that recent developments in the field of diagnostics for curative purposes render these methods more and more complex and technically sophisticated so that it is becoming increasingly difficult for medical or veterinary practitioners to have the means to carry them out. In this respect, they will hardly be hampered in their work by the existence of patents related to such methods. It is therefore difficult to see why applicants and inventors in the field of diagnostics should be deprived of a comprehensive patent protection.

6.2 In the present context, it is further to be considered that Article 84 EPC requires that the claims define the subject-matter for which patent protection is sought, and that they must be clear. It signifies that an independent

claim within the meaning of Rule 29 EPC should explicitly specify all of the essential features needed to define the invention, and that the meaning of these features should be clear for the person skilled in the art from the wording of the claim alone. The same should apply *mutatis mutandis* in respect of a claim relating to the subject-matter excluded from patent protection under Article 52(4) EPC. These requirements serve the overriding purpose of legal certainty.

6.2.1 Methods of surgery within the meaning of Article 52(4) EPC include any physical interventions on the human or animal body in which maintaining the life and health of the subject is of paramount importance. Methods of therapy referred to in Article 52(4) EPC concern the curing of a disease or malfunction of the human or animal body and cover prophylactic treatment such as immunisation against a certain disease. According to the established jurisprudence of the boards of appeal, a method claim falls under the prohibition of Article 52(4) EPC if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy. For example, within the meaning of Article 52(4) EPC, a claim including the feature "performing a lumbar puncture to deliver epidural injections" is to be considered to relate to a method of surgery, and a claim including the feature "administering a substance for prophylactic reasons" is to be regarded as a method of therapy. It follows that the surgical or therapeutic nature of a method claim can perfectly be established by a single method step without contravening Article 84 EPC. Diagnostic methods, however, differ in this respect from the methods of surgery and therapy.

6.2.2 The method steps to be carried out prior to making a diagnosis as an intellectual exercise (cf. point 5.2 above) are related to examination, data gathering and comparison (cf. point 5 above). If only one of the preceding steps which are constitutive for making such a diagnosis 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 (cf. T 385/86, point 3.3 of the Reasons). It follows that, whilst the surgical or therapeutic nature of a method claim can be achieved by a single method step (cf. point 6.2.1 above), several method steps are required to define a diagnostic method within the meaning of Article 52(4) EPC due to the inherent and inescapable multi-step nature of such a method (cf. point 5 above). Consequently, the restrictive interpretation of the patent exemption for diagnostic methods adopted by decision T 385/86 does not amount to setting a different standard for diagnostic methods than that established for methods of surgery or therapy, as has been asserted in decision T 964/99, point 3.6 of the Reasons.

6.2.3 If diagnosis as the deductive medical or veterinary decision phase is a purely intellectual exercise (cf. point 5.2 above), the feature pertaining to the diagnosis for curative purposes and the features relating to the preceding steps which are constitutive for making the diagnosis represent the essential features of a diagnostic method within the meaning of Article 52(4) EPC. Thus, in order to satisfy the requirements of Article 84 EPC, an independent claim relating to such a method must include these features. By way of contrast, if such a claim contained only one single feature relating to a particular step out of several preceding steps, and serving diagnostic purposes or being related to diagnosis for curative purposes (cf. T 964/99), the above-mentioned requirements would not be met. Since diagnosis for curative purposes is the final conclusion resulting from a thorough and comprehensive evaluation of the clinical picture by assessing all the data gathered in the preceding steps as a whole, it would indeed be inconsistent with the multi-step nature of making a diagnosis for curative purposes if one were to consider such a claim to relate to a diagnostic method as referred to in Article 52(4) EPC. Intermediate findings of diagnostic relevance must not be confounded with diagnosis for curative purposes *stricto sensu* as referred to under point 5 above, which consists in attributing the detected deviation to a particular clinical picture. It follows that a method for obtaining such results or findings does not constitute a sufficient basis for denying patentability by virtue of Article 52(4) EPC. To decide otherwise would give rise to such a broad interpretation of the scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods that it could hardly be reconciled with the requirement of legal certainty.

6.2.4 It has been argued that, in the event of a narrow interpretation as referred to under point 6 above, the exclusion of a diagnostic method under Article 52(4) EPC could perhaps be circumvented by missing out one of the essential features of the method (cf. point 6.2.3 above) in the independent claim concerned. However, this does not seem to pose a real risk having regard to the well-established jurisprudence of the EPO in respect of Article 84 EPC, which requires that, in order to be patentable, an independent claim must recite all the essential features which are necessary for clearly and completely defining a particular invention. These features are for the most part of a technical nature. But, if a non-technical feature is to be regarded as constitutive for defining the invention, it must likewise be included as an essential feature in the independent claim. Thus, although diagnosis *stricto sensu* is a purely intellectual exercise unless it is carried out by a device (cf. point 5.2 above), the feature pertaining to it is such an essential feature to be included in the independent claim. The same applies to a feature relating to a method step of a non-technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes (cf. point 6.4.1 below).

As regards in particular the non-technical feature pertaining to diagnosis for curative purposes referred to above, it is to be included as an essential feature in the respective independent claim if its essentialness is

unambiguously inferable from the respective European patent application or European patent as a whole. This is the case if the application or patent in question discloses a method for obtaining findings of diagnostic relevance which, contrary to the situation mentioned under point 6.2.3 above, allow the attribution of the detected deviation to a particular clinical picture.

6.3 In the judgment of the Enlarged Board of Appeal, the qualification of an activity as having a diagnostic character may not depend on who is involved. The wording of Article 52(4) EPC is unequivocal in that the exclusion relates only to the method, and not to the person carrying out the method. Furthermore, no indication can be found in the preparatory documents to the EPC which would restrict the exclusion of diagnostic methods from patentability to a certain group of persons such as medical or veterinary practitioners. Also, as already mentioned under point 6.1 above, defining the medical or veterinary practitioner on a European level within the framework of the EPC is difficult if not altogether impossible. To allow the grant of a European patent to depend on the involvement of such a person would therefore introduce legal uncertainty into the patent granting procedure. Thus, whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC should neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medicinal or non-medicinal support staff, the patient himself or herself or an automated system. This also reflects the well-known fact that technological advances penetrate human and veterinary medicine and the medical and veterinary profession. Today, and more than at any time before, technology is about to fundamentally alter how and by whom health care is administered, with the result that human and veterinary medicine is gradually being reshaped by technology. In a changing medical or veterinary environment brought about by technological progress, the need for reconsidering the relationship between medical or veterinary practitioners and non-medicinal support staff will become more pressing than ever before. This will have implications for the non-medicinal support staff in terms of profile and expansion in that a great variety of diagnostic and other information will have to be procured and gathered by these persons. Moreover, no distinction should be made in this context between essential method steps having diagnostic character and non-essential method steps lacking it. The reason for this judgment lies in the fact that, again contrary to the requirement of legal certainty, the assessment of the factual and legal situation in connection with these issues could change considerably in time. As has been mentioned under point 6.1 above, consideration might be given to exploring the possibility of protecting the activities of medical and veterinary practitioners by other means on the national level.

6.4 As a further restriction, Article 52(4) EPC requires that, to be excluded from patent protection, the diagnostic methods have to be practised on the human or animal body. From the fact that Article 52(4) EPC further refers to methods of surgery and therapy it can be inferred that these diagnostic methods serve curative purposes and are thus meant to be practised on the living human or animal body.

6.4.1 The criterion "practised on the human or animal body" is to be considered only in respect of method steps of a technical nature. Thus, it does not apply to the diagnosis for curative purposes *stricto sensu*, i.e. the deductive decision phase, which as a purely intellectual exercise cannot be practised on the human or animal body. Also, in a diagnostic method, the preceding steps which are constitutive for making a diagnosis for curative purposes may, in addition to method steps of a technical nature, include method steps such as comparing data collected in the examination phase (cf. point 5 above) with standard values belonging to the common general knowledge of the person skilled in the art. These activities are predominantly of a non-technical nature and, in any event, are not normally practised on the human or animal body.

6.4.2 Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body. Thus, each of the method steps of a technical nature referred to under point 6.4.1 above is either invasive or non-invasive. The non-invasive method steps may involve direct physical contact with the human or animal body or may be practised at a certain distance to it. Furthermore, the performance of each one of these method steps may or may not involve the use of data collecting devices and/or diagnostic equipment for measurement and analysis purposes. It follows that each and every one of these method steps satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.

6.4.3 However, if - unlike the situation considered under point 6.4.2 above - some or all of the method steps of a technical nature referred to under point 6.4.1 above are carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, these steps may not be considered to satisfy the criterion "practised on the human or animal body", because their performance does not necessitate the presence of the latter. By the same token, this criterion is neither complied with in respect of method steps carried out *in vitro* in a laboratory. This also covers method steps carried out *in vitro* by diagnostic devices known as DNA microarrays. Therefore, the arguments in favour of a broad interpretation of the scope of the exclusion from patentability under Article 52(4) EPC, submitted in an *amicus curiae* brief (cf. paragraph III.(b)(ii) above), and which are based on method steps of this kind, are not convincing.

6.4.4 From the very wording of Article 52(4) EPC in respect of diagnostic methods it already follows that the various method steps of a technical nature (cf. point 6.4.1 above) relating to such a method are basically meant to be performed on the human or animal body, implying an interaction with the latter, rather than *in vitro.* Since a narrow interpretation of the scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods is equitable (cf. point 6.1 above), it is thus justified to require that all method steps of a technical nature of such a method should satisfy the criterion "practised on the human or animal body", i.e. the performance of each and every one of these steps should imply an interaction with the human or animal body, necessitating the presence of the latter (cf. point 6.4.2 above). This is true all the more as a broad interpretation of that criterion, to the effect that only one single method step of the diagnostic method needs to be performed on the human or animal body, which may or may not be the step that constitutes an essential diagnostic activity (cf. paragraphs II.(xi) and II.(xii) above), would contravene the overriding principle of legal certainty for the reasons already indicated under points 6.1, 6.2.3 and 6.3 above.

Recapitulation

7. The diagnostic methods referred to in Article 52(4) EPC include the method step related to the deductive medical or veterinary decision phase, i.e. the diagnosis *stricto sensu*¸ representing a purely intellectual exercise.

8. The scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods is to be interpreted in a narrow manner (cf. point 6 above). Thus, in order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include (in view of Article 84 EPC) the feature pertaining to the diagnosis for curative purposes as a purely intellectual exercise representing the deductive medical or veterinary decision phase (cf. point 6.2.3 above), as well as the features relating to (i) the preceding steps which are constitutive for making the diagnosis (cf. point 6.2.3 above), and (ii) the specific interactions with the human or animal body which occur when carrying those out among said preceding steps which are of a technical nature (cf. point 6.4.4 above).

9. The grant of a European patent in respect of a diagnostic method which includes preceding method steps of a technical nature carried out by a device (cf. point 6.4.3 above) does not contravene Article 52(4) EPC, because the performance of the respective method steps does not satisfy the criterion "practised on the human or animal body". However, in the event of patent protection, it will normally be sufficient to purchase the device in question in order to be entitled to carry out such a method. In cases where the same diagnostic conclusions can be attained by a method not including the use of the device, those carrying it out will not be inhibited by the patent. Therefore, the medical or veterinary practitioners cannot be considered to be hampered by the existence of such a patent.

Act revising the EPC

10. From Article 1, items 17 and 18 of the 'Act revising the Convention on the grant of European patents' (published in Special Edition No. 4, OJ EPO 2001, 3) it follows that new Article 53(c) EPC provides *inter alia* that, as an exception to patentability, European patents shall not be granted in respect of diagnostic methods practised on the human or animal body, whereas existing Article 52(4) EPC is to be deleted without substitution. Item 6 of the explanatory remarks concerning the 'Transitional provisions' (published in Special Edition No. 4, OJ EPO 2001, 134) states that shifting "the substance of existing Article 52(4) [EPC] to [new] Article 53(c) [EPC] is a purely editorial change" and that the new wording of the substantive provisions laid down in amended Articles 52 and 53 EPC "does not change the actual legal position". The motive for the change was the realisation that these methods were excluded from patentability for reasons of public health and that, consequently, one should not base the argument on lack of industrial applicability any more.

11. The patent exemption for diagnostic methods practised on the human or animal body under existing Article 52(4) EPC pertains to inventions which are susceptible of industrial application within the meaning of Article 57 EPC (cf. point 4 above), which remains unaltered. The same applies to the patent exemption for such methods laid down in new Article 53(c) EPC. Thus, in this respect, the actual legal position remains unchanged. The present interpretation of the scope of the exclusion from patentability under existing Article 52(4) EPC in respect of diagnostic methods practised on the human or animal body will therefore remain valid when the revised version of the EPC comes into force.

Conclusion

For these reasons

the point of law referred to the Enlarged Board of Appeal by the President of the EPO is answered as follows:

1. In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:

(i) the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise,

(ii) the preceding steps which are constitutive for making that diagnosis, and

(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

2. Whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC may neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medical or technical support staff, the patient himself or herself or an automated system. Moreover, no distinction is to be made in this context between essential method steps having diagnostic character and non-essential method steps lacking it.

3. In a diagnostic method under Article 52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* must satisfy the criterion "practised on the human or animal body".

4. Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.