EUROPEAN PATENTS ON DIAGNOSTIC METHODS: WHAT ARE THE REQUIREMENTS AND PERSPECTIVES FOR APPLICANTS?

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Summary

On 16 December 2005, the Enlarged Board of Appeal of the European Patent Office ('the EPO') published its opinion on the patentability of diagnostic methods in the case G1/04.[1] In its opinion, the Board laid down the criteria that allow applicants to assess whether a method is considered to be a diagnostic method and as such excluded from patentability under the European Patent Convention ('the EPC'). There is good news for the applicants: the Board confirmed the established case law of the EPO stating that the legal requirements for an exception of diagnostic methods from patentability must be interpreted narrowly. One conclusion is that diagnostic methods in which not all essential technical steps are performed on the human or animal body are still patentable inventions. However, diagnostic methods that are practised on the human or animal body and that contain all of the preceding steps which are required for making a diagnosis, including the deductive medical or veterinary decision phase, are to be excluded from patent protection. Therefore, when claiming a (diagnostic) method, applicants now have to carefully consider whether they fall within the exclusion criteria as established in the recent opinion of the Enlarged Board of Appeal. This article highlights the most important facts and summarises the background of the opinion of the Enlarged Board of Appeal. In addition, some practical guidelines are provided for applicants that could be helpful to define whether a method falls within the exemption from patentability or not.

The Background

The EPC stipulates in Article 52(4) that 'methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are to be excluded from patentability'. It is further stipulated that 'this provision shall not apply to products, in particular substances or compositions, for use in any of these methods'. The purpose of this exclusion is to restrict the concept of industrial application in the field of medical and veterinary treatments. Medical and veterinary practitioners should be free in diagnosing an illness and applying certain medical treatments to the patient, and may not be inhibited in their actions by patents.

The question of whether a (diagnostic) method falls under the exemption of Article 52(4) EPC has been discussed controversially in different decisions of the Technical Boards of Appeal of the EPO, and there has been legal uncertainty in respect of diagnostic methods and the requirements defining the grounds for such an exclusion from patentability. The referral to the Enlarged Board of Appeal was based on two contradictory decisions, T385/86 and T964/99, which both originated from the same Technical Board of Appeal (3.4.1), which at the time of the decisions was composed of different members. In view of the non-unitary case law with regard to diagnostic methods and the contradictory criteria laid down in these decisions, the issue was referred to the Enlarged Board of Appeal. Since the outcome of the decision would have a huge impact on pharmaceutical and biotech companies, numerous statements from third parties were filed in favour of both a narrow and broad interpretation of the patent exemption for diagnostic methods falling under Article 52(4) EPC.

The contradiction decisions underlying the referral to the Enlarged Board of Appeal will be summarised in order to make clear the reasoning behind the opinion.

In the first decision, T385/86,[2] it was held by the Technical Board of Appeal 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. This was only the case if all essential method steps were performed on the human or animal body. Methods providing only interim results were thus not considered to be diagnostic methods. In accordance with this decision, diagnostic methods that comprise an analysis of a sample obtained from a patient and that are performed *in vitro* were considered as being patentable inventions. Most Technical Boards of Appeal adopted this interpretation of the decision, which is in line with the legal needs of most applicants.

On the contrary, the later decision T964/99[3] diverged from the former case law by stating that 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. Accordingly, methods in which only one essential step for diagnosis was practised on the human or animal body were considered to be excluded from patent protection. The result of this decision was highly unsatisfactory for most applicants since the mere provision of a blood sample from a patient in a diagnostic method would result in an exclusion from patentability regardless of whether all the subsequent steps were performed *in vitro* (and as such not on the human or animal body) or not. For example, according to this interpretation, the step of extracting a blood, urine or saliva sample from a patient and the subsequent analysis in a laboratory would be construed to be a diagnostic method and as such excluded from patent protection.

In the opinion G1/04, the Enlarged Board of Appeal followed the established case law as reflected in the principal decision T385/86. Thus, a diagnostic method will only be excluded from patent protection if all of the steps of the claimed method are practised on the human or animal body for the purpose of reaching a medical diagnosis.

What is Meant by 'Diagnosis' or 'Diagnostic Method'?

Very often the scientific definition of a term differs from its legal interpretation as established by the various national courts, Appeal Boards or Patent Offices. One example is the still ongoing controversial discussion relating to the terms 'embryo' and 'embryonic stem cells', which has now resulted in a referral to the Enlarged Board of Appeal (pending case number G2/06).[4] In G1/04, the Enlarged Board of Appeal largely adopted the scientific interpretation found in textbooks, and defined the term 'diagnosis' in connection with the patent exemption for diagnostic methods under the EPC as 'the determination of the nature of a medical condition intended to identify or uncover a pathology'. The Board further noted that it includes a negative finding that a particular condition can be ruled out.

The essential steps that need to be carried out when making a diagnosis as part of the medical treatment of humans or animals for curative purposes therefore 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, that is, a symptom, during the comparison, and
(iv) the attribution of the deviation to a particular clinical picture, that is, the deductive medical or veterinary decision phase.

One question to be answered was whether the diagnostic methods to be excluded under Article 52(4) EPC comprise only the deductive medical or veterinary decision phase consisting in attributing the detected deviation to a particular clinical picture, that is, 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. The Board held that a deductive medical or veterinary decision phase (iv) in itself is an intellectual exercise and is therefore not regarded as an invention, unless, as a result of developments in the field of diagnostic technology, a device capable of reaching diagnostic conclusion can be used. If the deductive medical or veterinary decision phase (iv) is a purely intellectual exercise without having a technical nature, a diagnostic method necessarily must include preceding steps that have such a technical nature in order for it to be regarded as an invention. In this regard it was considered to be irrelevant whether the method as a whole comprises non-technical features, as long as the method as a whole brings about a technical effect.

Applicants are reminded, however, that the non-technical features cannot just be taken out of a claim in order to circumvent the exclusion from patentability under Article 52(4) EPC. It is a prerequisite under the EPC that a claim shall specify all of the essential technical features required to define the invention (Article 84 EPC) and to solve the objective technical problem underlying the invention (Article 56 EPC). Therefore, the Board stated that, in order to comply with these requirements, the non-essential features must also be included in the claim.

It follows from the above that there remains the possibility of drafting patent claims for a method that does not in itself result in a diagnosis but that may provide the relevant data for use in making a diagnosis. An example is a method for determination of the bone density in a human or animal body. Both the device and the method for determination constitute patentable inventions under Article 52(4) EPC, since the latter does not result in a diagnosis. In order to make a diagnosis, the obtained results need to be compared with standard values in order to determine a physiologically significant deviation. In a subsequent step, the deviation needs to be attributed to a particular pathological condition or illness. However, if these steps are not present in the claim and are not necessary to perform the method, the method does not constitute a diagnostic method as defined by the essential four steps (i) to (iv) mentioned above, and may therefore not be excluded from patentability.

What is Meant by the Criterion 'Practised on the Human or Animal Body'?

In order to arrive at a medical diagnosis, the practitioner can obtain, for instance, a liquid sample from a patient that contains concentrations of certain molecules or cells. These

concentrations are compared with standard concentrations of said molecules or cells. A deviation of the measured values from referenced standard values is taken as an indicator for the presence or absence of a particular pathological condition or disease in the patient. In other diagnostic methods, the practitioner obtains measurement values by using methods that do not require a direct invasive intervention with the human or animal body. Typical examples for such non-invasive methods are radiographic pictures obtained by X-ray radiation, local and high-resolution magnetic resonance measurements ('LMR'), or the use of skin sensors to determine physiological parameters such as the body temperature, fat content, heart rate and blood pressure of a patient. These procedures, although being part of the method, do not require an invasive intervention with the human or animal body but are performed at a certain distance from it.

The Enlarged Board of Appeal has now made clear that the criterion 'practised on the human or animal body' does not require a specific type and/or intensity of interaction with the human or animal body. The non-invasive method steps may involve direct physical contact with the human or animal body or may be practised at a certain distance from it similar to the examples mentioned above. Any of the method steps may or may not involve the use of data collection and/or diagnostic equipment for measurement and analysis purposes. Therefore, any invasive or non-invasive steps in a diagnostic method satisfy the criterion 'practised on the human or animal body'. However, if the presence of the human or animal body is not required, for example, when using a specific software program, this criterion is not fulfilled. Similarly, claims directed to *in vitro* methods such as DNA microarrays for genetic analysis or enzyme-linked immunosorbent assays ('ELISA') are not covered by the scope of exclusion from patentability under Article 52(4) EPC, and may therefore be claimed in a European patent provided that the other requirements for patentability (such as novelty, inventive step and industrial application) are fulfilled with respect to these claims.

Role of the Practitioner

According to the opinion of the Enlarged Board of Appeal, the nature and qualification of the person who carries out the method is irrelevant since the exclusion relates only to the method and not the person carrying out this method. For legal certainty, the question of whether a method is considered to be a diagnostic method depends neither on the participation or presence of a medical or veterinary practitioner nor on the fact that all method steps can only be practised by human intervention or an automated system. At present, when making a diagnosis, a medical practitioner is often involved in attributing a diagnostic finding to a specific disease. However, as the technical development proceeds, the step of attributing data to a specific disease will be increasingly effected by automated (computer) systems. For example, by collecting and comparing the signal intensities in a patient sample with referenced standard values (for example, by ELISA) it is possible to detect a deviation from 'normal' and to determine whether the patient suffers from a certain disease or not. This data comparison and the deductive decision phase could be taken over by the software of an automated machine, and thus there would no longer be any involvement of a practitioner at this step.

When does a Method Qualify as a Diagnostic Method?

The scope of exclusion from patentability in respect of diagnostic methods has to be interpreted in a narrow manner. Thus, a patent claim falls under this exception if it contains all the features relating to the diagnosis for curative purposes *stricto sensu*. These features include specific interactions with the human or animal body, the deductive medical or veterinary decision phase, and all of the preceding steps that are constitutive for making a diagnosis.

The question of whether a method is regarded as a diagnostic method falling under the exception from patentability according to Article 52(4) EPC depends neither 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. In this regard, no distinction is made between method steps having diagnostic character and non-essential method steps lacking it.

In addition, in a diagnostic method that is excluded from patentability according to Article 52(4) EPC, 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'. As mentioned earlier, a specific type and intensity of interaction with the human or animal body is not required. Any interaction in the presence of the human or animal body in a preceding step of the method is considered to be 'practised on the human or animal body'. If all method steps are practised on the human or animal body, the method is to be excluded from patentability under Article 52(4) EPC.

The following are typical examples for diagnostic methods that are now (or still) excluded under the opinion: 'allergy tests in which the abnormal deviation can be detected by a change of the skin'; 'a method for analysing the blood sugar concentration of a patient, whereby the patient is identified as having diabetes'; '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 observed'; 'a method in which scarlet-fever spots are directly observed or photographed'; and 'a method directed to an endoscopic examination carried out to ascertain liver damage'.[5] Apparently these methods include steps that require a more or less intense intervention of the human or animal body, and immediately result in a diagnosis for the presence of a particular disease.

It follows that methods that result in intermediate findings of diagnostic relevance for curative purposes are not diagnostic methods falling within the meaning of Article 52(4) EPC, even if they can be utilised in making a diagnosis. The same is true of method claims that are directed to a method of diagnosis, wherein the claim comprises all of the above mentioned steps (i) to (iv) if one of the steps preceding the diagnosis *stricto sensu* is not performed on the body. This is the case, for instance, if a body sample is extracted and analysed in a device outside the human or animal body. The Board made it clear that any other interpretation of the exclusion requirement would hardly be reconcilable with the requirement of legal certainty.

If a method only comprises the steps of data acquisition or data processing, without comparing the obtained values with reference values, an attribution to a pathological condition or disease is impossible. The presence or absence of a particular disease cannot be determined solely from a value that is obtained from a patient´s sample. Only if the steps of differentiation and comparison are incorporated into the claim does the claimed method of measuring a physical variable on the human or animal body become a diagnostic method falling under the exclusion requirement, regardless of whether these steps are performed by a practitioner or by a computer system. Thus, a method that relates to the collection of a patient´s data or their processing, even if the obtained data can be used to arrive at a diagnosis of a particular disease, may still be claimed in a European patent.

For example, a method claim which is formulated as comprising, for instance, the steps of 'obtaining a blood sample from a human or animal individual, measuring a certain physical parameter in said sample, comparing said physical parameter to reference parameters, finding a significant deviation of the measured parameter to the reference parameter, and attributing the deviation to a particular disease' (that is, the steps that are necessary to make a diagnosis, see above) is excluded from patentability because:

(i) the method is practised on the human or animal body, and
(ii) the method comprises all the steps essential to arrive at a diagnosis, including the deductive medical or veterinary decision phase.

Applicants should be aware that, considering the opinion of the Enlarged Board of Appeal, patent claims should be formulated in such a way that either the method is recognised as an *in vitro* method not requiring the presence of the human or animal body, or the method results in intermediate findings that may be useful for diagnostic purposes while not being sufficient for making a direct diagnosis. For example, the measurement of blood pressure that results in an absolute value reveals an irregularity when compared with referenced values of healthy persons having the same age and weight. Furthermore, 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, outside the body, into visible light. However, even then a pathological condition can only be ascertained when the density structure of the picture has been actually compared with 'normal' standard values. Therefore, it is through the comparison and the explicit indication of how great the deviation must be in order to be characteristic of a particular disease or group of diseases that a method is regarded as a diagnostic method.

In order to avoid a claimed method falling under the exemption of Article 52(4) EPC, applicants may draft their claims in such a way that the method is directed to aspects other than the diagnosis of a pathological condition such as, for instance, to a method for the determination of certain physiological parameters or a method of processing the measured data, or to an *in vitro* method which does not contain a step of being practised on the human or animal body.

Finally, it should be mentioned that on a national level, the interpretation of the meaning of 'diagnostic method' may somewhat differ in the respective Contracting States of the EPC. While the Paris Court of Appeal construes the term 'diagnostic methods' narrowly,[6] decisions of the Swiss Federal Supreme Court,[7] the German Federal Patent Court[8] and the Swedish Patent Appeal Court[9] apply a broader interpretation. These considerations may become relevant if it comes to nullity proceedings against the national part of a European patent.

Looking into the Future: Diagnostic Methods under the EPC 2000

In 2007, the new EPC 2000 will come into force.[10] The question is whether there will be any change with respect to diagnostic methods and the new criteria established by the Enlarged Board of Appeal. The good news for the applicants is that there will be only an editorial change in the law and no change in interpretation and the criteria laid down in the opinion G 1/04. The stipulation of the exclusions as defined in Article 52(4) EPC will be found in the new Article 53(c) of the EPC 2000. This shifting is of a purely editorial nature and does

not change the actual legal position. The reason for this editorial change was that Article 53 EPC excludes methods from patentability for reasons of public health, whereas Article 52 EPC, as l*ex specialis* to Article 57 EPC, excludes inventions that are not susceptible to industrial application. The opinion of the Enlarged Board of Appeal and the interpretation of the scope of exclusion from patentability are therefore fully applicable to the new EPC 2000.

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1) Official Journal EPO, 2006, at 334.

2) Official Journal EPO, 1998, at 308.

3) Official Journal EPO, 2002, at 4.

4) Official Journal EPO, 2006, at 393.

5) See T385/86, Official Journal EPO, 1998, at 308.

6) PIBD, 1983, No. 329, III, at 189.

7) GRUR International, 1983, at 316.

8) GRUR, 1985, at 278.

9) Törnroth *et al*., *Patentlagsstiftningen*, 1980, at 54 and GRUR International, 1985, at 617.

10) http://patlaw-reform.european-patent-office.org/epc2000.