

Patentability of Diagnostic Methods Under the Most Recent Decision of the Enlarged Board of Appeal G 1/04

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Introduction

The present article deals with a recent decision of the Enlarged Board of Appeal (EBA) of the EPO, G 1/04, concerning the patentability of diagnostic methods which may fall under the exclusion provisions in the EPC.

Article 52(4) EPC stipulates that "Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application [...]. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

The Boards of Appeal made conflicting decisions regarding what construes a diagnostic method excluded under Article 52(4) EPC. Whereas T 385/86 offered a narrow interpretation of the scope of the exclusion under Article 52(4) EPC, T 964/99 offered a broad interpretation. According to the narrow interpretation, Article 52(4) EPC excludes diagnostic methods practiced on the human or animal body only if all of the steps which are constitutive for making a diagnosis are performed on the living human or animal body. In contrast, according to the broad interpretation, Article 52(4) EPC excludes all methods practiced on the human or animal body which relate to the diagnosis or which are of value for the purpose of diagnosis. For further details on the history in this field, please see Zimmer and Langheinrich, BLR No. 4, page 402 (2004).

The Questions Referred to the EBA

In view of the conflicting decisions of the Boards of Appeal, on 29 December 2003, the President of the EPO referred the following point of law to the EBA:

"1(a) Are "diagnostic methods practiced 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 the claimed method a "diagnostic method" if

it contains at least one procedural step considered as essential for a "diagnostic

method” and “requiring the presence of a physician (Alternative 1), or it does not require the presence of a physician but presupposes that a physician bears the responsibility (Alternative 2), or all procedural steps can also or only be practiced by medical or technical support staff, the patient himself or an ultimate 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 practiced 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 “practiced on human or animal body” mean that the procedural steps take place in direct contact with the body and that only such steps practiced 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 practiced directly on the body?”

The Reasons of the EBA

First of all, the EBA points out that 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. With such spirit, the EBA considers that the principle of a narrow interpretation of an exclusion clause is to apply in respect to the scope of the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods.

Secondly, according to the EBA, from the systematics of Article 52 EPC, it follows that diagnostic methods

practiced 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. However, the exclusion from patentability of the above-mentioned method under Article 52(4) EPC seems actually to be based on socio-ethical and public health considerations. The policy behind the legal fiction referred to above appears to be aimed at insuring 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. Consequently, it will be necessary to define the persons that are considered to be such practitioners. However, it is difficult, if not impossible, to give such a definition on the 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 grant procedure may not be rendered dependent on the involvement of such practitioners.

Furthermore, the EBA is of the opinion that 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. Therefore, 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 practiced by medical or non-medical support staff, the patient himself or herself or an automated system.

Thirdly, 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

the examination phase involving the collection of data
 the comparison of these data with standard values
 the finding of any significant deviation, i.e. a symptom, during the comparison and
 the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase

Therefore, 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. This is in contrast to the method of treatment of the human or animal body by surgery or therapy within the meaning of Article 52(4) EPC, wherein the surgical or therapeutic nature of a method claim can be achieved by a single method step. Therefore, a method of data acquisition or data processing is not a diagnostic method. Furthermore, intermediate findings of diagnostic relevance must not be confounded with diagnosis for curative purposes which consists in attributing the detected deviation to a particular clinical picture.

Fourthly, as a further restriction, Article 52(4) EPC requires that, to be excluded from patent protection, the diagnostic methods have to be practiced 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 practiced on the living human or animal body. It is thus justified to require that all method steps of a technical nature of such a diagnostic method should satisfy the criterion "practiced on the human or animal body." Method steps carried out by a device without implying any interaction with the human or animal body or method steps carried out *in vitro* in a laboratory do not satisfy the criterion "practiced on the human or animal body". Furthermore, it is noted that

Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body.

The Answers Provided by the EBA

In conclusion, the EBA answered the point of law referred by the President of the EPO as follows:

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

the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise, the preceding steps which are constitutive for making that diagnosis, and the specific interactions with the human or animal body which occur when carrying those out among the preceding steps which are of a technical feature.

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 practiced 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 diagnostic methods 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 "practiced 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 does satisfy the criterion "practiced on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter."

Implications for Drafting New Applications

It follows from G 1/04 that a method which does not comprise all the necessary steps for making a diagnosis for a curative purpose, including (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, is not a method of diagnosis under exclusion of Article 52(4) EPC. Furthermore, a diagnostic method does not fall under the exclusion of Article 52(4) EPC unless all of the preceding steps which are of a technical nature prior to the deductive medical or veterinary decision phase require the specific interaction with the human or animal body.

Consequently, claims relating to methods of examination, sample collection, data gathering and/or data comparison, i.e., one or more, but not all, necessary steps of diagnosis, should be allowable under Article 52(4) EPC.

In particular, a method of monitoring, e.g., the detection of change of a marker during the course of a therapy, which may involve the interaction with the human or animal body in all monitoring steps but which lacks the deductive decision step is not excluded by Article 54(2) EPC. Methods of interest in this category include e.g., *in vivo* imaging.

Furthermore, diagnostic methods comprising at least one technical step which does not require the specific interaction with the human or animal body should be allowable under Article 52(4) EPC. Such a technical step may be carried out *in vitro* (e.g., the detection of a protein in a sample by ELISA, the sequencing of a DNA in a sample) or may be carried out by a device without interaction with the human or animal body (e.g., the use of a software program in data comparison).

When determining whether or not a technical step requires the specific interaction with the human or animal body, it should be emphasized that Article 52(4) EPC does not specify the type or intensity of interaction with the human or animal body. Therefore, both invasive (e.g., resection of a tissue, blood drawing) and non-invasive (e.g., MRI, X-ray, temperature measurement) methods, as long as they require the presence of the human or animal body, are considered to require the specific interaction with the human or animal body, i.e., are "practiced on the human or animal body".

Lastly, it should be noted that even though the omission of a step, e.g., the medical or veterinary decision phase, from a diagnostic method practiced on the human or animal body may avoid exclusion of the method under Article 52(4) EPC, it would result in an objection of lack of clarity under Article 84 and Rule 29 EPC because the claimed method does not contain all of the essential steps in obtaining a diagnosis.

Therefore, when all of the technical steps of a method relating to diagnosis are practiced on the human or animal body, draft a claim directed at a method of sample collection, data collection, and/or sample analysis or the like instead of a method of diagnosis and leave out at least one of the necessary steps for making a diagnosis as defined by the EBA to avoid the exclusion under

Article 52(4) EPC and/or an objection under Article 84 EPC.

Implications for Pending Applications

As discussed above, any pending claims which relate to a method of diagnosis and which do not recite all the necessary steps for making a diagnosis as defined by the EBA may from now on be objected to under Article 84 EPC for lacking essential steps.

There are basically two possible ways of remedying the situation:

(1) incorporate all the missing essential steps for diagnosis into the claim, provided that there is support for such addition and that the resulting claims does not fall under the exclusion by Article 52(4) EPC (e.g., because some steps are not performed on the human or animal body); or

(2) amend the preamble of the claim to restrict the claimed subject matter to the step(s) recited, e.g., "a method of obtaining a sample", "a method for detecting ... in a sample", or "a method suitable for use in the diagnosis of ...", rather than calling the method a "method for diagnosing...". Support for the amendment in this case should not be problematic since it should be possible to argue that the amendment is directly derivable from the disclosure of the application as filed.