

Europe: Landmark decision on patentability of diagnostic methods

The Enlarged Board of Appeal of the European Patent Office (EPO) has recently issued a decision on the patentability of diagnostic methods which had been eagerly awaited by patent practitioners throughout Europe. In its decision of 16 December 2005, the Enlarged Board of Appeal construes the exclusion clause of Article 52(4) EPC referring to diagnostic methods in a restrictive manner, thus encouraging inventors in the field of medical technology to file patent applications in Europe. A number of examination proceedings which had been suspended by the EPO in order to wait for the outcome of the decision should soon be resumed.

I. Background to the decision

According to Article 52(4) EPC,

"methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body"

are excluded from patentability. Similar regulations can be found in a number of national patent acts in Europe and worldwide.

Whereas the EPO and various national patent authorities, for example the German Federal Patent Court in Munich, had established a rather consistent case law on the question how a "method for treatment of the human or animal body by surgery or therapy" is defined, the situation was less clear in the field of diagnostic methods. On a European level, various Technical Boards of Appeal of the EPO had taken inconsistent decisions.

On 29 December 2003 the President of the EPO therefore referred several questions regarding the exclusion of diagnostic methods from patentability to the Enlarged Board of Appeal. His referral, among others, in particular raised the following questions:

- a. Is a diagnostic method within the meaning of Article 52(4) EPC necessarily a method containing **all** the procedural steps to be carried out during medical diagnosis, or is a method claimed excluded from patentability if it only contains **one** such step?
- b. Is a claimed method necessarily a "diagnostic method" if at least one of its steps requires the presence of a physician?
- c. How is the requirement "practised on the human or animal body" in Article 52(4) EPC to be interpreted?

II. Findings of the Enlarged Board of Appeal

As a starting point, the Enlarged Board of Appeal has confirmed the established jurisprudence of the EPO according to which a technical teaching, in order to represent a "diagnostic method", has to include the following method steps:

- (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 terminology of the Enlarged Board of Appeal, the last step (iv) represents the actual diagnosis for curative purposes, whereas steps (i) to (iii) represent so-called preceding steps.

As step (iv) represents a purely intellectual exercise, at least one of the preceding steps has to be of a technical nature for the entire method to have a technical character. However, as analysed by the Enlarged Board of Appeal, method steps such as comparing data collected in the examination phase, i.e. step (ii) defined above, are also predominantly of a non-technical nature.

Based on this definition and characterization of method steps, the Enlarged Board of Appeal has ruled as follows (Official Headnotes):

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.

III. Consequences of the decision for applicants

The decision confirms the restrictive interpretation of the patent exemption for diagnostic methods which had been adapted by several Technical Boards of Appeal. Inventions referring exclusively to new methods carried out during the examination phase in order to collect clinical data of a human being or animal independent from the subsequent use of these data may no longer be excluded from patentability under Article 52(4) EPC. As an example, measurements of blood parameters, clinical X-ray image processing methods etc. represent patentable inventions. Furthermore, European Examiners may no longer raise objections against method claims merely due to the fact that they include steps which usually depend on the participation of a medical or veterinary practitioner. The Enlarged Board of Appeal's decision thus encourages patent applications in the field of diagnostic technology, for example clinical data acquisition or data processing.

On the other hand, the Enlarged Board of Appeal has clearly explained that in cases where an invention does refer to a diagnostic method, not to a preceding method of data acquisition or data processing, the patent exemption of Article 52(4) EPC cannot be circumvented by simply omitting one of the essential method steps as defined above, in particular step (iv) referring to the actual diagnosis, from the patent claim. Such a method claim would contravene 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.

The EPO's decision is in good agreement with corresponding German case law, in particular the jurisprudence of the German Federal Patent Court. It can be expected to have considerable impact on the national jurisprudence in other EPC member states as well.