

Patent Briefing Paper: *European Patent*

PATENTABILITY OF DIAGNOSTIC METHODS REFERRED TO ENLARGED BOARD OF APPEAL – G1/04

The President of the European Patent Office has recently referred points of law relating to the interpretation of the term "diagnostic methods practiced on the human or animal body" within the meaning of Article 52(4) EPC to the Enlarged Board of Appeal. The questions referred are:

- 1A. 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
- 1B. 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 question 1b 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?
- 3A. 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 practiced by medical or technical support staff, the patient himself or an automated system (Alternative 3)?*
- 3B. 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 the 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.

Until the Enlarged Board of Appeal has issued its decision in this case, all proceedings before the EPO first-instance departments (examining and opposition divisions) where the decision depends entirely on the Enlarged Board of Appeal's decision will be suspended.

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