



# The European Patent Office and the patentability of diagnostic methods.

# The recent opinion of the Enlarged Board of Appeal seems to confirm the established case law

**ROBERTO PISTOLESI**

**Dragotti & Associati**  
Via Turati 32  
20121 Milano, Italy  
Tel +39 02 29014418  
Fax +39 02 29003139  
pistolesi@dragotti.com  
www.dragotti.com

**BACKGROUND**

The Enlarged Board of Appeal is a special department of the EPO which consists of five legal members and two technical experts. It is responsible for deciding points of law referred to it by the Boards of Appeal and giving opinions on points of law referred to by the President of the EPO where two Boards of Appeal have given different decisions on the same issue (2). A decision of the Enlarged Board of Appeal is binding on the Board of Appeal which made the referral and may affect pending decisions of other Boards of Appeal, although it has no effect on decisions which have already become final; in practice, a decision of the Enlarged Board of Appeal has a very strong influence on the future practice and case law of the EPO on that particular subject-matter.

In the present case, the conflicting decisions concerned the patentability of diagnostic methods and, in particular, the interpretation of Art. 52(4) EPC (3), according to which *methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial applications within the meaning of paragraph 1*; that is, they are not considered patentable inventions (4).

The established EPO case law, as set out by decision T 385/86 (5), held in fact 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*. Which, in turn, was only the case if the claimed method contained all steps involved in reaching a medical diagnosis that is: 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 Art. 52(4) EPC.

Departing from this interpretation, decision T 964/99 (6) 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. Art. 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 the exclusion from patentability 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*. In particular, decision T 964/99 pointed out that the requirement of 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 only if they comprised one single step of a surgical or therapeutic nature.

For this reason, on December 29, 2003, the President of the EPO referred the

On December 16, 2005, the Enlarged Board of Appeal of the European Patent Office (1) issued the opinion G 1/04 on the patentability of diagnostic methods. In this opinion, the Enlarged Board of Appeal essentially concluded in favour of the patentability of diagnostic methods wherein not all the claimed essential technical steps are performed on the human or animal body, thus apparently confirming the established case law of the EPO according to which the exclusion from patentability of diagnostic methods must be interpreted narrowly.

following point of law to the Enlarged Board of Appeal:

- 1a. Are “diagnostic methods practised on the human or animal body” within the meaning of Art. 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 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 practised 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 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?

## REASONS FOR THE OPINION

In order to provide the requested opinion, the Enlarged Board of Appeal firstly defined the expressions *diagnostic*

*methods* and *practised on the human or animal body*. In particular, the Board specified that “diagnostic methods referred to in Art. 52(4) EPC” do not comprise only the deductive medical or veterinary decision phase consisting in attributing the detected deviation to a particular clinical picture, but they also include one or more of the preceding steps related to examination, data gathering and comparison.

As the Board explained, diagnosis is the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology; otherwise stated, diagnosis is an intellectual exercise and, accordingly, it is not regarded as a patentable invention within the meaning of the EPC. Consequently, since diagnostic methods referred to in Art. 52(4) EPC are inventions within the meaning of Art. 52(1) EPC, 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 of technical nature, in order to satisfy the requirements of Art. 52(1) EPC.

As to the issue of what has to be “practised on the human or animal body”, the Board stated that a narrow interpretation of the scope of the exclusion presupposes that Art. 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 are performed on a living human or animal body, whereas a broad interpretation 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.

In this connection the Board observed that Art. 52(4) EPC 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, 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. From this it follows that, for reasons of legal

certainty, the European patent grant procedure may not be rendered dependent on the involvement of such practitioners and that a narrow interpretation of the scope of the exclusion from patentability appears therefore to be equitable.

The Board also pointed out that Art. 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 should 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 Art. 52(4) EPC.

The Board went on observing that methods of surgery within the meaning of Art. 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 Art. 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 EPO case law, a method claim falls under the prohibition of Art. 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 Art. 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 Art. 84 EPC.

Diagnostic methods, however, differ in this respect from the methods of surgery and therapy. The method steps to be carried out prior to making a diagnosis as an intellectual exercise are related to examination, data gathering and comparison. 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. It follows that, while the surgical or therapeutic nature of a method claim can be achieved by a single method step, several method steps are required to define a diagnostic

method due to the inherent and inescapable multi-step nature the method itself. 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 by the EPO case law for methods of surgery or therapy.

Therefore, if diagnosis is a purely intellectual exercise, 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 Art. 52(4) EPC. Thus, in order to satisfy the requirements of Art. 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, the above-mentioned requirements would not be met.

Secondly, as the Board stated, the criterion "practised on the human or animal body" is to be considered only in respect of method steps of a technical nature and it does not apply to 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 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.

The scope of the exclusion from patentability under Art. 52(4) EPC in respect of diagnostic methods is therefore to be interpreted in a narrow manner. 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 Art. 52(4) EPC, the claim is to include the feature pertaining to the diagnosis for curative purposes as a purely intellectual exercise representing the deductive medical or veterinary decision phase, as well as the features relating to (i) the preceding steps which are constitutive for making the diagnosis, 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.

In view of the above arguments the Enlarged Board of Appeal answered as

follows to the referral made by the President of the EPO:

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 Art. 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 Art. 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 Art. 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. *Art. 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.*

## CONCLUSIONS

Although, contrarily to the standards of the Enlarged Board of Appeal, the G1/04 opinion appears to be a little bit confusing, in particular as far as the reasons are concerned, it essentially confirmed the established case law of the EPO according to which diagnostic methods wherein not all essential technical steps are performed on the human or animal body are patentable.

In particular, the Enlarged Board of

Appeal made clear that diagnostic treatments always include:

- i) the examination phase involving the collection of data;
- ii) the comparison of these data with standard value;
- 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.

It follows therefore that methods for obtaining intermediate results or findings of diagnostic relevance are not excluded from patentability; furthermore, the exclusion from patentability does not depend on the participation of a medical or veterinary practitioner to the method itself.

Consequently, in cases where the examination phase involving the collection of data (i) is performed on the human or animal body, it is up to the patent agent or attorney to draft claims which do not include additional steps such as the comparison of the data with standard values (ii), the finding of a significant deviation (iii) or the attribution of the deviation to a particular clinical picture (iv).

For instance, a claim limited to a method for measuring the quantitative expression of an isolated variable, such as the temperature or pH value within a give part of a human or animal body, shall be considered allowable by EPO examiners. This however should in principle apply only to situations where the nature of the disease is not immediately clear from the obtained value; if this is not the case, in fact, examiners might reasonably argue that subsequent steps i) to iv) are implicitly included and, consequently reject the claim for non compliance with the EPC. On the other hand, when the examination phase i) is not performed on the human or animal body, as for instance *in vitro*, the presence of steps ii), iii) and iv) should not affect the patentability of the claims.

The future application of this opinion by examiners and Boards of Appeal of the EPO will further clarify possible doubts about what constitutes a diagnostic method "practised on the human or animal body" within the meaning of the EPC.

## REFERENCES AND NOTES

- 1) Hereinafter referred to as EPO
- 2) Art. 22 and Art. 112 EPC
- 3) European Patent Convention
- 4) This exclusion does not apply to products, in particular substances or compositions, for use in any of these methods
- 5) *O.J. EPO 1988*, 308
- 6) *O.J. EPO 2002*, 4