J.A.KEMP & CO.

CIRCULAR

PATENTABILITY OF DIAGNOSTIC METHODS AT THE EUROPEAN PATENT OFFICE

Summary

The extent to which claims directed to diagnostic methods are allowable before the European Patent Office (EPO) was resolved by opinion G 1/04 of the Enlarged Board of Appeal. G 1/04 sets out the circumstances under which diagnostic methods are considered patentable at the EPO.

Based on G 1/04, it appears that most methods carried out for diagnostic purposes will now be considered patentable by the EPO. In order to be excluded from patentability, two requirements must be met. Firstly, the method must include all the steps necessary to reach a medical decision on diagnosis. Secondly, all the technical steps of the method must require the presence of the human or animal body. Only if both of these requirements are met will a method be excluded from patentability as a diagnostic method. It is irrelevant whether or not the method requires the participation of a medical or veterinary practitioner.

Introduction

During the drafting of the original European Patent Convention ("EPC1977"), exclusions were included in Article 52(4) EPC1977 (see Annex I) specifying that methods of therapy, surgery and diagnosis carried out on the human or animal body were not considered to be susceptible of industrial application and were therefore not patentable. These exclusions were introduced on socio-ethical and public health grounds to ensure that medical and veterinary practitioners remained free to take action necessary to treat or diagnose illnesses.

As a result of questions referred by the President of the EPO, the Enlarged Board of Appeal issued decision G 1/04 to clarify the breadth of the exclusion relating to diagnostic methods practised on the human or animal body. The conclusions of the Enlarged Board of Appeal are set out in Annex II.

A revised version of the European Patent Convention ("EPC2000") came into force in December 2007. Article 53(c) EPC2000 is similar in scope to Article 52(4) EPC1977 (see Annex I). The Enlarged Board of Appeal indicated in G1/04 that the implementation of EPC2000 would not alter the legal position in relation to diagnostic methods because the changes made to the relevant provisions of the EPC were purely editorial. The opinion given in G1/04 in relation to Article 52(4) EPC1977 will therefore also apply under Article 53(c) EPC2000.

What constitutes a "diagnostic method"?

The Enlarged Board stated in G 1/04 that, because it is an exclusion, the scope of Article 52(4) EPC1977 should be interpreted narrowly. The Enlarged Board noted that a number of steps need to be carried out in a diagnostic method. These include:

(i) an 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 that deviation or symptom to a particular clinical picture, i.e. the diagnosis.

The Enlarged Board stated that a diagnostic method excluded from patentability by Article 52(4) EPC1977 must include all the steps necessary to gather data, analyse the data, and draw a diagnostic conclusion. The method must therefore contain all of steps (i) to (iv) above. In particular, in order to be excluded from patentability, a claim to a diagnostic method must result in a deductive medical decision in which the detected deviation is actually attributed to a particular clinical picture.

If a method lacks even one of steps (i) to (iv), then there is no diagnostic method within the meaning of Article 52(4) EPC1977. Rather, the Enlarged Board said that such a method was at best a method of data acquisition or data processing that could be used in a diagnostic method. Such methods are patentable. Similarly, a method which gives only intermediate results that may be of diagnostic significance does not fall within the exclusion of Article 52(4) EPC1977 if no actual diagnosis is obtained.

However, the Enlarged Board made it clear that the exclusion under Article 52(4) EPC1977 cannot be avoided simply by excluding essential steps from a claim. Under EPO practice, an independent claim must include all the essential features needed to define the invention. Where the invention is a diagnostic method, that includes non-technical features such as drawing a conclusion or reaching a diagnosis on the basis of any deviation that is found when data collected from a patient is compared with standard values.

The Enlarged Board noted that the essential features of a claim are determined by considering the disclosure of the application as a whole and that, if the description makes it clear that a method includes essential steps not specified in a claim, these steps should be included in the claim. For example, where the clinical diagnosis is immediately evident from the results of the method, the step of making the diagnosis is an essential feature of the claim and the exclusion under Article 52(4) EPC1977 cannot be avoided simply by omitting that step from the claim.

Involvement of a medical or veterinary practitioner

In view of the rationale underlying Article 52(4) EPC1977, i.e. that patents should not hinder the activities of medical practitioners in treating and diagnosing patients, it had previously been suggested that a key feature determining whether a method claim fell within the exclusion of Article 52(4) EPC1977 was whether the method included steps that would be carried out by a medical or veterinary practitioner.

The Enlarged Board disagreed with this approach. The Enlarged Board noted that it is not practical for the EPO to determine who should or should not be considered a relevant practitioner under all the various healthcare systems in Europe. The introduction of such a requirement would introduce legal uncertainty.

The Enlarged Board concluded that the classification of a method as diagnostic should not depend on who is involved in carrying out the method. In particular, they noted that whether a method is a diagnostic method within the meaning of Article 52(4) EPC1977 should not depend either on the participation of a medical or veterinary practitioner or on whether all the method steps could also, or only, be practised by medical or technical support staff, by the patient themself or by an automated system.

"Practised on the human or animal body"

The Enlarged Board noted that Article 52(4) EPC1977 does not specify a required degree or intensity of interaction with the body. Steps in a diagnostic method may be invasive (e.g. taking a blood sample from a patient) or non-invasive (e.g. taking an X-ray). The Enlarged Board held that a method step satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the body, whether invasive or non-invasive, so long as the presence of the body is necessary for the step to be carried out.

The Enlarged Board further specified that, in order to fall within the exclusion of Article 52(4) EPC1977, all method steps of a technical nature should be "practised on the human or animal body". This means that the performance of each and every step which is not purely intellectual in nature should involve an interaction with the body, necessitating the presence of that body. A claim to a diagnostic method in which at least one technical step is carried out separately from the body, for example by using a specific software program on a computer or by carrying out a step *in vitro* on a sample of tissue obtained from the body, will therefore not be excluded from patentability by Article 52(4) EPC1977.

Surgical method steps

Some diagnostic methods incorporate steps that involve an invasive interaction with the human body, for example taking a blood sample or administration by injection. Such a step is undoubtedly a step of a technical nature "practised on the human or animal body". As discussed above, it will therefore depend upon the nature of the other steps of the claimed method to determine whether the method as a whole is excluded from patentability under Article 53(c) EPC2000 as being a diagnostic method.

Article 53(c) EPC2000 also excludes from patentability "methods of treatment of the human or animal body by surgery". EPO Examiners generally consider "surgery" to encompass any invasive procedure, including injections and the removal of blood. Such invasive steps may therefore give rise to objections under Article 53(c) EPC2000 as being surgical steps that exclude the claimed methods from patentability

The exact scope of this exclusion of surgical methods is currently unclear. In particular, it is unclear whether this provision excludes all methods that include steps of a surgical nature or only those methods where the surgical steps are carried out as part of a method of treatment. In view of this lack of clarity, a number of questions have been referred to the Enlarged Board of Appeal in case G1/07. The specific questions that have been referred are set out in Annex III. A decision from the Enlarged Board of Appeal on these issues is awaited.

Use-limited product claims

In addition to diagnostic method claims, it is also possible to obtain product claims in Europe directed to a substance or composition for use in diagnosis. Thus:

- Under Article 54(4) EPC2000 (see Annex I), where a product has not previously been used for a diagnostic purpose, it is in principle possible to obtain a broad "first diagnostic use" claim that refers to any diagnostic use of the product. A suitable claim may be drafted in the format "substance or composition X for use in a diagnostic method practised on the human or animal body".

- Under Article 54(5) EPC2000 (see Annex I), where a specific new diagnostic use has been invented for a product that may or may not have been previously used for a diagnostic purpose, a claim may be directed to the product for use in the specific diagnostic method. A suitable claim may be drafted in the format "substance or composition X for use in [specific diagnostic method]".

Recommendations

1. If any technical step of a claimed method is carried out in the absence of the body, then the method should not be considered a diagnostic method excluded from patentability by Article 53(c) EPC2000. The exclusion under Article 53(c) EPC2000 can thus be avoided, for example, if a method claim includes at least one *in vitro* step of a technical nature. Where possible we recommend that explicit basis is included in patent applications specifying that one or more of the technical steps of a diagnostic method may be carried out *in vitro*.

2. Methods that do not lead to an actual diagnosis of a clinical picture, for example methods of collecting data or methods which will lead to results of diagnostic relevance but not an actual medical diagnosis, are not excluded from patentability under Article 53(c) EPC2000. We recommend that, as a precaution, where such methods are claimed, the word "diagnosis" is avoided in the claims.

3. Care should be taken to include all "essential features" of an invention in the claim. It should not be possible to avoid the exclusion under Article 53(c) EPC2000 simply by excluding one step of a diagnostic method if it is clear from the application as a whole that the excluded step is an essential feature of the method. It may be helpful when drafting new applications to include basis for one or more of these steps being optional. It may also be helpful to include basis for a claim to a method of collecting or analysing data which explicitly omits one or more of the steps (i) to (iv) described above.

4. Method steps that relate to invasive procedures such as the removal of blood or the injection of an agent to a patient may lead to the method being excluded from patentability as a surgical method. Until this issue is clarified by the Enlarged Board of Appeal, we recommend that such steps are not included in method claims where possible. For example, claims can be amended to refer to a sample from a patient rather than setting out a particular step of obtaining the sample. For claims that refer to administration of a diagnostic agent to a patient it may be possible to draft use-limited product claims as discussed above based on the particular diagnostic agent.

J. A. Kemp & Co — November 2008

14 South Square, Gray's Inn
London WC1R 5JJ
Telephone +44 20 7405 3292
e-mail mail@jakemp.com
website www.jakemp.com

ANNEX I - Legal Provisions

Article 52(4) EPC1977 - Patentable inventions

(4) 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 application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 53(c) EPC2000 - Exceptions to patentability

European patents shall not be granted in respect of:
...
(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 54 EPC2000 - Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

ANNEX II - Conclusions of the Enlarged Board of Appeal in G 1/04

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.

ANNEX III - Referral by the Technical Board of Appeal to the Enlarged Board of Appeal dated 23 April 2007 (G 1/07)

The following questions are referred to the Enlarged Board of Appeal:

1. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04), which comprises or encompasses a step consisting in a physical intervention practised on the human or animal body (in the present case, an injection of a contrast agent into the heart), to be excluded from patent protection as a "*method for treatment of the human or animal body by surgery*" pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?

2. If the answer to question 1 is in the affirmative, could the exclusion from patent protection be avoided by amending the wording of the claim so as to omit the step at issue, or disclaim it, or let the claim encompass it without being limited to it?

3. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04) to be considered as being a constitutive step of a "*treatment of the human or animal body by surgery*" pursuant to Article 52(4) EPC if the data obtained by the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention?