The Exclusion from Patentability of Diagnostic Methods at the European Patent Office

Article 53(c) of the European Patent Convention (EPC) specifies various exceptions to patentability, one of which includes: *"diagnostic methods practised on the human or animal body"*. In Decision G1/04[1], the Enlarged Board of Appeal identified the requirements that must both be met for a diagnostic method claim to be excluded from patentability.

What Constitutes a "Diagnostic Method"?

In G 1/04, the Enlarged Board noted that a number of steps need to be carried out in a diagnostic method. These include:

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

A diagnostic method excluded from patentability must include ***all*** the steps necessary to gather data, analyse the data, and draw a diagnostic conclusion. If a method lacks even one of steps (i) to (iv), then there is no diagnostic method within the meaning of Article 53(c) EPC. Such a method is 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 that gives only intermediate results that may be of diagnostic significance does not fall within the exclusion of Article 53(c) EPC if no actual diagnosis is obtained.

Following the reasoning in G 1/04, the EPO's Technical Boards of Appeal have subsequently found a number of inventions in this field to be patentable because they are methods of data acquisition that do not lead to the diagnosis of a clinical picture. These include a method of determining ear temperature (T 1255/06[2]), a method of measuring a (non-specified) parameter in a sample (T 330/03[3]), a method of imaging an artery in a patient using magnetic resonance imaging (T 663/02[4]) and a method of detecting regional variations in oxygen uptake from the lungs (T 990/03[5]).

However, the Enlarged Board made it clear in G 1/04 that the exclusion for diagnostic methods cannot be avoided merely by drafting claims that omit one or more of the steps (i) to (iv) if those steps are in fact essential for properly carrying out the invention disclosed. Under EPO practice, an independent claim must include all the essential features needed to define the invention. If the application as originally filed makes it clear that a method includes further essential steps that are not specified in a claim, these steps should be included in the claim.

For example, decision T 125/02[8] related to methods for ascertaining lung function by measuring changes in the nitrogen monoxide content of exhaled air. The Board considered that it was clear from the description and the dependent claims that this method was to be used to identify impaired lung function, i.e. to diagnose a clinical picture. The methods were therefore excluded from patentability. Similarly, in decision T 143/04[9] the claims as originally filed were directed to a method of diagnosing Alzheimer's disease. The applicant amended the claims to include only the examination phase (i) and to remove references to a comparison and diagnosis. The Board did not allow this amendment because the application as filed did not describe an independent data collection method, only a method of diagnosis that included those data collection steps.

Moreover, section G-II, 4.2.1.3 of the EPO Guidelines for Examination[6] notes that due account should be taken of steps which may be considered to be implicit. For example, the presence of step (ii) in a claim (comparing data with standard values) may be deemed to imply the finding of a significant deviation, i.e. step (iii). Indeed, in T 1197/02[7], the Board noted that the comparison of collected thresholds with standard values exhibited by subjects of normal vision (in a method of assessing the presence of glaucomatous damage to the visual system of a subject) implied the finding of a significant deviation resulting from the comparison, i.e. the symptom.

Involvement of a Medical or Veterinary Practitioner

The original rationale for excluding methods of diagnosis from patentability was that patents should not hinder the activities of medical practitioners in treating and diagnosing patients. However, the Enlarged Board noted in G 1/04 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 Enlarged Board therefore concluded that the classification of a method as an excluded diagnostic method should not depend on who is involved in carrying out the method.

"Practised on the Human or Animal Body"

Article 53(c) EPC refers to diagnostic methods *"practised on the human or animal body"*. The Enlarged Board held in G 1/04 that a method step is deemed to be 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 be excluded from patentability as a method of diagnosis, all the 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, requiring 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 carrying out a step *in vitro* on a sample of tissue obtained from the body, will therefore not be excluded from patentability under Article 53(c) EPC.

For example, in T 666/05[10], the patent claimed methods for diagnosing a predisposition for breast cancer by looking for a mutation in the BRCA1 gene in a tissue sample from the subject. All the technical steps of this method were performed on an *in vitro* tissue sample, not on the subject. This method was therefore found not to be excluded from patentability under Article 53(c) EPC.

Only technical steps that form part of steps (i) to (iv) are to be considered. The steps of phases (ii) and (iii) that consist of comparing the data collected in the examination phase with standard values and finding a significant deviation resulting from the comparison are not subject to this criterion, because these activities are predominantly of a non-technical nature and are normally not practised on the human or animal body. The exclusion cannot be avoided by including additional technical steps that do not require the presence of the human or animal body if those additional steps do not form part of steps (i) to (iv) as set out above.

In decisions T 1197/02[7], T 143/04[9] and T 1016/10[11], the claims included additional intermediate steps carried out between the data collection and the comparison of the collected data with standard values. In these decisions, the Boards considered that such additional steps may be included in a claim for completeness, but only the steps (i) to (iv) as set out above are essential to identify a diagnostic method. It is therefore irrelevant whether the additional steps are carried out in the presence of the human or animal body.

Surgical Methods

Some diagnostic methods incorporate procedures that involve an invasive interaction with the human body, for example taking a blood sample or administration by injection. When considering such diagnostic methods, it is necessary to consider not only the exclusion for diagnostic methods but also the exclusion for surgical methods. In particular, Article 53(c) EPC also excludes from patentability *"methods of treatment of the human or animal body by surgery"*.

The Enlarged Board indicated in their decision G 1/07[12] that invasive method steps representing a substantial physical intervention on the body which require professional medical expertise to be carried out and which entail a health risk, even when carried out using such expertise, will be excluded from patentability under Article 53(c) EPC as being surgical steps. This is discussed further in our separate briefing paper on surgical methods[13]. A method will be excluded under this provision if it includes or encompasses a single such surgical step.

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. In particular, under Article 54(4) EPC, 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) EPC, 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]"*.

Conclusions and 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) EPC. The exclusion can thus be avoided by, for example, specifying that at least one technical step is carried out *ex vivo*. Where possible, we recommend that explicit basis is included when patent applications are drafted specifying that one or more of the technical steps of a diagnostic method may be carried out *ex vivo*.
2. Methods that do not lead to the diagnosis of a clinical picture are not excluded from patentability under Article 53(c) EPC. For example, methods of data collection based on step (i) above should be patentable. Similarly, a method of data collection or analysis that does not include step (iv) above will often be patentable. We recommend that, as a precaution, where such methods are claimed, the word "diagnosis" is avoided in the claims.
3. When drafting patent applications in this field under circumstances where all relevant steps are carried on the body, care should be taken to avoid giving the impression that all of steps (i) to (iv) set out above are essential for properly carrying out the invention. Thus, explicit basis should be provided for a claim which lacks one of steps (i) to (iv), and ideally some explanation should be provided as to why it is possible to practise the invention without that step.
4. Method steps that relate to substantial invasive procedures may lead to the method being excluded from patentability as a surgical method. For claims where the surgical step is not essential to the invention, this exclusion may be avoided by omitting the surgical step from the claim. For example, language such as *"pre-implanted"* or *"pre-delivered"* may be used to avoid the exclusion.
5. If a claimed process does constitute a diagnostic method, it may be possible to draft a use-limited product claim directed to a known substance or composition for use in the specified diagnostic method.

Footnotes

1. G 1/04 16-12-2005
2. T 1255/06 23-09-2008
3. T 330/03 07-02-2006
4. T 663/02 17-03-2011
5. T 990/03 19-10-2006
6. G-II, 4.2.1.3 of the EPO Guidelines for Examination

7. T 1197/02 12-07-2006

8. T 125/02 23-05-2006

9. T 143/04 12-09-2006

10. T 666/05 13-11-2008

11. T 1016/10 11-04-2014

12. G 1/07 15-02-2010

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