

Decision on Diagnostic methods (G-1/04)
(European Patent Office, Enlarged Board of Appeal, 16 December 2005)

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Summary

The Enlarged Board of Appeal (EBoA) decided that as a matter of principle, a European patent is to be granted for an invention which meets the patentability criteria, and, as such, the principle of a narrow interpretation is to apply to clauses excluding patentability, for instance of diagnostic methods. For a method to be considered a diagnostic method, it must include all the steps relating to it. There is no diagnostic method if one of the steps is lacking. Hence, such claims are excluded if they include the feature relating to all the diagnostic steps and involve interactions with the human or animal body.

Facts

Article 52(4) of the European Patent Convention (EPC) (after EPC revision now Article 53(c)) excludes from patentability methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. In 2003, the President of the European Patent Office sought clarity from the Enlarged Board of Appeal (EBoA) on the scope of the exclusion, pointing out a number of conflicting decisions of the EBoA on the issue. Third parties submitted their arguments favouring a narrow or broad interpretation of the patent exemption for diagnostic methods.

Legal issues

The case involved defining what a diagnostic method is, for the purpose of determining when it should be excluded. It also includes secondary issue on the standard for the interpretation of provisions providing for exclusion of a subject matter from patentability. The EBoA observed that diagnostic methods are inventions – patentable subject matter – that are excluded based on socio- ethical and public health considerations. Medical and veterinary practitioners should be free to take the actions they consider suited to diagnose illnesses by means of investigative methods. The EPC lays down the fundamental maxim of a general entitlement to patent protection to the effect that, as a matter of principle, a European patent is to be granted for an invention which meets the patentability criteria, and, as such, the principle of a narrow interpretation is to apply to exclusion clauses.

The Concept of Diagnostic Methods

The EBoA noted that according to the established jurisprudence, the method steps to be carried out when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes include:

- (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.

The first three are ‘preceding steps’ towards the last step that represents the actual diagnosis for curative purpose. The question is whether the diagnostic methods referred to in the EPC comprise only the fourth (the deductive medical or veterinary decision phase) *stricto sensu* or whether they are also meant to include one or more of the preceding steps related to examination, data gathering and comparison. In this respect, first the EBoA ruled that as the deductive medical or veterinary decision phase (iv), diagnosis for curative purposes is an intellectual exercise – a step of a non-technical nature. For the deductive decision phase – the non-technical intellectual exercise – to be regarded as an invention under the EPC, it needs to include the preceding steps (i-iii) that are of a technical nature. In addition, Article 52(4) EPC does not make reference to particular steps pertaining to diagnostic methods, nor does it contain a wording such as "relating to diagnosis" or "of value for diagnostic purposes". Hence, for a method to be considered a diagnostic method, it must include all the steps relating to it. 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.

The EBoA further elaborated how diagnostic methods differ from surgical and therapeutic methods that are also excluded from patentability. A method claim falls under the exclusion of Article 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. It follows that the surgical or therapeutic nature of a method claim can perfectly be established by a single method step. However, the same cannot be said with respect to diagnostic methods. Whilst 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 within the meaning of Article 52(4) EPC due to the inherent and inescapable multi-step nature of such a method.

“Practiced” on Human or Animal Body

According to Article 52(4) of the EPC, the diagnostic methods have to be practised on the human or animal body be excluded from patent protection. The EBoA first ruled that the exclusion relates only to the ‘method’ and not to the person carrying out the method.

Secondly, the criterion "practised on the human or animal body" is to be considered only in respect of method steps of a technical nature. Thus, it does not apply to the diagnosis for curative purposes *stricto sensu*, i.e. the deductive decision phase (iv), 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. However, Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body. Thus, each of the method steps of a technical nature is either invasive or non-invasive, and the performance of each one of the steps may or may not involve the use of data collecting devices and/or diagnostic equipment for measurement and analysis purposes.

It follows that each and every one of these method steps 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. Conversely, if some or all of the method steps of a technical nature are carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, these steps may not be considered to satisfy the criterion "practised on the human or animal body", because their performance does not necessitate the presence of the latter. By the same token, this criterion is neither complied with in respect of method steps carried out in vitro in a laboratory. This also covers method steps carried out in vitro by diagnostic devices known as DNA microarrays. Therefore, what is justifiable in the context of the narrower interpretation principle is that all method steps of a technical nature should satisfy the criterion "practised on the human or animal body", i.e. the performance of each and every one of these steps should imply an interaction with the human or animal body, necessitating the presence of the latter.

Points of Significance

1. Note that the exclusion of diagnostic, therapeutic and surgical method does not prevent the patenting of product patent on substances and devices used for the same purposes.
2. Diagnostic methods are patentable when the method is carried out separately from the human or animal body. In this case, the EBoA allowed patenting of methods carried out on human or animal body if not all the method steps to be carried out when making a diagnosis involve interaction with the human or animal body. The decision in effect allowed patenting of methods carried out during the diagnostic steps (taken separately), for example, to collect clinical data. The EBoA confirmed the possibility for a patent claim to be construed in a manner that avoids a subject matter excluded from patent protection, provided that the claims explicitly specify all of the essential features needed to define the invention.
3. Some argue that the decision rendered the exclusion of diagnostic methods from patentability under the EPC redundant.¹

Keywords: ‘diagnostic method;’ ‘surgical method;’ ‘therapeutic method;’ exclusion.

Available at: <http://www.epo.org/law-practice/case-law-appeals/recent/g040001ep1.html>

¹ See, Sterckx, Sigrid and Julian Cockbain, Exclusions from Patentability: How Far Has the European Patent Office Eroded, Cambridge Intellectual Property and Information Law, Cambridge, 2012, 156.