Like the USPTO, the European Patent Office (EPO) considers that the discovery of a natural phenomenon is not patent eligible. However, unlike the USPTO, the EPO takes the view that a patentable invention can derive from a practical use of that discovery (EPO Guidelines for Examination G-II, 3.1), such as its use in a method of diagnosis. For example, the discovery of a naturally-occurring correlation between a biomarker and a disease can be put to a practical use in the form of a method for diagnosing the disease. A claim directed to a method of diagnosing the disease involving detecting the presence or amount of that biomarker may therefore be patentable at the EPO, even if the underlying naturally-occurring correlation is not patentable.

The main issue with diagnostic methods at the EPO is not their reliance on naturally-occurring products or effects, but instead is a general exclusion from patentability of diagnostic methods that are practiced on the human or animal body (Article 53(c) EPC). In practice, a claim to a method of diagnosis is not patentable in Europe if:

- the method is carried out on the human or animal body, and
- it includes (explicitly or implicitly) all the steps of collecting data, comparing the data with standard values, finding a deviation from normal (a symptom), and attributing that deviation/symptom to a clinical picture (i.e. making a diagnosis) (decision G1/04).

A method that avoids any of these requirements is not considered to be a diagnostic method that is practiced on the human or animal body, and so that method is patent eligible at the EPO.

If the technical steps of the claimed diagnostic method can be carried out separately from the body, then the method can be patent eligible at the EPO. For example, a diagnostic method that is carried out on an in vitro tissue sample is not carried out on the human or animal body so can be patented (decision T666/05).

Similarly a method that merely provides information or intermediate results, without actually leading to a diagnosis of what is wrong with the patient, is not a method that attributes the information to a clinical picture and so can be claimed at the EPO. Examples of such methods that do not reach a final diagnosis include a method of determining ear temperature (decision T1555/06) and a method of imaging an artery in a patient by MRI (decision T663/02).

However, a claim to a diagnostic method cannot be made patentable by omitting one or more steps in the claim, if it is clear that those steps are actually essential for carrying out the method. A method of ascertaining lung function by measuring changes in the nitrogen monoxide content of exhaled air was found to be an excluded method of diagnosis because it allowed the user to directly diagnose impaired lung function (decision T125/02). It is also
necessary for any claimed method to be suitably described in the application as originally filed. In decision T143/04, the EPO would not allow conversion of an unallowable diagnostic method claim to an allowable data collection method by removing the comparison and diagnosis steps, because the application as filed did not provide formal support for a method that did not include those steps, only for the full method of diagnosis.

In addition, some methods that fulfil all the requirements for an excluded method of diagnosis may still be patented at the EPO by using other claim formats. Article 53(c) EPC notes that although diagnostic methods practiced on the human or animal body are not patentable, substances or compositions for use in such methods may be patented. When a method of diagnosis cannot be patented at the EPO, it may still be possible to draft a patentable claim in the format “[substance or composition] for use in a method of [specific method of diagnosis]”, as long as a suitable substance or composition can be identified in the method. If the method uses a device or apparatus, rather than a substance or composition, then this claim format is not available, but the exclusion of Article 53(c) EPC can be avoided by claiming the device or apparatus per se, rather than claiming a method of using the device. When the method uses computer-aided diagnosis, it may be possible to claim a computer system configured to perform the diagnostic method.

The approach to patenting diagnostics is therefore very different in Europe to that in the United States, and many methods that may receive objections under 35 USC §101 in the United States may have no such patent eligibility problems at the EPO. Diagnostic methods that are carried out on in vitro samples can be patented in Europe, as can methods that do not reach a diagnostic conclusion. Where an invention does relate to a method of diagnosis that is performed on the human or animal body, some claim types may still be patentable in Europe, as long as they were described in the patent application as originally filed. We recommend considering global claiming strategies when the patent application is drafted, so that suitable language can be included in the application to allow for filing such alternative claim types at the EPO in due course.

For more information on patent eligible subject matter in the United States and Europe, please see our webinar on Drafting the “Global” Patent Application.

Tags
European Patent Office (EPO), Patentability, first medical use, dosage claim, medical device, diagnostics, patent eligibility

Contacts

Hazel Ford Ph.D.
Partner, European Patent Attorney
London
+ 44 (0)20 7864 2820
Email

Philip L. Cupitt Ph.D.
Partner, European Patent Attorney
London
+44 (0)20 7864 2811
Email

Disclaimer: Although we wish to hear from you, information exchanged in this blog cannot and does not create an attorney-client relationship. Please do not post any information that you consider to be personal or confidential. If you wish for Finnegan, Henderson, Farabow, Garrett & Dunner, LLP to consider representing you, in order to establish an attorney-client relationship you must first enter a written representation agreement with Finnegan. Contact us for additional information. One of our lawyers will be happy to discuss the possibility of representation with you. Additional disclaimer information.