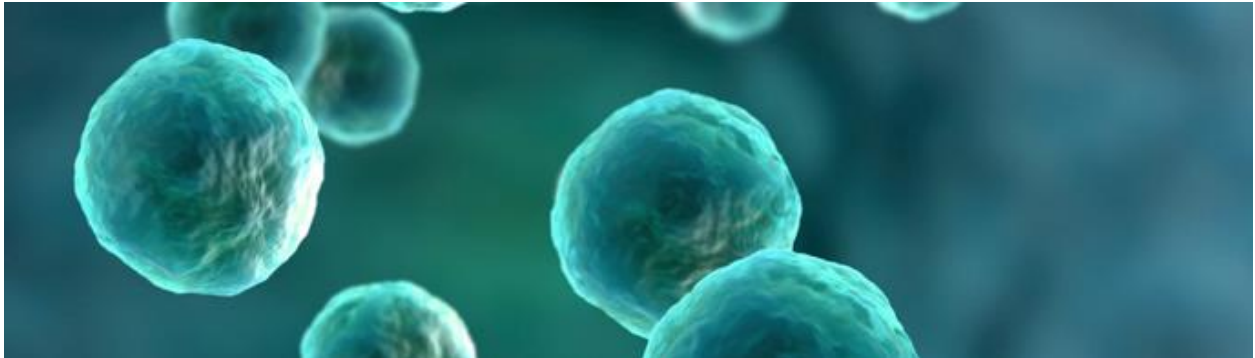


Biomarkers



A biomarker is any substance that can be used as an indicator of a disease. Examples of biomarkers include metabolites and gene expressions. Biomarkers are useful in selecting a patient population, and for monitoring the treatment of diseases.

In the European Patent Office (EPO), methods for treatment of the human or animal body are excluded from patentability under [Article 53\(c\) EPC](#). Moreover, a patent claim cannot simply cover the biomarker as it is found in nature, as this would be regarded as merely a discovery under [EPC Art. 52\(2\)](#). However, patent protection should be available in the EPO provided the biomarker is isolated and purified, or some other process has occurred that would not occur in nature. Acceptable patent claims relating to biomarkers may include claims to an isolated biomarker, other compounds used to detect the biomarker, methods of diagnosis using the biomarker, and medical uses made possible by the biomarker determination.

So long as methods of diagnosis using the biomarker are not practised on the human or animal body, they are generally patentable. The patent claims cannot cover steps that would be conducted by a medical professional in the course of their normal duties, nor can they cover steps which require intervention on the body (EPO decision [G 1/07](#)). In most cases, these exclusions can be overcome by careful patent drafting, for example, by excluding a step of taking a sample from a patient. Alternatively or additionally, *in vitro* diagnosis methods can be claimed (EPO decision [G 1/04](#)).

Patent claims to medical uses of a biomarker need to reference the biomarker and the disease being treated, and must be in standard EPO format for medical use claims (detailed in our AL Factsheet [First and Second Medical Uses](#)) in order to be acceptable (EPO decision [G 5/83](#)). This is still the case when a drug is already known for treatment of that disease, provided the means of diagnosis of the disease is novel (EPO decisions [T1399/04](#), [T836/01](#)). However, experimental evidence is required for showing that the method of diagnosis results in some improvement over previous methods. This will usually be an improvement in safety or efficacy of the treatment due to improved patient selection.

Patents related to biomarkers have proven to be commercially important and have been the subject of litigation. Examples of EP patents which relate to methods of diagnosis using biomarkers include [EP1115403B1](#) and [EP0699754B2](#) (the EP equivalents of the leading US cases *Mayo vs. Prometheus* case, and *AMP vs. Myriad*).

We have explained the general principles of biomarker-related patents in Europe in this AL Factsheet but it is only an introduction, and any live situation will need individual assessment. Please contact us if you need more detailed information.