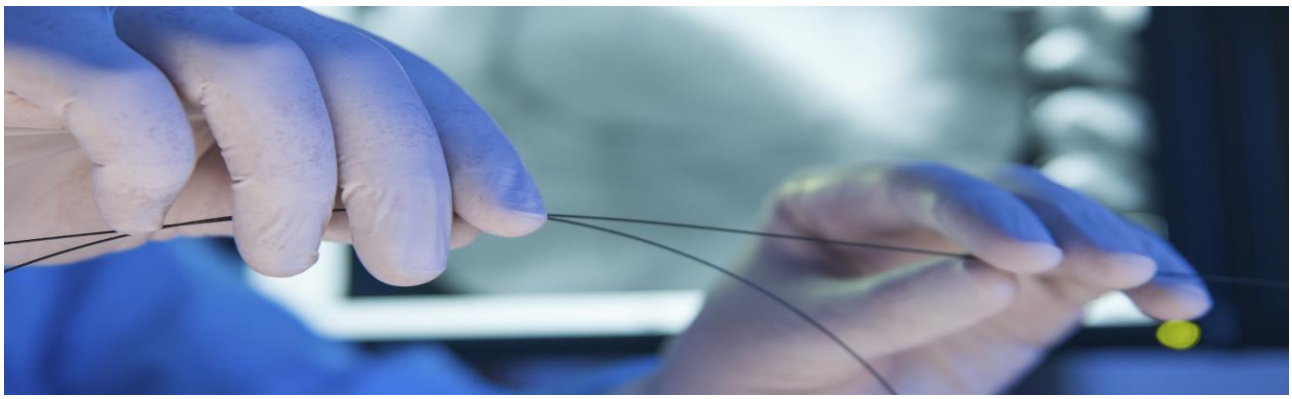
Biosensors



Biosensors are analytical devices that are used to detect a target chemical compound. Biosensors use a biological component, which interacts with the target chemical compound and a measurement component or transducer which transforms the interaction into a readable result.

Typically, biosensors include genetically modified nucleic acids or proteins (antibodies or enzymes, organelles or whole cells, etc.). Such genetically modified material can be held on a functionalised support, such as an array, electrode, or nanoparticle, and configured to bind to a target chemical. A signal is generated and subsequently detected by electronic components. A signal may be induced by electrons, ions, fluorescence, luminescence, or mechanical deformation. There have been many examples of biosensor usage in healthcare applications. It is believed that US3539455, relating to blood glucose sensors for diabetes sufferers, filed by the inventor Clark Leland C Jr. in 1970, was the first ever glucose biosensor patent. However, biosensors have applications in other sectors, including air and water quality, drug discovery and food analysis.

Patents granted by the European Patent Office (EPO) on biosensor inventions may contain apparatus or product claims and claims directed towards their methods of manufacture. When biosensors are used in a non-medical context their uses may also be claimed. However, claims to methods of treatment of the human or animal body by surgery, therapy or methods of diagnosis practised on the human or animal body using biosensors cannot be patented in the EPO (Art. 53(c) EPC). It is not possible to shore up the position by using the types of medical use claims the EPO accept for medical substances, as described in AL Factsheet Patenting First and Second Medical Uses. They do not apply to medical uses of biosensors.

However, some diagnostic methods may be patentable. The EPO established in decision G 1/04 that claims to diagnostic methods partly carried out *in vitro* may be allowed, as may claims to methods which are not part of a treatment regime carried out on a patient; for example, methods carried out for statistical purposes. There have been a number of later legal decisions allowing claims to diagnostic-type methods. One example is EP1070261A1, which claimed a method of detecting regional variations in oxygen uptake from the lungs using a hyperpolarized gas for MRI detection (T 990/03). The purpose was collection, and this method was held not to be excluded from patent protection. It can be seen that with careful patent preparation, certain biosensor-related medical use inventions may be patentable.

We have explained the general principles of protecting biosensors 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.