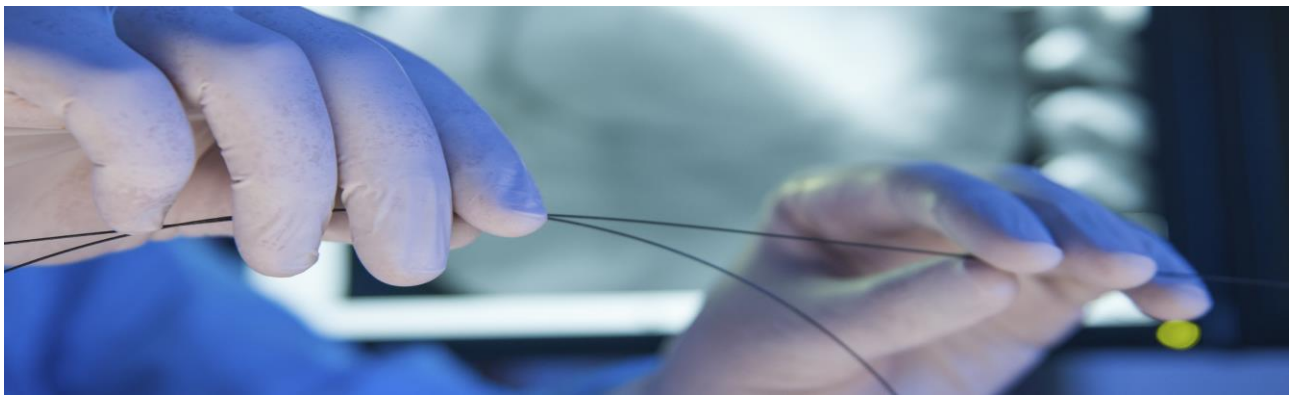
Medical devices



Broadly speaking, a medical device is any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, intended to be used to diagnose, monitor, treat or alleviate a disease or an injury. Medical devices may be used to investigate, replace or support the anatomy or a physiological process. Medical devices can support or sustain life, control conception or examine specimens *in vitro*. Medical devices do not achieve their purpose by pharmacological, immunological or metabolic means, but by physical, mechanical or thermal means, acting on the human or animal body. This is important: the European Patent Office (EPO) handles medical devices differently from medicinal compounds.

EP patents on medical device inventions usually contain apparatus or product claims and claims directed towards their methods of manufacture. However, claims to methods of using medical devices are restricted. In the EPO, 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 cannot be patented (Art. 53(c) EPC).

The EPO has attempted to clarify the 'medical method exclusions' in EPO decisions G 1/04 and G 1/07. It is now understood that a method claim is prohibited if it includes at least one feature that constitutes a method for treatment of the human or animal body by surgery or therapy. It does not have to be invasive, involving tissue penetration, to be an excluded method. In the case of surgery, it does not have to be curative surgery to be excluded. However, cosmetic hair or skin treatments could be patentable. A therapeutic treatment is unpatentable if it takes place outside the body prior to return, e.g. blood dialysis; whereas a method of treatment of blood for storage in a blood bank would be patentable. Contraceptive methods (not having a therapeutic aspect) could be patented since pregnancy is not an illness. In the case of diagnostic methods, the position is a little more permissive. 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.

Medicine will offer numerous varied advances, and it is certain that patent handling for medical device inventions is far from settled. Nevertheless, the current position can be summarised as follows:

- Many methods of using medical devices will not be patentable. It may sometimes be possible to include claims to methods of using a medical device, for example, when the intended use is not 'medical treatment' as the EPO views it.

- It is not possible to shore up the position by using the types of medical use claims the EPO accepts for medicinal compounds. It has been confirmed in a recent EPO decision T 0773/10 that these do not apply to medical devices.

- As a consequence of these restrictions, the objective in the EPO is usually to secure product claims to the medical devices themselves, including if possible their key features and manufacture.

EP patents directed to medical devices can last for a maximum of 20 years. There is some divergence between European countries as to whether Supplementary Protection Certificates (SPCs) can be granted, giving a further 5 years of protection for a medical device which has a marketing authorisation under the Medical *Devices* Directive. SPCs are established for medical compounds which have a marketing authorisation under the Medicinal *Products* Directive. The UK has refused to grant SPCs for medical devices, taking the view that an authorisation obtained under the Medical *Devices* Directive is not equivalent to one obtained under the Medicinal *Products* Directive. However, in Italy, France, the Netherlands and Germany, SPCs have been granted under the Medical *Devices* Directive. It appears that, for now, the valid granting of SPCs for medical devices in Europe is uncertain, but allowed in some countries, and will be decided on a country by country and case by case basis.

We have explained the general principles of protecting medical device inventions 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.