The European Patent Office’s (EPO’s) approach to patentability in the field of medicine is based on the underlying principle that medical and veterinary practitioners should be free to use their skills and their knowledge of the best available treatments to achieve the utmost benefit for their patients, uninhibited by any worry that some treatment might be covered by a patent (decision G1/07, Reasons 3.3.6). The European Patent Convention therefore includes a general exclusion for medical methods carried out on the body:

“European patents shall not be granted in respect of … methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body” (Article 53(c) EPC).

Despite this apparent exclusion for all surgical, therapeutic and diagnostic methods, it is possible in practice to protect many medical inventions under the European patent system. Although a “method of treatment” is not patentable in Europe, a substance or composition may be patented for a specific use in a method of surgery, therapy or diagnosis (Article 54(5) EPC). This leads to the “purpose-limited product” claim, having the format “[substance or composition X] for use in [medical method Y]”. Any method that would be excluded under Article 53(c) EPC can theoretically be presented in this claim format, as long as the method is based on the effect of a substance or composition. Such a claim can derive novelty and inventive step from the substance or composition that is used, or from the method that it is used in.

Where a substance or composition is used for the first time in medicine, either because the product itself is new, or because it has only been used before in non-medical methods, then it may be possible to obtain a “first medical use” claim in Europe, covering all possible medical uses of that product (Article 54(4) EPC). For example, a claim in the format “[substance or composition X] for use in a method of treating the human or animal body by therapy” might be used to protect all therapeutic uses of a new product.

Where a substance or composition has been used previously in medicine, a purpose-limited product claim may be used to protect a specific new method of use. The new use may be a new disease to be treated, or it may be a different treatment of the same disease previously treated by that product (decision G2/08). Novelty and inventive step can be based on the characteristics or steps of the method specified in the claim, such as a new dosage, a new route of administration, a new administration regimen or a new patient group. Such specific new methods can be protected by a claim in the format: “[substance or composition X] for use in a method of treating [disease Y], the method comprising [specific method]”.

Claims in the purpose-limited product format may only relate to methods that are excluded from patentability under Article 53(c) EPC. This includes methods for curing diseases, for symptomatic therapy, or for prophylactic treatment. The presence of a single step having a
therapeutic effect renders a method claim unpatentable, but opens up the possibility of redrafting as a purpose-limited product claim.

The purpose-limited product claim is not just for use in claiming therapeutic inventions, it can also be used to obtain protection for some diagnostic or surgical inventions that cannot be protected using method claims in Europe. For example, methods of diagnosis are not patentable at the EPO if the methods are carried out on the human or animal body, and they include (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). Methods of surgery are not patentable at the EPO if they are invasive methods involving a substantial physical intervention on the body, which require professional medical expertise, and where the surgery itself entails a substantial health risk, even when carried out with suitable expertise (decision G1/07). A purpose-limited product claim can be used to protect such diagnostic or surgical inventions as long as a suitable substance or composition used in the method can be identified.

If a therapeutic, diagnostic or surgical invention relates to a medical device or apparatus, rather than a substance or composition, then the purpose-limited product claim cannot be used, 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.

In practice, therefore, many medical methods that are not patentable at the EPO in a method claim format can still be patented by converting into a purpose-limited product claim or a claim to the product itself.

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

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