

An introduction to patenting biological and medical inventions in Europe



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Introduction

This article focuses on patents for biological and medical inventions. In so doing it addresses the reasons for obtaining patent protection and the types of biological and medical inventions that may be protected with a patent. It also reviews the requirements for patenting biological and medical inventions. The basic requirements are the same as those for any other invention; however, there are some important differences including specific exclusions and the provisions for protecting medical use type inventions.

Why do I need patent protection?

If an invention is protected by a granted patent, the patent provides the proprietor(s) with exclusive rights to prevent other parties making use of the patented invention. For example, in the UK where the patented invention is a product, the patent provides the right to prevent others from making, selling, offering (for sale) using, importing or keeping the patented invention. The patent proprietor, and in some cases a licensee, may enforce the rights conferred by a patent by taking legal action against anyone carrying out such activities without the proprietor's permission.

Clearly such rights are of enormous commercial importance, particularly in the biotech, pharmaceutical and medical device industries where huge research and development (R&D) investments are required in order to get a product to market. Therefore, it is important that such companies also establish strong patent portfolios so that they are able to control the exploitation of the inventions that they create. This control may take the form of exploiting the invention themselves, for example by manufacturing and selling a patented product, assigning or licensing the rights to 3rd parties, or a combination of these strategies.

If patent protection is not obtained for an invention, then the invention may be used by anyone without the permission of the individual or company that made the invention. Another way to control use of an invention is to keep it a secret, a so-called 'trade-secret'; however, this is clearly impractical for many inventions, for example those which are exploited to produce products (or are themselves products) for sale and whereby the invention may be understood and copied by person analyzing the publicly available product.

Despite the clear importance to many companies of obtaining a strong patent portfolio, it is important to realise that a patent does not provide 'freedom to operate'. It is possible for a patent proprietor, who sells a product protected by his patent, to infringe the rights of another patent proprietor. Consider a first patent for a pharmaceutical composition containing A+B. A second patent may be granted for new pharmaceutical composition containing A+B+C. However, the proprietor of the second patent will infringe the rights conferred by the first patent if he makes a product containing A+B+C, as this product would contain A+B (the composition protected by the first patent). In this situation, it may be necessary for the proprietor of the second patent to undertake a licence from the proprietor of the first patent in order to exploit his invention.

What biological and medical inventions can a patent protect?

Patents may be granted for a wide range of medical and pharmaceutical products including:

- therapeutics, for example small molecule drugs, vaccines, antibodies and recombinant proteins,
- diagnostic tools, for example nucleic acid probes, antibodies and kits, and
- apparatus, for example medical devices.

In addition, patents may be granted for new processes including:

- purification methods,
- screening methods, and
- *in vitro* diagnostic methods.

What are the main requirements for patentability?

There are specific legal provisions relevant to some biological and medical inventions, which are discussed below. However, it is important not to lose sight of the fact that such inventions must, like any other invention, meet the basic requirements for patentability.

To be patentable in the UK and Europe, an invention must be:

- New – an invention is new if it has not been disclosed to the public in any way (e.g. by written or oral communication, use etc.), anywhere in world, before the filing date of the application
- Inventive – an invention involves an inventive step if it would not have been obvious to the notional ‘skilled person’ at the filing date of the application (or the priority date, if the application claims priority from an earlier application) . The assessment must be made through the eyes of the ‘skilled person’ who was working in the relevant technical field at the time. To understand the “skilled person” in more detail it is necessary to consider the ‘common general knowledge’ as this is what makes the “skilled person” skilled. “Common general knowledge” is the technical background of the “skilled person” and includes all the material available at that time in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it; and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work
- Industrially applicable – an invention is industrially applicable if it can be “made or used in any kind of industry”. The UK courts have held that “*The notion of industry must be construed broadly. It includes all manufacturing, extracting and processing activities of enterprises that are carried out continuously, independently and for commercial gain*”... “*However, it need not necessarily be conducted for profit*” (Eli Lilly and Company v. Human Genome Sciences, Inc. [2008] EWHC 1903 (Pat)).

The test is whether the “skilled person” (with the benefit of the ‘common general knowledge’) can derive from the description of the patent (or patent application) that the invention is capable of industrial exploitation. Therefore, most inventions will satisfy this requirement. A notable exception is a gene sequence. Applications filed for gene sequences are refused if they do not contain sufficient details of the functions and applications of the gene sequence.

In addition to the positive requirements for patentability, there exist a number of exclusions which prevent certain subject matter and certain inventions from being patented.

What is excluded?

There are 4 main groups of exclusions:

1. Things that are not deemed to be inventions including discoveries, scientific theories, mathematical methods, literary works etc. For example, the fact that a known material is found to have a hitherto unknown property is a discovery (not an invention); however, if the

discovery leads to the conclusion that the material can be used for making a particular article or in a particular process, then the article or process could be patentable

2. Inventions, the commercial exploitation of which would be contrary to public policy or morality. For example, the cloning of humans, land mines etc. However, an invention is not excluded from patentability solely because an action or act that is part of the invention is prohibited by law or regulation in some or all of the member states of the European Patent Organisation
3. Some biotechnological inventions including:
 - a) The human body and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, although an isolated gene may be patented in conjunction with an (industrial) application of it;
 - b) Processes for cloning humans;
 - c) Processes for modifying the germ line genetic identity of humans;
 - d) Uses of human embryos for industrial or commercial purposes;
 - e) Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes; and
 - f) Any variety of animal or plant¹ or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process. Although plant varieties cannot be individually claimed, European case law indicates that it is possible to have a patent granted for transgenic plants, which does not identify specific plant varieties, but because of the technical nature of the invention does embrace certain plant varieties. For example, assuming the basic requirements for patentability were met, a patent could be granted for a transgenic plant expressing a particular soya protein. Such a patent would cover all plant varieties expressing that protein.
4. Methods of treatment of the human or animal body by surgery or therapy, and methods of diagnosis to be practiced on the human or animal body. These exclusions are aimed at preventing the law being used to interfere with the way in which a doctor or veterinary surgeon treats his/her patients.

¹ “*Plant variety*” is defined under the European Patent Convention (EPC) as “*any plant grouping within a single botanical taxon of the lowest known rank, which...can be: a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and c) considered as a unit with regard to its suitability for being propagated unchanged.*” – r.26(4).

However, the following are not excluded from patentability:

- Compositions and apparatus for use in such methods, as discussed below.
- Methods of diagnosis if they are performed on samples permanently removed from the human body.

It is not possible to protect subject matter or inventions that fall entirely within one or more of the above exclusions. However, where only part of the subject matter falls within an exclusion, it is often possible to craft patent applications which avoid the exclusions whilst still achieving protection for the desired invention. This is frequently the case for medical use inventions.

What is special about medical use inventions?

Substances or compositions for use in methods of medical treatment are patentable, even though the methods themselves cannot be patented. Moreover, a substance or composition may meet the requirements for patentability even if it is not new *per se*. It is possible to obtain patents for such compositions by using different forms of claim, so called first and second medical use claims. The extent of protection of a patent is determined by the claims, with the description and drawings of the patent being used to interpret the claims. Therefore, the wording of claims is of great importance.

The use of first and second medical use claims is illustrated by the following hypothetical example. If aspirin was first synthesised and its analgesic properties discovered tomorrow, the scientist responsible could file a patent application. The broadest protection would be provided by a patent with a claim to the compound, acetylsalicylic acid, *per se*. However, if the structure of the compound had already been made available to the public, such a patent would not be granted since the compound would not be considered 'new'. In this situation, first or second medical use claims might be used to obtain patent protection.

If the structure of aspirin is known, but its use as a medical treatment has not previously been disclosed to the public, it may be possible for the scientist to obtain a patent with first medical use claims e.g. "Aspirin for use as a medicament". In this case the medical use of aspirin must be novel and inventive. A first medical use claim is narrower than a claim to the compound *per se*, as a first medical use claim only covers the compound in a form suitable for medical use.

If a medical use has already been disclosed for aspirin e.g. if it is known that aspirin has analgesic properties, it would not be possible to obtain a patent for aspirin with a first medical use claim. However, if the scientist had uncovered a new medical use for aspirin e.g. use as an anti-inflammatory, it might still be possible to obtain a patent with a second

medical use claim e.g. "Aspirin for use in the treatment of inflammatory disorders". In theory, such a claim would be narrower in scope than a first medical use claim because it would be limited to preparations of aspirin suitable for the specific medical use that is described in the claim.

Summary

Biological and medical inventions may be protected by patents. This protection manifests itself in the ability to prevent others making use of the patented invention.

Therefore, a strong patent portfolio provides the power to control the use of inventions generated through R & D effort and in so doing maximise the revenue generated from R & D.

In order to be patentable, a biological or medical invention must satisfy the basic patentability requirements; it must be new, involve an inventive step and be capable of industrial application. In addition, it must not fall within a number of narrowly defined exclusions, some of which are specific to biological and medical inventions.

Substances and compositions for use in methods of medical treatment are patentable. Furthermore, such inventions may be patented even if the substance or composition itself is known; first medical use claims may be used if a medical use has not previously been disclosed, in which case the medical use must be new and inventive; and second medical use claims may be used even if a medical use has previously been disclosed, such claims are directed to one or more specific medical uses and require these uses to be novel and inventive.