

Patenting biotechnological inventions

Biotechnology has given us the power to manipulate genes, proteins and organisms. It has the potential to revolutionise the way that diseases are diagnosed and treated, our food is produced, our energy is generated and how we deal with our waste. The patentability of biotechnological inventions is judged in the same way as other inventions: the invention must be novel, non-obvious and capable of an industrial use.

What is a patent application?

A patent application is essentially a 20-50 page book which describes an invention in a combination of legal and scientific language. After the patent application has been submitted, examined and, if necessary, amended, the patent may be granted (based on the text of the patent application). The patent will include 'claims' which define the scope of the invention. After the patent has been granted, the Applicant will be given rights to stop others from making, using and selling the invention - as defined in the patent claims - in the countries where patents have been granted.

What can be patented?

The patent system allows patent protection to be obtained for products, processes and methods of use. In the context of bioscience inventions, patents are often granted for products such as polypeptides, nucleic acids, cell lines, vectors, gene delivery systems, micro-organisms, genetically modified plants and animals, antibodies, vaccines and pharmaceuticals; and methods such as diagnostic assays, therapeutic methods, screening methods, purification protocols, sequencing protocols and cell culture techniques.

Proteins and nucleic acids

The patentability of proteins and DNA/RNA is assessed by the Patent Offices in the same way as any other chemical entities. If they are claimed in isolated or purified form, then that form will be novel over the forms that are present in the organism from which they are obtained. And if it can be shown that it was not obvious to produce those proteins or DNA/RNA, then the inventive step hurdle may be overcome. Patents may also be granted for artificial DNA constructs such as cDNA, and genetically-engineered proteins

Antibodies

There are several ways to claim antibodies in patent applications: these range from purely functional definitions based on the antibody's binding affinity, by reference to CDR sequences, through to defining the complete heavy and light chain amino acid sequences of the antibodies. Increasingly, the Patent Offices are requiring more structural (i.e. sequence) information in the patent claims as it becomes more recognised that small changes to the antibody's sequence can have profound effects on its properties.

Micro-organisms

Novel and non-obvious micro-organisms are patentable. Here, it must be remembered that the 'novelty' criterion for patentability does not mean "is it new?" in terms of "did it previously exist?"; it means "has it previously been made available to the public?" Hence newly-discovered bacteria are patentable. Genetically-modified bacteria are also patentable.

Transgenic plants and animals

The Patent Offices treat transgenic plants and transgenic animals as complex chemical compositions. For example, if the insertion of a foreign gene into a known organism produces a novel and non-obvious transgenic organism, then that organism is novel and potentially patentable. Transgenic plants and animals are generally claimed by reference to a parent plant or animal, and the new gene which has been inserted into it.

Methods of diagnosis and therapy

New methods of diagnosis and methods of therapy are also patentable. In method of diagnosis patents, the patent claims refer to one or more of the steps which form part of the diagnosis. Therapeutic methods are also patentable, although the format of the patent claims varies from country to country. Generally, new uses of known drugs are patentable, as are new formulations, new dosage regimes and new methods of administration.

Exclusions and restrictions

Whilst the above comments apply to biotechnological inventions in general, there are numerous differences between countries as to what is patentable and the way in which inventions are claimed. For example, as a result of a decision from the US Supreme Court, products of nature (including genomic DNA and naturally-occurring proteins) are no longer patentable in the US. This decision only applies, however, to US patents. It is therefore important to seek specialist advice on any particular matter.

How we can help

Dehns has a large team of experienced patent attorneys specialising in the fields of life sciences and biotechnology, and so we are extremely well-placed to provide further advice on this matter. Please contact us using the details below if you wish to receive further advice or if we can assist you in any way. It must be emphasised that details of new inventions must be kept confidential until such time as any desired patent applications have been filed, as any non-confidential disclosure could preclude obtaining valid protection.

Further reading

More detailed information on each of the above and other biotech inventions may be found in the Dehns booklet "Patenting of medical and biotech inventions" which is available from our website [here](#).



Contact Dehns

T: +44 (0)20 7632 7200

E: mail@dehns.com

W: www.dehns.com

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