

Patenting biotechnological inventions

Biotechnology has given us the power to manipulate genes, proteins and organisms. It has 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. For the most part, patentability of biotechnological inventions is judged no differently to any other invention and so must be novel, non-obvious and capable of industrial use, although some specific technologies in the field are excluded from patentability in some countries. In addition, the exploitation of certain biotechnological inventions may be regulated by legislation beyond patent legislation.

What is a patent?

Patents may be granted for inventions and give the owner the right to prevent others from using the invention. More details may be found in our briefing note **"What is a Patent?"**

What can be patented?

In general, the patent system allows patent protection to be obtained for products, processes and methods of use. In the context of bioscience inventions the same holds true, subject to certain specific subject matter restrictions in certain jurisdictions. For instance, patents are often granted for products such as polypeptides, nucleic acids, cell lines, vectors, gene delivery systems, microorganisms, genetically modified plants and animals, antibodies, vaccines and pharmaceuticals; and methods such as diagnostic assays, screening methods, purification protocols, sequencing protocols and cell culture techniques.

Specifically excluded from patentability in the UK and at the European Patent Office (EPO) are inventions which

concern processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; processes for modifying the genetic identity of animals which are likely to cause them suffering without substantial medical benefit and also animals resulting from such processes; and the human body at various stages of its development (and the simple discovery of one of its elements). In view of these exceptions in the UK and at the EPO, the mere discovery of a new polypeptide or nucleic acid sequence is not enough to make the invention patentable - a credible function of the polypeptide or the nucleic acid sequence must also be disclosed in the patent.

Patenting microorganisms or animals?

The patenting of microorganisms is far from new. Patents were granted for types of yeast in Belgium in 1833 and in Finland in 1843. More recently, patents to genetically engineered mice have been granted by the EPO. Such mice were modified to be particularly

sensitive to carcinogens. Thus, although the genetic modifications may have caused them suffering, the use of such mice in laboratory testing might greatly reduce the overall number of laboratory animals that are used in testing new medicines and so a clear benefit to medicine was apparent. Plants have also been patented. Many companies are involved in genetically manipulating plants to make them drought or frost resistant, or to increase their nutritional value. It is not hard to appreciate the value such plants could have, particularly to developing countries, and the importance of protecting such inventions.

Biotechnology patent laws in the UK and at the EPO

The European Commission passed a Directive in 1998 (the **EU Biotechnology Directive 98/44/EC** requiring EU member states to harmonise their patent laws with regards to the patentability of biotechnological inventions. The UK patent laws and the European Patent Convention (the EPC, the patent law which applies to the European Patent Office) have been amended to take into account the key provisions of this Directive.

Moral implications and excluded matter in the UK and at the EPO

The UK patent laws and the EPC require that patents may only be granted for inventions the commercial exploitation of which would not be contrary to public policy or morality. To some extent, specific guidance has been given in the above-mentioned EC Directive on the effect of this provision on what is patentable in the field of biotechnology (the exclusions discussed above). However, some controversy does remain in some biomedical areas, such as those technologies involving human embryonic stem cells.

No right of exploitation

As mentioned above, the grant of a patent allows the owner of the patent to prevent others from doing what is claimed in the patent. However, it does not give the owner any specific right to exploit the patent himself. Before the patent owner is able to exploit the patent, he must

take into consideration any patent rights held by third parties and whether any other laws apply to the activity he is proposing. In particular, EU legislation exists that controls genetic experimentation and the introduction of genetically modified organisms into the environment. Within the legislative framework of the UK, genetic experimentation is strictly controlled by the **Health and Safety Executive**; deliberate environmental release and marketing of genetically modified organisms is controlled by the **Department for Environment Food and Rural Affairs** and genetically modified food safety is controlled by the **Food Standards Agency (FSA)**.

Summary

UK law and the EPC has specific provisions relating to the patentability of biotechnological inventions that work together with the general provisions of the UK patent law and the EPC to provide a framework that allows owners of biotechnological inventions to obtain strong protection for that invention whilst ensuring that patents are not granted for inventions which are against public policy or morality. The public is further safeguarded by non-patent legislation which covers the exploitation of biotechnological inventions.

How we can help

Dehns has a large team of experienced patent attorneys specialising in the field 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

Dehns has a large team of experienced patent attorneys assist you in any way.

EPO guide on patenting biotechnological inventions

UK Intellectual Property Office guide on patenting biotechnological inventions



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