Genomics

Genomics is a discipline within genetics that applies bioinformatics, DNA sequencing and recombinant DNA methods to analyse, produce and manipulate genomes.

The genomics industry is now able to apply a growing understanding of genomes to medical and industrial uses. This is leading to personalised medicine that uses drugs which can be tailored to a patient through identification of specific genetic variations. It is also leading to the manipulation of genomes to provide specific functionality through synthetic biology. The apparatus used to produce and manipulate genomes have also advanced, with rapid developments in sequencing technology.

Innovations in this field can lead to a wide array of potential claims in a patent application. For example, the finding of a disease-causing gene polymorphism can lead to patent claims toward a diagnostic test, a polynucleotide comprising the polymorphism, probes capable of detecting the polymorphism, a protein comprising the mutation, an antibody for detecting the mutation, vectors, and transgenic animals.

In Europe, the provisions for patentability in relation to biotechnology are led by the "Biotech Directive" (EU Directive 98/44/EC), which confirmed that biological material isolated from its environment or produced by means of a technical process is patentable even if it has occurred previously in nature. Further, an invention relating specifically to gene sequences can also be patentable.

However, the Biotech Directive also rules out the patentability of certain inventions. In particular, the Directive rules out the patentability of the human body in all its developmental phases and the discovery of a gene sequence. Likewise, processes for cloning human beings, processes for modifying the germ-line genetic identity of human beings and 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 animals resulting from such processes, are also exempted.

Despite these exclusions, a wide range of inventions in this area are considered patentable in Europe. However, if patentability be achieved, all the other requirements of patentability must also be fulfilled. In order to provide a commercial usable scope of protection, claims towards polynucleotide and polypeptide sequences will normally cover variants. Due to the resulting broad scope of the claims, objections in relation to a lack of sufficient information, industrial applicability and inventive step are commonly encountered if adequate supporting data is not present. Accordingly, it is important to ensure that patent applications contain appropriate disclosures and data to support the scope claimed. *In vitro* data may be sufficient initially, and *in vivo* data obtained later can normally be post-filed, during the examination procedure, to support arguments of sufficiency and inventive step.

Two well-known patent series in this field are the Myriad BRCA1 and BRCA2 patents. In 2001, the EPO granted Myriad, a patent relating to the BRCA1 gene: EP0705902B2, entitled "*Nucleic acid probes comprising a fragment of the 17q-linked breast and ovarian cancer susceptibility gene*". In 2003, the EPO granted a patent claiming the BRCA2 gene: EP0785216B2, entitled "*Chromosome 13-linked breast cancer susceptibility gene BRCA2*". Both of these patents were maintained as amended following opposition proceedings at the EPO. The upheld claims of each patent are to a nucleic acid probe with a defined nucleotide sequence, to a replicative cloning vector comprising isolated DNA and a replicon operative in a host cell for said vector, and to a host cell transformed with said vector.

In the US, the Myriad BRCA patents were litigated up to the Supreme Court, where it was decided that a naturally occurring DNA segment is a product of nature and therefore not patent eligible, merely because it has been isolated. However, cDNA methods to new applications of knowledge about the naturally occurring DNA segments and naturally occurring DNA segments where the nucleotides have been altered are still patentable in the US. For more information on the position in the US see our AL Factsheet US????. (being written by Simon Bradbury)

Many of the patent applications now running through the patent examination process are focused on linking particular therapeutic compositions or dosage regimes to an individual having specific mutation or sequence. The real economic and social value in the naturally occurring DNA sequences is not owning the sequence *per se*, but tailoring therapies to those individuals having these sequences.

This is an active and complex area in terms of patent filings and litigation. We have explained the general principles of protecting genomics-related 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.