Myriad and Prometheus- Comparison of US and EP Positions

Following the recent Myriad and Prometheus decisions of the US court, the law relating to the patentability of isolated genes has changed in the US such that it is different to the corresponding law in Europe. The purpose of this note is to explain this difference and provide guidance to potential applicants in Europe for use when drafting new patent applications.

Myriad and Prometheus Decisions

The US Supreme Court recently issued its decision in the case of Association for Molecular Pathology v Myriad Genetics, Inc. This decision has set the US apart from other global patent systems with regard to the exclusion from patentability of isolated genes.

The case involved a diagnostic test for detection of mutations in the BRCA 1 and BRCA 2 genes. Certain mutations in these genes may indicate an increased risk of breast and ovarian cancer. Myriad determined the location and sequence of the BRCA 1 and BRCA2 genes and sought to obtain patent protection for their gene sequences.

Genes include coding regions (exons) and non-coding regions (introns). The coding regions are the functional part of DNA and produce the instructions needed to create proteins. It had long been the practice at the United States Patent & Trademark Office (USPTO) that claims to both isolated DNA, i.e. the sequence of both the coding and non-coding regions of a gene as it would exist excised from the rest of the genomic DNA, and complementary DNA (cDNA), i.e. a copy of only the coding region of the gene, were patentable. The Myriad patents included both types of claim.

The decision of the Supreme Court stated that 'claims directed to "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2", and mutations in those sequences associated with predisposition to breast and ovarian cancers, claim naturally occurring phenomena and thus are not drawn to patentable subject matter'. The Supreme Court held that no alteration of the encoded genetic information had occurred and, since the isolated DNA claims of the Myriad patents simply claimed the sequence of the genes as they existed in nature, this constituted claims directed to naturally occurring phenomena.

The Supreme Court also found that claims to cDNA were eligible for patentability 'since cDNA is not naturally occurring and differs from natural DNA, in that non-coding "introns" have been removed, and since cDNA sequence, although it is dictated by nature and retains naturally occurring exons, is newly created product that is distinct from DNA from which it is derived'.

This decision follows the same reasoning of the earlier case of Mayo v Prometheus which concerned a patent including claims related to a method for determining the optimal dosage of thiopurine drugs in the treatment of autoimmune diseases. In March 2012, the Supreme Court considered the relationship between the concentration of metabolite and the optimised dosage to be a "law of nature", and thus to be unpatentable.

Impact of Decisions on US Patent Law

The US Patent and Trademark Office (USPTO) recently published guidance for determining the eligibility of claims reciting or involving laws of nature, natural phenomena and natural products. The guidance was issued in light of the Supreme Court decisions in the Myriad and Prometheus cases. The guidance seeks to clarify the USPTO approach in determining "whether a claim reflects a significant difference from what

exists in nature and thus is eligible (for patent protection), or whether a claim is effectively drawn to something that is naturally occurring".

In summary, the USPTO has taken a strict approach with regard to what can be considered "a significant difference". In light of the guidance, it may be essential to explicitly recite how the claimed subject matter has been altered from what was found in nature, for example, how the structure of a claimed compound differs from a naturally occurring compound, or to recite any additional elements that might be required in order to enable a practical application of a natural product. As the guidance also applies to applications currently pending at the USPTO, a thorough review of pending applications claiming naturally occurring subject matter may also be advisable.

European Position

The European position is different to the US position. Isolated gene sequences are considered patentable subject matter, as provided in the Biotechnology Directive 98/44/EC, wherein Article 5(2) states that:

> "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

Thus, in Europe, claims relating to genes, proteins, antibodies, enzymes, viruses and cells are generally considered to be patentable. However, the gene product of the isolated gene must have a known function and the isolated DNA must also fulfil the requirements of novelty, inventive step, and industrial application.

Plant and animal varieties, human embryos and processes that involve the destruction of such embryos cannot be patented in Europe.

Following the Myriad and Prometheus decisions, it is suggested that patent applications comprising subject matter relating to DNA technology include claims to both isolated DNA and cDNA. This should ensure the greatest scope of protection for patent systems outside the US and, after deletion of the isolated DNA claims, provide claims that should be allowable in the US.

In addition, due to the strict requirements in Europe relating to the addition of subject matter, we advise ensuring that the native DNA sequence of the invention is included in the specification when the application is filed. This will mean that when it comes to filing a European patent application or entering the European national phase, there will be basis for including claims relating to this subject matter.

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