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Myriad effects

In July 2013, the US Supreme Court held that isolated DNA sequences are not patent eligible, thus overturning years of established practice by the US Patent and Trademark Office.

However, the decision in *Association for Molecular Pathology v. Myriad Genetics* raises more questions than it answers, and the implications for the patentability of other naturally-occurring products are uncertain. For example, it is not clear whether isolated naturally-occurring proteins comprising an amino acid sequence that is identical to that found in a cell or an organism will continue to be patent eligible in the US. It could be argued that such proteins should be assessed in the same way as isolated DNA molecules, and this question will need to be interpreted by the courts.

Similar uncertainty surrounds the patentability of microRNAs (miRNAs), small RNA molecules that are naturally expressed in cells. These miRNA molecules may be exploited therapeutically and diagnostically and many recently-issued US patents include claims directed to nucleic acid molecules with the sequence of an miRNA isolated from cells. However, the Myriad decision casts doubt on the validity of such miRNA claims and it will be for the courts to decide whether such isolated miRNA molecules are still patentable in the US.

Another field of technology that may be affected by the Myriad decision is the patenting of new natural compounds with therapeutic activity, such as compounds purified from exotic plants or deep sea organisms. Although the purified forms of these compounds are identical to their natural forms, they may have useful therapeutic properties when purified, as is the case for antibiotics. Such purified compounds have hitherto been considered patentable in the US, even though they are identical to the natural products, but this may well change following the Myriad decision and will depend on whether a distinction is drawn between 'purified' and 'isolated' products.

However, it should be emphasised that in the Myriad decision, the Supreme Court expressly limited its analysis to isolated DNA molecules and whether its findings extend by analogy to other isolated, or even purified, naturally-occurring products will depend on how the US courts interpret the decision. Therefore, for the time being, we can only speculate about the implications of the Myriad decision for other areas of technology.

Despite this, one known consequence of the decision is that granted US patents relating to isolated DNA molecules are almost certainly invalid. Such patents are likely to be challenged or simply ignored by parties intending to use the claimed sequence. Licence agreements for patents including claims to isolated DNA molecules will also be affected; licensors may suffer a loss of royalties and licensees may consider re-negotiating licence terms for licences based exclusively on patents relating to isolated DNA molecules.

On the other hand, the Myriad decision does not preclude the patenting of non-naturally occurring nucleotide sequences in the US, such as cDNA sequences or methods of using isolated DNA molecules (even naturally-occurring ones), provided the methods are based on a new application of the DNA molecule. Therefore, the validity of patent claims relating to such non-naturally occurring DNA sequences and methods of using such sequences should not be affected, thus lessening the impact of the decision on the biotech sector. As many granted US patents relating to gene sequences also include claims directed to man-made cDNA sequences and to methods of using these sequences in diagnostic testing, such patents will still be at least partially valid and enforceable. Indeed, following the Supreme Court ruling, Myriad has already challenged patents based on such claims by filing two infringement suits against providers offering its BRCA gene-directed genetic diagnostic tests.

Looking ahead, patent applicants should avoid including claims relating to DNA molecules with naturally-occurring nucleotide sequences in their US patent applications, and instead focus on claims directed to cDNAs and other engineered nucleic acids that have a sequence that is different from any naturally-occurring nucleic acid, as well as method of use claims based on new applications of nucleic acids of interest.

Given that almost all human genomic sequences are now in the public domain and that the genome sequences of many other organisms have been sequenced and published, it is unlikely that claims relating to isolated DNA molecules *per se* would be considered novel in newly-filed US patent applications, therefore new patent applications may not be greatly affected.

However, just how far-reaching the consequences of the Myriad decision will be for the patentability of other naturally-occurring products in the US remains to be seen. However, it should be remembered that isolated DNA molecules are still considered patent eligible in Europe and in many other countries around the world.

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